

1 **Wednesday, 24th March 2021**

2 **(10.00 am)**

3 **SIR BRIAN LANGSTAFF:** Good morning, professor.

4 **THE WITNESS:** Good morning, Sir Brian.

5 **SIR BRIAN LANGSTAFF:** You can see me?

6 **THE WITNESS:** Yes, I can see and hear you.

7 **SIR BRIAN LANGSTAFF:** Most of me I hope, and you can hear

8 me?

9 **THE WITNESS:** Yes.

10 **SIR BRIAN LANGSTAFF:** Now, you are at home, I think, with

11 your wife?

12 **THE WITNESS:** Yes.

13 **SIR BRIAN LANGSTAFF:** You are on your own at the moment,

14 are you?

15 **THE WITNESS:** Now we've set up the system, yes, I am in

16 that room by myself.

17 **SIR BRIAN LANGSTAFF:** Let me tell you who you are talking

18 to. Here at Fleetbank House, we have a room big

19 enough number for 200, we have at the moment eight

20 people in it, all of whom, bar one, are wearing masks

21 and that one is Ms Richards, who will be asking you

22 the questions in a moment or two.

23 Names you will hear are Mary, who will ask you

24 to take the oath in a moment or two, and Soumik, whose

25 job it is to make sure that any documents which we

1

1 **Q.** And then in 1987 you took up a post as the

2 departmental chair of medicine at St Mary's Hospital

3 Medical School, and then at some stage after that you

4 became head of hepatology and gastroenterology at the

5 Imperial College Medical School before retiring from

6 that post in 2011. Is that right?

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

8 **Q.** Now, you have been a member of multiple working

9 parties, committees and advisory groups detailed in

10 your witness statement. I am not going to ask you to

11 list them, but we will touch on some of them in the

12 course of your evidence.

13 You gave evidence to the Archer Inquiry and to

14 the Penrose Inquiry. Is that correct?

15 **A.** Yes, yes.

16 **Q.** And you were then director of the Skipton Fund from

17 around late 2012/early 2013 until 2018 and a trustee

18 of the Caxton Foundation from 2011 to 2018?

19 **A.** Yes, that's right.

20 **Q.** Now I am going to ask you, first of all, today about

21 the Skipton Fund and the Caxton Foundation and your

22 involvement with both of those bodies, and then I am

23 going to ask you after that some more general

24 questions relating to your work in hepatitis, your

25 involvement in some of the working parties and groups.

3

1 want to refer you to can be displayed on your screen

2 and to the public generally. The public generally,

3 there were yesterday just under 250 people watching.

4 There will be very similar numbers, I think, today.

5 They are watching from various locations around the

6 country on a mixture of YouTube and live stream. They

7 are the people you are really talking to when you are

8 giving your evidence.

9 Without more ado, I will ask Mary to ask you to

10 take the oath?

11 **THE WITNESS:** I need to get a bible, do I?

12 **SIR BRIAN LANGSTAFF:** Yes, you do.

13 **THE WITNESS:** Give me a second.

14 **PROFESSOR HOWARD CHRISTOPHER THOMAS (sworn)**

15 **Questions by MS RICHARDS**

16 **MS RICHARDS:** Professor Thomas, can you see and hear me?

17 **A.** Yes, I can.

18 **Q.** You are Emeritus Professor of Hepatology in the

19 department of medicine at Imperial College London?

20 **A.** That's correct.

21 **Q.** Prior to that -- I am not going to go through the full

22 details of your career -- from 1974 to 1987 you worked

23 at the Royal Free Hospital teaching, undertaking

24 research and involved in patient care. Is that right?

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

2

1 **A.** Perhaps I should say in relation to the Skipton Fund,

2 when it became a company, a limited company, then

3 I was a director -- I think there were three or four

4 of us -- but I wasn't the director, if I could ...

5 **Q.** Yes. You were one of a number of directors?

6 **A.** Yes.

7 **Q.** Our understanding is you were the first medical

8 director.

9 **A.** That is right, Ms Richards.

10 **Q.** Then you were joined in at that role by

11 Professor Dusheiko two or three years later?

12 **A.** Yes.

13 **Q.** Now, as I say, I'm going to start with the Skipton

14 Fund, but I am going to ask you about your involvement

15 at a much earlier stage.

16 So a number of years before you became one of

17 the directors you had some early involvement in the

18 setting up of the scheme.

19 If we could look at SCGV0000265\_004, please,

20 Soumik.

21 So we can see, professor, this is headed:

22 "Ex gratia payment scheme for people infected

23 with Hepatitis C as a result of treatment with NHS

24 blood and products.

25 "Meeting to discuss the medical trigger point

4

1 for the proposed higher payment 14th October 2003."

2 Then we can see who is present: a number of  
3 medical commissions, including yourself and  
4 Professor Dusheiko, then a number of representatives  
5 of the Scottish Executive, the Department of Health  
6 and the National Assembly for Wales -- or senior  
7 medical officer, I think that must be, National  
8 Assembly for Wales.

9 If we look a little further down, under the  
10 heading "Preliminary Discussions", we can see in  
11 paragraph 1 it says:

12 "Following items 1 and 2 on the agenda  
13 (Introductions and Background to Scottish Scheme), the  
14 experts were asked for their initial thoughts on the  
15 medical trigger for the second (higher) payment."

16 Before we look at some of the discussions in  
17 this meeting, can you assist us with this: how was it  
18 you came to be involved in this meeting?

19 **A.** Well, I had been appointed initially I think in 1987.  
20 I was a member of the advisory group on hepatitis.  
21 And then I think in 1999 to 2009 I was the chairman.  
22 I presume that, since I was already involved with the  
23 Department of Health, I was one of the named people  
24 who they thought might be able to help. And in  
25 particular a lady called Anna Lok, who was an American

5

1 many would be asymptomatic. And cirrhosis brought  
2 with it all sorts of symptomatic problems and also  
3 a change in life expectancy.

4 **Q.** Did you, either through your involvement with this  
5 group or through your more general involvement with  
6 the Department of Health, gain any understanding of  
7 why it had been decided that the Skipton Fund would be  
8 set up on a national UK-wide basis?

9 **A.** No. I really was only involved in this focused issue  
10 really of, you know, why this was stage 2 and how  
11 could we determine when somebody had cirrhosis without  
12 doing a liver biopsy.

13 **Q.** If we then look at the terms of paragraph 1, it says  
14 in the third line:

15 "It was felt that this [the medical trigger for  
16 the second payment] should be a recognised stage of  
17 the disease, rather than subjective symptoms of  
18 illness."

19 Can you assist with why that was the view of  
20 the experts?

21 **A.** I think it was -- we were looking for objectivity,  
22 really, something that would allow whoever to  
23 implement this with a solid break-point, really, when  
24 you move from stage 1 to stage 2. I think that was  
25 the main reason.

7

1 research fellow who was working with me, had written  
2 a paper describing how one could determine whether  
3 somebody had cirrhosis, which is one of the main  
4 trigger points for payment of the stage 2 level. They  
5 thought that we might be able to throw some light on  
6 that particular aspect of the organisation of the --  
7 Skipton, and particularly the transition from stage 1  
8 to stage 2 payments. So I think that's why I got  
9 involved.

10 **Q.** Now, as we have seen from the heading on the document  
11 and paragraph 1, the meeting was specifically looking  
12 at the trigger point for the stage 2 payment. Had you  
13 been involved in any of the wider discussions about  
14 what the shape of the Skipton Fund should be or  
15 whether payment should be made on an ex gratia or  
16 compensatory basis?

17 **A.** No. I was just brought in with the other people that  
18 you have got at the heading of this paper as people  
19 who could provide medical help -- information,  
20 particularly hepatological information on when  
21 somebody had cirrhosis, which was going to be one the  
22 main trigger points.

23 That was chosen as a trigger point, by the way,  
24 for the larger payments, because up until people have  
25 cirrhosis, many are -- or we thought at that stage

6

1 **Q.** And then -- sorry, carry on.

2 **A.** Later on actually -- I think you have some evidence --  
3 I was asked to provide a document on, really, the  
4 equivalents in terms of symptomology and life  
5 expectancies between stage 1 and stage 2 of  
6 hepatitis C and HIV, the stages of that, and you have  
7 got that in your documents later on.

8 **Q.** Yes, yes, and I will also come on to your involvement  
9 in what became known as the special category mechanism  
10 as well.

11 **A.** That's right, yes. I should emphasise, you know, at  
12 all stages I was doing research in this area. And  
13 as -- as I published papers that showed our initial  
14 views may not have been 100% correct -- and this was  
15 the case with the SCM, when we realised that some  
16 stage 1 patients did have problems of depression, and  
17 also a cognitive abnormality which we showed was  
18 related to an infection of the brain.

19 **Q.** Again, I am going to come on to those. Then we can  
20 see the next sentence of paragraph 1:

21 "All agreed that the trigger point should not  
22 be left until too late in the course stage of the  
23 disease, as in the late stages patients might have  
24 a very poor life expectancy."

25 Is that the reason why the trigger point was

8

1 not limited to liver transplant or cancer, but  
 2 included cirrhosis?  
 3 **A.** Yes, very much so.  
 4 There was one other thing that was included at  
 5 this sort of earlier stage, before you had a chance of  
 6 developing liver failure and liver cancer, and that  
 7 was non-Hodgkin's lymphoma, which was one of the  
 8 objective determinants of the stage 2 payment.  
 9 **Q.** Now we can see -- sorry?  
 10 **A.** So this is a tumour of the lymphoid system and also  
 11 requires quite a lot of additional therapies of one  
 12 sort or another.  
 13 **Q.** Now we can see in paragraph 2 then the discussion  
 14 alights on cirrhosis as the most practical trigger  
 15 point. Then there was a discussion about reluctance  
 16 to make payments contingent upon liver biopsy,  
 17 particularly for patients with haemophilia, and so  
 18 a desire to explore the possibility of using  
 19 non-invasive tests as a viable alternative.  
 20 If we then go over the page, so that we can  
 21 follow through the discussion, at paragraph 5 under the  
 22 heading "Non-invasive tests" it refers to a range of  
 23 haematological and biochemical tests, I'm not going to  
 24 go through each of them but there is a list I think  
 25 appended to this document, and then halfway through

1 test, which was a computation of an AST, which is  
 2 a measure of liver cell damage, and a platelet count,  
 3 which is a measure of how large the spleen is and is  
 4 a measure of portal hypertension, which is invariably  
 5 found in patients with cirrhosis.  
 6 These two tests together were thought to be the  
 7 best that was available but, depending on the level at  
 8 which you set the trigger point and Dr Lok, and  
 9 subsequently this committee, decided that would be  
 10 a figure of greater than 2. When the AST started to  
 11 go up and the platelet count started to go down, then  
 12 the AST divided by the platelet count would give  
 13 what's called the APRI score. If you set it at 2, it  
 14 would be 91% specific. In other words, you didn't  
 15 pick up people without cirrhosis. The sensitivity,  
 16 however, at this level was not ideal. It was about,  
 17 I think, 50% or something like that.  
 18 That was the reason why we combined that with  
 19 the AST over the ALT, because when you have cirrhosis,  
 20 although both of these tests measure liver cell  
 21 damage, the AST goes up higher than the ALT when you  
 22 have cirrhosis. So we combined these two tests, which  
 23 is now mentioned in the document when people apply for  
 24 stage 1 or stage 2 payments, and it explains  
 25 specifically the levels which will indicate that

1 this paragraph it says this:  
 2 "Although these were commonly performed tests,  
 3 there appeared to be limited experience in using  
 4 various combinations to predict accurately the  
 5 presence of cirrhosis in clinical practice. However,  
 6 there were a number of scientific papers that sought  
 7 to validate particular combinations of these tests in  
 8 patients with chronic hepatitis C that could be used  
 9 as a basis for determining the optimum combination of  
 10 tests."  
 11 Could you just assist us a little further in  
 12 understanding the difficulty there and the reference  
 13 to there being limited experience in using various  
 14 combinations to predict cirrhosis?  
 15 **A.** This wasn't a problem limited to the haemophilia  
 16 population, but they did have a particular problem  
 17 because of their failure -- inability of the blood to  
 18 clot, but it was a common problem with all cirrhotic  
 19 patients who had coagulation problems and, as  
 20 hepatologists, we really didn't want to do biopsies  
 21 until absolutely necessary.  
 22 Anna Lok, who, as I say, had been a fellow with  
 23 me, I think by this time had gone back to the United  
 24 States to take up an appointment, had written a paper,  
 25 which was essentially screening describing the APRI

1 somebody has cirrhosis. But even so, even with AST  
 2 and ALT added to this APRI score, there were some  
 3 people who would have cirrhosis and wouldn't be picked  
 4 up by these two tests.  
 5 So we said that the physicians or nurses  
 6 looking after the patients could add other data, which  
 7 might include scanning of one sort, ultrasound, CT and  
 8 then latterly MRI scanning or endoscopy, when you can  
 9 look down the patient's throat to see if they have  
 10 varices, which are an indication that the patient has  
 11 portal hypertension, which is always or invariably  
 12 an indication of cirrhosis. You can add in these to  
 13 make a better platform.  
 14 I think over time this was quite a good  
 15 combination of things. Most of the stage 2 payments  
 16 were not appealed by the appeal group later on, which  
 17 is not the case with stage 1, of course.  
 18 **Q.** Yes. Then if we look at paragraph 7 -- paragraph 6  
 19 refers to the combination of non-invasive tests and  
 20 thresholds, as you have just described. Then  
 21 paragraph 7 says:  
 22 "A hepatologist or other clinician familiar  
 23 with the patient, their circumstances and medical  
 24 history should be able to advise patients who had not  
 25 undergone liver biopsy, whether on the basis of the

1 panel of chosen tests there were grounds for seeking  
2 the second payment."

3 So it would appear that the expectation of this  
4 group was that this was going to be a judgment for the  
5 hepatologist or other clinician who was actually  
6 caring for or familiar with the patient; is that  
7 right?

8 **A.** Yes, and it had a function in addition to triggering  
9 a stage 2 payment and that is related to the fact that  
10 patients when they have cirrhosis are at risk of  
11 primary liver cell cancer. Between 2 and 4% of people  
12 with cirrhosis, irrespective of what it is due to --  
13 so it could be due to hepatitis B or hepatitis C or  
14 alcohol or indeed now obesity-related fatty liver --  
15 any patient, particularly males, who develop  
16 cirrhosis, because they have this risk of developing  
17 primary liver cell cancer, should have yearly  
18 ultrasounds to try to pick up the tumours at a time  
19 when we could resect them or we could suggest the  
20 patient to go forward for liver transplantation.

21 So we were looking for something that was  
22 integrated into the general mechanism of care of  
23 patients but would, because it was being done for  
24 these routine issues around the patient's care, could  
25 also be used to trigger a stage 2 payment.

13

1 cell cancer. So we weren't very keen on these  
2 additional tests, except the ones that I mentioned  
3 earlier, which were also tests being done routinely in  
4 British units, you know, such as various scans and  
5 endoscopy where there is a fibro endoscope put into  
6 the patient's stomach to look. This would be done  
7 routinely for patients. That latter test, of course,  
8 was a way of seeing whether the patient did have  
9 varices. There were ways of preventing the patient  
10 having a variceal haemorrhage, which was  
11 a catastrophic haemorrhage and very disturbing for the  
12 patient. So we wanted to know if a patient was at  
13 risk of that so we could give them drugs to reduce  
14 that risk.

15 Lastly -- I have forgotten it. Whenever I used  
16 to lecture we were always told don't say you're going  
17 to make three points because by the time you got to  
18 the third point you couldn't remember what it was.  
19 I am sorry, I have forgotten the third point.

20 **Q.** It is equally applicable to barristers, professor, so  
21 don't worry.

22 If we go to the top of the next page we can see  
23 on the very top line:

24 "It was also acknowledged that a group of  
25 'experts' might need to be available to adjudicate in

15

1 **Q.** Then if we look at paragraph 8, it appears that the  
2 group within this meeting:

3 "... recognised that there may be a small  
4 number of cases where a panel of simple and readily  
5 available tests might not provide a clear answer."

6 In those cases, is this right, there might need  
7 to be further testing. There is relation to the  
8 "Fibrotest", is that what we now understand to be the  
9 Fibroscan or is that something different?

10 **A.** No, it is something different. This was something  
11 that the French had come up with, which they were  
12 selling via the web as a way of the patients, and  
13 indeed the physicians looking after the patients, to  
14 tell whether they might have cirrhosis. So you filled  
15 in certain bits of information, clinical information,  
16 and you then, with a fee, could get the hyaluronic  
17 acid or other blood tests done which would say you  
18 have such a probability of having cirrhosis.

19 We didn't like that very much, because what we  
20 wanted to do was have something that was -- didn't  
21 involve patients going through additional tests. It  
22 would use information that was being routinely  
23 collected for the care of the patient, as I have  
24 already said, so that should they develop cirrhosis,  
25 we could start ultrasound screening for primary liver

14

1 particularly difficult cases."

2 Was it right to understand that the scheme, as  
3 envisaged by this group, was that the vast majority of  
4 cases would turn on the opinion of the treating  
5 clinician but there might be a small category or small  
6 number of particularly difficult cases where a broader  
7 range of expert opinion might need to be sought?

8 **A.** Basically that's it and, in the period before either  
9 myself or Geoff Dusheiko were formally involved,  
10 because I had been involved through the advisory group  
11 on hepatitis and then this group setting up the issues  
12 around stage 2, Nick Fish, who was the administrator  
13 for the Trust, would be able to really sign off on  
14 a series of patient's stage 2 payments, because these  
15 APRI scores and the AST/ALT ratio supported by other  
16 clinical information were sufficiently robust that if  
17 this information was on the application sheet, this  
18 meant the majority would just go through fairly  
19 rapidly.

20 Then, before I became a director, Nick would  
21 ask me to help with individual cases if it wasn't --  
22 if the payment couldn't be triggered on the data that  
23 was on the sheet, really. But the clinicians looking  
24 after the patients would provide the APRI score and  
25 AST/ALT ratio and say also which additional test the

16

1 patient had done and then say "I think he has  
2 cirrhosis or she has cirrhosis, sign off on it", and  
3 then this would flow through the system without delays  
4 for people like me or Dr Dusheiko getting involved.

5 **Q.** If we then look at the heading "Discussion of  
6 Item 4 -- Clearance of Hepatitis C Virus", there is  
7 then a discussion about whether there should be  
8 included within the scheme or not those who  
9 spontaneously cleared and those who cleared  
10 post-treatment. Can I ask you first of all about  
11 those who spontaneously cleared? We have also had  
12 them referred to as natural clearers. What's recorded  
13 in paragraph 10 is:

14 "It was agreed that a patient who remained PCR  
15 negative six months after the virus had first cleared  
16 spontaneously ..."

17 I am going to leave aside treatment:  
18 "... was highly unlikely to relapse during the  
19 course of their lifetime. This was thought to be the  
20 case in 98% of cases."

21 If we just look, before I ask you a question  
22 about that, at paragraph 12, we can see:

23 "Experts agreed that people still had a very  
24 small chance of developing liver cancer following ..."

25 I am leaving aside successful treatment:

17

1 being talked about here, and if they have already  
2 developed cirrhosis, albeit having cleared the  
3 virus -- if they have already developed cirrhosis,  
4 then they will be at risk of about 1% per year  
5 developing liver cancer.

6 If you still have the virus when you have  
7 cirrhosis, then it is about 2-4% develop liver cancer  
8 every year. If you have developed cirrhosis but have  
9 cleared the virus, either spontaneously, and a few  
10 people do that every year, or on these modern  
11 treatments which are now virtually 100% effective in  
12 clearing the virus, even if you clear the virus but  
13 you have developed cirrhosis, you will still be at  
14 risk of developing primary liver cell cancer. But it  
15 drops to about 50% of the incidence of what you would  
16 see if the patient is still having the presence of the  
17 virus. Did I manage to explain that okay?

18 **Q.** Yes. Can I just ask you, first of all, about the  
19 category of those who do naturally or spontaneously  
20 clear the virus within a six-month period?

21 **A.** Right. Yes.

22 **Q.** The decision was taken to exclude that category from  
23 the scheme, the Skipton Fund. Was any consideration  
24 given either at this meeting or, to your knowledge, at  
25 any other meetings to the psychological consequences,

19

1 "... spontaneous viral clearance."

2 Now, the scheme that was set up did not include  
3 those who had spontaneously or naturally cleared the  
4 virus in the way described here. What was the view of  
5 the expert group on that issue, as far as you can  
6 recall?

7 **A.** There were two types of patient who would be  
8 identified with antibody and a negative PCR. If  
9 I could just remind people that the antibody indicates  
10 that there has been infection and would be positive in  
11 continuing the infection and also in those who have  
12 cleared it, whereas the PCR does detect the continued  
13 presence of the virus.

14 Now, the group -- if somebody has been  
15 infected, 20 or 30% of those patients will clear the  
16 virus within three to six months. In that group the  
17 liver will go back to complete normality. They are  
18 not at risk of liver cancer. The group that I think  
19 is being alluded to here is a group who, unbeknown to  
20 the patient, and sometimes unbeknown to their  
21 physicians because they may not have been under  
22 a physician's care, they may have moved on to chronic  
23 infection and 1% of those is the guesstimate that may  
24 then after many, many years clear the virus. They  
25 still have antibodies, so they are in the group that's

18

1 the anxiety, the stress, the fear that that category  
2 of patients might nonetheless experience?

3 **A.** At this stage I think the answer is no, particularly  
4 with at that group who cleared the virus in three to  
5 six months.

6 Later on, when we had been using interferons  
7 for a long time, for instance, which, you know, clear  
8 only 20% of patients with chronic infection of the  
9 virus, this causes quite long-term symptoms. And that  
10 was the reason, having observed that -- in other  
11 words, once patients had had interferon treatment for  
12 treatment of the chronic infection, they would have  
13 continuing problems. That was the reason why  
14 I thought we should think about having an additional  
15 payment in stage 1 patients, and why the SCM came  
16 about, and with it, as you will see later, a lot of  
17 subjectivity really.

18 **Q.** Yes.

19 **A.** That introduction later on of an SCM payment in  
20 stage 1 was recognition that -- of what you are  
21 talking about, but the acute infection, which is  
22 people who cleared the virus in the first three to six  
23 months, we believed then, and I think we probably  
24 believe now, that that group return to complete  
25 normality once they have cleared the virus. That

20

1 doesn't mean to say they have not had concerns during  
 2 the three to six months when they have been infected,  
 3 but after that phase they should, if they have been  
 4 properly reassured by their physicians and nurses,  
 5 return to normal or the pre-infection stage, we  
 6 thought.

7 **Q.** Can I then ask you just a little more about what's  
 8 said here about the position of patients who have  
 9 cleared the virus following treatment?

10 If we look at paragraph 13, under the heading  
 11 "Financial assistance for successfully treated  
 12 patients", it says:

13 "There followed a short discussion on whether  
 14 people who had successfully cleared the virus after  
 15 treatment should qualify for the initial payment.  
 16 Experts argued both for and against this."

17 Then there is a reference to a patient possibly  
 18 having waited a considerable period before receiving  
 19 treatment.

20 Then paragraph 14:

21 "During this time and the treatment, the  
 22 patient may claim they had suffered and therefore that  
 23 they should receive financial assistance. However,  
 24 this is also the case for a huge number of everyday  
 25 NHS patients who do not qualify for any assistance.

21

1 arthritis worse, it could make a thyroid condition  
 2 worse. It could also make depressive problems worse,  
 3 to the extent that in my unit we used to refer  
 4 patients -- or we had a psychiatrist working with us  
 5 who often gave them anti-depressant treatment before  
 6 we started interferon treatment because we knew there  
 7 could be problems during the period of treatment and  
 8 afterward.

9 So I think the bottom line is it changed after  
 10 we had seen what interferon treatment was like, but  
 11 before then, at the time when we were discussing these  
 12 issues we, rightly or wrongly, thought that when  
 13 patients had cleared the virus, then they should  
 14 return to their pre-treatment, pre-infection stage,  
 15 and that should be relatively normal, unless there was  
 16 knowledge that they had problems before, such as  
 17 anxiety or depressive problems.

18 So, I mean, this was an attempt at a pragmatic  
 19 approach I suppose.

20 **Q.** Paragraph 14 also says, in the sentence before the one  
 21 that's highlighted:

22 "... this is also the case for a huge number of  
 23 everyday NHS patients who do not qualify for any  
 24 assistance."

25 Did the expert group or the group holding this

23

1 The danger of treatment becoming a disincentive was  
 2 also highlighted. Experts recognised that this should  
 3 ultimately be a policy decision."

4 Can I ask you to assist with two matters,  
 5 professor? The first is the reference to the danger  
 6 of treatment becoming a disincentive. Was it  
 7 a genuine concern that patients would not go through  
 8 treatment for what was a very, very serious condition  
 9 simply because they wanted to obtain financial  
 10 support?

11 **A.** Well, I think at the time I don't think we knew  
 12 anything about what would motivate people to do one  
 13 thing or another. But later on, of course, this  
 14 became a very important issue in so much as, with the  
 15 current drugs we have, a three-month course of  
 16 anti-virals clears 100% of patients. And in the last  
 17 years of the scheme, those of us involved in it often  
 18 saw patients who had applied for an ex gratia payment  
 19 after having cleared the virus and -- whereas, you  
 20 know, they -- at that time we thought they should have  
 21 returned to complete normality. Unless they had had  
 22 interferon at the earlier stage, where we know now,  
 23 and we were becoming aware at the stage that I am  
 24 talking about, that the interferon could induce  
 25 auto-immune diseases, it could make rheumatoid

22

1 meeting not recognise that this cohort of patients  
 2 might be said to be in a very different position from  
 3 everyday NHS patients, because this cohort of patients  
 4 had been infected by the NHS, which won't be the case  
 5 for everyday NHS patients?

6 **A.** No. I appreciate that's another factor. We were, you  
 7 know, not only thinking of the haemophilia patients.  
 8 We were also trying to provide recommendations for the  
 9 majority of people with non-A, non-B or hepatitis C.  
 10 And I should mention here that about 80-90% of people  
 11 with hepatitis C virus infection had acquired it by  
 12 mechanisms other than by NHS blood or blood products.

13 In addition, there was a great deal of  
 14 complexity around those other than the haemophilia  
 15 population who had acquired the infection as a result  
 16 of a blood transfusion, usually for treatment of  
 17 a malignant state. So I think it was extremely  
 18 complicated, is what I am trying to say, and we  
 19 couldn't come up with a group of criteria that were  
 20 suitable for all situations.

21 And the ultimate determinant of who got ex  
 22 gratia payments, of course, was the Department of  
 23 Health, and then up to the Minister. You will know  
 24 that the Skipton was, in fact, a body which received  
 25 money and a set of rules on how to distribute that

24

1 money. You might rightly say that I and three or four  
 2 other people were involved in setting up the rules, at  
 3 least for stage 2, and that's the case, so we would  
 4 take responsibility for those rules that were stemming  
 5 from the stage 2 policy decisions, but the sort of  
 6 issues that you are talking about became more of  
 7 an issue in stage 1, where -- not only the issue  
 8 about, you know, how much people's lives had been  
 9 disrupted by these infectious agents -- and HIV was  
 10 added in there as well. There were those issues, but  
 11 also issues about insurance, all manner of things. So  
 12 we tried to come up with a set of rules that could be  
 13 easily interpreted.

