Infected Blood Inquiry

1	Wednesday, 24th March 2021	1	want to refer you to can be displayed on your screen
2	(10.00 am)	2	and to the public generally. The public generally,
3	SIR BRIAN LANGSTAFF: Good morning, professor.	3	there were yesterday just under 250 people watching.
4	THE WITNESS: Good morning, Sir Brian.	4	There will be very similar numbers, I think, today.
5	SIR BRIAN LANGSTAFF: You can see me?	5	They are watching from various locations around the
6	THE WITNESS: Yes, I can see and hear you.	6	country on a mixture of YouTube and live stream. They
7	SIR BRIAN LANGSTAFF: Most of me I hope, and you can hear	7	are the people you are really talking to when you are
8	me?	8	giving your evidence.
9	THE WITNESS: Yes.	9	Without more ado, I will ask Mary to ask you to
10	SIR BRIAN LANGSTAFF: Now, you are at home, I think, with	10	take the oath?
11	your wife?	11	THE WITNESS: I need to get a bible, do I?
12	THE WITNESS: Yes.	12	SIR BRIAN LANGSTAFF: Yes, you do.
13	SIR BRIAN LANGSTAFF: You are on your own at the moment,	13	THE WITNESS: Give me a second.
14	are you?	14	PROFESSOR HOWARD CHRISTOPHER THOMAS (sworn)
15	THE WITNESS: Now we've set up the system, yes, I am in	15	Questions by MS RICHARDS
16	that room by myself.	16	MS RICHARDS: Professor Thomas, can you see and hear me?
17	SIR BRIAN LANGSTAFF: Let me tell you who you are talking	17	A. Yes, I can.
18	to. Here at Fleetbank House, we have a room big	18	Q. You are Emeritus Professor of Hepatology in the
19	enough number for 200, we have at the moment eight	19	department of medicine at Imperial College London?
20	people in it, all of whom, bar one, are wearing masks	20	A. That's correct.
21	and that one is Ms Richards, who will be asking you	21	Q. Prior to that I am not going to go through the full
22	the questions in a moment or two.	22	details of your career from 1974 to 1987 you worked
23	Names you will hear are Mary, who will ask you	23	at the Royal Free Hospital teaching, undertaking
24	to take the oath in a moment or two, and Soumik, whose	24	research and involved in patient care. Is that right?
25	job it is to make sure that any documents which we	25	A. That's correct, yes.
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1	Q. And then in 1987 you took up a post as the	1	A. Perhaps I should say in relation to the Skipton Fund,
2	departmental chair of medicine at St Mary's Hospital	2	when it became a company, a limited company, then
3	Medical School, and then at some stage after that you	3	I was a director I think there were three or four
4	became head of hepatology and gastroenterology at the	4	of us but I wasn't the director, if I could
5	Imperial College Medical School before retiring from	5	Q. Yes. You were one of a number of directors?
6	that post in 2011. Is that right?	6	A. Yes.
7	A. That's correct.	7	Q. Our understanding is you were the first medical
8	Q. Now, you have been a member of multiple working	8	director.
9	parties, committees and advisory groups detailed in	9	A. That is right, Ms Richards.
10	your witness statement. I am not going to ask you to	10	Q. Then you were joined in at that role by
11	list them, but we will touch on some of them in the	11	Professor Dusheiko two or three years later?
12	course of your evidence.	12	A. Yes.
13	You gave evidence to the Archer Inquiry and to	13	Q. Now, as I say, I'm going to start with the Skipton
14	the Penrose Inquiry. Is that correct?	14	Fund, but I am going to ask you about your involvement
15	A. Yes, yes.	15	at a much earlier stage.
16	Q. And you were then director of the Skipton Fund from	16	So a number of years before you became one of
17	around late 2012/early 2013 until 2018 and a trustee	17	the directors you had some early involvement in the
18	of the Caxton Foundation from 2011 to 2018?	18	setting up of the scheme.
19	A. Yes, that's right.	19	If we could look at SCGV0000265_004, please,
20	Q. Now I am going to ask you, first of all, today about	20	Soumik.
21	the Skipton Fund and the Caxton Foundation and your	21	So we can see, professor, this is headed:
22	involvement with both of those bodies, and then I am	22	"Ex gratia payment scheme for people infected
23	going to ask you after that some more general	23	with Hepatitis C as a result of treatment with NHS
24	questions relating to your work in hepatitis, your	24	blood and products.
25	involvement in some of the working parties and groups.	25	"Meeting to discuss the medical trigger point
	3		4 (1) Pages 1 - 4

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for the proposed higher payment 14th October 2003."

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

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

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

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

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

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

- Q. Did you, either through your involvement with this group or through your more general involvement with the Department of Health, gain any understanding of why it had been decided that the Skipton Fund would be set up on a national UK-wide basis?
- A. No. I really was only involved in this focused issue really of, you know, why this was stage 2 and how could we determine when somebody had cirrhosis without doing a liver biopsy.
- Q. If we then look at the terms of paragraph 1, it says in the third line:

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

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

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

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.

- Q. Now, as we have seen from the heading on the document and paragraph 1, the meeting was specifically looking at the trigger point for the stage 2 payment. Had you been involved in any of the wider discussions about what the shape of the Skipton Fund should be or whether payment should be made on an ex gratia or compensatory basis?
- A. No. I was just brought in with the other people that you have got at the heading of this paper as people who could provide medical help -- information, particularly hepatological information on when somebody had cirrhosis, which was going to be one the main trigger points.

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

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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.

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

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

Is that the reason why the trigger point was

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included cirrhosis?

There was one other thing that was included at this sort of earlier stage, before you had a chance of developing liver failure and liver cancer, and that was non-Hodgkin's lymphoma, which was one of the objective determinants of the stage 2 payment.

- Q. Now we can see -- sorry?
- A. So this is a tumour of the lymphoid system and also requires quite a lot of additional therapies of one sort or another.
- Q. Now we can see in paragraph 2 then the discussion alights on cirrhosis as the most practical trigger point. Then there was a discussion about reluctance to make payments contingent upon liver biopsy, particularly for patients with haemophilia, and so a desire to explore the possibility of using non-invasive tests as a viable alternative.

If we then go over the page, so that we can follow through the discussion, at paragraph 5 under the heading "Non-invasive tests" it refers to a range of haematological and biochemical tests, I'm not going to go through each of them but there is a list I think appended to this document, and then halfway through

test, which was a computation of an AST, which is a measure of liver cell damage, and a platelet count, which is a measure of how large the spleen is and is a measure of portal hypertension, which is invariably found in patients with cirrhosis.