14 **Q.** Just to complete the picture about these early  
 15 discussions, there's a second meeting to discuss the  
 16 medical trigger point in January 2004.

17 Soumik, that's at DHSC0004425\_159.

18 We can see there it is the second meeting,  
 19 27 January, and the attendance there set out,  
 20 including yourself.

21 I am not going to go through the detail of it,  
 22 but if we go over the page and we just look at  
 23 paragraph 4, you have referred already to Dr Lok. Is  
 24 that what is being referred to here, the work that had  
 25 been undertaken by Anna Lok?

25

1 without consulting the medical people.

2 **Q.** If we go to the next page, 15, we can see that process  
 3 I think that you described clearly envisaged there.  
 4 Paragraph 15, under the heading "Whose  
 5 responsibility?":

6 "In the first instance, it was suggested that  
 7 the patient/patient's clinician should initiate  
 8 a claim. If not by biopsy, this would require  
 9 submitting the application form, presenting the  
 10 clinical information from the test(s) to the Skipton  
 11 Fund. If the results were clear-cut ..."

12 Then we see the criteria there set:

13 "... the claim would be validated and  
 14 authorised by the fund. If not, a medical panel would  
 15 consider the results or perhaps commission Poynard  
 16 'Fibrotest'. If still inconclusive, it is envisaged  
 17 the medical panel would review the case."

18 So that, I think, is what you were describing:  
 19 the group's understanding of how the system was going  
 20 to work?

21 **A.** Exactly.

22 **Q.** If we just look at the very bottom of this page, under  
 23 the heading "[Any Other Business]", in paragraph 19:

24 "Following the tabling of the press statement  
 25 that announced the details of the Skipton Fund,

27

1 **A.** That's right. And the two tests that ultimately were  
 2 on the application form for stage 2 payments were the  
 3 APRI score and ALT/AST ration. And it explains there  
 4 what the trigger points are, what -- the APRI score  
 5 should be greater than 2 and the AST/ALT ratio should  
 6 be less than 1, if cirrhosis is present.

7 And that really had been tested by Dr Lok in  
 8 a prospective way; in other words, once she had  
 9 decided this might be satisfactory, then she looked at  
 10 it in a group of patients who were going forward for  
 11 liver biopsies. She would then, for other reasons,  
 12 determine what sort of liver disease they had, as  
 13 opposed to the severity. She would look at these  
 14 tests and see how they correlated with the liver  
 15 biopsy, which was the gold standard, if you like, for  
 16 cirrhosis.

17 So yes, it was that -- APRI score and the  
 18 AST ratio is what was taken forward into the forms,  
 19 and the physician or the nurse filling in the form  
 20 with the patient would mention these. And if they  
 21 were positive and they had already been receiving  
 22 a stage 1 payment, indicating that it was accepted  
 23 that they had been infected from NHS blood or blood  
 24 products, then that -- Nick Fish, I think, would  
 25 automatically pass those through to -- for payment,

26

1 Dr Giangrande and Professor Bassendine both expressed  
 2 disappointment that the scheme had not been extended  
 3 to dependants of those who had died."

4 Had you been involved in any discussions about  
 5 whether the scheme should or shouldn't include  
 6 dependants?

7 **A.** Well, somewhere along the line, and I can't remember  
 8 whether it was the Archer or the Penrose that I had  
 9 also been involved with, it did seem that this was an  
 10 important issue, that -- and particularly in the  
 11 haemophilia population, where, because it is -- can  
 12 occur sporadically, but is often genetically  
 13 determined and affects males, is -- and often, except  
 14 in today's world it is probably no longer true, the  
 15 men might be the person supporting the family, it  
 16 was -- you know, if that person died, then it would  
 17 leave the family in a terrible situation.

18 So I think we also shared the concerns that  
 19 Maggie Bassendine -- I don't know Dr Giangrande, but  
 20 I do know Maggie Bassendine, who worked for me for  
 21 a long time. I shared her views. I think it had been  
 22 mentioned in the Penrose, had it not?

23 **Q.** Yes. That was rather later.

24 **A.** Right. Yes. It is difficult, when I was involved in  
 25 all those things -- those two or three things, to

28

1 remember what was decided at what situation. But  
 2 I think there was general agreement with what  
 3 Maggie Bassendine said there.

4 **Q.** Now, I am not going to go to the document, but  
 5 following this meeting, I think, you were copied into  
 6 some e-mails, as were the others of the group, that  
 7 looked at the design of the form. Did you after  
 8 that -- so that was in early 2004.

9 We know the Skipton Fund became operational in  
 10 July 2004. Did you after that have any ongoing  
 11 involvement with the Skipton Fund other than such  
 12 approaches as Nick Fish might make to you about  
 13 individual cases prior to your appointment as  
 14 a director?

15 **A.** I can't remember the temporal sequence. I was trying  
 16 to do that this morning and trying to find out what  
 17 Nick had said actually. Because I thought I had been  
 18 involved before 2011, which is the point when I --  
 19 I think it was 2012 I was actually appointed to be  
 20 a medical director, but I've got a feeling I was  
 21 involved in individual cases before then, but  
 22 certainly my formal arrangement came after I was  
 23 appointed to the Caxton, which I think was 2011.

24 **Q.** Yes.

25 **A.** And it soon became apparent that I didn't have a big

29

1 too much about the earlier one, to be honest. I'd  
 2 need to see those documents again.

3 **Q.** I was not proposing to ask you any questions about --

4 **A.** It's okay.

5 **Q.** -- professor, but it may explain why you had some  
 6 recollection of some other involvement.

7 I just then want to turn to 2012. And this is  
 8 shortly before you, I think, became a director.

9 If we go to SKIP -- just let me get the  
 10 reference -- SKIP0000030\_011, please, Soumik.

11 These are the minutes of a meeting of the board  
 12 of directors of Skipton, 26th March 2012. If we go  
 13 a little further down the page under the heading  
 14 "Matters Arising", it says:

15 "The Scheme Administrator ..."

16 So that's Mr Fish.

17 "... reported that the expected increase in  
 18 borderline stage two applications had occurred. As a  
 19 result, a meeting had recently taken place with  
 20 Professor Howard Thomas, a world expert in hepatitis C  
 21 and liver disease, during which a collection of  
 22 borderline claims had been discussed. The meeting had  
 23 been extremely useful and resulted in a decision being  
 24 made on each case to either approve, decline or write  
 25 back to the applicant for specific further

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1 contribution to make there, because I wasn't more --  
 2 the Department of Work and Pensions and these sort of  
 3 things, and I gave a talk to the Caxton at the  
 4 beginning on some aspects of the history of -- and the  
 5 main problems in hepatitis C. And then I was invited  
 6 to become a director of the Skipton in a formal sense,  
 7 but -- I cannot remember where the break-point is but  
 8 I am pretty sure I was involved before that actually.  
 9 But Nick Fish ought to be able to tell you that, so --  
 10 so when I came -- but the formal appointment was in  
 11 2011.

12 **Q.** Again, I am not proposing to take you to individual  
 13 documentation relating to this, but I think it is also  
 14 right that you provided witness statements for the  
 15 Department of Health in response to two separate  
 16 judicial review challenges to aspects of the Skipton  
 17 Fund, one I think in around 2010, when there was  
 18 a challenge about the position of those who had  
 19 cleared the virus, and you provided a statement, and  
 20 then I think later in 2017 you provided a witness  
 21 statement for the Department of Health in a challenge  
 22 that looked at the comparison between HIV and  
 23 hepatitis C. Is that correct?

24 **A.** Yes. I certainly remember the second one, trying to  
 25 compare hepatitis C with HIV, yes. I can't remember

30

1 information. The meeting had been useful in  
 2 pinpointing biochemical trends which are indicative of  
 3 cirrhosis as well as other symptoms which are  
 4 significant when assessing the likelihood of advanced  
 5 liver disease. When borderline claims are received in  
 6 the future, the lessons learned from Professor Thomas  
 7 would be applied, with the option of referral to him  
 8 if there is any doubt."

9 There is then a discussion about Fibroscan, or  
 10 transient elastography, and we can see one of the  
 11 directors, Mr Spellman:

12 "... asked if there was a recognised 'trigger'  
 13 at which a Fibroscan reading was indicative of  
 14 cirrhosis. The Scheme Administrator responded that  
 15 a reading of 15 was accepted as being 90% indicative  
 16 of cirrhosis based on information provided by  
 17 Dr David Mutimer, a leading liver specialist who is  
 18 also a member of the independent appeal panel. The  
 19 Board requested that this reading be double checked  
 20 with Professor Thomas."

21 Now, I am going to come on to the Fibroscan  
 22 trigger in a moment, so if we could just leave that  
 23 aside for a moment. Can you recall anything about the  
 24 broader discussions as it how to deal with borderline  
 25 claims that you and Mr Fish appear to have had and, in

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1 particular, what's said to be biochemical trends  
 2 indicative of cirrhosis and other symptoms?  
 3 **A.** Yes. I mean, other than the APRI score and the  
 4 AST/ALT ratio, I mentioned earlier if someone has  
 5 cirrhosis then blood has difficulty flowing through  
 6 the liver, which makes the spleen become larger, then  
 7 the spleen takes out of the circulating blood  
 8 platelets. So when somebody has cirrhosis, the blood  
 9 can't go through the liver so readily and all the  
 10 blood from the intestine, I should say, and from the  
 11 spleen goes up through the liver.  
 12 But if that flow is impeded, the spleen gets  
 13 larger, the platelets go down, and either a low  
 14 platelet count or endoscopic evidence of -- endoscopy  
 15 is where you have a fiberoptic scope popped down into  
 16 stomach, where you can seek the lining of the  
 17 stomach -- if there is portal hypertension, difficulty  
 18 in the blood going through the liver, then the veins  
 19 in the lower oesophagus and stomach are distended. So  
 20 that is evidence of portal hypertension and invariably  
 21 indicates cirrhosis.  
 22 So that would be one set of observations that  
 23 would also lead to cirrhosis.  
 24 The Fibroscan was a mechanism whereby you put  
 25 a sheering impulse into the liver through

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1 transaminases, that's the ALT and the AST, which  
 2 normally should be within the liver and when the liver  
 3 cells are damaged leak out, so the blood levels are  
 4 higher, those tests only tell you about whether  
 5 there's ongoing liver damage. But the liver also  
 6 makes coagulation factors, albumin, and a whole host  
 7 of the other proteins. All the proteins in the blood  
 8 are made in the liver. So when the liver shrinks in  
 9 size, which happens with cirrhosis, then the albumin  
 10 particularly goes down. The coagulation factors also  
 11 become abnormal, not helpful -- still helpful in the  
 12 haemophilia situation, because there are ones which  
 13 aren't abnormal in haemophilia, but are reduced when  
 14 the liver size is reduced by cirrhosis.  
 15 So those three main groups of things -- portal  
 16 hypertension evidenced by endoscopy, stiffness of the  
 17 liver as measured latterly by the Fibroscan, and the  
 18 inability of liver to produce the blood proteins  
 19 because of a reduced liver size -- would be other bits  
 20 of information that might make us think and, in  
 21 particular, the physician or the nurse helping the  
 22 patient fill in the form might put in there to  
 23 convince Skipton that this was a case of cirrhosis and  
 24 should trigger a stage 2 payment.  
 25 **Q.** If we look at a meeting the following March, we can

35

1 an ultrasound probe and you look at how much the liver  
 2 wobbles, much as a jelly, you know, would wobble if  
 3 you shook it. A normal liver would wobble quite  
 4 a lot, whereas one which has cirrhosis would become  
 5 stiff and wouldn't wobble. That was the basis for the  
 6 Fibroscan.  
 7 I think later on, and you may be coming to this  
 8 later on, I think we thought that we should have  
 9 a lower score than 15. I think was it 12 or something  
 10 like that?  
 11 **Q.** I am going to pick that up with the next document we  
 12 look at, Professor Thomas?  
 13 **A.** Yes, because I thought that 15 -- David Mutimer's  
 14 thinking, really, was that he wanted to get  
 15 specificity up high; in other words, he didn't want to  
 16 misdiagnose cirrhosis, but that would mean when you  
 17 increased the specificity, then the sensitivity goes  
 18 down. So I thought we would be better and fairer to  
 19 the patients if we set it at a lower level where we  
 20 would let some people through who didn't have  
 21 cirrhosis but were probably very near it anyway and we  
 22 wouldn't miss many. So that's the component of the  
 23 other tests.  
 24 The other things that happen when you are near  
 25 to cirrhosis is that the liver, as well as releasing

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1 see the issue of the Fibroscan being picked up.  
 2 That's SKIP000030\_085, please, Soumik. We can see  
 3 this is 11th March 2013 meeting of Board of Directors  
 4 of the Skipton Fund. You are present and we can see  
 5 from the first paragraph:  
 6 "Welcome to Professor Thomas.  
 7 "The Board welcomed Professor H Thomas  
 8 a director and looked forward to his expert help."  
 9 So this the first meeting, as far as we can  
 10 understand it, that you attended as a director. Then  
 11 if we look towards the bottom of the page, we can see  
 12 the issue of Fibroscan being referred to:  
 13 "The Scheme Administrator referred to the  
 14 Fibroscan reading that was considered to be indicative  
 15 of cirrhosis."  
 16 Then there is reference to Dr Mutimer's view  
 17 which we looked at in the previous set of minutes.  
 18 Then reference to a medical bulletin having been  
 19 submitted, taken from the Hong Kong medical diary  
 20 which suggested a reading of 12.5 or over as  
 21 an indicator of cirrhosis. Then this records you  
 22 citing:  
 23 "... a NICE study into the effects on the liver  
 24 of hepatitis B which suggested that 10 ... or above  
 25 was an indicator that cirrhosis might be present. It

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1 was agreed that, due to the range of differing  
 2 opinions, all transient elastography readings (of  
 3 which Fibroscan is one brand) would continue to be  
 4 considered along with other test results and markers  
 5 to determine the likelihood of cirrhosis. Borderline  
 6 applications would be referred to Professor Thomas for  
 7 his expert opinion."

8 So that appears to be the way in which the  
 9 issue of Fibroscan reading was addressed at that  
 10 stage. No absolute cut-off point one way or another,  
 11 but not reliance upon -- or not requiring a reading of  
 12 15 or above; is that right?

13 **A.** Yes, and I rapidly thought when that responsibility  
 14 decided on me, who else I could get to be involved,  
 15 and that's where I thought it would be a good idea to  
 16 get Professor Dusheiko involved, because I think when  
 17 there are -- you know, when it is marginal, it is good  
 18 to get other people's views and that's why I got --  
 19 put forward -- got Professor Dusheiko involved as  
 20 well, because he was equally well-informed in this  
 21 area as I had become.

22 **Q.** Then there is one further discussion about Fibroscan  
 23 readings I want to ask you about. It's a couple of  
 24 years later, SKIP0000030\_068. So we can see these are  
 25 the minutes of the meeting of the Board of Directors

1 **A.** Yes, in short, but I thought we had a bigger effect  
 2 on -- well, I mean, there was already very few cases  
 3 of stage 2 refusal overturned by the Appeals Panel,  
 4 I thought, and that was because that was highly  
 5 objective in the way that we have just been  
 6 discussing. It was the stage 1s that were the problem  
 7 really, where it had to be more than 50% probable that  
 8 the individual had received NHS blood or blood  
 9 products at a time when medical records were often not  
 10 available.

11 We went to extreme ends to try to provide, even  
 12 before the Appeal Panel were involved, evidence to  
 13 suggest that they had received a blood transfusion.  
 14 But that was a soft process made a lot worse by the  
 15 fact that I think after seven years most records were  
 16 no longer available, in general, not just in this  
 17 setting. So, for instance, if you had been involved  
 18 in a road accident and your pelvis had been fractured  
 19 or one of the long bones of the leg had been  
 20 fractured, it was likely you would be having more than  
 21 two units of blood.

22 So I went online and asked the question of how  
 23 many patients, you know, who had been involved in  
 24 a road accident and had fractured their pelvis would  
 25 receive a blood transfusion, and there's a NICE study

1 of Skipton, 10 March 2015. You are present, as is now  
 2 Professor Dusheiko. We can see from the "Welcome to  
 3 the new Director and Finance Manager" that this is  
 4 Professor Dusheiko's arrival on the Board of  
 5 Directors. If we then go to the bottom half of the  
 6 page, there is reference under the heading "Matters  
 7 arising". If we just look at the paragraph that has  
 8 the number 165 next to it, it says:

9 "The Scheme Administrator reported that, since  
 10 the Fund had greater board level medical expertise,  
 11 the success rate at the more recent Appeals Panel  
 12 meetings had been less than the overall average of  
 13 circa 50%. It was agreed that the appointment of  
 14 Professor Dusheiko meant it was no longer deemed  
 15 necessary to appoint another medical director,  
 16 especially as there was often good medical data  
 17 published online to assist with applications where  
 18 records of a medical procedure were provided but not  
 19 specifically that referenced treatment with blood or  
 20 blood products."

21 Now, that's obviously concerned with the  
 22 stage 1 process, but was it your understanding that  
 23 fewer cases were being overturned on appeal because of  
 24 your and then Professor Dusheiko's involvement with  
 25 the stage 1 process?

1 on that showing that virtually everybody did. So we  
 2 were able to say anybody with scars showing they had  
 3 had a fracture of the femur or historical evidence  
 4 that they had had a fractured pelvis, then we could  
 5 say that would be taken as evidence.

6 So we are trying to build a case to help those  
 7 that had -- who were putting in a stage 1 application  
 8 at a time when they couldn't actually lay hands on  
 9 notes really, and Geoff and I -- Geoff Dusheiko and  
 10 I -- often met to think of ways in which we could do  
 11 that, for instance, taking photographs to see what  
 12 sort of operation they had had. It might seem strange  
 13 but patients actually went along with that and sent  
 14 a picture to show they had had a caesarean section,  
 15 where quite a few patients would have a blood  
 16 transfusion and these sort of issues really.

17 **Q.** I will come back to stage 1. If we go over the page  
 18 whilst we're on this document we can then pick up --

19 **A.** Stage 2 then, specifically, we did manage to get that  
 20 down to a very good level of acceptability and with  
 21 very few appeals overturning.

22 **Q.** We can see the discussion in the long top paragraph on  
 23 this page, further discussion about Fibroscan  
 24 readings. So it says:

25 "Professor Thomas reported that he had recently

1 attended a British Association for the Study of the  
 2 Liver/British Society of Gastroenterology meeting  
 3 about the new HCV treatments during which he  
 4 summarised the Skipton Fund's assessment process for  
 5 determining if cirrhosis was probable for the stage 2  
 6 payment. The data supported a Fibroscan score of  
 7 14.5 kPa as an indicator of a greater than 50%  
 8 probability of cirrhosis in the absence of other  
 9 markers. At the meeting the clinicians had  
 10 recommended a Fibroscan score for advanced fibrosis  
 11 ... of 11.5 ... which was lower than that used for  
 12 Skipton Fund stage 2 assessments, as they wanted to  
 13 make sure the sensitivity for offering treatment was  
 14 high ([over] 80%). Although a good approach from  
 15 a treatment point of view, as it limited the chance of  
 16 missing a patient with cirrhosis, from the Fund's  
 17 point of view it would mean that cirrhosis would be  
 18 overestimated in many cases. Professor Thomas would  
 19 make the Department of Health aware of this difference  
 20 in approach and that, unless requested otherwise, the  
 21 Fund would continue to consider applications for  
 22 evidence of a greater than 50% probability of  
 23 cirrhosis."

24 If we just go back up the page so we see the  
 25 whole of that first paragraph, Soumik. Thanks.

41

1 course, when it got to 6 and they had cirrhosis then  
 2 they would be at risk of developing primary liver cell  
 3 cancer.

4 So I felt uncomfortable watching this and this  
 5 was at the stage when these new drugs came in, which  
 6 were virtually 100% effective. So I thought we should  
 7 be giving these new drugs to people in the  
 8 pre-cirrhotic stage, Ishak 5, rather than waiting  
 9 until they had cirrhosis. The Department of Health  
 10 had already decided that patients with cirrhosis would  
 11 get these drugs before it had been considered by NICE,  
 12 and I think they made provision for 500 people to get  
 13 this, but I wanted to include, for the reasons I have  
 14 just said, that Ishak 5 should be included, and that  
 15 didn't come about, because -- I don't know why, it  
 16 wasn't my decision. But I wrote to the Minister  
 17 saying I thought we should do this and it didn't come  
 18 about.

19 But that's why, because that was going on in  
 20 the background, I thought we should be moving down to  
 21 a Fibroscan score of about 12, really because we would  
 22 then be including quite a few of these Ishak 5s. If  
 23 you like, it was a covert way of getting these  
 24 patients into the scheme.

25 Q. This document reads as though the score that was as

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1 This would tend to suggest by this stage,  
 2 March 2015, the Skipton Fund was using 14.5 Fibroscan  
 3 score as its indicator of a probability of cirrhosis,  
 4 whereas what we looked at previously suggested it was  
 5 going to be lower than that. Can you assist us with  
 6 understanding the position?

7 A. I mean, we did move it downwards. There is no doubt  
 8 about that and we alighted on 12. That was  
 9 principally because Ishak 5, which is just  
 10 pre-cirrhotic and Ishak 6, which is cirrhosis, are not  
 11 that different, even at a biopsy level. I was  
 12 concerned that -- I think I included -- at one stage  
 13 when we were doing serial Fibroscans, it was apparent  
 14 that some patients were moving from a pre-cirrhotic to  
 15 a cirrhotic stage.

16 Pre-cirrhotic would be 5 to cirrhosis at 6.

17 Once you have cirrhosis, as I mentioned earlier, then,  
 18 even if the virus is cleared, you don't go back to  
 19 lower levels of fibrosis and ultimately to normal,  
 20 whereas if you are treated at Ishak 5 and you get rid  
 21 the virus, the liver goes back to complete normality.  
 22 We were seeing patients who were having serial scans  
 23 who were moving from 4 or 5 up to 6, you know. During  
 24 the period of a year there were 90 cases I brought to  
 25 the attention of the Department of Health. Then, of

42

1 a matter of fact being used by the Skipton Fund was  
 2 14.5. Is it your recollection that that's not correct  
 3 then?

4 A. I can't really remember, to be honest. I remember the  
 5 meeting with the British Society of Gastroenterology,  
 6 where we did come on to, you know, this figure of  
 7 14.5, but I think it is recorded somewhere we did  
 8 decide to use the figure of 12 in the Skipton. So,  
 9 for the reasons I have just said, I thought it was  
 10 better to include those slightly lower levels, because  
 11 we might pick up some that were going to process to 6  
 12 in the very short-term, namely the next year.

13 **SIR BRIAN LANGSTAFF:** It might depend upon the quality of  
 14 the person who took the minutes or the quality of  
 15 the minutes rather, because the reference to "the data  
 16 supported a Fibroscan score" might not be the  
 17 conclusion of Professor Thomas, it might be his report  
 18 of what the British Association made of the data, in  
 19 context.

20 **MS RICHARDS:** Yes, indeed. It is not clear.

21 **SIR BRIAN LANGSTAFF:** It is not entirely clear.

22 **MS RICHARDS:** Which is the reason for asking the question,  
 23 sir --

24 **SIR BRIAN LANGSTAFF:** Obviously.

25 **MS RICHARDS:** -- because the documentation doesn't, I

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1 think, provide a clear answer.  
 2 Professor, do you know whether the Skipton Fund  
 3 published anything about what its approach to  
 4 Fibroscan scores was so that clinicians would know  
 5 whether it was worth assisting their patients to make  
 6 an application to the Skipton Fund on the basis of  
 7 a Fibroscan result or not?

8 **A.** I can't recall whether we did or didn't, really.  
 9 Certainly, the British association for the study of  
 10 the liver, BSG, did -- that was published. I mean,  
 11 the BSG and EASL, and the British Association, always  
 12 published their meetings, because the British Society  
 13 of Gastroenterology owned Gut and they tended to put  
 14 these sort of policy decisions into Gut so everybody  
 15 could see it. But it was a contentious issue really,  
 16 not just from the point of view of whether patients  
 17 should get an ex gratia payment but, as I mentioned  
 18 before, when patients were deemed to have cirrhosis,  
 19 they are at risk, 2 to 4% per year, of developing  
 20 primary liver cell cancer, and that requires that they  
 21 have some form of imaging, usually an ultrasound but  
 22 possibly a CT scan or MR scan, so that the tumour is  
 23 picked up when we could resect it or recommend the  
 24 patient for a liver transplant.

25 So that meeting of the BSG was also serving

1 **A.** It is important to say "a director", by the way,  
 2 because we had group responsibility. I think you are  
 3 promoting me to a level that I didn't attain. Peter  
 4 Stevens was "the director" -- the chairman of the  
 5 directors I should say.

6 **Q.** If we look at the bottom of the page, we can see that  
 7 the board considered here the issue of "Stage 2  
 8 applications from the estates of people who were  
 9 co-infected with hepatitis and HIV, who died before  
 10 29th August 2003 and whose records have been  
 11 destroyed".

12 Then we see:

13 "The Scheme Administrator reported that there  
 14 had been a number of Stage 2 applications from the  
 15 estates of people who had died and whose records had  
 16 now been destroyed. In many cases it was apparent  
 17 that the family member, most often a widow, distinctly  
 18 recalled that the deceased had been diagnosed with  
 19 cirrhosis, but because of the lack of records the  
 20 application had been declined. Some of these cases  
 21 were also declined by the Appeal Panel, which had then  
 22 undertaken extensive research into the matter."

23 Then there is a reference to a suggestion by  
 24 Dr Mutimer. Then it is the next paragraph I wanted to  
 25 ask you about. It says:

1 that function. It wasn't purely on the issue of  
 2 whether the Skipton stage 2 payments would be  
 3 triggered. Professor Mutimer, of course -- actually,  
 4 he was on the Appeal Panel at that stage, was he not?

5 **Q.** Yes.

6 **A.** I think he was very keen to be as precise as possible,  
 7 really, and I was a little bit more on the side of  
 8 sort of saying "It is going to be in the patient's  
 9 benefit to go for a slightly lower level", which is  
 10 why I thought we agreed on 12 in the end.

11 What is agreed at this meeting is one thing,  
 12 about what Skipton decided to do, which I am surprised  
 13 can't be found -- I would hope it could be found  
 14 somewhere in the minutes of various Skipton meetings,  
 15 I am pretty sure we agreed with 12.

16 Professor Dusheiko might be able to help there --

17 **Q.** Thank you. We will check that.

18 **A.** -- because he might recall better than I can,  
 19 probably.

20 **Q.** I want to go back then, on a different issue, to the  
 21 previous set of minutes we looked at, so that's  
 22 SKIP0000030\_085.