These two tests together were thought to be the best that was available but, depending on the level at which you set the trigger point and Dr Lok, and subsequently this committee, decided that would be a figure of greater than 2. When the AST started to go up and the platelet count started to go down, then the AST divided by the platelet count would give what's called the APRI score. If you set it at 2, it would be 91% specific. In other words, you didn't pick up people without cirrhosis. The sensitivity, however, at this level was not ideal. It was about, I think, 50% or something like that.

That was the reason why we combined that with the AST over the ALT, because when you have cirrhosis, although both of these tests measure liver cell damage, the AST goes up higher than the ALT when you have cirrhosis. So we combined these two tests, which is now mentioned in the document when people apply for stage 1 or stage 2 payments, and it explains specifically the levels which will indicate that

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this paragraph it says this:

"Although these were commonly performed tests, there appeared to be limited experience in using various combinations to predict accurately the presence of cirrhosis in clinical practice. However, there were a number of scientific papers that sought to validate particular combinations of these tests in patients with chronic hepatitis C that could be used as a basis for determining the optimum combination of tests."

Could you just assist us a little further in understanding the difficulty there and the reference to there being limited experience in using various combinations to predict cirrhosis?

A. This wasn't a problem limited to the haemophilia population, but they did have a particular problem because of their failure -- inability of the blood to clot, but it was a common problem with all cirrhotic patients who had coagulation problems and, as hepatologists, we really didn't want to do biopsies until absolutely necessary.

Anna Lok, who, as I say, had been a fellow with me, I think by this time had gone back to the United States to take up an appointment, had written a paper, which was essentially screening describing the APRI

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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 looking after the patients could add other data, which might include scanning of one sort, ultrasound, CT and then latterly MRI scanning or endoscopy, when you can look down the patient's throat to see if they have varices, which are an indication that the patient has portal hypertension, which is always or invariably an indication of cirrhosis. You can add in these to make a better platform.

I think over time this was quite a good combination of things. Most of the stage 2 payments were not appealed by the appeal group later on, which is not the case with stage 1, of course.

Q. Yes. Then if we look at paragraph 7 -- paragraph 6 refers to the combination of non-invasive tests and thresholds, as you have just described. Then paragraph 7 says:

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"A hepatologist or other clinician familiar with the patient, their circumstances and medical history should be able to advise patients who had not undergone liver biopsy, whether on the basis of the

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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particularly difficult cases."

Was it right to understand that the scheme, as envisaged by this group, was that the vast majority of cases would turn on the opinion of the treating clinician but there might be a small category or small number of particularly difficult cases where a broader range of expert opinion might need to be sought? A. Basically that's it and, in the period before either

myself or Geoff Dusheiko were formally involved, because I had been involved through the advisory group on hepatitis and then this group setting up the issues around stage 2, Nick Fish, who was the administrator for the Trust, would be able to really sign off on a series of patient's stage 2 payments, because these APRI scores and the AST/ALT ratio supported by other clinical information were sufficiently robust that if this information was on the application sheet, this meant the majority would just go through fairly rapidly.

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

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

Q. If we then look at the heading "Discussion of
Item 4 -- Clearance of Hepatitis C Virus", there is

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

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

I am going to leave aside treatment:

"... was highly unlikely to relapse during the course of their lifetime. This was thought to be the case in 98% of cases."

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

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

I am leaving aside successful treatment:

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

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

- Q. Yes. Can I just ask you, first of all, about the category of those who do naturally or spontaneously clear the virus within a six-month period?
- A. Right. Yes.
 - Q. The decision was taken to exclude that category from the scheme, the Skipton Fund. Was any consideration given either at this meeting or, to your knowledge, at any other meetings to the psychological consequences,

"... spontaneous viral clearance."

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

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

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

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

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

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

Q. Yes.

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

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Infected Blood Inquiry 1 doesn't mean to say they have not had concerns during The danger of treatment becoming a disincentive was 2 the three to six months when they have been infected, 2 also highlighted. Experts recognised that this should 3 3 but after that phase they should, if they have been ultimately be a policy decision." 4 properly reassured by their physicians and nurses, 4 Can I ask you to assist with two matters, 5 return to normal or the pre-infection stage, we 5 professor? The first is the reference to the danger 6 6 thought. of treatment becoming a disincentive. Was it 7 Q. Can I then ask you just a little more about what's 7 a genuine concern that patients would not go through 8 8 said here about the position of patients who have treatment for what was a very, very serious condition 9 9 cleared the virus following treatment? simply because they wanted to obtain financial 10 10 If we look at paragraph 13, under the heading support? "Financial assistance for successfully treated 11 11 A. Well, I think at the time I don't think we knew 12 patients", it says: 12 anything about what would motivate people to do one 13 "There followed a short discussion on whether 13 thing or another. But later on, of course, this 14 people who had successfully cleared the virus after 14 became a very important issue in so much as, with the 15 15 treatment should qualify for the initial payment. current drugs we have, a three-month course of 16 Experts argued both for and against this." 16 anti-virals clears 100% of patients. And in the last 17 17 Then there is a reference to a patient possibly years of the scheme, those of us involved in it often 18 18 having waited a considerable period before receiving saw patients who had applied for an ex gratia payment 19 treatment. 19 after having cleared the virus and -- whereas, you 20 Then paragraph 14: 20 know, they -- at that time we thought they should have 21 "During this time and the treatment, the 21 returned to complete normality. Unless they had had 22 22 patient may claim they had suffered and therefore that interferon at the earlier stage, where we know now, 23 they should receive financial assistance. However, 23 and we were becoming aware at the stage that I am 24 this is also the case for a huge number of everyday 24 talking about, that the interferon could induce 25 NHS patients who do not qualify for any assistance. 25 auto-immune diseases, it could make rheumatoid 21 22 1 arthritis worse, it could make a thyroid condition 1 meeting not recognise that this cohort of patients 2 2 worse. It could also make depressive problems worse, might be said to be in a very different position from 3 to the extent that in my unit we used to refer 3 everyday NHS patients, because this cohort of patients 4 4 patients -- or we had a psychiatrist working with us had been infected by the NHS, which won't be the case 5 who often gave them anti-depressant treatment before 5 for everyday NHS patients? 6 we started interferon treatment because we knew there 6 A. No. I appreciate that's another factor. We were, you 7 7 know, not only thinking of the haemophilia patients. could be problems during the period of treatment and 8 8 afterward. We were also trying to provide recommendations for the 9 9 So I think the bottom line is it changed after majority of people with non-A, non-B or hepatitis C. 10 we had seen what interferon treatment was like, but 10 And I should mention here that about 80-90% of people 11 before then, at the time when we were discussing these 11 with hepatitis C virus infection had acquired it by 12 issues we, rightly or wrongly, thought that when 12 mechanisms other than by NHS blood or blood products. 13 patients had cleared the virus, then they should 13 return to their pre-treatment, pre-infection stage, 14 14 15 15 and that should be relatively normal, unless there was 16 16 knowledge that they had problems before, such as 17 anxiety or depressive problems. 17 18 So, I mean, this was an attempt at a pragmatic 18

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approach I suppose.

that's highlighted:

assistance."