23 So this is the March 2013 meeting, your first  
 24 meeting as director again.

25 If we look now at the second page --

1 "After further meetings and research, and with  
 2 the help of Professor Thomas, a model had been created  
 3 based on average fibrosis progression rates in people  
 4 who were mono-infected with hepatitis C and  
 5 co-infected with hepatitis C and HIV. The Scheme  
 6 Administrator summarised the model, the values  
 7 and dates that had been used ... and the reasons why  
 8 these figures had been used. Around 40 declined  
 9 applications from the estates of co-infected people  
 10 would need reviewing on the basis of this model."

11 Can you assist us, because I don't think we  
 12 have the underlying model itself, with what this model  
 13 was and what it told you and how it was used?

14 **A.** I can't remember a heck of a lot about this, I am  
 15 afraid. There was a paper produced, and I think  
 16 Professor Dusheiko was involved with this, plus one of  
 17 the Cambridge mathematical modelers, and the focus was  
 18 to look at people with hepatitis C mono-infection as  
 19 opposed to those with hepatitis C and HIV. That  
 20 allowed us to come up with a formula really for saying  
 21 that -- depending whether they had the mono-infection  
 22 or the co-infection, what would be the probability in  
 23 the absence of a post mortem that that patient had  
 24 cirrhosis.

25 I could look up the papers again, but that was

1 essentially the summary. I can't remember, you know,  
 2 what the detail of the formula was, but -- and that  
 3 did mean that we could say with a reasonable  
 4 probability, the magical greater than 50% probability,  
 5 that the patient had cirrhosis and had died, and --  
 6 and no post mortem being done, of course, which, in  
 7 the case of HIV co-infected individuals, there was  
 8 a reluctance to do this, so it was required that we  
 9 should have some sort of model.

10 I can't really say anything more about the  
 11 detail of it, but I could look it up in due course if  
 12 you wanted.

13 **Q.** Thank you. I think we understand from other documents  
 14 it is described as giving rise to predictive formulae  
 15 for progression to cirrhosis?

16 **A.** Yes.

17 **Q.** So the aim was to apply it, whatever precisely it  
 18 looked like, to the cases of those who were dead and  
 19 for whom no records, or no relevant records, existed  
 20 to work out what the possibility was that they would  
 21 have progressed to cirrhosis by the time they died.  
 22 Is that right?

23 **A.** Yes -- I am sorry. A bird is just banging on the  
 24 window, so I was distracted there.

25 Would you mind saying that again?

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1 your evidence, but not before. But in the meantime  
 2 you can just talk about anything else you like.  
 3 11.45.

4 **A.** Okay.

5 (11.18 am)

(Short break)

7 (11.45 am)

8 **SIR BRIAN LANGSTAFF:** Yes.

9 **MS RICHARDS:** Professor Thomas, I am going to ask you  
 10 a little more about the stage 1 decision-making  
 11 process now. I am going to ask you to look at  
 12 a passage in your witness statement.

13 Soumik, could we have WITN3824007, please, and  
 14 if we could go to page 29.

15 That's different from the version I have got.

16 Give me a second. Okay. We can pick it up at the top  
 17 of the page. So this is in paragraph 112, I think, of  
 18 your statement. It says:

19 "In general patients were concerned about the  
 20 evidence needed to establish that the PTH  
 21 [post-transfusion hepatitis] was probably (greater  
 22 than 50% likely) due to NHS blood and not other means  
 23 of infection such as IVDU, tattooing etc. All  
 24 haemophilia patients who had received factor VIII  
 25 concentrate were automatically accepted as infected by

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1 **Q.** Yes. It was, as we understand it, a predictive  
 2 formula -- that's how it is described in other Sipton  
 3 documents -- for progression to cirrhosis?

4 **A.** Yes.

5 **Q.** So whatever the precise data was -- it perhaps does  
 6 not matter for present purposes -- it was then applied  
 7 to work out what the probability was that someone who  
 8 was dead, for whom there are no records or relevant  
 9 tests, would have progressed to cirrhosis?

10 **A.** Correct.

11 **Q.** Sir, I note the time. I am going to move on to  
 12 stage 1 applications in a little more detail now. So  
 13 perhaps this is a good moment for a break?

14 **SIR BRIAN LANGSTAFF:** Yes. We will take a break until  
 15 11.45. It will allow you to get some refreshment,  
 16 professor, and those who want to do the same. So  
 17 11.45.

18 **MS RICHARDS:** Sir, I can't remember whether you gave the  
 19 professor the warning.

20 **SIR BRIAN LANGSTAFF:** I haven't.

21 Let me just tell you what the rules are. You  
 22 must not during this break, or any other break that we  
 23 may have, discuss with anyone the evidence you have  
 24 given or the evidence that you are yet potentially to  
 25 give. You can discuss that after you have finished

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1 NHS material; this was established by several  
 2 prospective studies showing that the incidence of  
 3 abnormal ALTs after concentrate infusion, both in the  
 4 literature and our own study, was almost 100%.  
 5 Nick Fish signed off on these cases without clinical  
 6 input."

7 Then you turn to transfusion cases and say  
 8 this:

9 "In cases of blood and plasma transfusion, we  
 10 had to say that it was more than 50% likely to be due  
 11 to transfusion. In the absence of GP or hospital case  
 12 notes this was very difficult. Occasionally we had  
 13 evidence of a major operation where in virtually all  
 14 cases blood transfusion would have been necessary eg  
 15 cardiac valve replacement or major trauma resulting in  
 16 pelvic or femur fractures. These cases usually  
 17 involved both Professor Dusheiko and myself and  
 18 involved detailed consideration. In my view this was  
 19 as objective as possible.

20 "In the absence of case notes it was almost  
 21 impossible for Professor Dusheiko and myself to  
 22 provide this level of certainty. In many cases all we  
 23 could do was to exclude non-transfusion related modes  
 24 of transmission such as body piercing and IVDU.  
 25 Sometimes we had evidence of surgery which did not

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1 usually require transfusion but infrequently did; this  
2 again required clinical judgement."

3 Now can I ask you, first of all, just to assist  
4 us with understanding how you would use your clinical  
5 judgement to make the assessment of whether the  
6 applicant was probably infected by blood transfusion?

7 **A.** Well, it's really just a second way of saying what  
8 I have mentioned earlier, in so much as if, you know,  
9 a surgical procedure or, as I mentioned, trauma were  
10 invariably needing transfusion, then that was -- then  
11 we would take that as given. And the way we  
12 established those precedents, if you like, was by  
13 going to the literature.

14 So I would Google in, as I think  
15 Professor Dusheiko did as well, you know, "percentage  
16 of patients receiving blood during aortic valve  
17 replacement" or "during the pinning of a pelvic  
18 fracture". Surgeons have often, and indeed  
19 haematologists, have looked at series where they can  
20 provide this sort of data. Where we find that, then  
21 we sort of moved that on to the group of patients  
22 needing just a sign-off without any further  
23 consideration.

24 I mean, there was very little else that one  
25 could look at. There were GP's notes, which in the

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1 surgery? How would you approach those types of cases?  
2 Would those applications be rejected if you couldn't  
3 find anything in the notes that gave a hint of  
4 a haemorrhage?

5 **A.** Yes. In the main that would be the case, because  
6 I took the view, when I was doing this by myself, that  
7 if at that stage there was no evidence -- it was our  
8 mandate to say whether it was more than 50% likely  
9 that the transfusion had occurred. If there were no  
10 notes and no evidence of the type that I have been  
11 describing, then I couldn't say that. But I know that  
12 Nick Fish and I also would point out that the patient  
13 could appeal this. And the appeal group had a much  
14 stronger position. You know, their view would be  
15 held, irrespective of how solid it was -- when I say  
16 "solid", medically based.

17 Indeed, for some time there was a minimum of  
18 medical input on the appeals group. I think only one  
19 of the people were medically qualified. So I took the  
20 view that -- you know, large sums of money were  
21 involved, the Department of Health were taking this  
22 out of the NHS budget, that I should, you know, use my  
23 medical knowledge to take out those cases where  
24 I could definitely say there had been NHS blood or  
25 blood transfusion and no evidence of other

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1 main were not destroyed after seven years, which seems  
2 to be the case in hospital-based medical practice.

3 Many GPs have these sort of cards where they, you  
4 know, note down over maybe 20 or 30 years what has  
5 happened to a patient. So, you know, occasionally we  
6 would find in a woman that she had had, you know,  
7 a major haemorrhage during delivery of a child. So,  
8 you know, we know that caesarean sections, you know,  
9 with placenta previa, often results in massive  
10 haemorrhage. So there were little incidents like that  
11 where we did our best to say, "Well, in most cases  
12 this would require transfusion". That's what I meant  
13 by "clinical judgment". Whereas, in contrast to  
14 stage 2, it was -- as I say, it was cast iron  
15 dependent on the APRI score and AST/ALT ratio.

16 **Q.** What about cases where there were no medical records  
17 revealing a transfusion, either because the records  
18 had been lost or destroyed or because they are  
19 incomplete or, as may often be the case, they don't  
20 actually record the administration of blood, and you  
21 can't say, as a result of your research, "These are  
22 cases which almost invariably involve a requirement  
23 for transfusion", but you do know, either on the basis  
24 of what the applicant has told you or on the basis of  
25 what their GP has told you, that they had some form of

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1 possibilities. For instance, you know, some people --  
2 there was one case where the gentleman was taking  
3 methadone, which is usually only given for intravenous  
4 drug use, and he argued that he had only taken  
5 non-intravenously administered drugs. So, I mean, one  
6 could weed out cases like that and go through, in  
7 a positive sense, the ones where there was evidence of  
8 blood transfusion, and then it was up to the appeals  
9 group to use a much more subjective set of rules. And  
10 their opinion was final. So I thought that that  
11 fallback position safeguarded the patient's interests  
12 should, on further inquiry, something else came up  
13 that I or Geoff hadn't noted.

14 **Q.** We know both from the documents and from Mr Fish's  
15 evidence that at the stage of Mr Fish looking at it  
16 with the assistance of one of the directors, what was  
17 looked at was essentially medical information, what  
18 the record showed or didn't show. There was no  
19 provision, for example, to consider and receive  
20 a personal statement from the applicant setting out  
21 their recollection of events or a statement from  
22 a family member setting out their recollection that  
23 their relative had received a transfusion, whereas  
24 that material could be considered at the Appeal Panel  
25 stage.

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1 A. Yes.

2 Q. Was there any reason you were aware of as to why that

3 information couldn't be considered at the first stage

4 by the administrator and a director?

5 A. We did see cases where what you said was the case, and

6 a relative would say, for instance, "Well, when I came

7 in to see my husband", or wife or what have you, "they

8 had an intravenous transfusion device up, and I could

9 see", the relative would say "and I could see a little

10 bit of blood just near to the point of insertion

11 through the skin". And always, in any transfusion of

12 clear fluids, in other words, saline for rehydration,

13 there is always reflex of blood into that last 1 to

14 2 centimetres of the tubing, and that, for someone who

15 isn't involved in medicine or transfusion, they would

16 take to indicate cast iron visual evidence of

17 transfusion, but it isn't.

18 So we listened to everything, and Mr Fish

19 actually often had conversations with the person on

20 the telephone to recommend evidence that might be

21 provided, but -- I make no bones about it, this was

22 an extremely difficult stage of the assessment and why

23 I initially, and latterly Geoff Dusheiko, put so much

24 emphasis on objective evidence that we could bring

25 forward for stage 2 payments, because we were quite

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1 through a drug or sexual route or they'd been infected

2 via transfused blood?

3 A. Well, I think that, in retrospect, could have been

4 a way of proceeding, but I took the view that this

5 attitude could be applied at the stage of the appeal.

6 We did recommend in the letter that Nick sent out that

7 the appeal process was open, and a very large number

8 of the people where we had not found positive evidence

9 for involvement of NHS blood and where these other

10 risk factors were not present, a high percentage of

11 these did go on to appeal. So we felt that this was

12 the stage at which that could and should happen.

13 We, at every corner really, tried to do the

14 best by the patients, and make sure there was some

15 uniformity of the process that was being used. We

16 didn't talk to the Appeal Panel in these terms, but

17 I think every single letter would say, you know, "We

18 can't find any involvement of NHS blood here, but it

19 is open to you to go to the Appeal Panel". So we felt

20 we had not been inappropriately -- you know, we had

21 not been putting the patients to a major disadvantage

22 really.

23 And many of the comments or the evidence the

24 patient came up with were of the type that were

25 completely plausible. I mean, this business of,

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1 aware of the fact that the stage 1 process was, you

2 know, highly subjective.

3 Q. Your statement refers, in the bottom paragraph on the

4 screen, to how:

5 "In many cases, all we could do was to exclude

6 non-transfusion related modes of transmission such as

7 body piercing and IVDU."

8 Did it ever occur to you or any of the other

9 directors or Mr Fish to take a slightly different

10 approach to stage 1 applications and look to see which

11 was the least unlikely mode of transmission?

12 A. The least unlikely.

13 Q. If I can suggest a hypothetical scenario to you. You

14 had someone for whom no evidence whatsoever to suggest

15 they had ever had a tattoo or a piercing or any

16 likelihood of sexual transmission, which we know was,

17 I think, a low risk in any event, and no evidence

18 whatsoever to suggest intravenous drug use, no

19 evidence of overseas medical treatment of a serious

20 nature. They had to have got their hepatitis C

21 somehow. If they could point to some form of surgical

22 intervention that they had undertaken within the NHS,

23 why not take the approach of looking at which is the

24 least unlikely: that this 70-year old individual,

25 married for 50 years, has been infected with HIV

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1 "Well, I could see that there was a transfusion in

2 place and there was blood staining in the area, the

3 last 2 to 3 centimetres, does this not indicate the

4 patient had a blood transfusion?" The answer is no,

5 but it is quite reasonable the patient would believe

6 this is the case and the patient's relative would also

7 believe this was the case.

8 As I say, we were of the view this would then

9 be -- the Appeal Panel could actually say, you know,

10 "Well, we think, on balance, there is no reason for

11 not believing this patient. Let's pass it through".

12 Q. Now, you and Professor Dusheiko -- sorry.

13 A. Do you think that was unfair? I mean, there was

14 a well-trodden track for the patient to continue to

15 prosecute their claim in the system, if you like,

16 through the appeal process.

17 Q. You and Professor Dusheiko, your area of expertise,

18 both of you, was hepatology?

19 A. And general medicine. We both did general medical

20 take, we call it, where for one day a week, usually,

21 you take all the cases that come into an acute

22 hospital. Then you look after them for 24 hours, the

23 next day you usually get a specialist to look after

24 them, unless it is a more pressing concern, where you

25 get a cardiologist or an endocrinologist to help

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1 during the night hours.  
 2 **Q.** You would be having to make clinical judgments about  
 3 whether a particular operation or intervention might  
 4 have required a transfusion. Was there ever a system  
 5 in place or contemplated whereby other medical  
 6 experts -- perhaps an orthopaedic surgeon if it had  
 7 been orthopaedic surgery, or an ENT specialist if it  
 8 had been ENT interventions -- to ask for their take or  
 9 input? Was that ever considered?

10 **A.** Yes, and that's why we went -- we didn't actually --  
 11 the way of getting that bit of information, of course,  
 12 was to look online at the literature, look at NIH  
 13 PubMed, which is a way of accessing all medical  
 14 literature. You could just ask, you know, "percentage  
 15 of patients undergoing an operation who received  
 16 blood?" and it is surprising how much of that type of  
 17 information is in there.

18 For instance, tonsillectomies very rarely, if  
 19 ever, require a blood transfusion, whereas pelvic  
 20 fractures and fractures of the femur do, you know. So  
 21 that information is there without having to ask one  
 22 particular surgeon. These were series that you could  
 23 find through NIH PubMed. NIH is National Institute of  
 24 Health and PubMed is a public database. You could  
 25 actually find the date when it was done, because blood

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1 generally required, but could -- obviously depending  
 2 upon what precisely happened during the surgery --  
 3 from time to time be required, what would the approach  
 4 be to that? Would that be sufficient, coupled with  
 5 perhaps evidence from medical records that there had  
 6 been some form of surgery, or did you require there to  
 7 be positive evidence that most such operations would  
 8 involve transfusion?

9 **A.** Well, we were interested in a percentage that required  
 10 blood transfusion because don't forget our mandate --  
 11 we were implementing recommendations that had to be  
 12 probably, which meant in legal terms, I gather, that  
 13 it was more than 50% likely that any occurrence had  
 14 occurred. With that constraint -- one of the reasons  
 15 we went to the publications in NIH PubMed was there  
 16 was, you know, objective quantitative data. You know,  
 17 a surgeon would like to be -- would say "Well, all the  
 18 bowel resections I have done" and there are maybe 150  
 19 in a surgeon's life with one particular operation, he  
 20 would have recorded, possibly for an MD or an MSc that  
 21 only 70% of these required blood transfusion, in which  
 22 case we could authoritatively sign off on that. But  
 23 it might say "only 3% required blood", in which case  
 24 we would be less likely to agree that.

25 All the time, of course, we knew that the

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1 requirement for an operation varied over time. So you  
 2 could look then at when the paper was found in NIH  
 3 PubMed database, it would say "published by so and so  
 4 surgeons in the UK in 1983" or "2020". So you got  
 5 an idea of what was happening at one particular time.

6 This was quite important because we became very  
 7 concerned about unnecessary use of blood once non-A,  
 8 non-B in the late 1970s became known about. There was  
 9 a mandate -- not a mandate -- a suggestion from most  
 10 blood transfusion doctors that if you only need to  
 11 give a patient one or two units of blood, you probably  
 12 didn't need to give them a transfusion at all and that  
 13 you could protect them from this risk. This was only  
 14 evident in the more recent years in transfusion  
 15 medicine, whereas back in the 1970s, or so, people or  
 16 doctors would transfuse their patients with relatively  
 17 small amounts of blood which probably wasn't  
 18 necessary. They could just have clear fluids, which  
 19 didn't carry any risks.

20 So that's how we avoided the bias of going to  
 21 one surgeon. The NIH PubMed is a much better way of  
 22 doing it.

23 **Q.** If that research showed not that transfusion was  
 24 usually required in the majority of cases, or indeed  
 25 a near certainty, but that transfusion was not

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1 appeal group could actually say "No, we find we should  
 2 give the patient the benefit of the doubt". The  
 3 appeal group were operating to different rules. They  
 4 were told that whatever they decide was absolute. We  
 5 knew that what we decided was going to be reviewed by  
 6 an appeal board, and we didn't want to be either  
 7 positive or over-negative. We tried to implement the  
 8 rules as we saw them. In other words, if there are  
 9 definite notes in the case notes of a transfusion,  
 10 that was fine. If the patient had a history of  
 11 intravenous drug use or had received a transfusion  
 12 abroad, as well as one in the UK, it would be more  
 13 likely that the one or the behavioural problem were  
 14 the cause.

15 I will give you an example, for instance. In  
 16 Egypt, after the attempt to eradicate schistosomiasis,  
 17 something like 20 to 30% of the Egyptian population  
 18 were hepatitis C positive. So if we heard, as we did  
 19 in one case, that somebody had had an operation in  
 20 Egypt, it was more than likely they had had infected  
 21 blood in Egypt.

22 The other information we tried to integrate, by  
 23 the way, which I should mention here, was what  
 24 genotype of the virus was involved. You probably know  
 25 from earlier people that there are maybe five or six

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1 genotypes, which is a variant of the hepatitis C virus  
 2 and the prevalence in different countries is markedly  
 3 different. If I remember correctly, genotype 5 is  
 4 common in China and if the patient had lived part of  
 5 his life in China and part in Britain, whereas the  
 6 common genotypes here are 1 and 3, and the patient had  
 7 genotype 5, we would conclude that it is likely to, on  
 8 probability, to have been acquired by something that  
 9 happened in China.

10 So all that sort of information had to be  
 11 integrated and a decision made with a safety net  
 12 mentioned in the letter that if the patient felt  
 13 strongly, or felt at all, that he had been  
 14 disadvantaged, then he or she could say, "I'd like to  
 15 go to appeal", and Nick Fish would actually suggest  
 16 that they might want to look at the genotype in these  
 17 type of issues to see if that information could be  
 18 presented, you know, to help the patient's case.

19 That's all I can say on that but we recognised  
 20 it wasn't ideal but combined with the appeal process  
 21 we felt it was not going to disadvantage the patients  
 22 if we were -- if we applied the rules as they were  
 23 mandated to us.

24 **Q.** If I can just go back to the evidence that you might  
 25 look for through the published medical material. You

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1 point in time with a particular operation what the  
 2 probability was, but I would be misguiding people if  
 3 I said, well, you know, I can tell that by 49%  
 4 refused, 51%, you know, let the case go through. It  
 5 would be plus or minus, you know, maybe 10 or 20%.  
 6 I could justify that in my own mind by the fact three  
 7 or four other people would then look at it at the  
 8 appeal process.

9 **Q.** We can take that down.

10 Mr Fish accepted yesterday that there might be  
 11 three problematic consequences of pinning too much  
 12 faith on the appeal process and I just want to explore  
 13 those with you and see whether you have got any  
 14 comment on it.

15 The first might be that some people, very ill  
 16 with hepatitis C, for example, suffering depression,  
 17 suffering brain fog and the like, might not go to  
 18 appeal. They might feel there is no point. They  
 19 might feel too ill. Not all refusals were appealed.  
 20 The Inquiry has seen examples, for example, of  
 21 somebody who had dyslexia and felt he couldn't go  
 22 through a further appeal process. So would you accept  
 23 that would be potentially a problem, that some people  
 24 might just give up at the first stage?

25 **A.** Yes, I mean, undoubtedly that could be a possibility.

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1 gave us two examples, one of evidence to suggest that  
 2 in only 3% of cases a transfusion for a particular  
 3 type of procedure might be required, the other that in  
 4 70% of cases a transfusion might be required.

5 Did you need evidence of transfusions being  
 6 used in more than 50% of cases for a particular  
 7 procedure, in order to be satisfied without there  
 8 being supportive evidence in the medical records?

9 **A.** Yes. I mean, they tended to be very polar. I mean,  
 10 you know, most operations were things like  
 11 cholecystectomy and tonsillectomies and, you know,  
 12 very few, in single figures, would require transfusion  
 13 there, whereas as trauma, cardiac operations, you  
 14 know, in the early days, would require a transfusion  
 15 in the majority of cases.

16 I mean, just to give another example to  
 17 illustrate, for instance, more recently during liver  
 18 transplantation some surgeons managed to do the liver  
 19 transplant without the requirement for any  
 20 transfusion. That was related by a blood-saving  
 21 technique where they aspirate the blood that is spilt  
 22 into the wound, wash it and put the red blood cells  
 23 back.

24 So, you know, that's why I make the case of --  
 25 you know, with leeway we tried to get a view at one

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1 I would imagine that's quite rare. Most people --  
 2 I don't have the figures in front of me -- a large  
 3 proportion of patients did go through to appeal,  
 4 having been initially turned down.

5 **Q.** The second potential problematic consequence of  
 6 pinning one's hopes on the appeal process would be it  
 7 is requiring people who, as I say, may already be very  
 8 ill, debilitated, to go through not just one  
 9 application process but to go through a second process  
 10 as well, which might in itself take a toll on them.  
 11 Would you accept that?

12 **A.** Yes, I would, of course. It is worthwhile looking at  
 13 the figures that you have later on in your data.  
 14 I think you say there is 6,712 patients who applied  
 15 for a stage 1 application, approved at first stage  
 16 5,529, you know, which is 80%. So, you know, not  
 17 that -- you know, we waved through a large number.  
 18 Whenever the issues of patient feedback were put  
 19 before either Skipton or Caxton, it was always  
 20 apparent that complaints were looked at very carefully  
 21 but nobody ever looked at the proportion of patients  
 22 who thought their case had been handled very well.  
 23 That's 80% according to these figures.

24 I think the figures of stage 2 applicants that  
 25 thought that their case was handled quite well, or

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1 even very well, you know, was high. So I wouldn't  
 2 want you to present the view, you know, that the  
 3 system was absolutely, you know, useless and rough  
 4 riding over people's views, really. I think that  
 5 would be wrong.

6 **Q.** I am simply trying to --

7 **A.** Undoubtedly, there were holes in the system. There  
 8 were less holes in the stage 2 process that doctors  
 9 were involved in deciding, not because we are any  
 10 better than anybody else, but stage 1 was an almost  
 11 impossible task and, when you add the special care  
 12 mechanism to it, it became a terrible situation.  
 13 Dr Main, who was involved, when it was transferred to  
 14 the NHS business with me, we took the view that if the  
 15 patient's GP and/or the hospital doctor said that the  
 16 patient's depression and brain fog were due to  
 17 hepatitis C, we said "Who are we to gainsay that?" We  
 18 signed all those off, probably to the annoyance of  
 19 whoever had to pay the bill.

20 So, you know, we had to work with a mandate.  
 21 We had some input into deciding who got what, in other  
 22 words what the criteria were, but if some criteria  
 23 were put forward that we couldn't operate, however  
 24 much goodwill we put into it, you know, what do we do?  
 25 With the special care mechanism we waved through most

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1 a well validated history of intravenous drug use, you  
 2 could virtually be certain that that was the cause of  
 3 their hepatitis.

4 I mean, the other figure you need to know is,  
 5 of the total population of hepatitis C cases that  
 6 Health Protection England reviewed every year,  
 7 although the percentage acquiring it through blood or  
 8 blood transfusions or non-intravenous drug methods  
 9 maybe a decade or two decades ago would be maybe 30 --  
 10 30% or so were due to transfusion, but in latter years  
 11 it is virtually that everybody, or greater than 95%,  
 12 are due to intravenous drug use.

13 It is not sufficient, when you are trying to  
 14 elucidate the story of the drug users, to just ask  
 15 the patient in a clinic once "Did you use drugs?"  
 16 Nobody wants to admit that. But one of the aspects of  
 17 being a doctor, and a liver doctor interested in viral  
 18 hepatitis, is you soon learned that you had to gain  
 19 the patient's confidence, and you -- you know, at the  
 20 first consultation you might ask if you used drugs and  
 21 they would say "No", but after four or five returns  
 22 and follow-up clinics, they would say "Well, actually,  
 23 as a student once I did use them". And, you know,  
 24 just once is enough. Because, of course, who -- I am  
 25 digressing now I suspect, but, you know, when you are

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1 people and that was partly because of our own  
 2 experience. Dr Main, myself and Geoff were fully  
 3 engaged in research into viral hepatitis, particularly  
 4 this type, and we always tried to bring to the table  
 5 the most modern research, which often resulted in us  
 6 changing our view from maybe five years ago.

7 So we tried to keep it up-to-date. We did the  
 8 best we could and recognised that it was far from  
 9 foolproof, but we didn't design the system, other than  
 10 the stage 2 system.

11 **Q.** Can I just ask what your policy or approach was in  
 12 relation to cases where there was some evidence or  
 13 suggestion of intravenous drug use?

14 Mr Fish told us yesterday that he was told when  
 15 he was learning the job, essentially, that that would  
 16 always be a more likely route of transmission than  
 17 transfusion, and that was then effectively his  
 18 approach, so that intravenous drug use cases would be  
 19 rejected.