Q. Paragraph 14 also says, in the sentence before the one

everyday NHS patients who do not qualify for any

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"... this is also the case for a huge number of

Did the expert group or the group holding this

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

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

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

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

Soumik, that's at DHSC0004425_159.

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

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

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without consulting the medical people.

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

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

Then we see the criteria there set:

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

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

- A. Exactly.
- Q. If we just look at the very bottom of this page, under the hearing "[Any Other Business]", in paragraph 19:

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

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

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

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

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

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

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

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

- 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

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(7) Pages 25 - 28

Infected Blood Inquiry

1		remember what was decided at what situation. But	4		contribution to make there because I ween't more
1 2			1 2		contribution to make there, because I wasn't more the Department of Work and Pensions and these sort of
3		I think there was general agreement with what Maggie Bassendine said there.	3		things, and I gave a talk to the Caxton at the
4	Λ	Now, I am not going to go to the document, but	4		beginning on some aspects of the history of and the
5	Œ.	following this meeting, I think, you were copied into	5		main problems in hepatitis C. And then I was invited
6		some e-mails, as were the others of the group, that	6		to become a director of the Skipton in a formal sense,
7		looked at the design of the form. Did you after	7		but I cannot remember where the break-point is but
8		that so that was in early 2004.	8		I am pretty sure I was involved before that actually.
9		We know the Skipton Fund became operational in	9		But Nick Fish ought to be able to tell you that, so
10		July 2004. Did you after that have any ongoing	10		so when I came but the formal appointment was in
11		involvement with the Skipton Fund other than such	11		2011.
12		approaches as Nick Fish might make to you about	12	O	Again, I am not proposing to take you to individual
13		individual cases prior to your appointment as	13	GĘ.	documentation relating to this, but I think it is also
14		a director?	14		right that you provided witness statements for the
15	Α	I can't remember the temporal sequence. I was trying	15		Department of Health in response to two separate
16		to do that this morning and trying to find out what	16		judicial review challenges to aspects of the Skipton
17		Nick had said actually. Because I thought I had been	17		Fund, one I think in around 2010, when there was
18		involved before 2011, which is the point when I	18		a challenge about the position of those who had
19		I think it was 2012 I was actually appointed to be	19		cleared the virus, and you provided a statement, and
20		a medical director, but I've got a feeling I was	20		then I think later in 2017 you provided a witness
21		involved in individual cases before then, but	21		statement for the Department of Health in a challenge
22		certainly my formal arrangement came after I was	22		that looked at the comparison between HIV and
23		appointed to the Caxton, which I think was 2011.	23		hepatitis C. Is that correct?
24	Q.	Yes.	24	Α.	Yes. I certainly remember the second one, trying to
25	A.	And it soon became apparent that I didn't have a big	25		compare hepatitis C with HIV, yes. I can't remember
		29			
		29			30
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1		too much about the earlier one, to be honest. I'd	1		
1 2		too much about the earlier one, to be honest. I'd			information. The meeting had been useful in
	Q.		1 2 3		
2		too much about the earlier one, to be honest. I'd need to see those documents again.	2		information. The meeting had been useful in pinpointing biochemical trends which are indicative of cirrhosis as well as other symptoms which are
2		too much about the earlier one, to be honest. I'd need to see those documents again. I was not proposing to ask you any questions about	2 3		information. The meeting had been useful in pinpointing biochemical trends which are indicative of
2 3 4	A.	too much about the earlier one, to be honest. I'd need to see those documents again. I was not proposing to ask you any questions about It's okay.	2 3 4		information. The meeting had been useful in pinpointing biochemical trends which are indicative of cirrhosis as well as other symptoms which are significant when assessing the likelihood of advanced
2 3 4 5	A.	too much about the earlier one, to be honest. I'd need to see those documents again. I was not proposing to ask you any questions about It's okay. professor, but it may explain why you had some	2 3 4 5		information. The meeting had been useful in pinpointing biochemical trends which are indicative of cirrhosis as well as other symptoms which are significant when assessing the likelihood of advanced liver disease. When borderline claims are received in
2 3 4 5 6	A.	too much about the earlier one, to be honest. I'd need to see those documents again. I was not proposing to ask you any questions about It's okay. professor, but it may explain why you had some recollection of some other involvement.	2 3 4 5 6		information. The meeting had been useful in pinpointing biochemical trends which are indicative of cirrhosis as well as other symptoms which are significant when assessing the likelihood of advanced liver disease. When borderline claims are received in the future, the lessons learned from Professor Thomas
2 3 4 5 6 7	A.	too much about the earlier one, to be honest. I'd need to see those documents again. I was not proposing to ask you any questions about It's okay professor, but it may explain why you had some recollection of some other involvement. I just then want to turn to 2012. And this is	2 3 4 5 6 7		information. The meeting had been useful in pinpointing biochemical trends which are indicative of cirrhosis as well as other symptoms which are significant when assessing the likelihood of advanced liver disease. When borderline claims are received in the future, the lessons learned from Professor Thomas would be applied, with the option of referral to him
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A.	too much about the earlier one, to be honest. I'd need to see those documents again. I was not proposing to ask you any questions about It's okay professor, but it may explain why you had some recollection of some other involvement. I just then want to turn to 2012. And this is shortly before you, I think, became a director. If we go to SKIP just let me get the reference SKIP0000030_011, please, Soumik. These are the minutes of a meeting of the board of directors of Skipton, 26th March 2012. If we go a little further down the page under the heading "Matters Arising", it says: "The Scheme Administrator" So that's Mr Fish. " reported that the expected increase in borderline stage two applications had occurred. As a result, a meeting had recently taken place with Professor Howard Thomas, a world expert in hepatitis C	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20		information. The meeting had been useful in pinpointing biochemical trends which are indicative of cirrhosis as well as other symptoms which are significant when assessing the likelihood of advanced liver disease. When borderline claims are received in the future, the lessons learned from Professor Thomas would be applied, with the option of referral to him if there is any doubt." There is then a discussion about Fibroscan, or transient elastography, and we can see one of the directors, Mr Spellman: " asked if there was a recognised 'trigger' at which a Fibroscan reading was indicative of cirrhosis. The Scheme Administrator responded that a reading of 15 was accepted as being 90% indicative of cirrhosis based on information provided by Dr David Mutimer, a leading liver specialist who is also a member of the independent appeal panel. The Board requested that this reading be double checked with Professor Thomas."
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A.	too much about the earlier one, to be honest. I'd need to see those documents again. I was not proposing to ask you any questions about It's okay professor, but it may explain why you had some recollection of some other involvement. I just then want to turn to 2012. And this is shortly before you, I think, became a director. If we go to SKIP just let me get the reference SKIP0000030_011, please, Soumik. These are the minutes of a meeting of the board of directors of Skipton, 26th March 2012. If we go a little further down the page under the heading "Matters Arising", it says: "The Scheme Administrator" So that's Mr Fish. " reported that the expected increase in borderline stage two applications had occurred. As a result, a meeting had recently taken place with Professor Howard Thomas, a world expert in hepatitis C and liver disease, during which a collection of borderline claims had been discussed. The meeting had	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22		information. The meeting had been useful in pinpointing biochemical trends which are indicative of cirrhosis as well as other symptoms which are significant when assessing the likelihood of advanced liver disease. When borderline claims are received in the future, the lessons learned from Professor Thomas would be applied, with the option of referral to him if there is any doubt." There is then a discussion about Fibroscan, or transient elastography, and we can see one of the directors, Mr Spellman: " asked if there was a recognised 'trigger' at which a Fibroscan reading was indicative of cirrhosis. The Scheme Administrator responded that a reading of 15 was accepted as being 90% indicative of cirrhosis based on information provided by Dr David Mutimer, a leading liver specialist who is also a member of the independent appeal panel. The Board requested that this reading be double checked with Professor Thomas." Now, I am going to come on to the Fibroscan trigger in a moment, so if we could just leave that

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particular, what's said to be biochemical trends indicative of cirrhosis and other symptoms? A. Yes. I mean, other than the APRI score and the AST/ALT ratio, I mentioned earlier if someone has cirrhosis then blood has difficulty flowing through the liver, which makes the spleen become larger, then the spleen takes out of the circulating blood platelets. So when somebody has cirrhosis, the blood can't go through the liver so readily and all the blood from the intestine, I should say, and from the spleen goes up through the liver. But if that flow is impeded, the spleen gets larger, the platelets go down, and either a low platelet count or endoscopic evidence of -- endoscopy is where you have a fiberoptic scope popped down into stomach, where you can seek the lining of the

So that would be one set of observations that would also lead to cirrhosis.

that is evidence of portal hypertension and invariably

in the lower oesophagus and stomach are distended. So

stomach -- if there is portal hypertension, difficulty

in the blood going through the liver, then the veins

The Fibroscan was a mechanism whereby you put a sheering impulse into the liver through

indicates cirrhosis.

transaminases, that's the ALT and the AST, which normally should be within the liver and when the liver cells are damaged leak out, so the blood levels are higher, those tests only tell you about whether there's ongoing liver damage. But the liver also makes coagulation factors, albumin, and a whole host of the other proteins. All the proteins in the blood are made in the liver. So when the liver shrinks in size, which happens with cirrhosis, then the albumin particularly goes down. The coagulation factors also become abnormal, not helpful -- still helpful in the haemophilia situation, because there are ones which aren't abnormal in haemophilia, but are reduced when the liver size is reduced by cirrhosis.

So those three main groups of things -- portal hypertension evidenced by endoscopy, stiffness of the liver as measured latterly by the Fibroscan, and the inability of liver to produce the blood proteins because of a reduced liver size -- would be other bits of information that might make us think and, in particular, the physician or the nurse helping the patient fill in the form might put in there to convince Skipton that this was a case of cirrhosis and should trigger a stage 2 payment.

an ultrasound probe and you look at how much the liver wobbles, much as a jelly, you know, would wobble if you shook it. A normal liver would wobble quite a lot, whereas one which has cirrhosis would become stiff and wouldn't wobble. That was the basis for the Fibroscan.

I think later on, and you may be coming to this later on, I think we thought that we should have a lower score than 15. I think was it 12 or something like that?

- **Q.** I am going to pick that up with the next document we look at, Professor Thomas?
- A. Yes, because I thought that 15 -- David Mutimer's thinking, really, was that he wanted to get specificity up high; in other words, he didn't want to misdiagnose cirrhosis, but that would mean when you increased the specificity, then the sensitivity goes down. So I thought we would be better and fairer to the patients if we set it at a lower level where we would let some people through who didn't have cirrhosis but were probably very near it anyway and we wouldn't miss many. So that's the component of the other tests.

The other things that happen when you are near to cirrhosis is that the liver, as well as releasing

see the issue of the Fibroscan being picked up.
That's SKIP0000030_085, please, Soumik. We can see this is 11th March 2013 meeting of Board of Directors of the Skipton Fund. You are present and we can see from the first paragraph:

"Welcome to Professor Thomas.

"The Board welcomed Professor H Thomas a director and looked forward to his expert help."

So this the first meeting, as far as we can understand it, that you attended as a director. Then if we look towards the bottom of the page, we can see the issue of Fibroscan being referred to:

"The Scheme Administrator referred to the Fibroscan reading that was considered to be indicative of cirrhosis."

Then there is reference to Dr Mutimer's view which we looked at in the previous set of minutes. Then reference to a medical bulletin having been submitted, taken from the Hong Kong medical diary which suggested a reading of 12.5 or over as an indicator of cirrhosis. Then this records you citing:

"... a NICE study into the effects on the liver of hepatitis B which suggested that 10 ... or above was an indicator that cirrhosis might be present. It

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

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

- A. Yes, and I rapidly thought when that responsibility decided on me, who else I could get to be involved, and that's where I thought it would be a good idea to get Professor Dusheiko involved, because I think when there are -- you know, when it is marginal, it is good to get other people's views and that's why I got -put forward -- got Professor Dusheiko involved as well, because he was equally well-informed in this area as I had become.
- Q. Then there is one further discussion about Fibroscan readings I want to ask you about. It's a couple of years later, SKIP0000030_068. So we can see these are the minutes of the meeting of the Board of Directors

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

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

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

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

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

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

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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 that they had had a fractured pelvis, then we could 5 say that would be taken as evidence. So we are trying to build a case to help those 7

that had -- who were putting in a stage 1 application at a time when they couldn't actually lay hands on notes really, and Geoff and I -- Geoff Dusheiko and I -- often met to think of ways in which we could do that, for instance, taking photographs to see what sort of operation they had had. It might seem strange but patients actually went along with that and sent a picture to show they had had a caesarean section, where quite a few patients would have a blood transfusion and these sort of issues really.