20 Did you have much involvement in cases  
 21 involving suggested intravenous drug use?

22 **A.** I think the background information to that is that if  
 23 you look at populations of patients who are  
 24 intravenous drug users, then you will find it is  
 25 virtually 100% have hepatitis C. So if there was

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1 at a party and somebody says "Would you like drugs?",  
 2 I mean, who is offering it but somebody selling drugs  
 3 who will have been using themselves. So they are  
 4 almost certainly giving you a needle system, because  
 5 your mother doesn't give you a needle to go out with  
 6 when you go out to a party. You will be actually  
 7 using a drug provided by somebody selling drugs and  
 8 you will become infected. So almost synonymous with  
 9 hepatitis C, outside the context of blood transfusion,  
 10 a positive result is indicative or highly likely that  
 11 that patient at some stage, past or present, has used  
 12 drugs. And that's why that -- what Nick Fish said,  
 13 I suspect why he said it.

14 **Q.** I understand that was policy and approach of the  
 15 Skipton Fund. Did you yourself have involvement in  
 16 deciding IVDU stage 1 applications as far as you can  
 17 recall or were you generally only called in for review  
 18 when there were clinical judgments to be made?

19 **A.** Oh, no, I was involved in judging stage 1, yes.

20 **Q.** But were you involved in rejecting applications on the  
 21 sole basis that there was evidence of IVDU?

22 **A.** Certainly some. I don't know whether it was all of  
 23 the ones I saw, but certainly some of them.

24 Just go back to the figure. 6,712 stage 1s, of  
 25 which 5,519 -- or 29 -- were passed through. You

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1 know, no -- just on the basis of the paperwork. So we  
 2 were all focusing on -- you know, I think 1400 of the  
 3 cases, which is less than 20%, where one had to  
 4 decide, on the basis of no written evidence of blood  
 5 transfusion, what the other possibilities were. And  
 6 that's where Nick would look at them first, then  
 7 I would, and then on occasion all three of us would  
 8 have looked at it. And you ended up by saying, "Well,  
 9 it is a possibility it was a blood transfusion, but we  
 10 can't be certain. Let's pass the ball to the appeal  
 11 group."

12 **Q.** Can I ask you next about another category of cases?  
 13 These are cases where the infected person was  
 14 deceased. We have looked already at the issue about  
 15 trying to determine cirrhosis for stage 2 purposes,  
 16 but if the question was, for example, for the purposes  
 17 of a bereavement payment, whether hepatitis C made  
 18 a cause or contribution to the death, were you  
 19 involved in assessing those applications?

20 **A.** Where hepatitis C was a cause of contributing to  
 21 death?

22 **Q.** Yes.

23 **A.** Well, I am sure I must have been, because that would  
 24 be -- you know, I mean, I think probably Nick Fish and  
 25 Geoff and I would all have discussed those sorts of

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1 Skipton.

2 **Q.** So in terms of your involvement with the Caxton  
 3 Foundation, is this right: it largely involved just  
 4 attending the trustee meetings?

5 **A.** Yes.

6 **Q.** And contributing to general discussions about policy?

7 **A.** Yes.

8 **Q.** How often were you called upon to provide medical  
 9 information to either employees or your fellow  
 10 trustees at Caxton about hepatitis C?

11 **A.** When I was appointed to Caxton, I was conscious of the  
 12 fact that I didn't have a heck of a lot to contribute,  
 13 as I say, because it was social aspects and Department  
 14 of Work and Pensions were involved. So I offered to  
 15 give a presentation, really, on -- really, a bit like  
 16 the thing I prepared for Penrose and I think you have  
 17 cited in some of your paperwork. I had a nice set of  
 18 slides for that. So I did a presentation.

19 And when Geoff Dusheiko joined us, he updated  
 20 that on the newer methods of treatment. So, you know,  
 21 we were looking, in the context of Caxton and Skipton,  
 22 as how we could contribute really.

23 **Q.** Can I ask you to look at one set of minutes? It is at  
 24 CAXT00000109\_105, please, Soumik.

25 **SIR BRIAN LANGSTAFF:** There is something wrong with your

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1 cases. That's why, in the end, we came up with that  
 2 formula that I mentioned earlier where the mortality  
 3 rate of mono-infected and dual-infected people, which  
 4 I think was in Nature or something like that, a highly  
 5 respected journal, and that provided wonderful data  
 6 which allowed us to come up with a formula.

7 **Q.** I am going to move now to the Caxton Foundation. You  
 8 were involved with the Caxton Foundation from 2011  
 9 onwards. But I think this is right, you didn't sit on  
 10 the National Welfare Committee, so you weren't  
 11 involved in decision-making about individual grant  
 12 applications?

13 **A.** No, no. I was allocated to the audit committee,  
 14 which -- a gentleman called Thomas, another Thomas,  
 15 and I sat down once a year with the audit company --  
 16 I have forgotten who they were -- just to make sure  
 17 that it all stacked up. Because following the  
 18 fraudulent episode that occurred in the -- I think  
 19 I have forgotten which one -- that was the Macfarlane,  
 20 wasn't it?

21 **Q.** No, the Skipton Fund.

22 **A.** Yes -- yes, we were all aware of the need for audit,  
 23 so -- and it was apparent that I had medical knowledge  
 24 but not much else that was useful to the Caxton. So  
 25 I didn't -- I then got transferred across to the

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1 number of zeros.

2 **MS RICHARDS:** I have too many zeros in it. It is  
 3 CAXT0000109\_105. Thank you, sir.

4 So these are the minutes of a meeting of the  
 5 board, 1 November 2012. We can see that you are  
 6 present there.

7 If we go to the third page, please, Soumik, we  
 8 can see there is an overall heading "Regular Payment  
 9 Scheme". Then if we go just a little further down the  
 10 page, we can see a paragraph beginning:

11 "Professor Thomas suggested ..."

12 So:

13 "Professor Thomas suggested a plan to contact  
 14 the 12-15 Haemophilia Clinical Specialists in the  
 15 country to help 'advertise' Caxton to their patients.  
 16 It was noted that not all these patients would be  
 17 eligible but it was a worthwhile starting point. The  
 18 Board agreed that Professor Thomas should discuss this  
 19 with the ICEO to further inform the communication  
 20 strategy."

21 Now we know from other material we have looked  
 22 at, Professor Thomas, one of the issues for Caxton was  
 23 it had a relatively low number of registrants in the  
 24 early years. Fewer people were applying to be  
 25 registered and to receive assistance from Caxton than

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1 had perhaps been expected and an issue arose for the  
2 board about how to make people more aware of the  
3 existence of the Caxton Foundation. This suggests you  
4 had suggested making contact with perhaps haemophilia  
5 centres or haemophilia specialists. Can you recall  
6 whether that was taken forward?

7 **A.** What does ICEO stand for?

8 **SIR BRIAN LANGSTAFF:** Interim Chief Executive officer.

9 **MS RICHARDS:** It is, yes.

10 **A.** Interim chief -- was that Jan Barlow?

11 **MS RICHARDS:** There was a temporary officer. After  
12 Mr Harvey stepped down and before Ms Barlow was  
13 appointed, there was an interim chief executive  
14 officer, and that's what that refers to.

15 **A.** Yes. I don't recall what happened as a result of  
16 that. The reason I said that was that I was very  
17 impressed, through my work at the Royal Free, and with  
18 Professor Kernoff particularly, who tragically died,  
19 with how integrated a national structure the  
20 haemophilia specialists grouping was. And if you  
21 wanted to reach specifically the haemophilia  
22 population, then that would be the vehicle for doing  
23 that. But I didn't have any suggestions as to how you  
24 would reach those that had had blood transfusions or  
25 blood products other than Factor VIII or IX

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1 the haemophilia services in the specialist centres  
2 also had a very close relationship with their  
3 patients, because they were patients from, you know,  
4 a few years of age right through to adult life and old  
5 age.

6 These nurses, I think -- the haemophilia  
7 service developed this first, but one of the things  
8 I helped develop was the formation of hepatology  
9 nurses, and we employed several in our unit at  
10 St Mary's. These people certainly raised the  
11 attention of the patients to the Skipton and to the  
12 Caxton -- more the Skipton than the Caxton I think,  
13 probably -- and would help the patients fill in the  
14 forms. Because a hepatology nurse was able to do it  
15 as well as the doctors.

16 **Q.** We can take that down now.

17 Were you ever asked to provide advice to the  
18 Caxton Foundation about the impact of the various  
19 different treatments for hepatitis C and in particular  
20 the impact upon an individual's ability to work and  
21 earn a living during treatment?

22 **A.** No, I can't remember what was in the slide set that  
23 I used, but Dr Dusheiko actually gave a lecture when  
24 he joined, which was about 2015/16 sort of a time, and  
25 he had masses of data, really, on the results with the

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1 concentrates.

2 I think that was the challenge to the system.  
3 That group of people were -- the only way of doing  
4 that would be through the Blood Transfusion Service.  
5 I guess that was the look-back service -- or study  
6 that was done. I don't know when it was in relation  
7 to this, whether it was before or after, but that  
8 would be the way to do that.

9 The other thing that was discussed at this  
10 meeting was, you know, how much there was a need for  
11 this, because there were several programmes on the  
12 television, Panorama and the like, and I don't think  
13 there were many people who had had a blood transfusion  
14 in the UK who hadn't seen one or other of these  
15 programmes. You might say how do I know that.  
16 I don't know that, but I think -- you know, they were  
17 shown on prime time TV many times. So I wasn't quite  
18 so concerned about that.

19 **Q.** Did you have any understanding from colleagues in the  
20 world of hepatology, any understanding of how  
21 well-known the existence of the Caxton Foundation was?

22 **A.** I think the hepatology nurses served a very useful  
23 function actually. They got to know the patients very  
24 well. I am talking now about the non-haemophilia  
25 patients, the ones I was talking about earlier, and

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1 various drugs. I'm not sure what else he included in  
2 that from memory I'm afraid.

3 **Q.** Now you have referred in your evidence earlier to the  
4 concern you had about the access to the new forms of  
5 treatment. I just want to look at the letter you  
6 wrote to the Minister on that issue.

7 It is WITN3824008, please, Soumik.

8 We can see it is dated 1 November 2014. It is  
9 from you and you say:

10 "Dear Minister,

11 "I am writing as a member of the Caxton Board  
12 and the Medical Director of the Skipton Fund, both  
13 involved in supporting those with hepatitis C acquired  
14 through receiving infected NHS blood or blood  
15 products."

16 Then you explain a little about the stage 1,  
17 stage 2 process. You say in the next paragraph:

18 "Around 90 patients receiving Skipton stage 1  
19 payments, progress to cirrhosis each year. Once this  
20 occurs the cirrhosis cannot be reversed even if  
21 anti-viral treatment is successful.

22 "In the last few months orally administered  
23 antiviral drugs which are curative in over 90% of  
24 cases, have been licensed and are currently being  
25 considered, but not yet recommended, by NICE. These

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1 drugs stop progression to cirrhosis thereby removing  
 2 the risk of death from liver failure or HCC. The  
 3 department has made these available to 500 patients on  
 4 liver transplant lists and I am writing now to bring  
 5 to your attention the fact that in the coming year  
 6 90 patients receiving ex gratia Skipton stage 1  
 7 payments, will develop irreversible cirrhosis which  
 8 can be prevented by rapid access to these drugs. At  
 9 Skipton we are aware of these cases and feel that you  
 10 would also wish to be made aware of the problem so  
 11 that you may consider whether these cases, where the  
 12 NHS has accepted responsibility for their  
 13 HCV infection, might also be considered for fast track  
 14 access to these virtually 100% curative -- but very  
 15 expensive -- antiviral drugs."

16 Did you receive, as far as you can recall,  
 17 a response from the Minister or from the Department of  
 18 Health to this letter?

19 **A.** Yes, we did. Of course I haven't got a copy of that,  
 20 but I wrote as a member of the Caxton board and I took  
 21 it to the Caxton board to make sure that they were  
 22 agreeable to me sending this. And Jan Barlow was the  
 23 chief executive at that time, and I have forgotten who  
 24 was the chairman of the meeting, but they said yes,  
 25 that I should send it off. And I think the reply came

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1 least, of the NHS, that particular argument fell on  
 2 deaf ears?

3 **A.** Well, no. I think the Minister said that it was  
 4 covered off by the rules and regulations covering  
 5 NICE. This was by that stage -- not yet recommended  
 6 by NICE. But if it wasn't recommended by NICE, then  
 7 the NICE rules wouldn't be relevant. This was quite  
 8 some time ago and I can't remember the detail of it.  
 9 I remember it didn't come about, really, is what it  
 10 amounts to.

11 **Q.** I just want to ask you a little next about the special  
 12 category mechanism and the discussions that you were  
 13 involved with in relation to that. If we could go to  
 14 DHSC --

15 **A.** By the way, can I just say that letter really followed  
 16 on from that debate that we had earlier about what was  
 17 the crucial cut-off for cirrhosis with Fibroscans, and  
 18 it was one of the reasons -- I am fairly sure it was  
 19 one of the reasons why I wanted to go for the lower  
 20 level, because I thought that would be another way of  
 21 skinning this particular cat and would include that  
 22 group, the Ishak 5s, which are just the pre-cirrhotic  
 23 group.

24 **Q.** I am going to ask you about the Special Category  
 25 Mechanism. I think they were originally referred to

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1 back to both of us, so it should be in the notes, but  
 2 essentially what -- I think what was said was that  
 3 they didn't want to -- the Department of Health didn't  
 4 want to give preferential treatment to one group of  
 5 patients rather than to another and that all should be  
 6 treated equally and come through the NICE system,  
 7 where -- and made the point that, whilst I was saying  
 8 that this group should be given prior access because  
 9 things could go wrong, as they went from Ishak 5 to  
 10 Ishak 6, as we were talking about earlier, and  
 11 detectable by Fibroscan, these people, since it was  
 12 now a NICE-recommended treatment, it was mandated by  
 13 NICE they should be treated I think within  
 14 three months, but I couldn't remember what the NICE  
 15 criteria was or is. I think it is that  
 16 NICE-recommended treatment should be available within  
 17 three months. You probably know that or can find it  
 18 out.

19 **Q.** Yes.

20 **A.** And that this would cover this issue.

21 **Q.** Yes. I think that was perhaps a little later in terms  
 22 of the chronology of events, but is this right: your  
 23 argument that perhaps there should be a fast-track  
 24 access because these were people who had been -- whose  
 25 infection was the responsibility, in a broad sense at

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1 as an individual assessment model or a health impact  
 2 assessment and then became known as the Special  
 3 Category Mechanism. If we could just pick it up at  
 4 CAXT0000094\_145.

5 There are multiple documents referring to this  
 6 issue, so I don't want to go through all of them. We  
 7 can see here these are parts of a meeting of the  
 8 Caxton Board on 15th February 2017. If we go to the  
 9 next page and look at the bottom of the page, in the  
 10 penultimate paragraph, beginning "The board noted", we  
 11 can see reference to the Special Category Mechanism:

12 "The board noted that CP, HT [that's you,  
 13 professor], MK and JB continued to be involved with  
 14 the Department of Health Reference Group."

15 There is reference to meetings having been  
 16 cancelled:

17 "The Special Category Mechanism ... had been  
 18 the main agenda item at recent meetings, but JB  
 19 reported that progress had been slow because the  
 20 criteria for this were being driven by DH's attempt to  
 21 counter the legal challenges."

22 Then there is reference to:

23 "... a further draft of the SCM, which the  
 24 Group had agreed was probably the best it could be in  
 25 the circumstances."

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1 Then you are recorded as saying this:  
 2 "... HT advised that the SCM eligibility  
 3 criteria were still very subjective and would be  
 4 difficult to assess."  
 5 What was your concern in that regard?  
 6 **A.** Well, this stemmed from work I had done with Daniel  
 7 Forton and Simon Taylor-Robinson, looking at whether  
 8 hepatitis C affected the brain. We were able to  
 9 isolate in the brain a virus variant of hepatitis C,  
 10 which was the regulatory element which controls  
 11 replication of the virus, from -- the one we got from  
 12 the brain was different from the one that was in the  
 13 cripple blood, indicating that it was a functional  
 14 virus working in the brain. Therefore I was convinced  
 15 when we did SF36 studies that was the observation that  
 16 we had made with Graham Foster and others that  
 17 depression and cognitive changes, what became known as  
 18 brain fog, were caused in a proportion of the patients  
 19 by hepatitis C.  
 20 The virus was in the brain and when we did  
 21 comparative studies of quality of life between  
 22 hepatitis C and hepatitis B as a control, these two  
 23 areas, depression and brain fog, cognitive defects,  
 24 came out as significantly different and associated  
 25 with hepatitis C.

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1 this work, to be honest, and I wanted the reference  
 2 group to try to work towards more objective ways of  
 3 dissecting out whether these problems were related to  
 4 hepatitis C or not and they weren't forthcoming.  
 5 So yes, I wanted the SCM to go through, but  
 6 I didn't want it to be another situation where we  
 7 really couldn't define the group where it was due to  
 8 hepatitis C. So when the NHS Business group took over  
 9 and this SCM was put into effect, Janice Main,  
 10 a colleague of mine, and I, used to go into Skipton  
 11 House before the NHS Business guys took all this up to  
 12 Newcastle. We sat down and tried to look at hundreds  
 13 of these cases coming through and we decided we  
 14 couldn't differentiate them and that if the GP or the  
 15 hospital consultant or a nurse said that this was --  
 16 well, they were given three choices. It was  
 17 improbable it was related hepatitis C, which think  
 18 only three people ever ticked out of hundreds, and it  
 19 is possible and probable.  
 20 So we gave everybody where it was said to be  
 21 possible and probable the tick for the payment because  
 22 we couldn't say one way or the other. If you like,  
 23 you may say we learned from our previous experience  
 24 with stage 1s. You know, in this subjective  
 25 environment you have to assume that the primary care

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1 So I felt that they should be taking some -- we  
 2 should be trying to dissect this away from the large  
 3 proportion of patients who had depressive problems and  
 4 even cognitive abnormalities in the general population  
 5 unrelated to hepatitis C, and it would be impossible  
 6 to differentiate these two.  
 7 Having set up objective criteria for stage 2  
 8 payments, which I think in retrospect were shown to  
 9 work quite well, and worked through at the time with  
 10 stage 1, found it very difficult to be objective in  
 11 this group, and to add this to it, a Special Category  
 12 Mechanism, which allowed additional payment or  
 13 significant payment for people who had depression and  
 14 cognitive abnormalities would actually mean that  
 15 virtually everybody would have them. It turned out to  
 16 be the case: virtually everybody applied for this, if  
 17 you wanted to be cynical, assuming that they were  
 18 depressed and assuming that their depression was  
 19 related to their infections. Not unreasonable, you  
 20 may say, but a significant proportion of people, of  
 21 course, in the general population have depression and  
 22 it is reasonable to assume that this proportion of  
 23 people with hepatitis C had the problem before  
 24 hepatitis C infection occurred.  
 25 So I didn't relish the fact of trying to make

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1 physician, the GP, or the consultant or nurse involved  
 2 in the hospital care of that patient, would be in the  
 3 best position to assess the patient, and if they said  
 4 it was probable, then the payment should go through.  
 5 But, you know, we had already given out very  
 6 large sums of money, I think over 300 million and  
 7 I felt we should try to be as objective as possible,  
 8 but this was impossible. So I felt at least I had to  
 9 say at the reference group that this was the case but  
 10 I didn't have a better suggestion really of how we  
 11 could differentiate.  
 12 **Q.** Then the reference group, as well as considering the  
 13 Special Category Mechanism, considered other aspects  
 14 of what the new Business Services Authority scheme  
 15 might include?  
 16 **SIR BRIAN LANGSTAFF:** Just before you go there, can I ask  
 17 this: how did you judge being related to hepatitis C,  
 18 because "being related to" may mean a number of  
 19 different things?  
 20 **A.** Yes. I take your point. It may be causatively  
 21 related or it may just be associated with.  
 22 **SIR BRIAN LANGSTAFF:** If causative related it may not be  
 23 the only cause but may be a contributing cause.  
 24 **A.** So it would be relevant whether the patient had  
 25 depression or cognitive problems beforehand. If

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1 hepatitis C could make it worse, that would be enough  
 2 to make the payment as well.  
 3 **SIR BRIAN LANGSTAFF:** That would follow legally in a case  
 4 in which there was a question of whether the condition  
 5 for which compensation was being sought had been  
 6 caused by what is generally a multi-factorial  
 7 condition.  
 8 **A.** I think later on I mentioned Koch's postulates.  
 9 I think Koch was a German infectious diseases or  
 10 epidemiologist. Koch's postulates say that before  
 11 an infectious agent can be thought to be causatively  
 12 related, which I appreciate, sir, that this is  
 13 different to what you are suggesting, you are just  
 14 saying it could be exacerbated by hepatitis C --  
 15 **SIR BRIAN LANGSTAFF:** I think the expression I would use  
 16 is "cause or contributed to".  
 17 **A.** Right, well, Koch said that for an agent to be  
 18 causatively related it should be found with the  
 19 disease or the symptom and when the virus or bacterium  
 20 or fungus, whatever, is cleared, then the symptom or  
 21 illness under consideration should disappear. In  
 22 other words, it came on with the infection and then  
 23 went away when the infection was cleared.  
 24 We tried to think about using Koch's postulates  
 25 in relation to this particular problem because, of

1 I think would have differentiated the virus caused  
 2 ones from the other causes, depression or brain fog,  
 3 that is unrelated to hepatitis C.  
 4 But it doesn't answer your question of whether  
 5 it is causatively related or contributed to. I don't  
 6 think you can differentiate those, except by looking  
 7 retrospectively as to whether it got better or  
 8 partially got better when the virus was cleared.  
 9 **SIR BRIAN LANGSTAFF:** Well, I think the magic of the  
 10 phrase "caused or contributed" means this covers both.  
 11 You don't actually have to differentiate between the  
 12 sole cause or one of a number of causes or  
 13 contributors to a condition.  
 14 **A.** Yes. Many conditions are caused by many for factors.  
 15 Of course, they can operate in conjunction with each  
 16 other as joint causes, yes. I take your point. The  
 17 bottom line is that we gave the SCM payments to  
 18 virtually everybody who applied for that very reason.  
 19 The other group that we thought should be given  
 20 be these payments were people who during their stage 1  
 21 illness had been treated with interferons, which  
 22 initially, I thought, wasn't justified, but experience  
 23 in reviewing these with individuals it clearly became  
 24 evident that many people did have the  
 25 interferon-related side effects.

1 course, virtually 100% of people with hepatitis C can  
 2 be cured. So there was a possibility of looking at  
 3 which of these problems got better when the virus was  
 4 cleared, in other words the second component of the  
 5 Koch's postulates. The Americans particularly said  
 6 that a lot of the depressive and cognitive  
 7 abnormalities, which were measured by instruments  
 8 called SF36, which just was a series of questions,  
 9 I think there were 36 of them, hence the name -- and  
 10 specialist variants of that where you could do serial  
 11 measurements before and after treatment.  
 12 The Americans argued that most of the symptoms  
 13 didn't go away after the virus was cleared, but it  
 14 turns out we were doing some studies with magnetic  
 15 resonance spectroscopy. It is a sophisticated system  
 16 that looks at various molecules in the brain. We  
 17 found, originally, that in HIV and in hepatitis C  
 18 stage 1 there was a sub group of patients who had this  
 19 particular pattern, which suggested there was a change  
 20 in the brain. It would have been possible to use  
 21 these scans, which cost a couple of hundred thousand  
 22 pounds each to do -- they were a research programme --  
 23 to tell whether individual patients had these  
 24 characteristic changes which we saw initially in HIV  
 25 but were also present in stage 1 hepatitis C, which

1 When you took care of patients going through  
 2 those interferon treatments, it wasn't surprising that  
 3 their memory had a long-term compromise, really. And  
 4 also, if they had rheumatoid arthritis or myxedema,  
 5 a thyroid condition, these were also made worse  
 6 afterwards. So I changed my view during that process,  
 7 you know. And when the SCM issue came up, we thought  
 8 that virtually anybody who had had interferon should  
 9 probably get these payments, because there was  
 10 a correlation -- maybe not causative, but  
 11 a correlation -- which, you know, might mean it was  
 12 related to, albeit not in the Koch's postulates way.  
 13 So I don't know if that has helped at all.  
 14 **MS RICHARDS:** If it assists -- and, sir, we will no doubt  
 15 look at this when we look at the current schemes in  
 16 May -- but the current Special Category Mechanism  
 17 application form, which I looked up this morning,  
 18 poses the question in this way of the clinician or  
 19 nurse:  
 20 "In your opinion how likely is it that your  
 21 patient's mental health problems are attributable to  
 22 the hepatitis C infection or its treatment or  
 23 effects?"  
 24 **SIR BRIAN LANGSTAFF:** It is the same question.  
 25 **MS RICHARDS:** It is, although the four potential answers

1 are:  
 2 "Not likely explained by other causes.  
 3 Possible.  
 4 Highly likely, and  
 5 Definite."  
 6 There doesn't appear to be a box for "likely".  
 7 But that's a question for the future rather than for  
 8 Professor Thomas.  
 9 Just before we break for lunch, professor, I  
 10 just have --  
 11 **A.** I just want to know -- is it possible to ask what  
 12 proportion are getting SCM payments? I think it is  
 13 virtually 100%, isn't it, of stage 1s, or is it?  
 14 **Q.** I think we will be in a better position to know that,  
 15 Professor Thomas, when we examine the evidence in May.  
 16 **A.** Sorry.  
 17 **Q.** I just have one further question about the reference  
 18 group discussions, not on the Special Category  
 19 Mechanism but on a different aspect of the  
 20 discussions.  
 21 If we could just look at DHSC0046884\_020, you  
 22 will see it is a reference group meeting,  
 23 16th November 2016.  
 24 Again, there is a discussion about the Special  
 25 Category Mechanism. I am not going ask you further

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1 **A.** Hold on. Yes, I think that was mentioned. Did that  
 2 happen or did it not happen?  
 3 **Q.** I am just asking you whether you have any recollection  
 4 of discussions about it. We can pick up what then got  
 5 translated into the scheme with the relevant civil  
 6 servants in due course.  
 7 **A.** No. The other issue that was raised here was whether  
 8 hepatitis B was mentioned. I know that one or two  
 9 people mentioned that but I can't remember what the  
 10 outcome was to be honest.  
 11 **Q.** You anticipated what was going to be my final question  
 12 before lunch, Professor Thomas, which was just about  
 13 hepatitis B.  
 14 Can I put it more generally than relating to  
 15 specific conversations within the reference group that  
 16 you may not recall?  
 17 Work on hepatitis B has formed a significant  
 18 part of your career over the years. Was the exclusion  
 19 of people infected with hepatitis B from the Skipton  
 20 Fund and Caxton Foundation something that ever came up  
 21 in any of the discussions or meetings you had over the  
 22 years with the Department of Health?  
 23 **A.** No. I think it was mentioned at the reference group.  
 24 As I say, I couldn't remember what the outcome was.  
 25 I think it does seem an anomaly that hepatitis B

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1 about that.  
 2 If we could go to the last page, we can see the  
 3 last heading is about "Policy for £10,000 payment [of]  
 4 the bereaved". Then it is said --  
 5 **SIR BRIAN LANGSTAFF:** I think it is probably "to the  
 6 bereaved". The T and the O are transposed.  
 7 **MS RICHARDS:** I think it probably is "to the bereaved",  
 8 reversed to O-T. Then it says:  
 9 "For the purpose of the proposed policy the  
 10 intention is that you qualify as 'partner or spouse'  
 11 of the deceased registrant/primary beneficiary if  
 12 either of the following applies."  
 13 Then there is a provision as to what amounts to  
 14 a partner or spouse."  
 15 Can you recall, Professor Thomas, whether there  
 16 was any discussion within the reference group of  
 17 widening the category of people who could receive the  
 18 bereavement payment to categories of relatives beyond  
 19 partners and spouses?  
 20 **A.** I can't really -- I ended up at one of these sort of  
 21 meetings with -- as one of the only -- well, we're  
 22 usually the only medic present focusing on those  
 23 issues, really, and I'm not sure I picked up on this.  
 24 No, I can't shed any light on that, I am afraid.  
 25 **Q.** We can --

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1 didn't feature. I felt that the hepatitis B  
 2 population -- this is -- what I am going to say is not  
 3 really relevant to those haemophiliacs and those who  
 4 received hepatitis C through a blood transfusion,  
 5 because don't forget I said earlier, about 95% of my  
 6 patients with hepatitis C were intravenous drug users.  
 7 And they deserved good treatment just like everybody  
 8 else but there was a stigma attached to that group of  
 9 patients. And my nurses and my staff gave these guys  
 10 expert care and they were very difficult to manage.  
 11 The hepatitis B patients were cross-stigmatised, if  
 12 I could use that phrase, because people didn't  
 13 differentiate between hepatitis B and hepatitis C.  
 14 Most people with hepatitis B were Asian,  
 15 Chinese in particular, where 10 or 15% of the Chinese  
 16 population were hepatitis B positive. They had  
 17 acquired it from their mother at birth. They often  
 18 were very sheepish coming to the clinic, because they  
 19 thought all viral hepatitis was related to intravenous  
 20 drug use.  
 21 Saying that, I spent a lot of my life looking  
 22 after people with intravenous drug-related hepatitis  
 23 C. So I am not saying they shouldn't have required  
 24 it, but I did think the hepatitis B patients were left  
 25 out, if I am making the point properly. You say

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1 I spent a lot of my life working on hepatitis C, but  
 2 I spent all of my career -- well, the majority of it,  
 3 except for the last couple of years -- working on  
 4 hepatitis B. I think it should have been much more to  
 5 the fore in some of these schemes. Some haemophiliacs  
 6 did get hepatitis B.