- Q. I will come back to stage 1. If we go over the page whilst we're on this document we can then pick up --
- A. Stage 2 then, specifically, we did manage to get that down to a very good level of acceptability and with very few appeals overturning.
- Q. We can see the discussion in the long top paragraph on this page, further discussion about Fibroscan readings. So it says:

"Professor Thomas reported that he had recently

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

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

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

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

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

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

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, whereas what we looked at previously suggested it was 4 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 about that and we alighted on 12. That was 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.

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

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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?

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

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

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,

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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 of Gastroenterology owned Gut and they tended to put 13 14 these sort of policy decisions into Gut so everybody 15 could see it. But it was a contentious issue really,

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So that meeting of the BSG was also serving

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patient for a liver transplant.

not just from the point of view of whether patients

they are at risk, 2 to 4% per year, of developing

should get an ex gratia payment but, as I mentioned

primary liver cell cancer, and that requires that they

have some form of imaging, usually an ultrasound but

possibly a CT scan or MR scan, so that the tumour is

picked up when we could resect it or recommend the

before, when patients were deemed to have cirrhosis,

- A. It is important to say "a director", by the way, because we had group responsibility. I think you are promoting me to a level that I didn't attain. Peter Stevens was "the director" -- the chairman of the directors I should say.
- Q. If we look at the bottom of the page, we can see that the board considered here the issue of "Stage 2 applications from the estates of people who were co-infected with hepatitis and HIV, who died before 29th August 2003 and whose records have been destroyed".

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

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

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.

A. I think he was very keen to be as precise as possible, really, and I was a little bit more on the side of sort of saying "It is going to be in the patient's 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, about what Skipton decided to do, which I am surprised can't be found -- I would hope it could be found somewhere in the minutes of various Skipton meetings, I am pretty sure we agreed with 12. 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
 - Q. I want to go back then, on a different issue, to the previous set of minutes we looked at, so that's SKIP0000030 085.

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

If we look now at the second page --

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

Can you assist us, because I don't think we have the underlying model itself, with what this model was and what it told you and how it was used? A. I can't remember a heck of a lot about this, I am afraid. There was a paper produced, and I think Professor Dusheiko was involved with this, plus one of the Cambridge mathematical modelers, and the focus was to look at people with hepatitis C mono-infection as opposed to those with hepatitis C and HIV. That allowed us to come up with a formula really for saying that -- depending whether they had the mono-infection or the co-infection, what would be the probability in the absence of a post mortem that that patient had cirrhosis.

I could look up the papers again, but that was

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Then we see:

Infected Blood Inquiry

1 essentially the summary. I can't remember, you know, Q. Yes. It was, as we understand it, a predictive 2 what the detail of the formula was, but -- and that 2 formula -- that's how it is described in other Skipton 3 3 did mean that we could say with a reasonable documents -- for progression to cirrhosis? 4 4 probability, the magical greater than 50% probability, A. Yes. 5 that the patient had cirrhosis and had died, and --5 Q. So whatever the precise data was -- it perhaps does 6 6 and no post mortem being done, of course, which, in not matter for present purposes -- it was then applied 7 the case of HIV co-infected individuals, there was 7 to work out what the probability was that someone who 8 8 a reluctance to do this, so it was required that we was dead, for whom there are no records or relevant 9 9 should have some sort of model. tests, would have progressed to cirrhosis? 10 10 I can't really say anything more about the A. Correct. 11 detail of it, but I could look it up in due course if 11 Q. Sir, I note the time. I am going to move on to 12 you wanted. 12 stage 1 applications in a little more detail now. So 13 Q. Thank you. I think we understand from other documents 13 perhaps this is a good moment for a break? 14 it is described as giving rise to predictive formulae 14 SIR BRIAN LANGSTAFF: Yes. We will take a break until 15 15 for progression to cirrhosis? 11.45. It will allow you to get some refreshment, 16 16 A. Yes. professor, and those who want to do the same. So 17 17 11.45. Q. So the aim was to apply it, whatever precisely it 18 18 MS RICHARDS: Sir, I can't remember whether you gave the looked like, to the cases of those who were dead and 19 for whom no records, or no relevant records, existed 19 professor the warning. 20 to work out what the possibility was that they would 20 SIR BRIAN LANGSTAFF: I haven't. 21 have progressed to cirrhosis by the time they died. 21 Let me just tell you what the rules are. You 22 22 Is that right? must not during this break, or any other break that we 23 A. Yes -- I am sorry. A bird is just banging on the 23 may have, discuss with anyone the evidence you have 24 window, so I was distracted there. 24 given or the evidence that you are yet potentially to 25 25 give. You can discuss that after you have finished Would you mind saying that again? 49 50 1 your evidence, but not before. But in the meantime 1 NHS material; this was established by several 2 2 you can just talk about anything else you like. prospective studies showing that the incidence of 3 11.45. 3 abnormal ALTs after concentrate infusion, both in the 4 4 A. Okay. literature and our own study, was almost 100%. 5 (11.18 am) 5 Nick Fish signed off on these cases without clinical 6 (Short break) 6 input." 7 7 Then you turn to transfusion cases and say (11.45 am) 8 8 SIR BRIAN LANGSTAFF: Yes. this: 9 9 MS RICHARDS: Professor Thomas, I am going to ask you "In cases of blood and plasma transfusion, we 10 a little more about the stage 1 decision-making 10 had to say that it was more than 50% likely to be due 11 process now. I am going to ask you to look at 11 to transfusion. In the absence of GP or hospital case 12 a passage in your witness statement. 12 notes this was very difficult. Occasionally we had 13 Soumik, could we have WITN3824007, please, and 13 evidence of a major operation where in virtually all if we could go to page 29 14 cases blood transfusion would have been necessary eq 14 15 That's different from the version I have got. 15 cardiac valve replacement or major trauma resulting in 16 16 Give me a second. Okay. We can pick it up at the top pelvic or femur fractures. These cases usually 17 of the page. So this is in paragraph 112, I think, of 17 involved both Professor Dusheiko and myself and 18 your statement. It says: 18 involved detailed consideration. In my view this was 19 "In general patients were concerned about the 19 as objective as possible. 20 evidence needed to establish that the PTH 20 "In the absence of case notes it was almost 21 [post-transfusion hepatitis] was probably (greater 21 impossible for Professor Dusheiko and myself to 22 22 than 50% likely) due to NHS blood and not other means provide this level of certainty. In many cases all we 23 of infection such as IVDU, tattooing etc. All 23 could do was to exclude non-transfusion related modes 24 haemophilia patients who had received factor VIII 24 of transmission such as body piercing and IVDU. 25 concentrate were automatically accepted as infected by 25 Sometimes we had evidence of surgery which did not

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usually require transfusion but infrequently did; this again required clinical judgement." Now can I ask you, first of all, just to assist

us with understanding how you would use your clinical

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judgement to make the assessment of whether the applicant was probably infected by blood transfusion? A. Well, it's really just a second way of saying what I have mentioned earlier, in so much as if, you know, a surgical procedure or, as I mentioned, trauma were invariably needing transfusion, then that was -- then we would take that as given. And the way we established those precedents, if you like, was by going to the literature.

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

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

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

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

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

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main were not destroyed after seven years, which seems to be the case in hospital-based medical practice. Many GPs have these sort of cards where they, you know, note down over maybe 20 or 30 years what has happened to a patient. So, you know, occasionally we would find in a woman that she had had, you know, a major haemorrhage during delivery of a child. So, you know, we know that caesarean sections, you know, 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.

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

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possibilities. For instance, you know, some people -there was one case where the gentleman was taking methadone, which is usually only given for intravenous drug use, and he argued that he had only taken non-intravenously administered drugs. So, I mean, one could weed out cases like that and go through, in a positive sense, the ones where there was evidence of blood transfusion, and then it was up to the appeals group to use a much more subjective set of rules. And their opinion was final. So I thought that that fallback position safeguarded the patient's interests should, on further inquiry, something else came up

that I or Geoff hadn't noted.

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

25 56 (14) Pages 53 - 56

stage.

A. Yes.
 Q. Was there any reason you were aware of as to why that information couldn't be considered at the first stage

by the administrator and a director?

A. We did see cases where what you said was the case, and a relative would say, for instance, "Well, when I came in to see my husband", or wife or what have you, "they had an intravenous transfusion device up, and I could see", the relative would say "and I could see a little bit of blood just near to the point of insertion through the skin". And always, in any transfusion of clear fluids, in other words, saline for rehydration, there is always reflex of blood into that last 1 to

So we listened to everything, and Mr Fish actually often had conversations with the person on the telephone to recommend evidence that might be provided, but -- I make no bones about it, this was an extremely difficult stage of the assessment and why I initially, and latterly Geoff Dusheiko, put so much emphasis on objective evidence that we could bring forward for stage 2 payments, because we were quite

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

isn't involved in medicine or transfusion, they would

take to indicate cast iron visual evidence of

transfusion, but it isn't.

through a drug or sexual route or they'd been infected via transfused blood?

A. Well, I think that, in retrospect, could have been a way of proceeding, but I took the view that this attitude could be applied at the stage of the appeal. We did recommend in the letter that Nick sent out that the appeal process was open, and a very large number of the people where we had not found positive evidence for involvement of NHS blood and where these other risk factors were not present, a high percentage of these did go on to appeal. So we felt that this was the stage at which that could and should happen.

We, at every corner really, tried to do the best by the patients, and make sure there was some uniformity of the process that was being used. We didn't talk to the Appeal Panel in these terms, but I think every single letter would say, you know, "We can't find any involvement of NHS blood here, but it is open to you to go to the Appeal Panel". So we felt we had not been inappropriately -- you know, we had not been putting the patients to a major disadvantage really.

And many of the comments or the evidence the patient came up with were of the type that were completely plausible. I mean, this business of,

aware of the fact that the stage 1 process was, you know, highly subjective.

Q. Your statement refers, in the bottom paragraph on the screen, to how:

"In many cases, all we could do was to exclude non-transfusion related modes of transmission such as body piercing and IVDU."

Did it ever occur to you or any of the other directors or Mr Fish to take a slightly different approach to stage 1 applications and look to see which was the least unlikely mode of transmission?

The least unlikely.

Q. If I can suggest a hypothetical scenario to you. You had someone for whom no evidence whatsoever to suggest they had ever had a tattoo or a piercing or any likelihood of sexual transmission, which we know was, I think, a low risk in any event, and no evidence whatsoever to suggest intravenous drug use, no evidence of overseas medical treatment of a serious nature. They had to have got their hepatitis C somehow. If they could point to some form of surgical intervention that they had undertaken within the NHS, why not take the approach of looking at which is the least unlikely: that this 70-year old individual, married for 50 years, has been infected with HIV

"Well, I could see that there was a transfusion in place and there was blood staining in the area, the last 2 to 3 centimetres, does this not indicate the patient had a blood transfusion?" The answer is no, but it is quite reasonable the patient would believe this is the case and the patient's relative would also believe this was the case.

As I say, we were of the view this would then be -- the Appeal Panel could actually say, you know, "Well, we think, on balance, there is no reason for not believing this patient. Let's pass it through".

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

- A. Do you think that was unfair? I mean, there was a well-trodden track for the patient to continue to prosecute their claim in the system, if you like, through the appeal process.
- 17 Q. You and Professor Dusheiko, your area of expertise,18 both of you, was hepatology?
- A. And general medicine. We both did general medical
 take, we call it, where for one day a week, usually,
 you take all the cases that come into an acute
 hospital. Then you look after them for 24 hours, the
 next day you usually get a specialist to look after
 them, unless it is a more pressing concern, where you
 get a cardiologist or an endocrinologist to help

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during the night hours.

Q. You would be having to make clinical judgments about whether a particular operation or intervention might have required a transfusion. Was there ever a system in place or contemplated whereby other medical experts -- perhaps an orthopaedic surgeon if it had been orthopaedic surgery, or an ENT specialist if it had been ENT interventions -- to ask for their take or input? Was that ever considered?

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

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

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

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

All the time, of course, we knew that the

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

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

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

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

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

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

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

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

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

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

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

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

Q. We can take that down.

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

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

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

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

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

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

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

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

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

Q. The second potential problematic consequence of
pinning one's hopes on the appeal process would

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

A. Yes, I would, of course. It is worthwhile looking at the figures that you have later on in your data.

I think you say there is 6,712 patients who applied for a stage 1 application, approved at first stage 5,529, you know, which is 80%. So, you know, not that -- you know, we waved through a large number. Whenever the issues of patient feedback were put before either Skipton or Caxton, it was always apparent that complaints were looked at very carefully but nobody ever looked at the proportion of patients who thought their case had been handled very well. That's 80% according to these figures.