7 The other thing to point out, though, in  
 8 relation to hepatitis B and hepatitis C, if you got  
 9 hepatitis B as an adult or even as a toddler, as many  
 10 haemophiliacs did, then you had an 80 or 90% chance of  
 11 getting a circumscribed acute episode with recovery,  
 12 whereas the converse was true with hepatitis C. 80%  
 13 got chronic infection and all the downsides of risk of  
 14 cirrhosis and what have you, and liver cancer, related  
 15 to the chronic infection. So I think that may have  
 16 been part of the explanation, although not the  
 17 justification, of why the hepatitis B group were left  
 18 out, really, but they used to come to our joint  
 19 hepatology clinic that we ran at the Royal Free with  
 20 the haemophilia group there with Professor Kernoff and  
 21 co.

22 **MS RICHARDS:** Sir, I note the time. I am going to move on  
 23 from the financial support schemes now to ask  
 24 Professor Thomas some more general questions relating  
 25 to hepatitis. So perhaps we can pick that up after

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1 a couple of your publications around this time in  
 2 a little while, but we can see this is the paper  
 3 presented at the symposium.

4 What I want to do is take you to the discussion  
 5 at that followed the presentation of the paper. We  
 6 can pick that up at page 42. We can see a question  
 7 being posed by Professor Stewart about active  
 8 hepatitis and the question is posed, in particular:

9 "What happens in the haemophiliac?"

10 We can see your answer, and you say this:

11 "The lesion of chronic active hepatitis, is  
 12 a progressive lesion, and one would, in a proportion  
 13 of these patients, expect an element of fibrosis,  
 14 and ultimately cirrhosis. None of our patients has  
 15 had cirrhosis, but then, if we are to believe that  
 16 this illness at the most has been going on since 1974  
 17 when the commercial concentrates from first  
 18 introduced, then this period is short in the course of  
 19 the disease. There are some indications that these  
 20 patients may have lesions which will turn to fibrosis  
 21 or cirrhosis."

22 Then you set out various observations  
 23 and measurements.

24 Then if we pick it up in the last six lines of  
 25 this page, you say:

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1 lunch?

2 **SIR BRIAN LANGSTAFF:** Let's do that. So we will take  
 3 a break until 2.05. 2.05, professor.

4 **A.** That's okay. Yes.

5 (1.04 pm)

(Lunch break)

7 (2.05 pm)

8 **MS RICHARDS:** Professor Thomas, I am going ask you next  
 9 about some aspects of your early involvement with  
 10 issues relating to non-A, non-B hepatitis and  
 11 hepatitis C.

12 If we could go, first of all, please, Soumik,  
 13 to RLIT0001242.

14 You will see, Professor Thomas, this is  
 15 "Unresolved problems in Haemophilia". And if you go  
 16 to page 3, we can see these are the proceedings of  
 17 an international symposium held in Glasgow in  
 18 September 1980, and you are one of a number of  
 19 speakers and attendees.

20 If we can then go to -- let's find the page --  
 21 I think it is page 33, Soumik.

22 We can see this is a short paper authored by  
 23 you, Dr Bamber and Dr Kernoff, "Clinical,  
 24 immunological and histological aspects of non-A, non-B  
 25 hepatitis in haemophiliacs". I may come back to

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1 "It is really now a question of how long ...  
 2 just because we have not seen it in this six-year  
 3 period, it does not mean that it will not happen.  
 4 I think the thinking is that it takes ten or twenty  
 5 years, or even thirty years, for these lesions to  
 6 progress. I think we have to realise that these are  
 7 young patients, with many years ahead, when we are  
 8 considering the significance of these lesions."

9 Then you go on to contrast that with the  
 10 situation in relation to chronic persistent hepatitis,  
 11 which would have a much better prognosis.

12 Can I just ask you, first of all, whether --  
 13 can I put it this way? What you appear to be saying  
 14 here, if I can paraphrase and if you can assist with  
 15 whether this is correct or not, is, although you are  
 16 not currently seeing levels of cirrhosis in the  
 17 patients whom you were concerned with and whom you had  
 18 been studying, your suggestion here was that was not  
 19 because that was not going to be a problem in the  
 20 future, but simply a reflection of the progressive  
 21 nature of the disease, and your expectation was that  
 22 there would be problems with chronic active hepatitis,  
 23 fibrosis and cirrhosis in the future for this cohort  
 24 of patients. Is that a correct understanding of the  
 25 message you were giving here?

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1 A. Yes, I think that's spot on, really. I mean, it was  
 2 one of the reasons for doing biopsies, because we knew  
 3 by analogy with chronic hepatitis B that if you saw  
 4 chronic persistent hepatitis, where the inflammatory  
 5 cells were in the portal tracts and not going into the  
 6 rest of the liver, then this was essentially a benign  
 7 condition, whereas if you saw, as the name implies,  
 8 chronic active hepatitis, then this -- the liver cells  
 9 in and around the portal tracts would be destroyed and  
 10 would be replaced by fibrous tissue, which would  
 11 ultimately result in nodule formation and bands of  
 12 fibrous tissue, which we call cirrhosis.

13 So the initial biopsies suggested that chronic  
 14 persistent hepatitis predominated and that chronic  
 15 active hepatitis then occurred, and that then went on  
 16 to cirrhosis.

17 I tried to demonstrate what the current  
 18 thinking was at any point in time by Sheila Sherlock's  
 19 book, which I think you mentioned somewhere else,  
 20 or I presented to the Penrose Inquiry, which showed  
 21 that -- in one particular edition she was saying --  
 22 she is the doyenne of liver disease -- dead now, of  
 23 course -- which at one stage, in one edition, the  
 24 earliest edition, I think '74 or something like that,  
 25 she was saying, "This is a mild condition and we don't

1 hepatitis B. You say:

2 "It is much more likely that this form, since  
 3 it is presumed to be caused by a virus, will be more  
 4 closely analogous to the hepatitis B form of chronic  
 5 active hepatitis ..."

6 Then if we just go to the bottom of the page,  
 7 you then refer to:

8 "An alternative approach is to observe [the  
 9 patients] for longer ..."

10 Then you say this:

11 "We are studying the patients fairly early on,  
 12 perhaps 2 years or so at the maximum after onset of  
 13 illness, and we are not seeing much in the way of  
 14 fibrosis, whereas Dr Triger is studying it perhaps  
 15 a few years further on and he has got a significant  
 16 incident of cirrhosis. So it may be a progressive  
 17 lesion."

18 Then in the next paragraph you give a further  
 19 reason for feeling this may be progressive.

20 Then you say in the third paragraph:

21 "One can predict that there will be problems in  
 22 the future."

23 Then you pose the question: should there be  
 24 trials being done or do you follow the patients for  
 25 longer?

1 have to worry too much", and then in the next edition,  
 2 when these biopsies had come through, she said, "Ah,  
 3 chronic active hepatitis, this is likely to be  
 4 progressive."

5 So, yes, you're completely correct, that the  
 6 presence of chronic active hepatitis was a bad  
 7 prognostic sign, and that as with hepatitis B, this  
 8 develops over decades rather than months or years or  
 9 small numbers of years.

10 Q. Then just to pick up the next -- no, I think two  
 11 papers on from this, Professor Preston and others'  
 12 paper.

13 Page 45, please, Soumik, of this.

14 This is a paper presented by Professor Preston,  
 15 Dr Triger and Dr Underwood. Again, if we go to the  
 16 discussion, it starts on page 50, and I wanted to pick  
 17 up your contributions, which begin on page 51.

18 If we look at the bottom half of the page, you  
 19 say this, picking it up I think three lines into your  
 20 observations:

21 "I would suggest that we are at a stage now  
 22 where we have got an idea of the sorts of lesions that  
 23 we are seeing. A significant proportion, perhaps 40  
 24 or 50%, have chronic active hepatitis."

25 Then there is a reference to the analogies with

1 Then if you can just, before I ask you to  
 2 comment, go to page 58. Bottom of the page you say  
 3 this, in the last four lines:

4 "As Dr Triger has said, it is in 10 years time  
 5 that we shall see the problems. Bearing in mind that  
 6 the proportion of the patients that are infected, or  
 7 have persistent abnormal liver function tests,  
 8 anything from 60 to 80%, it will be an enormous  
 9 problem when it happens."

10 Again, can you just assist us with what your  
 11 concerns were when you said "it will be an enormous  
 12 problem when it happens"?

13 A. Well, because a large number of patients, both with  
 14 coagulation abnormalities, like haemophilia, and also  
 15 the substantial number of people who we thought were  
 16 out there who had been infected because of blood or  
 17 blood transfusions, this cohort -- and we  
 18 guesstimated -- and by we, I mean the epidemiology  
 19 community and the Health Protection England guys and  
 20 girls, they were predicting there would probably be  
 21 150,000 to 200,000 people with chronic hepatitis C out  
 22 there, and if this was progressing then we were going  
 23 to end up with quite a lot of people with cirrhosis.  
 24 And I knew that cirrhosis, as did David Triger, had  
 25 a significant mortality.

1 In fact, the percentage with cirrhosis,  
 2 I always remember it by saying: every ten years there  
 3 is another 10% who have cirrhosis. So, you know, when  
 4 some of the young people -- for instance, there was a  
 5 haemo plasmapheresis cohort in Germany who got  
 6 infected because of infected plasma, you know, when  
 7 that group of people, who were several hundred  
 8 I think, would work through, then up to, you know,  
 9 20%, 30% would have cirrhosis. And a significant  
 10 number of those, as I have said, who were -- 2% to 3%  
 11 per year at risk of liver cell cancer. And, something  
 12 I haven't mentioned yet, 2% to 3% per year die of  
 13 liver failure and require -- the only treatment for  
 14 that is liver transplantation. So add all these  
 15 things up and it looks like a big problem on the  
 16 horizon, not to mention the problem from the patient's  
 17 point of view, because cirrhosis is not a pleasant  
 18 condition.

19 **Q.** So that's September 1980, that symposium. Then I want  
 20 to just ask you a little about a paper that you and  
 21 others published in 1981.

22 Soumik, that's RLIT0000497.

23 This is a paper which I think we haven't looked  
 24 at yet within an Inquiry hearing. It's  
 25 "Ultrastructural Features in Chronic Non-A, Non-B

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1 "Three patient groups were studied."  
 2 The first is those with non-A, non-B chronic  
 3 liver disease.

4 Before I do that if we just look at the top of  
 5 the page, just so we can understand the purpose of  
 6 this study and this paper, which is about  
 7 ultrastructural features, there's reference there to  
 8 "ultrastructural alterations" being described in  
 9 chimpanzees infected with serum from patients with  
 10 non-A, non-B hepatitis.

11 What was the particular purpose of the blind  
 12 control study that you were undertaking here?

13 **A.** Well, all patients really that came in with  
 14 unexplained transaminase elevation in Dame Sheila  
 15 Sherlock's unit would have a biopsy early on in the  
 16 management to decide several things. Obviously, we  
 17 would do serological tests to diagnose hepatitis A and  
 18 B, without going to the extent -- which carried risk  
 19 to the patient as well as to a lot of in-patient care,  
 20 before going to a biopsy, which would tell us exactly  
 21 whether this was acute or chronic disease, because you  
 22 may have noticed that in haemophiliac patients with  
 23 Factor VIII concentrates the transaminases go up and  
 24 down. They will have periods of normal transaminases  
 25 and then a week or so later the transaminase will go

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1 (NANB) Hepatitis: A Controlled Blind Study". We can  
 2 see from the bottom of the page it was accepted for  
 3 publication August 27, 1981 and it was published in  
 4 the Journal of Medical Virology in the course of 1981.

5 If we can just go up to the bottom of the  
 6 page again, we can see what the study entailed:

7 "Liver biopsies from 12 patients with chronic  
 8 non-A, non-B ... hepatitis, 7 with hepatitis B surface  
 9 antigen ... positive chronic liver disease, 1  
 10 [hepatitis B] positive normal carrier, and 4 patients  
 11 with non-viral liver disease, were examined by  
 12 electron microscopy for cytoplasmic and nuclear  
 13 changes."

14 Then if we look at the introduction just  
 15 a little further down, you and your fellow authors say  
 16 there:

17 "Following the development of diagnostic  
 18 serological tests for hepatitis A and B infection, it  
 19 became apparent that there were additional unknown  
 20 viruses causing hepatitis in man and these were been  
 21 named the Non-A, Non-B ... group ..."

22 So that's the background.

23 If we can go over the page, I am going to ask  
 24 you about the first patient group that you describe,  
 25 under the heading "Patients and methods". You say:

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1 up.

2 These patients came in with significant liver  
 3 test abnormalities. The first thing we required to  
 4 know was whether it was an acute episode, having  
 5 excluded hepatitis A and B, or whether it was acute  
 6 non-A, non-B, or whether it was already chronic  
 7 non-A, non-B, with chronic active hepatitis, which  
 8 would put the patient at risk of cirrhosis.

9 So the biopsies were done for diagnostic  
 10 routine clinical care but other patients coming  
 11 through the unit had had biopsies and the randomised  
 12 part of it was looking at a group of patients from  
 13 each of a series of designated or diagnosed diseases.  
 14 So chronic hepatitis B is diagnosed serologically to  
 15 assess what sort of liver disease they have in the  
 16 prognostic episodes and the prognostic outlook. They  
 17 would automatically get biopsies or routine biopsies.  
 18 Similarly, patients with ALT abnormalities attributed  
 19 to non-A, non-B.

20 The only way of determining what non-A, non-B  
 21 might be due to is there were studies in the United  
 22 States and in the London School of Hygiene here in the  
 23 UK, showing that there were certain electron  
 24 microscopic abnormalities found in patients with one  
 25 particular type of non-A, non-B, which subsequently

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1 turned out to be hepatitis C.  
 2 So what we wanted to do is to take biopsies  
 3 where we knew the diagnosis, which was hepatitis B,  
 4 and then take a similar number of biopsies, which had  
 5 been done for routine care reasons and look at them  
 6 all under the electron microscope really to see how  
 7 many had these changes, which at least in animals, in  
 8 chimpanzees, had been shown in the literature to be  
 9 due to non-A, non-B.

10 It was a way, if you like, of showing whether  
 11 this was one disease or several diseases and really  
 12 trying to get at least on one basis a diagnosis. So  
 13 that's why it was done.

14 It turned out that these electron microscopic  
 15 changes, intranuclear particles and changes in the  
 16 parts of the cell where proteins are made, called the  
 17 endoplasmic reticulum, these were similarly present in  
 18 human patients as they were in the animal studies, the  
 19 chimpanzees, mainly from NIH in the United States but  
 20 some done here in the UK, in the London School of  
 21 Hygiene.

22 So it was really to see if we could get  
 23 a histological basis for saying "This group have  
 24 a type of non-A, non-B". At that stage the people in  
 25 the United States said that there were two types of

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1 [chronic active hepatitis] with cirrhosis, 1 [chronic  
 2 active hepatitis] without cirrhosis ..."

3 So again 50% of those four with chronic active  
 4 hepatitis:

5 "... and 2 had chronic lobular hepatitis."

6 Just so we don't get confused about terminology  
 7 is chronic lobular hepatitis to be equated with  
 8 chronic persistent hepatitis or is it something else?

9 **A.** No, it's a third condition. It means that  
 10 inflammation is distributed throughout the liver  
 11 lobules. So the whole liver is full of cells. You  
 12 can't tell acute lobular hepatitis from chronic  
 13 lobular hepatitis, apart from by knowing the temporal  
 14 history, in other words how long the patient has had  
 15 an elevated transaminase, which would indicate that --  
 16 if at some stage during that chronic elevation of the  
 17 transaminases there has been a biopsy, and you see  
 18 a lobular hepatitis, then that is chronic. If the  
 19 patient has had abnormal LFTs for, let's say, two or  
 20 three months and you see a lobular hepatitis, in that  
 21 time-frame you would say it is probably acute  
 22 hepatitis, but until you follow that patient, you  
 23 won't know, because if he goes on to have  
 24 abnormalities for six months, that lobular hepatitis  
 25 seen in the first two to three months is presumed to

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1 non-A, non-B, with one with a short incubation and one  
 2 with a long incubation. So to get some other basis  
 3 for separating out the two, long and short incubation,  
 4 we needed another marker. So this was a study,  
 5 really, to look at that issue --

6 **Q.** Then if you --

7 **A.** -- and it turned out that these studies suggested it  
 8 was a fairly uniform disease in most non-A, non-B.

9 **Q.** If we just look at the next page, and this relates to  
 10 the specific patient's group, of those with non-A,  
 11 non-B hepatitis. Picking it up in the first main  
 12 paragraph, so the second line on the page:

13 "Eight haemophilia and 4 nonhaemophilic  
 14 patents underwent liver biopsies at between 6 and 36  
 15 months after either an episode of acute [non-A, non-B]  
 16 hepatitis (7) or the first detection of abnormal liver  
 17 function tests (5)."

18 Then we can see the results there:

19 "Four of the haemophilic patients demonstrated  
 20 chronic active hepatitis ... and 4 chronic persistent  
 21 hepatitis ..."

22 I appreciate the numbers are relatively small,  
 23 as with all of these biopsy studies, but you have 50%  
 24 with chronic active hepatitis there:

25 "Of the 4 nonhaemophilic patients, 1 had

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1 continue and represents a chronic lobular hepatitis.

2 So chronic lobular hepatitis isn't that helpful  
 3 in determining who is going to go on to cirrhosis. It  
 4 is a group really where you need to integrate their  
 5 biopsy with the temporal sequence of what has been  
 6 happening to the liver function tests. Have  
 7 I explained that all right?

8 **Q.** Yes. Thank you. So in relation to this group of  
 9 eight patients, the biopsies showed 50% of them with  
 10 chronic active hepatitis; is that correct?

11 **A.** Yes, yes, yes.

12 **Q.** I think we can see from the next paragraph that of  
 13 those who were within the haemophilic group of the  
 14 eight patients one had received only cryoprecipitate  
 15 but seven Factor VIII concentrate of a mainly  
 16 commercial source.

17 I then want to ask you about two studies that  
 18 you have referred to in your report to the Penrose  
 19 Inquiry. I am not going to ask you any detail about  
 20 the evidence you gave to Penrose. Rather than look at  
 21 the underlying studies, it's probably quicker just to  
 22 go to your report and take it from there. So it is  
 23 PRSE0004640. If we go to page 9, please, this is  
 24 under a heading of "The changing perception of  
 25 Severity of [non-A, non-B] hepatitis". Just pick it

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1 up, I think, in the last eight or lines -- I will pick  
 2 it up with the sentence that begins, about ten lines  
 3 down:  
 4 "Thus in the early days the liver disease was  
 5 thought to be relatively mild compared to that seen  
 6 with HBV for instance. This view started to change on  
 7 the basis of the accumulating data from liver  
 8 biopsies."  
 9 Then there is a reference there to Dame Sheila  
 10 Sherlock's book which you have already referred to.  
 11 Then we see two studies there set out. One is a study  
 12 of which you are a co-author, Bamber, Sherlock,  
 13 Scheuer and Thomas, 1981, Journal of Clinical  
 14 Pathology, "Clinical and histological features of a  
 15 group of patients with sporadic non-A, non-B  
 16 hepatitis". We have that if we need to look at but  
 17 I think we can take it from here. You record that  
 18 study as:  
 19 "... showing that biopsies from patients with  
 20 chronic [non-A, non-B] hepatitis 'covered the whole  
 21 spectrum of acute and chronic hepatitis and 1 patient  
 22 had cirrhosis' ..."  
 23 Then you referred to a US study entitled  
 24 "Non-A, non-B post-transfusion hepatitis: disaster  
 25 after decades?" If we just go over the top, at the  
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1 as present and you are there for Professor Dame Sheila  
 2 Sherlock?  
 3 **A.** Yes.  
 4 **Q.** Then if we can go to the third page, we just pick up  
 5 the heading, in the top of the page "Non-A, non-B  
 6 Hepatitis", we can see there:  
 7 "As previously reported the Department was  
 8 anxious to encourage research directed towards  
 9 establishing the extent of the problem in the UK and  
 10 the development of tests for the agent(s) of non-A,  
 11 non-B hepatitis."  
 12 There is reference to the medical research  
 13 council's interest in relation to that. The next  
 14 paragraph:  
 15 "Dr Dane proposed that clinicians should be  
 16 reminded of the importance of reporting all cases of  
 17 post-transfusion hepatitis including those which were  
 18 hepatitis B negative."  
 19 Then there is reference to studies that  
 20 Professor Zuckerman wants to undertake and then if we  
 21 look at the penultimate paragraph in this section:  
 22 "Dr Vandervelde/Mrs Supran said that the  
 23 arrangements for the notification of post-transfusion  
 24 jaundice cases were deficient, as anicteric  
 25 individuals do develop chronic liver disease and these  
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1 top of the page we can see that is a 1982 publication.  
 2 You say:  
 3 "... also reflected this changing view and  
 4 pointed out that [non-A, non-B] was a silent and  
 5 slowly progressive disease which ultimately did result  
 6 in cirrhosis in a proportion of cases."  
 7 Without going to the detail of those two  
 8 papers, is it fair to say what you were reporting and  
 9 what was reported in the American publication in 1981  
 10 and 1982 respectively is essentially consistent with  
 11 the message you had given at the symposium in 1980  
 12 and, indeed, the work from Sheffield and  
 13 Professor Preston, published in 1978?  
 14 **A.** Yes, yes. They were all in accord really.  
 15 **Q.** Thank you. We can put that away. Next I am going to  
 16 ask you just about a handful of the various working  
 17 groups and committees that you were involved with in  
 18 the late '70s and early '80s.  
 19 The first is the advisory group on testing for  
 20 the presence of hepatitis B surface antigen. If we  
 21 could go to CBLA0000931, we can see if we look at the  
 22 top of the page this is "Note of the 2nd meeting of  
 23 reconvened advisory group on testing for the presence  
 24 of hepatitis B surface antigen and its antibody". The  
 25 meeting is 2nd April 1979. A number of people listed  
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1 cases would be missed using the present system.  
 2 "It was thought that there is a need to alert  
 3 RTDs [so regional transfusion directors] and hospital  
 4 staff to the possibility of non-A, non-B hepatitis,  
 5 and urge notification and reporting of suspect cases,  
 6 sample materials being sent to Professor Zuckerman.  
 7 Disseminating this information could be via medical  
 8 journals, eg the BMJ and Lancet. This would be  
 9 brought to the attention of Regional Transfusion  
 10 Directors at their next meeting."  
 11 It would appear from this, Professor Thomas,  
 12 that both the Department of Health and the specific  
 13 attendees at this meeting were particularly concerned  
 14 by this time, April 1979, about non-A, non-B hepatitis  
 15 and keen to ensure that there was a proper  
 16 notification of non-A, non-B hepatitis cases. Is that  
 17 a correct understanding of what we see here?  
 18 **A.** Yes. Just to briefly re-state it, the only way we  
 19 could record post-transfusion hepatitis before was  
 20 jaundice screening, which was really the extreme end.  
 21 So if the patient went yellow after a blood  
 22 transfusion, then you knew they had post transfusion  
 23 hepatitis. But, of course, we know that most cases of  
 24 non-A, non-B hepatitis are anicteric, they don't cause  
 25 jaundice, and those cases wouldn't be picked up by  
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1 this post-transfusion jaundice screening. Therefore,  
2 we were only looking in the public health screening  
3 sense at post-transfusion hepatitis with a very  
4 insensitive test.

5 If you used AST or ALT screening -- these are  
6 the enzymes, you will recall, that indicate liver  
7 damage -- if you look at these after a blood  
8 transfusion, as happened in the United States, then  
9 you would get many more cases, and this is why -- one  
10 of the reasons why we thought there were very few  
11 cases in the UK and that the blood in the United  
12 States was much more contaminated. It turned out  
13 there is a difference but it is not as big as those  
14 original data suggested.

15 **Q.** Then if we go to just one further meeting of this  
16 particular advisory group, it is at CBLA0001020, and  
17 we go to the second page and look at the top of the  
18 page, this is the third meeting of the reconvened  
19 advisory group. The date is 1st November 1979.  
20 Again, you are there deputising for Professor Dame  
21 Sheila Sherlock. If we could go to the next page,  
22 please, Soumik, the bottom half the page, we can see,  
23 under the heading "Non-A, Non-B Hepatitis", the first  
24 paragraph is an update from Professor Zuckerman about  
25 the Medical Research Council Working Party. Then the

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1 those meetings.