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

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

Q. I am simply trying to --

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

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

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

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

It is not sufficient, when you are trying to elucidate the story of the drug users, to just ask the patient in a clinic once "Did you use drugs?" Nobody wants to admit that. But one of the aspects of being a doctor, and a liver doctor interested in viral hepatitis, is you soon learned that you had to gain the patient's confidence, and you -- you know, at the first consultation you might ask if you used drugs and just once is enough. Because, of course, who -- I am

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

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

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

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

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

22 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 almost certainly giving you a needle system, because your mother doesn't give you a needle to go out with when you go out to a party. You will be actually using a drug provided by somebody selling drugs and you will become infected. So almost synonymous with hepatitis C, outside the context of blood transfusion, a positive result is indicative or highly likely that 11 that patient at some stage, past or present, has used drugs. And that's why that -- what Nick Fish said,

- Q. I understand that was policy and approach of the Skipton Fund. Did you yourself have involvement in deciding IVDU stage 1 applications as far as you can recall or were you generally only called in for review when there were clinical judgments to be made?
- A. Oh, no, I was involved in judging stage 1, yes.

I suspect why he said it.

- Q. But were you involved in rejecting applications on the sole basis that there was evidence of IVDU?
 - A. Certainly some. I don't know whether it was all of the ones I saw, but certainly some of them.

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

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they would say "No", but after four or five returns

and follow-up clinics, they would say "Well, actually, as a student once I did use them". And, you know,

digressing now I suspect, but, you know, when you are

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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?

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

- A. Where hepatitis C was a cause of contributing to death?
- 22 **Q**. Yes.

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

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1 Skipton.

- Q. So in terms of your involvement with the Caxton
 Foundation, is this right: it largely involved just
 attending the trustee meetings?
- A. Yes.
- 6 Q. And contributing to general discussions about policy?
- 7 **A.** Yes.

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- Q. How often were you called upon to provide medical
 information to either employees or your fellow
 trustees at Caxton about hepatitis C?
 - A. When I was appointed to Caxton, I was conscious of the fact that I didn't have a heck of a lot to contribute, as I say, because it was social aspects and Department of Work and Pensions were involved. So I offered to give a presentation, really, on -- really, a bit like the thing I prepared for Penrose and I think you have cited in some of your paperwork. I had a nice set of slides for that. So I did a presentation.

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

Q. Can I ask you to look at one set of minutes? It is at CAXT00000109_105, please, Soumik.

SIR BRIAN LANGSTAFF: There is something wrong with your

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

- 7 Q. I am going to move now to the Caxton Foundation. You were involved with the Caxton Foundation from 2011 9 onwards. But I think this is right, you didn't sit on the National Welfare Committee, so you weren't involved in decision-making about individual grant 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?
 - Q. No, the Skipton Fund.
- A. Yes -- yes, we were all aware of the need for audit,
 so -- and it was apparent that I had medical knowledge
 but not much else that was useful to the Caxton. So
 I didn't -- I then got transferred across to the

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number of zeros.

MS RICHARDS: I have too many zeros in it. It is CAXT0000109_105. Thank you, sir.

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

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

"Professor Thomas suggested ..."

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

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

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1 had perhaps been expected and an issue arose for the concentrates. 2 board about how to make people more aware of the 2 I think that was the challenge to the system. 3 3 existence of the Caxton Foundation. This suggests you That group of people were -- the only way of doing 4 had suggested making contact with perhaps haemophilia 4 that would be through the Blood Transfusion Service. 5 centres or haemophilia specialists. Can you recall 5 I guess that was the look-back service -- or study 6 6 whether that was taken forward? that was done. I don't know when it was in relation 7 A. What does ICEO stand for? 7 to this, whether it was before or after, but that 8 8 SIR BRIAN LANGSTAFF: Interim Chief Executive officer. would be the way to do that. 9 9 MS RICHARDS: It is, yes. The other thing that was discussed at this 10 10 A. Interim chief -- was that Jan Barlow? meeting was, you know, how much there was a need for 11 MS RICHARDS: There was a temporary officer. After 11 this, because there were several programmes on the 12 Mr Harvey stepped down and before Ms Barlow was 12 television, Panorama and the like, and I don't think 13 13 appointed, there was an interim chief executive there were many people who had had a blood transfusion 14 officer, and that's what that refers to. 14 in the UK who hadn't seen one or other of these 15 A. Yes. I don't recall what happened as a result of 15 programmes. You might say how do I know that. 16 that. The reason I said that was that I was very 16 I don't know that, but I think -- you know, they were 17 17 shown on prime time TV many times. So I wasn't quite impressed, through my work at the Royal Free, and with 18 18 Professor Kernoff particularly, who tragically died, so concerned about that. 19 with how integrated a national structure the 19 Q. Did you have any understanding from colleagues in the 20 haemophilia specialists grouping was. And if you 20 world of hepatology, any understanding of how 21 wanted to reach specifically the haemophilia 21 well-known the existence of the Caxton Foundation was? 22 22 population, then that would be the vehicle for doing A. I think the hepatology nurses served a very useful 23 that. But I didn't have any suggestions as to how you 23 function actually. They got to know the patients very 24 would reach those that had had blood transfusions or 24 well. I am talking now about the non-haemophilia 25 blood products other than Factor VIII or IX 25 patients, the ones I was talking about earlier, and 77 78 1 the haemophilia services in the specialist centres 1 various drugs. I'm not sure what else he included in 2 2 also had a very close relationship with their that from memory I'm afraid. 3 patients, because they were patients from, you know, 3 Q. Now you have referred in your evidence earlier to the 4 4 a few years of age right through to adult life and old concern you had about the access to the new forms of 5 5 treatment. I just want to look at the letter you age. 6 These nurses, I think -- the haemophilia 6 wrote to the Minister on that issue. 7 7 service developed this first, but one of the things It is WITN3824008, please, Soumik. 8 8 I helped develop was the formation of hepatology We can see it is dated 1 November 2014. It is 9 9 nurses, and we employed several in our unit at from you and you say: 10 St Mary's. These people certainly raised the 10 "Dear Minister, 11 attention of the patients to the Skipton and to the 11 "I am writing as a member of the Caxton Board 12 Caxton -- more the Skipton than the Caxton I think, 12 and the Medical Director of the Skipton Fund, both 13 probably -- and would help the patients fill in the 13 involved in supporting those with hepatitis C acquired 14 forms. Because a hepatology nurse was able to do it 14 through receiving infected NHS blood or blood 15 as well as the doctors. 15 products." 16 16 Then you explain a little about the stage 1,

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Q. We can take that down now.

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

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

antiviral drugs which are curative in over 90% of cases, have been licensed and are currently being considered, but not yet recommended, by NICE. These

"In the last few months orally administered

"Around 90 patients receiving Skipton stage 1

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stage 2 process. You say in the next paragraph:

occurs the cirrhosis cannot be reversed even if

anti-viral treatment is successful.

payments, progress to cirrhosis each year. Once this

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Infected Blood Inquiry

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

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

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

least, of the NHS, that particular argument fell ondeaf ears?