2 Could we next go to a third working party, the  
3 Working Party on Post-Transfusion Hepatitis. That's  
4 NHBT0000068\_049. So we can see if we look at the top  
5 of the page:

6 "Blood transfusion research committee.  
7 "Working Party on Post-Transfusion Hepatitis.  
8 "Minutes of the second meeting held on ...  
9 June 25th, 1981 ..."

10 We can see, again, a number of attendees,  
11 including you, again, representing Dame Sheila  
12 Sherlock.

13 If we go to the third page, just picking it up  
14 in the third paragraph, it says:

15 "Dr Howard Thomas said that efforts had been  
16 made at the Royal Free Hospital to develop  
17 a radioimmunoassay test for non-A, non-B hepatitis  
18 using radio labelled convalescent sera from  
19 haemophiliacs ..."

20 Then further details given, and it says:

21 "Further work was needed with this test."

22 Can you assist us with what the efforts were  
23 that were being made that you were involved with to  
24 develop and RIA test for non-A, non-B hepatitis?

25 **A.** Yes, I did publish that data. It was from a Chinese

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1 second paragraph says this:

2 "It was agreed that Professor Zuckerman in  
3 consultation with Dr Dane and Professor Dame Sheila  
4 Sherlock should write to the medical press (eg the  
5 Lancet), to draw attention to the possibility of  
6 non-A, non-B hepatitis and to ask clinicians to  
7 provide serum samples to Blood Transfusion Directors  
8 with details of cases of hepatitis occurring after the  
9 administration of blood and blood products including  
10 Factor VIII, and which had been shown to be  
11 [hepatitis B antigen] negative."

12 Then if we go to the last paragraph there:

13 "It was agreed that all cases would be notified  
14 to the PHLS [so the Public Health Laboratory Service]  
15 as well ..."

16 So, again, it would appear that there's  
17 a concern here to enhance medical awareness of non-A,  
18 non-B hepatitis and to set in train a system of all  
19 cases, not simply those picked up through the  
20 identification of jaundice, to the Public Health  
21 Laboratory Service; is that correct?

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

23 **Q.** Now, you were also lay member of the UKHCDO's  
24 Hepatitis Working Party but I am not going to ask you  
25 any specific questions relating to your attendance at

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1 guy who was a research fellow and he was very diligent  
2 and what he wanted to do was to try to develop  
3 an assay and my laboratory ran all the hepatitis B  
4 surface antigen testing and the hepatitis A testing.  
5 So after we had done those tests, which were necessary  
6 to designate hepatitis as non-A, non-B -- we would  
7 have to exclude the serological involvement of those  
8 cases -- then we kept that serum for maybe six months  
9 or up to two years, depending on how the freezers  
10 would accommodate it, and we divided them up into  
11 anonymised groups. So there would be one saying  
12 "normal laboratory personnel", which was my own and  
13 all our staff, one hepatitis B, one hepatitis A, one  
14 non-A, non-B, alcohol, fatty liver, autoimmune chronic  
15 hepatitis, all the different groups, and renal unit  
16 and the haemophilia unit.

17 If we could develop the test, the only way we  
18 could tell whether it might be related to a virus  
19 causing non-A, non-B would be by showing that it is  
20 more common in the groups where we knew clinically  
21 there was a lot of non-A, non-B, which would be the  
22 haemophilia unit and the renal unit, but hopefully  
23 none in the laboratory staff, including myself.

24 So what my Chinese research fellow did, he took  
25 half a millilitre of serum from one of these specimens

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1 where there had been a transaminase elevation. He  
 2 prepared an immunoglobulin from it, which is the  
 3 antibody containing a fraction of blood. Then he used  
 4 that antibody to coat microtitre wells and then he  
 5 took another specimen and produced the globulin from  
 6 it and radio labelled that, in the hope that he would  
 7 then have what's called a sandwich immunoassay.  
 8 He then went to the haemophilia patients. The  
 9 antibody from one of the specimens was stuck to the  
 10 microtitre plate. If the serum in that contains the  
 11 antigen to which that antibody was reactive and then  
 12 you put on the radio labelled antibody from another  
 13 patient's residual serum, then you would see a signal,  
 14 in other words, there will have been binding of the  
 15 radio label. This he applied to, I think, I don't  
 16 know, 50 or so from the haemophilia unit, 50 from the  
 17 renal unit, 50 from my lab staff, 50 alcoholics, in  
 18 the hope that he might be able to -- he might see  
 19 a higher prevalence of the antigen in the groups that  
 20 we knew developed non-A, non-B, and that would be the  
 21 haemophilia patients. The renal unit also had a high  
 22 proportion but we hoped not to see it in hepatitis A  
 23 and hepatitis B or in alcoholics, nor indeed in the  
 24 laboratory staff populations. This he found, he found  
 25 that this antigen, which was being detected by these

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1 undertaking work with Dr Janossy on diagnostic tests  
 2 and working with Dr Dane on a radioimmunoassay test  
 3 for non-A, non-B hepatitis. Are those all separate  
 4 pieces of work?  
 5 **A.** No. They were all -- because I was developing new  
 6 assays and trying to find non-A, non-B, I had  
 7 a collaboration going with Dr Janossy in which we  
 8 would try to produce most monoclonal antibodies to the  
 9 components of hepatitis A and hepatitis B, so that we  
 10 might improve on the existing assays which Abbott  
 11 produced and which involved sheep antiserum produced  
 12 by inoculating a sheep with, let's say, hepatitis B  
 13 surface antigen.  
 14 In order to make that reproducible monoclonal  
 15 antibody technology had been developed by Cesar  
 16 Milstein. I had shown an interest in that, as had  
 17 George Janossy, as Professor of Immunology. I  
 18 purified viral antigens, in particular hepatitis B  
 19 surface antigen and hepatitis B core. We immunised  
 20 mice with those antigens and produced monoclonal  
 21 antibodies, which are pure antibodies. Do you  
 22 understand? Sorry, I am not being rude but do you  
 23 understand the monoclonal antibody term?  
 24 **Q.** In fact, one of the questions I have been asked by  
 25 Core Participants to ask you, which was going to be my

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1 antibodies, was present in anonymised serum from these  
 2 various groups.  
 3 Then we wrote that up in -- I have forgotten  
 4 the publication, but you have got it -- which showed  
 5 that, yes, there was an antigen in the patients from  
 6 the haemophilia unit and the renal unit but not in  
 7 alcohol or hepatitis A or hepatitis B cases. We  
 8 thought "Well, this could be then a component of the  
 9 non-A, non-B virus", which it turned out it wasn't  
 10 actually. It was an antiglobulin, but that's why the  
 11 experiments were done.  
 12 The experiments, as I say, were done with serum  
 13 that was left after we had tested for hepatitis A and  
 14 B, which was part of the diagnostic service that my  
 15 laboratory provided in diagnosing non-A, non-B,  
 16 excluding hepatitis A and hepatitis B. So we kept the  
 17 residual serum from those cases, which was usually  
 18 about half to 1 millilitre of serum in the hope they  
 19 would be of use in the future. We would throw them  
 20 out after six months when the freezer -- we had two  
 21 freezers -- when those freezers became full. So  
 22 that's what that study was about and I think it was Dr  
 23 Luo -- L-U-O, I think -- of which you have his paper.  
 24 I alluded to that assay in the Glasgow meeting.  
 25 **Q.** The documents from the early '80s also refer to you

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1 next question, was if you could tell us what you mean  
 2 by "monoclonal antibodies"?  
 3 **A.** Well, what Mr Milstein showed, with Greg Winters, who  
 4 was at Imperial, and Alan Fish, if you immunise  
 5 a mouse with, let's say, hepatitis B surface antigen,  
 6 then that mouse will produce a heap of antibodies to  
 7 different parts of the viral protein. So there might  
 8 be 100 or 200 different antibodies all binding to  
 9 different parts of the viral antigen. So you  
 10 immunised a mouse with the antigen and then you took  
 11 the spleen cells from that immune mouse and fuse them  
 12 in a myeloma cell, which is a malignant antibody  
 13 producing cell. Then the progeny from that fusion,  
 14 so-called hybrids, would have the joint function of or  
 15 the joint property of being malignant, so they kept on  
 16 producing the antibody, and each hybrid would produce  
 17 a different single antibody, because we cloned them  
 18 out.  
 19 So monoclonal antibody is a malignant cell  
 20 line producing 100% pure antibody to a particular  
 21 epitope. An epitope is just a part of an antigen.  
 22 Remember, I just said an antigen might have 100 or  
 23 more epitopes, fragments of the antigen to which the  
 24 antibodies bind. Those antibodies are very useful to  
 25 produce radioimmunoassays or enzyme immunoassays.

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1 I have developed some, with funding from NRDC, I think  
 2 it was called then, but then it became British  
 3 Technology Group, and George Janossy and I were funded  
 4 for a lot of money to produce these antibodies, which  
 5 would be a leap forward in diagnostic hepatitis  
 6 testing.

7 Luckily, we were successful in doing that and  
 8 we were using that assay, the monoclonal antibody  
 9 tested assay, as well as the commercial antibody assay  
 10 for testing four hepatitis B surface antigen. We  
 11 found that the monoclonal antibody based assay was  
 12 much more sensitive. We got positives in specimens  
 13 that were otherwise negative by the commercial AbID  
 14 assay for hepatitis B surface antigen.

15 At that stage we wondered whether those extra  
 16 ones were a sort of spin-off of hepatitis B, which the  
 17 French and a group in America had suggested, that we  
 18 were picking up with our monoclonal antibodies and  
 19 this monoclonal antibody assay for hepatitis B surface  
 20 antigen might be picking up a non-A, non-B assay. It  
 21 turned out that wasn't the case, but the assay was  
 22 subsequently commercialised by a variety of companies,  
 23 who paid royalties to the Royal Free and a proportion  
 24 of the royalty to George Janossy and myself and  
 25 another lady who helped. So that's the basis of that

1 They were wanting to do -- the Americans had done  
 2 this, as did the Germans. They had effectively picked  
 3 up some cases of non-A, non-B. It was called  
 4 a surrogate test. Before we had the discovery of the  
 5 hepatitis C virus, the Americans and the Germans had  
 6 decided they would use these surrogates, an ALT screen  
 7 and an anti-core screen to pick up these non-A,  
 8 non-Bs.

9 We had a meeting -- I don't know which  
 10 committee it was -- it was discussion of whether we  
 11 could use them in the United Kingdom really, and the  
 12 Blood Transfusion Service were a little bit against  
 13 it, because they said they would pick up a lot of  
 14 people, particularly with the ALT part of that  
 15 combination -- a large number of people with  
 16 alcohol-related liver disease or type 2 diabetes,  
 17 fatty liver, which would be true, and therefore before  
 18 we could determine how useful that ALT screen with the  
 19 anti-core screen -- and I should add at this stage  
 20 that anti-core picked up people with a lifestyle which  
 21 was deemed to be high risks, so a lot of intravenous  
 22 drug users had antibody to hepatitis B core, as did  
 23 people with a lot of sexual partners, they might have  
 24 antibody to core as well.

25 You probably know that the Blood Transfusion

1 story.

2 **Q.** We can take the document down, thank you.

3 You say in your witness statement that you  
 4 offered to provide monoclonal antibodies to  
 5 Dr McClelland for the purpose of a study. You weren't  
 6 sure whether that offer was taken up, I think, from  
 7 what your statement suggests.

8 **A.** Right.

9 **Q.** What was the purpose of the offer to Dr McClelland?

10 **A.** Well, as well as producing antibodies to hepatitis B  
 11 surface antigen, which is the envelope of hepatitis B,  
 12 we also produced antibodies to what is called the  
 13 core, the centre of the hepatitis B virus. We then  
 14 were able to -- it doesn't matter the detail -- but we  
 15 produced that monoclonal antibody to produce a very  
 16 sensitive and reproducible assay to mention antibody  
 17 to hepatitis B core. Everybody who was infected,  
 18 either acutely or chronically, and the acute ones that  
 19 get better, all of this group will have antibodies to  
 20 hepatitis B core, okay? So it was a good indication  
 21 of infection, acute or chronic, cured or persistent --  
 22 self-cured or persistent -- for hepatitis B.

23 The Americans and the Germans had used what  
 24 they call surrogate tests to try and detect high risk  
 25 donors, high risk donors transmitting non-A, non-B.

1 Service in the UK had been interviewing patients prior  
 2 to accepting them as donors to try and identify  
 3 whether they had a high risk lifestyle, for want of  
 4 a better term. Had they used drugs? Were they  
 5 promiscuous? So the surrogate of ALT and anti-core  
 6 was being evaluated and the BTS, Blood Transfusion  
 7 Service, in the UK thought we were going to get a lot  
 8 of false positives.

9 Dr McClelland -- so they wouldn't introduce it  
 10 on the basis of what had been done in America and  
 11 Germany. They wanted to see what the yield of  
 12 infected material by preventing non-A, non-B  
 13 post-transfusion hepatitis would occur in the UK.

14 Then the cost of that came up and the  
 15 Department of -- I think it was Dr Metters, was it,  
 16 who was the medical officer in the Department of  
 17 Health at that stage, said "If we did a trial, how  
 18 much would that cost?" In other words, screening  
 19 everybody and looking at how many would be taken out.  
 20 That, when we worked it through, was going to be very  
 21 expensive. So I said "Well, monoclonal antibodies  
 22 cost me nothing". I mean, one mouse produces enough  
 23 antibodies probably for a million tests. So I said he  
 24 could have that monoclonal antibody assay in Edinburgh  
 25 if he was willing to do the test.



1 I gave him the telephone number of  
 2 Peter Karayiannis, who was an academic colleague in  
 3 the department, telling -- or asking Brian McClelland  
 4 to bring him if he wanted to take up that offer, and  
 5 Peter would have sent him the antibody. But I think  
 6 for some reason or other it didn't happen.  
 7 **Q.** You said in the statement that your view was that  
 8 anti-HBc and ALT surrogate, non-A, non-B screening of  
 9 blood donations should have been introduced. Is that  
 10 correct?  
 11 **A.** Yes. I thought it was -- we should have introduced  
 12 it. But at least we should, having heard the counter  
 13 argument, which we were going to get a lot of false  
 14 positives -- which was reasonable -- I mean, I took  
 15 that on board. I thought that it could be reasonable  
 16 then to do a trial, just to see how many units we lost  
 17 and whether we did reduce the incidence of  
 18 post-transfusion non-A, non-B, and then we could work  
 19 on a much better basis.  
 20 That's why -- if we could reduce the cost with  
 21 free anti-core, which was the expensive component of  
 22 that trial, then it might make it more plausible -- or  
 23 possible, rather, not plausible.  
 24 **Q.** Then can I then just turn to the question of screening  
 25 for hepatitis C once an antibody assay was available?

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1 "In this paper, the argument for 'Blood  
 2 transfusion services should have begun screening for  
 3 hepatitis C when an' -- if we go to the top of the  
 4 next column -- 'antibody assay first became available'  
 5 will be developed by examining what is known about the  
 6 serology of hepatitis C to determine (i) how many  
 7 donations would be excluded by screening for  
 8 anti-C100, (ii) how many cases of [post-transfusion  
 9 hepatitis] could be avoided by eliminating blood  
 10 products positive for anti-C100 and (iii) how many  
 11 cases of [post-transfusion hepatitis] would not be  
 12 prevented by such a screening programme."  
 13 I am not going to go through the detail of the  
 14 arguments, but we just pick up your conclusion, bottom  
 15 of the next page. Under the heading "Conclusion",  
 16 very bottom of the page:  
 17 "The introduction of an HCV screening programme  
 18 for blood products using the anti-C100 assay would  
 19 cost about £6-25 million/year, would result in the  
 20 loss of", top of the next page, "12,500 to 25,000  
 21 donations/year and prevent between 2,500 and 5,000  
 22 cases of [post-transfusion hepatitis] per year.  
 23 Between 1,250 and 2,500 cases of chronic liver disease  
 24 ... [per] year and 250-500 cases of cirrhosis/year  
 25 could be prevented, but a similar number of cases

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1 I am going to direct your attention to an article you  
 2 wrote with a colleague, Dr Brown. It is NHBT0088770.  
 3 This is published in Medical Virology. It is  
 4 entitled "Blood Transfusion Services Should Have Begun  
 5 Screening for Hepatitis C When an Antibody assay First  
 6 Became Available". For, so in favour of that  
 7 proposition, Dr Brown and you. And then against,  
 8 Dr Barbara from the Colindale Blood Transfusion  
 9 Centre.  
 10 Then if we can just look at the bottom half of  
 11 the page, I want to pick up in the left-hand column,  
 12 three paragraphs up from the bottom it says:  
 13 "In the early 1980s it was shown that the  
 14 incidence of [non-A, non-B hepatitis] could be almost  
 15 halved by the exclusion of donors with antibodies to  
 16 hepatitis B core ... or abnormal liver function  
 17 tests ..."  
 18 I think that was the issue you were addressing  
 19 a few minutes ago. Then:  
 20 "The presence of these surrogate markers for  
 21 [non-A, non-B] hepatitis resulted in a loss of only 4%  
 22 of the donors."  
 23 Then you refer to the identification in 1989 of  
 24 the hepatitis C virus.  
 25 Then you say at the bottom of the page:

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1 would still occur because of the 50% sensitivity of  
 2 the test."  
 3 Then you go on to say:  
 4 "Patients with CLD [chronic liver disease] will  
 5 consume NHS resources as they develop the  
 6 complications of portal hypertension; the cost of 250  
 7 liver transplants is about £8.75 million. It would  
 8 seem to us therefore that there are financial as well  
 9 as ethical considerations in HCV screening.  
 10 Clinicians tend to underestimate the magnitude of the  
 11 problem as 75% of PTH cases are anicteric; if we are  
 12 not doing everything possible to prevent NANB PTH we  
 13 may find ourselves in a difficult situation when the  
 14 first group of cirrhotics in the anti-C100 era become  
 15 litigious."  
 16 Then we have Dr Barbara's counter argument in  
 17 the rest of the article.  
 18 I think you said in your statement, Professor  
 19 Thomas, you don't have really anything to add to that,  
 20 but it is a perspective that we have not yet explored  
 21 and I wanted to ask, in addition to publishing this  
 22 article, whether you were involved in any meetings or  
 23 discussions with the Department of Health or Blood  
 24 Transfusion Service as to whether this screening  
 25 should have been introduced?

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1 A. Well, it was my view that we should introduce it.  
 2 I should say in the context of this article that  
 3 I guess -- the editor of this journal was  
 4 Professor Paul Griffiths, who was the Professor of  
 5 Virology at the Royal Free, and he had just set up  
 6 this journal and he was looking for someone to write  
 7 in favour of this, as opposed to a member of the Blood  
 8 Transfusion Service, whom he knew would be able to  
 9 write against it.  
 10 It was almost -- as I think I said at the  
 11 Penrose Inquiry, this was the sort of adversarial  
 12 format -- or, not an adversarial format but a --  
 13 where -- a bit like barristers, you know. One would  
 14 present one case, one aspect of an argument, I suppose  
 15 the defence, and another would produce the defence  
 16 (sic), you know. So I -- because I was a physician,  
 17 and physicians in the main are interested in  
 18 individual patients, whereas the Blood Transfusion  
 19 Service and epidemiologists are much more concerned  
 20 with populations of patients and economic issues.  
 21 So I thought it would be useful for Jonathan  
 22 Brown to work this through -- he was a registrar in my  
 23 department -- so I asked him to do this. We sat down  
 24 and talked about how we might do it and that's how it  
 25 came about.

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1 hadn't been introduced and that we were going to wait  
 2 until, I think, 1991, September, for the second  
 3 generation assay, which had got rid of a lot of the  
 4 false positives, which was more acceptable to the  
 5 Blood Transfusion Service because they would lose  
 6 a smaller number of units of blood.  
 7 And, you know, it's a proper concern, isn't it?  
 8 That, you know, if you are involved in a blood traffic  
 9 accident or you are going to have cardiac surgery, you  
 10 will expect the Blood Transfusion Service to provide  
 11 enough blood for you to get through that quite safely.  
 12 So he presented the argument for that and I presented  
 13 the argument for the number of patients who might die  
 14 by not using the first generation assay. So that's  
 15 the situation.  
 16 Clearly then it went internal into the health  
 17 service and -- into the health service and someone  
 18 somewhere decided that they wouldn't introduce it.  
 19 Q. The next and, for present purposes at least, the last  
 20 lot of questions I have for you, Professor Thomas,  
 21 relate to a study which Dr Kernoff was involved with  
 22 and in which you were involved.  
 23 If I can pick it up in your witness statement  
 24 at WITN3824007, and if we can go to -- can we try  
 25 page 10, Soumik. Mine is in a slightly different

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1 I can't -- I mean, there was this discussion,  
 2 not only about ALT and anti-core screening, as  
 3 I alluded to, which was in the context of blood  
 4 transfusion, but there were discussions also on --  
 5 which I think I was present at -- you know, looking at  
 6 whether we should go with the stage 1 or the first  
 7 available assay of anti-core or whether we should wait  
 8 for the second format, which was likely to be ready in  
 9 a year and would get rid of a lot of the false  
 10 positives.  
 11 So in answer to your question, this is how  
 12 I felt about it. I thought it would be useful to work  
 13 it through economically, because that would give solid  
 14 facts, but there is an ethical issue as well, and  
 15 Dr Barbara genuinely thought they would be losing  
 16 large numbers of units of blood and they wouldn't be  
 17 able to supply enough blood because of all the false  
 18 positive blood that would be lost. I could see that  
 19 argument as well. We were both friends and would we  
 20 said, "Well, let's do the best and write the arguments  
 21 for and against", and that's what we did.  
 22 I mean, it must have been taken up  
 23 subsequently, but I didn't hear any more about it, you  
 24 know, as to whether it had been introduced or not at  
 25 the time until it came through and it turned out it

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1 format. Yes.  
 2 So if we pick it up at the top of the page, you  
 3 refer there to a:  
 4 "... prospective study of 30 patients recording  
 5 the incidence of abnormal LFTs and persistent  
 6 abnormalities after infusion of cryoprecipitate, NHS  
 7 factor VIII And IX or USA factor VIII concentrate ..."  
 8 Then you refer in brackets to the article  
 9 itself:  
 10 "... (High risk of [non-A, non-B] after first  
 11 exposure to volunteer or commercial Factor VIII ...)."  
 12 We will look at that in a moment.  
 13 Then you say:  
 14 "This was done because abnormal liver tests had  
 15 already been reported in USA and it was important to  
 16 know in each case whether the abnormality had been  
 17 there before treatment in which case it would not be  
 18 due to [post transfusion non-A, non-B] hepatitis ..."  
 19 You refer a little further down to the study  
 20 being:  
 21 "... supervised by the Haemophilia Unit and  
 22 Professor Kernoff states in the paper that the study  
 23 was approved by the RFH Ethics Committee and all  
 24 patients gave verbal consent."  
 25 You say your contribution, as a hepatologist,

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1 was to provide advice on management of the liver  
 2 abnormalities.  
 3 I am going to ask you to look at the paper.  
 4 I have some questions I have been asked to ask you.  
 5 I don't know whether you are going to be able to  
 6 assist with casting further light on this but you will  
 7 appreciate they are not questions I can pose to  
 8 Dr Kernoff.  
 9 So if we go to PRSE0003439.  
 10 So this is the paper you have referred to in  
 11 your witness statement:  
 12 "High risk of non-A, non-B hepatitis after a  
 13 first exposure to volunteer or commercial clotting  
 14 factor concentrates ..."  
 15 And then we can see the authors there: Kernoff,  
 16 Lee, Karayiannis and you.  
 17 Then we see the summary:  
 18 "After a first exposure to factor VIII  
 19 concentrates, 9 [out of] 9 British patients treated  
 20 with USA-derived commercial products, and 10 [out of]  
 21 12 treated with British volunteer (NHS) products,  
 22 developed acute non-A, non-B ... hepatitis. Hepatitis  
 23 following commercial products was more severe, and of  
 24 shorter incubation."  
 25 Et cetera.

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1 things?" So these young, in the main, boys, in the  
 2 first few years of life, could then actually play and  
 3 develop normally as normal children.  
 4 So the use of these concentrates at this stage  
 5 was very important. People wanted to have them.  
 6 I think what shouldn't have happened, and the  
 7 haemophilia directors, of which Peter Kernoff was one,  
 8 had argued that only if you had severe haemophilia,  
 9 with virtually -- I am not a haemophilia doctor --  
 10 virtually a total deficiency of the Factor VIII in  
 11 your blood, would you need these concentrates. If you  
 12 had mild haemophilia, you could be treated with  
 13 cryoprecipitate, which was derived just from  
 14 eight units of blood. And already it was known that  
 15 the risk of getting non-A, non-B hepatitis after  
 16 cryoprecipitate use was much less than if you used  
 17 concentrates. And there was an agreement with the  
 18 haemophilia directors that -- you know, what the  
 19 cut-off would be, which patients would get  
 20 vasopressin, which released any remaining Factor VIII  
 21 globulins from the patient's liver cells, or could be  
 22 treated with cryoprecipitate rather than the higher  
 23 risk concentrates.  
 24 Of the group who had the more severe  
 25 haemophilia, when they came in with a bleeding

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1 Are you -- I don't know whether, as I say, you  
 2 can assist with this, but if, as your witness  
 3 statement suggests, this study was undertaken because  
 4 of concern over reports of abnormal liver function  
 5 tests from the USA, what was the justification for  
 6 Royal Free Hospital patients being moved from  
 7 cryoprecipitate to factor concentrates?  
 8 A. Well, I think the context of this was that -- I mean,  
 9 all the patients that went into this study had come  
 10 into the haemophilia unit at the Royal Free either  
 11 with a bleeding episode or, latterly -- I am not sure  
 12 whether the second group I am going to mention were  
 13 involved here, but -- or, latterly, when Factor VIII  
 14 concentrates were used prophylactically. In other  
 15 words, the haemophilia population found, you know, the  
 16 concentrates very patient-friendly, if I can put it,  
 17 to a patient, but, you know -- because we didn't know  
 18 about any of the problems that were being transmitted.  
 19 But, you know, if you had a painful haemarthrosis,  
 20 bleeding into your joint, which your doctors would  
 21 tell you would cause fibrosis and deformities, then  
 22 an injection of this material stopped that. And very  
 23 soon after it was a natural extension of this to ask,  
 24 "Well, if we took this three times a week, would it  
 25 prevent having haemarthrosis and muscle bleeds and

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1 episode, they would be -- in the middle of the night  
 2 often -- they would be given concentrate. And I think  
 3 what Peter Kernoff decided to do, with the agreement  
 4 of the ethics committee and the consent of the  
 5 patients, randomly allocate them to whether they  
 6 received NHS or commercial material. And they were  
 7 also following transaminases at this time, to see  
 8 whether, you know, patients did get ALT abnormalities,  
 9 and essentially virtually 100%, whether it was an NHS  
 10 concentrate or commercial concentrate, got  
 11 abnormalities.  
 12 That was predictable in a way, because the  
 13 incidence of hepatitis non-A, non-B was something like  
 14 0.5% in human -- in British donors and about 2 or 3%  
 15 in American commercial donors. And since something  
 16 like 1,500 litres or donations of blood were used for  
 17 each preparation, every single preparation would be  
 18 expected to contain the virus. And indeed this is  
 19 what turned out to be the case.  
 20 So what this study showed, in patients who  
 21 should have all had severe Factor VIII deficiency --  
 22 and I don't know whether any of them -- are there any  
 23 in the list of patients who had mild disease? Because  
 24 if there were, then those people shouldn't have had  
 25 the concentrates. They should have had the

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1 cryoprecipitate.  
 2 I think the intention was it should only have  
 3 been those patients who could only be treated with the  
 4 concentrate who would have been included in this  
 5 study. I think the protocol would have said,  
 6 I presume, that anybody with mild disease should not  
 7 be included, because they should be getting  
 8 cryoprecipitate, and indeed the majority would have  
 9 been. So I think that's the background to it.

10 Afterwards, when it turned out --  
 11 Professor Kernoff found that virtually everybody  
 12 developed abnormal transaminases after the use of  
 13 these concentrates, he then wanted to ask the question  
 14 of: was there an antibody out there in people who had  
 15 had concentrates in the past and had normal  
 16 transaminases, indicating that they possibly had  
 17 recovered from a non-A, non-B infection? If you used  
 18 the globulin from their blood, an antibody containing  
 19 globulin and gave it with the concentrates, where he  
 20 knew there would be 100% incidence of non-A, non-B, if  
 21 you give this antibody, could you prevent it  
 22 happening?

23 And again, he explained that to the patients,  
 24 and there was I think one or two cases where it looks  
 25 as if the immune serum globulin, as it was called,

1 a freezer. And the only thing that Peter tried to do  
 2 was make sure that any one patient, if they had  
 3 repeated episodes of either bleeding or having the  
 4 Factor VIII concentrate prophylactically, in other  
 5 words to try to prevent bleeding episodes, that that  
 6 patient's material was all kept aside from one  
 7 manufacturer, whether it was British or American, so  
 8 that they all got the same -- that that individual  
 9 would always get the same batch, which would, he  
 10 thought, reduce, if anything, the chance of them being  
 11 infected.

12 So Peter organised it extremely well. And  
 13 Christine Lee took over as the head of the unit,  
 14 technical unit. Professor Ted Tuddenham mainly did  
 15 research but Christine, I think, was the head of the  
 16 clinical service, and I think you have interviewed  
 17 her, really.

18 My role came in when -- if they had developed  
 19 abnormal transaminases, what it might be due to. And  
 20 that is when, you know, there was a discussion as to  
 21 what we should do, because we had done a trial in  
 22 patients with non-A, non-B outside the haemophilia  
 23 population and showed that interferon normalised their  
 24 liver test abnormalities. We wanted to discuss, in  
 25 the context of their liver, a joint clinic, where we

1 prevented Factor IX deficient patients, receiving  
 2 Factor IX concentrates, from developing hepatitis.  
 3 But it was -- it's one patient, it says here, just one  
 4 patient prepared to be protected. Which wouldn't seem  
 5 to be significant but did suggest that there might be  
 6 something called protective immunity which might be  
 7 useful in this context: severe haemophiliacs receiving  
 8 concentrates where they are all getting ALT  
 9 abnormalities.

10 I think that's the background of it, in the  
 11 main.

12 **Q.** You said, Professor Thomas, that Dr Kernoff discussed  
 13 matters with the patients and consent was given. Do  
 14 you have any first-hand knowledge yourself of what was  
 15 said to the patients who were participating in this  
 16 study?

17 **A.** No, but -- I mean, Peter Kernoff was an obsessive  
 18 individual. I mean, he ran the unit with a rod of  
 19 iron. And the reason occasional patients may have got  
 20 concentrate when they should have had cryo, if it was  
 21 mild haemophiliacs, was related to the fact he would  
 22 set up the rules and the patients who came in in the  
 23 middle of the night would be looked after by  
 24 a registrar or a haemophilia nurse, who would be, in  
 25 the middle of the night, looking for a concentrate in

1 had a registrar from the liver unit and a registrar  
 2 from the haemophilia unit, plus or minus consultants  
 3 in both those units, seeing all the cases in the  
 4 haemophilia unit that had abnormal liver tests. And  
 5 at these clinics that's where there would have been  
 6 discussions on behalf of the liver unit as to what  
 7 might be done. And we decided we would try to --  
 8 having published in the BMJ the demonstration that  
 9 liver tests became normal in non-haemophiliac patients  
 10 with non-A, non-B when treated with interferon, that  
 11 we would try it in the haemophiliac population.

12 It was a separate issue, because, of course,  
 13 because of the bleeding problems with a haemophiliac,  
 14 we would have to give it probably not intramuscularly  
 15 but intravenously and with cover of a coagulation  
 16 factor, which would involve giving more of one of the  
 17 concentrates.

18 Which is why I know that Peter Kernoff would be  
 19 very keen to make sure that there would be a batch  
 20 from one manufacturer which had a patient's name on  
 21 it, which would only be kept for that patient, for  
 22 instance, so they always got the same material. That  
 23 was one of the things he was concerned about if we  
 24 went into this trial, would be: since they would have  
 25 to get concentrates, which his study had shown were

1 transmitting non-A, non-B, he wanted to make sure that  
2 he wasn't giving them a second episode, because we  
3 thought there may be two viruses at that stage. So he  
4 used the same batch.

5 **Q.** As a --

6 **A.** So that was the background to all of that. And the  
7 trial was successful in the non-haemophiliac patients  
8 and that was published in the British Medical Journal.

9 **Q.** Just sticking with the study that we see here, as  
10 a hepatologist involved with this study, was it your  
11 expectation that the patients who were being enrolled  
12 in it and participating in it should have been advised  
13 of the risks of developing non-A, non-B hepatitis from  
14 the factor concentrates with which they were going to  
15 be treated?

16 **A.** Yes. I mean, these patients were drawn from the  
17 haemophilia clinics, and I think Peter and Christine  
18 say that they were asked for informed consent and the  
19 ethics committee of the Royal Free were asked to  
20 comment on it. Does it not say that in that text?

21 **Q.** It says they were asked to give consent but doesn't  
22 provide full details of what that consent process  
23 would have entailed.

24 So my question to you is, as a matter of  
25 principle, would you expect the information given to

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1 But we weren't -- the concentrates were being  
2 made from 1,500 units of blood. So even accepting the  
3 very low incidence of infected blood in the UK, on the  
4 basis of the Newcastle Oliver James study, every pint,  
5 every unit of Factor VIII concentrate would contain  
6 the virus. And indeed that turned out to be the case.

7 So I think they had reason to believe that  
8 hepatitis C was going to be the same after  
9 a volunteer, UK or American, but what was not going to  
10 be the same was the HIV incidence, because patients  
11 had not yet been described, as far as I can recall, in  
12 the UK, whereas in California and in the America  
13 system, HIV had already been described.

14 So there was going to be, I thought anyway, no  
15 difference in the prevalence of hepatitis C,  
16 non-A, non-B, with these two concentrates, but HIV,  
17 I think, probably with the benefit of hindsight, might  
18 have been shown to be different, because they had  
19 already seen it in the US and we were still looking  
20 for it in the UK.

21 That is quite a complicated issue really, and  
22 ...

23 **Q.** Yes. I am not going to be asking you about HIV.

24 Just two further questions in relation to this  
25 study. Do you recall how soon after the commencement

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1 patients who were being asked to participate in the  
2 study to have included an explanation of the high  
3 probability, if not near certainty, of developing  
4 non-A, non-B hepatitis?

5 **A.** Yes, I think you would have had to, you know, say  
6 there are two preparations and -- you know, "You would  
7 need to have one. We don't know which is the better  
8 one", although you might argue I suppose, you know,  
9 there was a suspicion, although it turned out to be  
10 wrong, that the American one was going to be more of  
11 a problem.

12 But I think it is worthwhile saying here that  
13 although -- because of the background information that  
14 was around, which was -- I think there was a paper  
15 from Oliver James, for instance, showing that after  
16 cardiac surgery -- in Newcastle -- the incidence of  
17 non-A, non-B after use of British blood was very low,  
18 whereas after cardiac surgery in the United States it  
19 was very high. But there was a feeling that even if  
20 it was low, as in the Newcastle study -- I think he  
21 said it was about 0.2% -- each patient for cardiac  
22 work would have about 6 or 8 units of blood. So the  
23 total risk would be about 1.5% of getting ALT  
24 elevation after transfusion, whereas the American  
25 incidence was two or three times that.

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1 of the study you began to receive abnormal liver  
2 function test results?

3 **A.** You mean after this --

4 **Q.** In the course of this study --

5 **A.** Yes.

6 **Q.** -- how soon after the study commenced were abnormal  
7 liver function test results being reported to you?  
8 Are you able to recall?

9 **A.** I can't recall really, because, as I say, I was  
10 involved, you know, in looking at how we would manage  
11 these patients afterwards and what the significance  
12 would be and also what we would need to do to find out  
13 what the cause of the abnormal ALT was, because at  
14 that stage there were at least three hypotheses. One  
15 was that it was a virus; the second was that it was  
16 due to chemicals which are used in the preparation of  
17 the concentrates, preservatives and what have you; and  
18 the third was that it might be related to immunisation  
19 against HLA proteins, human leukocyte or  
20 transplantation antigens, which can cause  
21 immunosuppression, which was relevant because the  
22 other thing that was of concern was whether HIV was  
23 being seen in British patients at that stage, and  
24 I think there were a lot of reasons why the patients  
25 with haemophilia might be immunosuppressed, one of

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1 which was just there was a lot of materials other than  
2 Factor VIII in the concentrates. HLA proteins, beta-2  
3 microglobulin were two which could depress the immune  
4 system.

5 So my contribution was to think of a better  
6 test which we would apply to each person when their  
7 ALT was known or perceived to be abnormal, to find out  
8 what it might be. It might have been due to  
9 hepatitis B, for instance, because there were some  
10 concentrates which were transmitting hepatitis B, for  
11 instance.

12 **Q.** As it became -- sorry.

13 **A.** So that was my role, to look at what was happening and  
14 why the patients had got abnormal ALTs.

15 **Q.** As it became apparent that the patients enrolled in  
16 this study were developing post transfusion  
17 non-A, non-B hepatitis, was it, in your view, ethical  
18 to continue with the study?

19 **A.** Well, luckily I wasn't involved in that situation.  
20 I suppose if they were seeing an equal incidence of  
21 abnormal transaminase in both groups, then I don't  
22 know -- was this -- I have forgotten now. Was this  
23 blinded; in other words, did they know which group  
24 were getting which product?

25 **Q.** I am afraid I don't know without checking, professor,

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1 hepatitis, that's one thing, but in that case one  
2 wonders why the study was going to be of any value.

3 **A.** Well, it wouldn't have been of value. Had they had  
4 abnormal ALTs before, then you wouldn't have been able  
5 to determine anything.

6 **SIR BRIAN LANGSTAFF:** The object of the study is to take  
7 people who had not shown any signs of non-A, non-B  
8 hepatitis and administer to them a product which it  
9 was hypothesised might give them less hepatitis if it  
10 was NHS-made and give them a lot more risk of it if it  
11 was commercial, on the basis that probably one or the  
12 other would provide it. There would have to be some  
13 therapeutic reason for the treatment.

14 How was that anticipated -- can you help -- in  
15 advance of the study actually being conducted that  
16 they were people who, although they have never had  
17 concentrate before, were likely to or might need it in  
18 the future, so that they could then be studied and  
19 asked for their consent to have this product  
20 administered to them?

21 **A.** Well, surely, the -- I mean, what -- I have not gone  
22 back over this recently and I assumed you would ask  
23 Professor Lee about this. You know, if somebody comes  
24 in -- these were severe haemophiliacs, I think, where  
25 vasopressin, which releases the patient's own

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1 whether that's the case or not.

2 **A.** But I think they must have -- bearing in mind the  
3 prevalence -- the incidence, rather, of abnormal liver  
4 test was the same with all the concentrates, they must  
5 have seen abnormal LFTs in all of the patients, you  
6 know, in the follow-up, and -- in which case, if you  
7 are seeing it after, you know, both and you are giving  
8 it for a bleeding episode, you know, you must know it  
9 is ethical to continue.

10 You know, the patient must get something. Or  
11 are you suggesting they might have at that stage  
12 switched to cryoprecipitate?

13 **Q.** That's the inference, professor, yes, not least  
14 because these are patients who were being exposed to  
15 concentrates for the first time, as the study tells  
16 us.

17 **A.** Oh, right. Yes.

18 **SIR BRIAN LANGSTAFF:** I was just going to ask about that.  
19 These were all patients who, by definition presumably,  
20 to be entered into the study, had no obvious sign of  
21 suffering from non-A, non-B hepatitis?

22 **A.** Well, presumably. Did they have ALTs beforehand?  
23 I think they did.

24 **SIR BRIAN LANGSTAFF:** Well, if they did and they were  
25 entered knowing that they were suffering from

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1 Factor VIII or cryoprecipitate, were ruled out. So  
2 the protocol I presume would have said patients coming  
3 in with bleeding episodes in the middle of the night  
4 or during the day would need treatment with one of the  
5 concentrates. So, you know, they would give one or  
6 other of the concentrates to treat the episode.

7 **SIR BRIAN LANGSTAFF:** I think rather than speculate --  
8 I have read the study at least a couple of times, but  
9 I probably ought to re-read it because it will answer  
10 the question I just raised.

11 **MS RICHARDS:** Yes. Sir, I was just going to point out,  
12 some of the patients, a minority, were "virgin  
13 haemophiliacs", that awful phrase, and most were  
14 described as needing infrequent treatment and  
15 therefore, I think, would be unlikely to be severe  
16 haemophiliacs. That's the bottom of page 2 of the  
17 report.

18 **SIR BRIAN LANGSTAFF:** Or severe haemophiliacs who just  
19 happened to be in that rare group that would require  
20 very little treatment.

21 **MS RICHARDS:** Yes.

22 **A.** Well, I think -- you know, obviously you can't  
23 interview Peter Kernoff, but the haemophilia doctors  
24 who were taking care of these patients at this time  
25 you can ask about these issues. As I said, my role

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1 was to work out why they had abnormal liver function  
 2 tests after these concentrates, and you might say  
 3 "Well, surely it would be obvious?", but, as I say --  
 4 and I think in other studies that were published at  
 5 this time, some patients had hepatitis B and C at the  
 6 same time. Some had hepatitis B and had delta virus  
 7 infection as well, and there were other patients who  
 8 had other, you know, problems. So, you know, we were  
 9 trying to, at that stage, also look at patients who  
 10 had persistent abnormalities to see whether or not  
 11 they should have -- whether they needed a liver biopsy  
 12 to determine this issue of whether they had chronic  
 13 persistent or chronic active hepatitis. In the main,  
 14 I think this was after we had already determined that  
 15 they had not had chronic active hepatitis, so I don't  
 16 think any of these did have liver biopsies. But you  
 17 really need to ask the haemophilia unit what was going  
 18 on. I saw them afterwards, after it had happened.  
 19 But that's all I can say about that at the moment,  
 20 unless you want me to read it again, because I --

21 **SIR BRIAN LANGSTAFF:** No, no. I think you have answered  
 22 very fairly in saying that, in essence, the study was  
 23 one which was organised by the haemophilia unit, and  
 24 we have already asked Professor Lee about this general  
 25 area and about her study. So I think I don't trouble

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1 **MS RICHARDS:** Professor Thomas, I have some various  
 2 questions, so we will dot around from topic to topic  
 3 because they have been identified --

4 **A.** Could I just ask, in fairness to Professor Kernoff,  
 5 who is dead, I have just read that paper during the  
 6 break, British Journal of Haematology, I just wanted  
 7 to make one other comment, really. Is it possible to  
 8 show that again just so that people can see precisely  
 9 what I am talking about?

10 **Q.** It is PRSE0003439.

11 **A.** If we go to the "Patients and methods" section.

12 **Q.** Page 2.

13 **A.** It is the third paragraph down. It is on page 471.

14 **Q.** Next page, please, Soumik.

15 **A.** Next page, please.

16 **Q.** Did you say it was the third paragraph, professor?

17 **A.** On that page it is the second paragraph down, and  
 18 particularly here:

19 "Treatment was given either ..."

20 I just wanted to paint the picture really:

21 "Treatment was given either to stop bleeding or  
 22 as prophylaxis before surgery. Duration and dosage of  
 23 therapy, and choice of therapeutic product, were  
 24 influenced by clinical circumstances, local  
 25 availability of products, and departmental policies

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1 you any further.

2 **MS RICHARDS:** Sir, those are the questions I have for  
 3 Professor Thomas.

4 We obviously need to give an opportunity to  
 5 Core Participants and their legal representatives to  
 6 suggest any further questions arising out of  
 7 Professor Thomas' evidence today. So if we could take  
 8 a break at this stage to enable me to receive and  
 9 consider any questions, and obviously to give  
 10 Professor Thomas a break as well.

11 **SIR BRIAN LANGSTAFF:** Yes, absolutely.

12 Just by way of explanation, professor, there  
 13 are quite a number of people who plainly aren't here  
 14 at the moment -- they are also remote -- who are  
 15 watching, who are entitled to ask, through counsel,  
 16 questions which they have in their minds arising out  
 17 of what you can say.

18 Counsel will receive and field those questions  
 19 and ask those that are appropriate to you when we come  
 20 back, which will be at 4.10.

21 **A.** Okay. Thank you very much.

22 (3.36 pm)

(Short break)

24 (4.10 pm)

25 **SIR BRIAN LANGSTAFF:** Yes.

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1 which operated at the time treatment was given. These  
 2 policies changed over the period of the study ..."

3 Just to make clear these patients were actively  
 4 bleeding or were just about to go into surgery when it  
 5 was known they were bleeding. These concentrates were  
 6 not given electively, if you like. They were given as  
 7 a method of treatment or, in the case of the surgery,  
 8 obviously, in the anticipation that there would be  
 9 bleeding. So they had to give exactly what was  
 10 available. Then they determined what each patient had  
 11 had after the event.

12 The reason they did serial LFTs afterwards was  
 13 what we alluded to before and that was that just  
 14 looking for jaundice after an episode of treatment  
 15 would miss a large number of cases. We already knew  
 16 that post-transfusion hepatitis was occurring after  
 17 use of concentrates and after single units of blood on  
 18 occasion. It was important to know, in individual  
 19 patients, for their own clinical care, whether they  
 20 were one that was getting these problems. So the  
 21 context was an acute bleeding episode, or before  
 22 surgery, in the context of knowing that liver function  
 23 tests were occurring, abnormalities were occurring  
 24 after use of these concentrates, and they wanted to  
 25 regard whether each individual patient had this for

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1 research reasons to see what the frequency would be,  
 2 but also in terms of management of the patient,  
 3 because there were lots of causes of abnormal AST, as  
 4 I mentioned non-A, non-B being the main one but some  
 5 people had hepatitis B and there were other causes,  
 6 chemical toxicity in the liver.

7 So I just wanted to make those points really,  
 8 because if Professor Kernoff were here I think he  
 9 would point out that, in the context of a bleeding  
 10 episode, mistakes are made and I think there were one  
 11 or two -- at least one case I know of -- where it  
 12 probably would have been, if it was decided in a cool,  
 13 calm, collected way that the patient received cryo  
 14 rather than concentrate, but he does say it is  
 15 dependent on what's available really.

16 So that's all I wanted to say, really. No  
 17 doubt, as I have said before, you have had a chance to  
 18 talk to Dr Lee about this (over talking).

19 **SIR BRIAN LANGSTAFF:** I think one of our difficulties may  
 20 have been that Dr Lee may have taken up her post when  
 21 the study was well advanced and a prospective study --  
 22 if patients are enrolled in a prospective study at the  
 23 start, one would expect the patients to be told then  
 24 what they might expect later. So it was really the  
 25 issue of consent that inspired the questions I asked.

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1 common (2-3%) in the UK and perhaps 10% in USA."

2 Are you able to assist with what the basis is  
 3 for the figures you have given there in relation to  
 4 the UK?

5 **A.** I think the best study was the one I alluded to just  
 6 before the break and that was there was a study of  
 7 cardiac surgery patients in Newcastle. The senior  
 8 author in that was Professor Oliver James. So if you  
 9 put into NIH PubMed "Oliver James", I think this  
 10 should come up. He calculated that, I think -- he  
 11 said that on average people after cardiac surgery  
 12 received about six or seven units of blood and after  
 13 an individual unit, I think he thought it was about  
 14 0.2 or 0.3, something like that, of each unit of blood  
 15 was calculated. Of course, the calculation was the  
 16 other way round. I think he found about 2 or 3% had  
 17 abnormal LFTs after cardiac surgery. On average, they  
 18 had had six units of blood. So he computed that the  
 19 number of infected units was 2 or 2.5 divided by 6,  
 20 which would give a figure of about 0.6%.

21 So it is worthwhile pointing out, this is the  
 22 hepatitis after blood transfusion. The number of  
 23 infected units would be dependent on the number of  
 24 units that we used in each transfusion. He calculated  
 25 that to be about six. So if you want the incidence

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1 I have to leave it there, because Dr Kernoff  
 2 would have been person to ask and, of course, we  
 3 can't.

4 **A.** Yes, yes, but I would just say, as I did say, that he  
 5 was a meticulous person and he has written in the  
 6 paper that the patients were appraised of what was  
 7 happening, although I notice some of them were three  
 8 or four months of age, so it would have been parents  
 9 that they were talking to. Anyway that's all I wanted  
 10 to say on that. As I say, the haemophilia doctors are  
 11 the ones who would be able to give you more  
 12 information, although I don't want -- I was involved  
 13 with the study and I was involved in the discussion  
 14 afterwards. So I don't want to argue that I wasn't  
 15 involved; I was. I was involved in what the cause of  
 16 the LFT might be.

17 **MS RICHARDS:** Sir, unless you think it useful, I am not  
 18 proposing to ask Professor Thomas further but I have  
 19 no doubt we will receive submissions about this study  
 20 in due course from Core Participants.

21 Professor Thomas, in your statement you say --  
 22 and this is -- if I just put your statement up on  
 23 screen, it is WITN3842007 -- you are ahead of me. If  
 24 we go to page 6, paragraph 12, you say:

25 "Hepatitis after blood transfusion was quite

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1 per unit of blood, it would be one-sixth of between 2  
 2 and 3.

3 **Q.** No, no. I was just trying to understand --

4 **A.** Sorry. The US study was the basis -- there was an NIH  
 5 study, National Institute of Health study at Bethesda  
 6 where I think that was -- well, Jay Hoofnagle was  
 7 involved and they were looking prospectively at doing  
 8 ALT screens after blood transfusion, the percentage  
 9 that were abnormal, and I think it was around about  
 10 10%. The other name to pick up is Blaine Hollinger  
 11 from Texas. He also did a post-transfusion hepatitis  
 12 incidence study.

13 **Q.** We can take that down. Thank you. The next question  
 14 I am asked to ask you relates to stage 1 Skipton  
 15 decisions, intravenous drug use. How would you have  
 16 dealt with a case where there was evidence to suggest  
 17 that there was a route of transmission through  
 18 transfusion of hepatitis C, prior to evidence of  
 19 intravenous drug use, and then evidence of intravenous  
 20 drug use post transfusion? Is it the case that the  
 21 record of intravenous drug use would still have been  
 22 enough to lead to the claim being rejected?

23 **A.** I think if you could be sure that the hepatitis was  
 24 noted before drug use, then, of course, you could say  
 25 that it was due to the blood transfusion, but how you

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1 know when an individual starts using drugs is more  
 2 difficult to determine really. Since it is addictive  
 3 behaviour, people aren't making open choices really --  
 4 they are addicted -- it is difficult to know when the  
 5 various things started. But if it was, you know,  
 6 validated -- demonstrated incontrovertibly that the  
 7 blood transfusion occurred and there were abnormal  
 8 LFTs and the drug use started later, then, yes, that  
 9 should have been adequate.

10 **Q.** Was there ever in relation to Skipton decisions,  
 11 whether stage 1 or stage 2, a policy of deliberately  
 12 delaying or deferring decisions in borderline cases to  
 13 see if the virus would progress or clear?

14 **A.** No, I certainly didn't know of any instances of that  
 15 really. Whether it was an acute episode -- 20 or 30%  
 16 would have cleared -- or whether it was an established  
 17 chronic episode, where 1% might clear after six  
 18 months, you know, we never waited or -- we just took  
 19 it at face value and looked at the statistical  
 20 probability, but the former was much more common than  
 21 the latter.

22 **Q.** Still with stage 1 Skipton applications, I want to ask  
 23 you about this hypothetical scenario. If you had  
 24 an applicant who was known to have had a particular  
 25 operation, if there was evidence of, say, 10 or 20% of

1 Chairman of the advisory group on hepatitis and I was  
 2 asked whether I would like to help with this and  
 3 I said "Yes", but I am also a clinician and  
 4 I recognise that throughout my career there have been  
 5 major constraints on healthcare and funding of it, but  
 6 I was not at all negative at the starting point over  
 7 whether a person should get it and, indeed, in  
 8 fairness to the NHS and the Department of Health, we  
 9 were never limited on the number of cases that we  
 10 could fund, you know. If they met the criteria and  
 11 greater than 50% probability was NHS, at stage 2  
 12 nobody ever said -- you know, we could recommend  
 13 unlimited numbers for this.

14 So that's the situation I took but, as  
 15 a director of the Skipton, of course, we did get  
 16 serial, you know -- at each yearly, Annual General  
 17 Meeting of the Board of Directors we were given  
 18 figures as to how much had been given out and these  
 19 sort of things. So whether it has a subconscious  
 20 effect, I don't know, but we didn't consciously go in  
 21 to try to limit the spend.

22 **Q.** In relation to stage 2 assessments, if you had a form  
 23 from the applicant's own clinician setting out their  
 24 view that the patient was cirrhotic, why was there  
 25 ever a need to look behind that, rather than Trust the

1 patients for that kind of operation needing  
 2 a transfusion and the applicant's recollection was  
 3 that they had a transfusion and there was no evidence  
 4 of any other risk behaviour, so no evidence of IVDU,  
 5 or anything of the kind, on what basis could it be  
 6 said that the claimed blood transfusion was not the  
 7 probable cause?

8 **A.** If I, as I was, the first person to look at this, and  
 9 I estimated it to be 20% probable, I would probably  
 10 have to turn it down, but if I was on the appeal  
 11 committee, I would have let it through. What I am  
 12 trying to say the process we had was that where there  
 13 was subjectivity, it should be applied at the appeal  
 14 committee stage and we should stick, as best we could,  
 15 to hard facts in determining, you know, what should be  
 16 the right way forward for the first step of the  
 17 evaluation.

18 **Q.** Did you feel an obligation to the Department of Health  
 19 or to the NHS more generally to limit stage 1 and  
 20 stage 2 approvals or take a more purist objective  
 21 approach, given what you described in your earlier  
 22 evidence as large amounts of NHS money having already  
 23 been spent?

24 **A.** Well, as a scientist I wanted to do what was right.  
 25 I mean, I came into this as a volunteer after I was

1 doctor most familiar with the patient's own diagnosis?

2 **A.** Well, I mean, it is partly dependent on whether -- on  
 3 some occasions, it would be a general physician who,  
 4 although he might be a very competent and expert  
 5 general physician, he wouldn't be an expert  
 6 hepatologist. So, you know, one looked at the basis  
 7 for why that individual had come to the conclusion  
 8 that it was a stage 2 triggering stage that the  
 9 patient had reached, you know, and, just as you have  
 10 asked me whether I came in with any sort of baggage,  
 11 for want of a better phrase, you know, of whether  
 12 I wanted to save money for the NHS, I think most of  
 13 the physicians filling in these forms really genuinely  
 14 wanted to look after the interests of their patients  
 15 and they would be a bit like defending counsel,  
 16 really.

17 They would want to, you know, present the best  
 18 case that they could. We were in a different  
 19 position. We were in the position of having to  
 20 evaluate it, depending on the data that was on the  
 21 sheet, not in terms of the person's opinion.

22 **Q.** The next question is about natural clearers. To what  
 23 extent has the updated medical knowledge about the  
 24 effects of hepatitis C, which has come to light over  
 25 the years since the Skipton Fund was first set up,

1 suggest there should be a reassessment of the  
 2 exclusion of natural clearers from the schemes?  
 3 **A.** It was known right from the earliest days, back in  
 4 1989/1990, that 20% or so of people cleared the virus,  
 5 as determined by clearing hepatitis C RNA measured by  
 6 PCR, and then they were just left with antibody. You  
 7 know, if you found somebody with antibody but who were  
 8 RNA negative, the probability was, since after  
 9 chronicity only a very small number would clear the  
 10 virus leaving antibody, hence the 1%, statistically it  
 11 was much more probable that it was an acute clearing  
 12 in the first three to six months, rather than  
 13 a chronic, longer than six months of infection,  
 14 clearing in the later stages.

15 The latter would have, under the rules that  
 16 were mandated by the Department of Health -- well, the  
 17 former wouldn't actually have qualified by the rules.

18 **Q.** Is it your view that the position in relation to  
 19 natural clearers has not changed?

20 **A.** I don't think it did. We had, you know, RNA,  
 21 so-called NAT acid -- nucleic acid tests for the  
 22 virus, direct measure of the presence of the virus,  
 23 and antibody tests right the way through from 1991 to  
 24 the present time. That study that I mentioned in NIH,  
 25 they were able to do sequential studies looking at,

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1 the same individual's spleen or liver.

2 So, you know, that showed that in some cases it  
 3 was in the brain but, in any individual before the  
 4 patient -- if they die, before we get post mortem  
 5 material, we couldn't say whether the virus was just  
 6 in the blood or whether it was in the blood and liver  
 7 and, in addition, in the brain.

8 But, I mean, do you think the question is  
 9 related to the fact that the brain might -- if there  
 10 was a dysfunction of the brain could it cause blood  
 11 pressure changes or things like that? Is that what  
 12 you are thinking about?

13 **Q.** Well, it is a question I have been asked to ask, so  
 14 I have no greater insight than the question  
 15 I formulated.

16 Damage to the brain may have an impact upon  
 17 cognitive functioning. I don't know whether you can  
 18 answer this or not. Does the damage to the brain that  
 19 you identified have any wider impact upon the  
 20 functioning of the body?

21 **A.** Not that we are able to demonstrate.

22 **Q.** The next two questions, I think, relate to  
 23 hepatitis B. As part of your work over the years on  
 24 hepatitis B, did you come to any conclusion about the  
 25 efficacy of the screening for hepatitis B that had

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1 you know, whether there was a window period when there  
 2 was RNA right at the beginning but no antibody, and  
 3 then the transaminase rise indicating liver damage and  
 4 then a period when the RNA would disappear and the  
 5 antibody would appear.

6 So, you know, that natural history of the  
 7 serology was evident in the 1991/92 period and is the  
 8 same present today.

9 **Q.** You told us about your research as regards the link  
 10 between hepatitis C infection and damage to the brain  
 11 and, indeed, we have got the papers in materials to  
 12 which you have referred. Are you able to assist with  
 13 this: to what extent does that damage to the brain  
 14 have an impact on the functioning of the whole body  
 15 and not just on cognitive functioning?

16 **A.** Well, we were able to say the virus was in the brain  
 17 because we had done this spectroscopy of the brain and  
 18 we found the same pattern in hepatitis C as we had  
 19 found in HIV, which had previously been known to  
 20 infect the brain, and, in addition, there was a brain  
 21 bank in Edinburgh and they will give pieces of post  
 22 mortem tissue to you if you want to look for various  
 23 things. We were able to show the virus in the brain  
 24 from those tissues and the virus that we cloned from  
 25 the brain was different from the one that we got from

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1 been introduced in the early 1970s?

2 **A.** In the general population or in the haemophiliac  
 3 population?

4 **Q.** I am afraid I am simply asking a question as  
 5 articulated to me. So ...

6 **A.** Well, perhaps let's interpret in as in the context of  
 7 infected blood. I mean, all blood was screened for  
 8 hepatitis B surface antigen from -- I don't know --  
 9 the discovery of hepatitis B, certainly in the 1960s,  
 10 and those sensitive assays that were available at that  
 11 time were immunoassays, whether it was radio or enzyme  
 12 assays, and that really removed most of the  
 13 hepatitis B-related post-transfusion hepatitis, you  
 14 know. It was fairly prevalent in the 1940s, 1950s  
 15 wartime period, but post the discovery of hepatitis B  
 16 and the availability of radioimmunoassays against  
 17 hepatitis B surface antigen, it was pretty much dealt  
 18 with.

19 Then just to finish, they went into NAT assays,  
 20 nucleic acid test assays where they look for hepatitis  
 21 B virus DNA, in the way that I have just been  
 22 describing, you can look for hepatitis C RNA. Then  
 23 there is virtually no hepatitis B post-transfusion.

24 **Q.** I think that does answer the question, thank you. Did  
 25 you yourself participate in any research to establish

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1 the prevalence of hepatitis B infection amongst  
2 haemophiliacs?  
3 **A.** No. I think there was quite a bit from previous  
4 periods, you know, the older haemophiliacs. The other  
5 problem about determining prevalence was what we call  
6 passive transfer. So cryoprecipitate and concentrates  
7 contain antibody, particularly the cryo, because it  
8 was cryoprecipitate of blood, and we were passively  
9 transferring antibody to surface antigen or antibody  
10 to core. That meant you couldn't tell whether they  
11 had had an active infection or if it was this passive  
12 transfer of antibody which was causing the positive in  
13 the antibody assays.

14 Reading between the lines, you know, without  
15 having solid data, I think there was a lot of  
16 hepatitis B in the haemophilic population from  
17 earlier periods before the screen (inaudible).

18 **Q.** We have explored, I think to some extent, through the  
19 mechanism of the Kernoff paper, hepatitis C prevalence  
20 in commercial concentrates versus NHS concentrates.  
21 What about the position in relation to hepatitis B?  
22 Do you have any knowledge or understanding of  
23 prevalence of hepatitis B in commercial concentrates  
24 as opposed to NHS concentrates?

25 **A.** No, not in a comparative sense, but some concentrates

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1 Although I claim to be a clinical scientist,  
2 I spent every day of my life seeing patients. So  
3 I prefer to be known as a clinician and a scientist.  
4 **MS RICHARDS:** Sir, those are the additional questions that  
5 I am proposing to ask.

6 **Questions by SIR BRIAN LANGSTAFF**

7 **SIR BRIAN LANGSTAFF:** Just one area that I would like to  
8 explore with you, if I may, and benefit from your  
9 knowledge at the time.

10 As I understand it, post war -- or during the  
11 war and immediately post war, as you have already told  
12 us, hepatitis was a well-known risk of transfusion.

13 **A.** Yes.

14 **SIR BRIAN LANGSTAFF:** And at that stage hepatitis A had  
15 not been identified. That took until 1973.

16 Hepatitis B wasn't identified until -- well, the  
17 earliest, the Australia antigen, is about 1966.  
18 Hepatitis C had to wait until 1988 and 1989 before  
19 there was any full record of what had been cloned in  
20 '88.

21 So am I right in thinking that what was then  
22 used to describe hepatitis was a very general term:  
23 serum hepatitis?

24 **A.** Yes, you would be correct. They talked about serum  
25 hepatitis and infectious hepatitis.

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1 did transmit B as well as C. We wrote one such case  
2 up. Another concentrate transmitted hepatitis B plus  
3 delta and C. So there was all sorts of -- carrier for  
4 all sorts of viruses in that concentrate, many of  
5 which we probably don't know about today.

6 **Q.** Then the last question reverts to the Skipton  
7 decision-making, in particular, I think, in relation  
8 to stage 1. You referred to being a scientist and you  
9 have used, from time to time, I think, language of  
10 being sure and not wanting to undertake a subjective  
11 assessment, which you left for the Appeal Panel,  
12 wanting to undertake a more objective assessment.

13 Do you think it is possible you may have been  
14 applying a scientific standard higher than balance of  
15 probabilities?

16 **A.** I doubt it actually, because the 50% probability was  
17 difficult enough to achieve in the absence of, you  
18 know, case notes. So we were really pushing the boat  
19 in favour of passing those. I'm thinking about the  
20 times when we went to look for scars -- the patient  
21 provided a picture of scars which might indicate they  
22 had an operation where there was a probability that  
23 the majority of patients having that operation had  
24 a blood transfusion. So, no, I don't think I am being  
25 too stringent with it.

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1 **SIR BRIAN LANGSTAFF:** And infectious hepatitis is what we  
2 now know as A?

3 **A.** A and E. But yes, mainly A, you are right.

4 **SIR BRIAN LANGSTAFF:** And B and C were serum hepatitis, in  
5 effect?

6 **A.** Yes, yes.

7 **SIR BRIAN LANGSTAFF:** So before the hepatitis B was  
8 identified -- and the Inquiry's note of screening was  
9 that it took place, or started in 1970, for some  
10 donations, 1972 generally in the blood supply in the  
11 UK, but before then, presumably, hepatologists,  
12 clinicians generally, had become aware of the nature  
13 of the hepatitis and what it might involve for the  
14 individual suffering from it?

15 **A.** Yes, yes.

16 **Q.** And was it known then that in some cases hepatitis was  
17 very slow to show itself? It might not have icteric  
18 phase?

19 **A.** No. I think for a long time we thought -- and that  
20 would have covered the time after the war -- you know,  
21 we really took post-transfusion hepatitis, or serum  
22 hepatitis, as indicated going by jaundice, which is  
23 a very crude determinant really. Although the Blood  
24 Transfusion Service did some very good things, they  
25 did stick with that for a bit too long. They looked

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1 at jaundice after their transfusions when the  
 2 Americans had reverted to doing transaminases  
 3 afterwards.  
 4 **SIR BRIAN LANGSTAFF:** I was going to ask, at what stage  
 5 did transaminases liver function tests come in,  
 6 roughly?  
 7 **A.** Oh, you mean as being available in every context?  
 8 **SIR BRIAN LANGSTAFF:** As being used to determine what  
 9 problems of a hepatitic sort in the liver?  
 10 **A.** I don't know the answer to that. They must --  
 11 **SIR BRIAN LANGSTAFF:** We can find that out from somewhere  
 12 else. But it was at some stage during the '50s  
 13 presumably, was it?  
 14 **A.** Yes. I think it would be before -- probably before  
 15 the war actually, but they were still talking about  
 16 serum and infectious hepatitis during the war. There  
 17 were some major outbreaks in the soldiers in Singapore  
 18 area, really massive outbreaks, and it was deemed to  
 19 be a major factor on who won any battle there, the  
 20 number of soldiers that went down with hepatitis,  
 21 infectious hepatitis, at that time, because of the  
 22 terrible conditions. It was a major proportion.  
 23 If you go through -- my hobby is going through  
 24 reading the war plaques in the cathedrals, and if you  
 25 read them, most of the -- if you look at the

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1 Hepatitis B in the context of the UK was pretty  
 2 unusual, but the Chinese, of course, as soon as the  
 3 Australia antigen became available, they noted that 10  
 4 or 15% of their population were chronically infected  
 5 with hepatitis B and they had acquired at birth from  
 6 their mother. And since immunising at birth, the  
 7 incidence of primary liver cell cancer, which is in  
 8 the Far East mainly due to hepatitis B, that has gone  
 9 down massively once the hepatitis B vaccine was used  
 10 extensively. And the main cause of primary liver cell  
 11 cancer now, reflecting the fact that the major cause  
 12 of cirrhosis -- which is, if you like, the  
 13 pre-malignant condition -- is now hepatitis C, because  
 14 hepatitis B has been controlled by vaccination.  
 15 We still do not have a vaccine for hepatitis C.  
 16 It is same problem as we are having with this current  
 17 pandemic. All of these viruses, hepatitis C and the  
 18 Covid 2 virus, the SARS virus, they are what we call  
 19 swarms of viruses. So with hepatitis C there may be,  
 20 you know, 10,000 or 100,000 virus particles, all  
 21 slightly different in their genetic structure. And as  
 22 the immune pressure comes on the virus, then one or  
 23 two virus particles will find they have an advantage,  
 24 they can break through the natural antibody response  
 25 or the vaccine response. And the same is true now of

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1 casualties which are looked at in the Boer War and all  
 2 these, it would say, you know:  
 3 "Killed in action ..."  
 4 I don't know. Just for argument's sake:  
 5 "... 10."  
 6 "Killed by dysentery/infectious  
 7 hepatitis: 100."  
 8 So ten times more. So the outcome of these  
 9 wars was purely dependent on, you know, how well they  
 10 could keep their soldiers. You know, very few were  
 11 hit by bullets or whatever else.  
 12 So I think, you know, they were very much aware  
 13 of all this, and I suspect there were transaminase as  
 14 well as those crude measures of jaundice being used at  
 15 that time, but I don't know for certain.  
 16 **SIR BRIAN LANGSTAFF:** The nature of hepatitis which might  
 17 develop after a transfusion, would that lead in quite  
 18 a number of cases to cirrhosis?  
 19 **A.** Yes. I mean, the big issue would have been, at that  
 20 stage, how many are due to alcohol. But the fatty  
 21 liver related to type 2 diabetes, which is in the next  
 22 year predicted to overtake alcohol as the major cause  
 23 of cirrhosis -- alcohol was before, the last few  
 24 years, that was certainly thought to be the most  
 25 common cause.

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1 SARS -- SARS-CoV-2. It is too long a name.  
 2 That is a mixture of different virus particles,  
 3 and when you apply an antibody immune pressure to the  
 4 virus, you will select out variants, which is going to  
 5 be our problem with the current vaccines and Covid 2.  
 6 I don't want to be too pessimistic about it, but  
 7 I think that will happen.  
 8 We were able to show this in the context of  
 9 hepatitis C by looking at agammaglobulinemics. The  
 10 envelope of hepatitis C varies massively over to  
 11 hyper-variable regions, to variable regions in the  
 12 envelope. This is in a person with a normal antibody  
 13 response. But if you look at somebody with  
 14 agammaglobulinemia, who can't produce antibodies,  
 15 there is no variation in the envelope. So it is the  
 16 patient's antibody response which selects out the  
 17 variants.  
 18 The same will be happening with SARS-CoV-2.  
 19 You know, as we put different antibody pressures on  
 20 the virus, you will be selecting out different  
 21 variants. And because we have a bigger proportion of  
 22 our population immune now, then we are selecting out  
 23 different variants, and hence we had the distinction  
 24 of having the UK or Kent variants named after us,  
 25 where we -- because we've had a lot of vaccine, we're

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1 seeing variants come through.  
 2 I must say, this is a retired armchair ex  
 3 virology clinician's view of the world, so ...  
 4 **SIR BRIAN LANGSTAFF:** Just taking that same retired  
 5 armchair clinician's view of the world, you mentioned  
 6 a moment or two ago, and earlier you were asked by  
 7 counsel questions about hepatitis B, you mentioned the  
 8 effectiveness, at least so far, of hepatitis B  
 9 vaccine. That, as we understand it, was introduced  
 10 only as a universal vaccine for children in this  
 11 country in 2017.

12 Do you have a view or did you have a view as to  
 13 whether that, in line with your views about testing  
 14 for hepatitis C and surrogate testing earlier, should  
 15 have been introduced earlier?

16 **A.** Well, it was introduced in the medical and nursing  
 17 profession, because it is -- the major incidence,  
 18 I think, is related to blood contamination either  
 19 through needle use or because of sexual activity, and  
 20 I think we do have an extensive programme where people  
 21 attending sexually transmitted disease clinics are  
 22 immunised against hepatitis B. That was something  
 23 that came to the advisory group on hepatitis that  
 24 I was involved in. We pushed really to get control of  
 25 that mechanism of transmission in our community. But

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1 Committee when the Swine Flu thing started, and there  
 2 the mathematical modellers said we were going to lose  
 3 millions of people and I think we lost about 18,000 in  
 4 the end. The recommendation that I and others was  
 5 involved in on this committee was we ought to buy  
 6 a lot of drugs. There were two drugs which were --  
 7 might work against flu, and, of course, that didn't  
 8 come about. So the Department of Health bought a lot  
 9 of drugs that they didn't need.

10 Then most recently I think, you know, it's been  
 11 a question of, you know, the vaccine versus drugs to  
 12 treat people. I happen to be working in a little  
 13 biotech company really making drugs for hepatitis --  
 14 making drugs for SARS-CoV-2 with Porton Down, and, you  
 15 know, again the focus has been on the vaccine and not  
 16 the individual really, but I think the driver to all  
 17 of this is that we have never been particularly  
 18 prepared in the UK, because we don't have any spare  
 19 capacity in our hospitals, and this isn't original.  
 20 I mean, everybody has said this, and I think it was  
 21 true right from the word go with non-A, non-B, where,  
 22 you know, treatment was expensive and there were  
 23 financial constraints, and it is the same true today  
 24 really, but otherwise money is always the root of the  
 25 problems. I would like to see that we spent a lot

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1 outside the sexually promiscuous and intravenous drug  
 2 users, then the transmission of hepatitis B is not  
 3 that great in the general population and, you know,  
 4 I think, therefore, at the earlier stage, probably  
 5 introducing a hepatitis B vaccine wasn't cost  
 6 effective.

7 I think a lot of -- there is now a hepatitis A  
 8 plus B vaccine. I think, for instance, when  
 9 university students are going on walkabout, you know,  
 10 on their gap year, then we recommend they are all  
 11 vaccinated. So as behaviour changes, then the vaccine  
 12 strategies change.

13 **SIR BRIAN LANGSTAFF:** Thank you very much. That's all  
 14 I am going to ask.

15 **MS RICHARDS:** Sir, I should have confirmed  
 16 Professor Thomas's counsel has no questions that she  
 17 seeks to ask.

18 Professor Thomas, is there anything further you  
 19 would wish to add to your evidence?

20 **A.** Not really. I think -- I don't think -- I have had  
 21 three different experiences as a clinician really:  
 22 this one on non-A, non-B, where I did get the  
 23 impression that the NHS was short of money and was,  
 24 you know, trying to make it go as far as possible; and  
 25 then, of course, I was on the new and emerging Virus

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1 more on the health service so that there was a better  
 2 level of preparedness really, but then you are going  
 3 to say, "What are you not going to spend money on?"  
 4 So that's a problem as well, but otherwise I don't  
 5 have anything to say.

6 **MS RICHARDS:** Thank you. Sir.

7 **SIR BRIAN LANGSTAFF:** You described yourself just shortly  
 8 ago as a clinician first and a scientist second.

9 I think certainly you have shown us a huge amount of  
 10 both sides of what you have to say, but you also have  
 11 indicated a third side, which is I think demonstrated  
 12 by the lectures which you have told us you gave from  
 13 time to time, in which you explain some of the  
 14 intricacies of science, and you have helped us to  
 15 explore some of those intricacies in a clear and  
 16 helpful way and given us access to some of the  
 17 information which, if I can say, has probably filled  
 18 a few gaps, for me certainly, and I am grateful, very  
 19 grateful, for that.

20 You have told us, so far as the Skipton is  
 21 concerned -- given us the detail of how you saw your  
 22 role and the way in which you applied what, to  
 23 a lawyer, is familiar territory: the burden of proof  
 24 on the balance of probabilities.

25 So thank you for all that, and thank you for

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1 allowing us a day of your time. I think you have had 1  
 2 experience of giving this type of evidence over 2  
 3 a number of occasions. So thank you for being 3  
 4 prepared to do it again to help us in this Inquiry. 4  
 5 **A.** Thanks for being so pleasant about the whole thing. 5  
 6 I must say the chaps setting up are really very 6  
 7 effective. 7  
 8 **SIR BRIAN LANGSTAFF:** Well, we have not I think lost any 8  
 9 transmission from you. We have had the odd problem 9  
 10 just recently, but only rarely, and so I am very glad 10  
 11 that you have that to say about them. So thank you 11  
 12 for that too. 12  
 13 **A.** Thank you, Sir Brian. 13  
 14 **MS RICHARDS:** Tomorrow, sir, we have the evidence of Mark 14  
 15 Mildred, first of all, as chair of the Skipton Appeal 15  
 16 Panel, and then we will be starting, after we have 16  
 17 completed his evidence tomorrow, with the evidence of 17  
 18 Charles Lister as one of the Caxton trustees. 18  
 19 **SIR BRIAN LANGSTAFF:** Yes. So 10 o'clock tomorrow. 19  
 20 **MS RICHARDS:** Thank you. 20  
 21 **(4.58 pm)** 21  
 22 **(Adjourned until 10.00 am the following day)** 22  
 23 23  
 24 24  
 25 25

**I N D E X**

2	PROFESSOR HOWARD CHRISTOPHER THOMAS .....	2
3	(sworn)	
4	Questions by MS RICHARDS .....	2
5	Questions by SIR BRIAN LANGSTAFF .....	171

<p><b>MS RICHARDS: [24]</b> 2/16 44/20 44/22 44/25 50/18 51/9 76/2 77/9 77/11 92/14 92/25 94/7 97/22 98/8 152/11 152/21 154/2 155/1 158/17 171/4 178/15 180/6 181/14 181/20</p> <p><b>SIR BRIAN LANGSTAFF: [46]</b> 1/3 1/5 1/7 1/10 1/13 1/17 2/12 44/13 44/21 44/24 50/14 50/20 51/8 75/25 77/8 88/16 88/22 89/3 89/15 91/9 92/24 94/5 98/2 150/18 150/24 151/6 152/7 152/18 153/21 154/11 154/25 157/19 171/7 171/14 172/1 172/4 172/7 173/4 173/8 173/11 174/16 177/4 178/13 180/7 181/8 181/19</p> <p><b>THE WITNESS: [7]</b> 1/4 1/6 1/9 1/12 1/15 2/11 2/13</p>	<p><b>1,500 [1]</b> 147/2 <b>1,500 litres [1]</b> 140/16 <b>1.04 [1]</b> 98/5 <b>1.5 [1]</b> 146/23 <b>10 [12]</b> 17/13 36/24 67/5 96/15 105/3 135/25 137/20 159/1 160/10 161/25 174/5 175/3 <b>10 March 2015 [1]</b> 38/1 <b>10 o'clock [1]</b> 181/19 <b>10 years [1]</b> 104/4 <b>10,000 [2]</b> 94/3 175/20 <b>10.00 [2]</b> 1/2 181/22 <b>100 [15]</b> 8/14 19/11 22/16 43/6 52/4 70/25 81/14 90/1 93/13 124/8 124/20 124/22 140/9 141/20 174/7 <b>100,000 [1]</b> 175/20 <b>105 [2]</b> 75/24 76/3 <b>11.18 [1]</b> 51/5 <b>11.45 [4]</b> 50/15 50/17 51/3 51/7 <b>11.5 [1]</b> 41/11 <b>112 [1]</b> 51/17 <b>11th March 2013 [1]</b> 36/3 <b>12 [10]</b> 17/22 34/9 42/8 43/21 44/8 46/10 46/15 106/7 137/21 158/24 <b>12,500 [1]</b> 131/20 <b>12-15 [1]</b> 76/14 <b>12.5 [1]</b> 36/20 <b>13 [1]</b> 21/10 <b>14 [2]</b> 21/20 23/20 <b>14.5 [3]</b> 42/2 44/2 44/7 <b>14.5 kPa [1]</b> 41/7 <b>1400 [1]</b> 73/2 <b>145 [1]</b> 84/4 <b>14th October 2003 [1]</b> 5/1 <b>15 [9]</b> 27/2 27/4 32/15 34/9 34/13 37/12 76/14 96/15 175/4 <b>150 [1]</b> 63/18 <b>150,000 [1]</b> 104/21 <b>159 [1]</b> 25/17 <b>15th February 2017</b> <b>[1]</b> 84/8 <b>16 [1]</b> 79/24 <b>165 [1]</b> 38/8 <b>16th November 2016</b> <b>[1]</b> 93/23 <b>18,000 [1]</b> 179/3 <b>19 [1]</b> 27/23 <b>1940s [1]</b> 168/14 <b>1950s [1]</b> 168/14 <b>1960s [1]</b> 168/9 <b>1966 [1]</b> 171/17</p>	<p><b>1970 [1]</b> 172/9 <b>1970s [3]</b> 62/8 62/15 168/1 <b>1972 [1]</b> 172/10 <b>1973 [1]</b> 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<p><b>W</b></p> <p><b>who...</b> [55] 82/24 86/3 86/13 90/18 91/18 91/20 92/8 94/17 96/3 104/15 104/16 105/3 105/5 105/7 105/10 112/3 112/13 120/1 124/3 125/23 125/25 126/17 128/16 129/2 133/4 135/13 139/24 140/20 140/23 141/3 141/4 141/14 142/15 142/22 142/24 145/11 146/1 150/14 150/19 151/7 151/16 152/18 152/24 153/7 153/9 154/13 154/14 154/15 155/5 158/11 161/24 164/3 165/7 173/19 176/14</p> <p><b>whoever</b> [2] 7/22 69/19</p> <p><b>whole</b> [6] 35/6 41/25 111/11 113/20 166/14 181/5</p> <p><b>whom</b> [7] 1/20 49/19 50/8 58/14 100/17 100/17 133/8</p> <p><b>whose</b> [5] 1/24 27/4 47/10 47/15 82/24</p> <p><b>why</b> [36] 6/8 7/7 7/10 7/19 8/25 11/18 20/13 20/15 31/5 37/18 43/15 43/19 46/10 48/7 57/2 57/22 58/23 61/10 66/24 72/12 72/13 74/1 83/19 97/17 109/13 117/9 117/10 122/10 129/20 144/18 148/24 149/14 151/2 153/1 163/24 164/7</p> <p><b>wide</b> [1] 7/8</p> <p><b>widening</b> [1] 94/17</p> <p><b>wider</b> [2] 6/13 167/19</p> <p><b>widow</b> [1] 47/17</p> <p><b>wife</b> [2] 1/11 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