- A. Well, no. I think the Minister said that it was covered off by the rules and regulations covering NICE. This was by that stage -- not yet recommended by NICE. But if it wasn't recommended by NICE, then the NICE rules wouldn't be relevant. This was quite some time ago and I can't remember the detail of it. I remember it didn't come about, really, is what it amounts to.
- Q. I just want to ask you a little next about the special category mechanism and the discussions that you were involved with in relation to that. If we could go to DHSC --
- A. By the way, can I just say that letter really followed on from that debate that we had earlier about what was the crucial cut-off for cirrhosis with Fibroscans, and it was one of the reasons -- I am fairly sure it was one of the reasons why I wanted to go for the lower level, because I thought that would be another way of skinning this particular cat and would include that group, the Ishak 5s, which are just the pre-cirrhotic group.
- Q. I am going to ask you about the Special Category Mechanism. I think they were originally referred to

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

19 Q. Yes.

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

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

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

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

There is reference to meetings having been cancelled:

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

Then there is reference to:

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

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Then you are recorded as saying this:
"... HT advised that the SCM eligibility
criteria were still very subjective and would be
difficult to assess."

What was your concern in that regard?
Well, this stemmed from work I had done with E

A. Well, this stemmed from work I had done with Daniel Forton and Simon Taylor-Robinson, looking at whether hepatitis C affected the brain. We were able to isolate in the brain a virus variant of hepatitis C, which was the regulatory element which controls replication of the virus, from -- the one we got from the brain was different from the one that was in the cripple blood, indicating that it was a functional virus working in the brain. Therefore I was convinced when we did SF36 studies that was the observation that we had made with Graham Foster and others that depression and cognitive changes, what became known as brain fog, were caused in a proportion of the patients by hepatitis C.

The virus was in the brain and when we did comparative studies of quality of life between hepatitis C and hepatitis B as a control, these two areas, depression and brain fog, cognitive defects, came out as significantly different and associated with hepatitis C.

this work, to be honest, and I wanted the reference group to try to work towards more objective ways of dissecting out whether these problems were related to hepatitis C or not and they weren't forthcoming.

So yes, I wanted the SCM to go through, but I didn't want it to be another situation where we really couldn't define the group where it was due to hepatitis C. So when the NHS Business group took over and this SCM was put into effect, Janice Main, a colleague of mine, and I, used to go into Skipton House before the NHS Business guys took all this up to Newcastle. We sat down and tried to look at hundreds of these cases coming through and we decided we couldn't differentiate them and that if the GP or the hospital consultant or a nurse said that this was -- well, they were given three choices. It was improbable it was related hepatitis C, which think only three people ever ticked out of hundreds, and it is possible and probable.

So we gave everybody where it was said to be possible and probable the tick for the payment because we couldn't say one way or the other. If you like, you may say we learned from our previous experience with stage 1s. You know, in this subjective environment you have to assume that the primary care

So I felt that they should be taking some -- we should be trying to dissect this away from the large proportion of patients who had depressive problems and even cognitive abnormalities in the general population unrelated to hepatitis C, and it would be impossible to differentiate these two.

Having set up objective criteria for stage 2 payments, which I think in retrospect were shown to work quite well, and worked through at the time with stage 1, found it very difficult to be objective in this group, and to add this to it, a Special Category Mechanism, which allowed additional payment or significant payment for people who had depression and cognitive abnormalities would actually mean that virtually everybody would have them. It turned out to be the case: virtually everybody applied for this, if you wanted to be cynical, assuming that they were depressed and assuming that their depression was related to their infections. Not unreasonable, you may say, but a significant proportion of people, of course, in the general population have depression and it is reasonable to assume that this proportion of people with hepatitis C had the problem before hepatitis C infection occurred.

So I didn't relish the fact of trying to make

physician, the GP, or the consultant or nurse involved in the hospital care of that patient, would be in the best position to assess the patient, and if they said it was probable, then the payment should go through.

But, you know, we had already given out very large sums of money, I think over 300 million and I felt we should try to be as objective as possible, but this was impossible. So I felt at least I had to say at the reference group that this was the case but I didn't have a better suggestion really of how we could differentiate.

Q. Then the reference group, as well as considering the Special Category Mechanism, considered other aspects of what the new Business Services Authority scheme might include?

SIR BRIAN LANGSTAFF: Just before you go there, can I ask this: how did you judge being related to hepatitis C, because "being related to" may mean a number of different things?

A. Yes. I take your point. It may be causatively related or it may just be associated with.

SIR BRIAN LANGSTAFF: If causative related it may not be the only cause but may be a contributing cause.

 A. So it would be relevant whether the patient had depression or cognitive problems beforehand. If

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4	handilia Carold make it was a that would be arrough	4	and the state of t
1	hepatitis C could make it worse, that would be enough	1	course, virtually 100% of people with hepatitis C can
2	to make the payment as well.	2	be cured. So there was a possibility of looking at
3	SIR BRIAN LANGSTAFF: That would follow legally in a case	3 4	which of these problems got better when the virus was
4 5	in which there was a question of whether the condition	5	cleared, in other words the second component of the
	for which compensation was being sought had been	6	Koch's postulates. The Americans particularly said
6 7	caused by what is generally a multi-factorial condition.	7	that a lot of the depressive and cognitive
8			abnormalities, which were measured by instruments
	A. I think later on I mentioned Koch's postulates. I think Koch was a German infectious diseases or	8	called SF36, which just was a series of questions, I think there were 36 of them, hence the name and
9		9	•
10 11	epidemiologist. Koch's postulates say that before	10 11	specialist variants of that where you could do serial measurements before and after treatment.
12	an infectious agent can be thought to be causatively	12	
13	related, which I appreciate, sir, that this is different to what you are suggesting, you are just	13	The Americans argued that most of the symptoms didn't go away after the virus was cleared, but it
14	saying it could be exacerbated by hepatitis C	14	turns out we were doing some studies with magnetic
15	SIR BRIAN LANGSTAFF: I think the expression I would use	15	resonance spectroscopy. It is a sophisticated system
16	is "cause or contributed to".	16	that looks at various molecules in the brain. We
17	Right, well, Koch said that for an agent to be	17	found, originally, that in HIV and in hepatitis C
18	causatively related it should be found with the	18	stage 1 there was a sub group of patients who had this
19	disease or the symptom and when the virus or bacterium	19	particular pattern, which suggested there was a change
20	or fungus, whatever, is cleared, then the symptom or	20	in the brain. It would have been possible to use
21	illness under consideration should disappear. In	21	these scans, which cost a couple of hundred thousand
22	other words, it came on with the infection and then	22	pounds each to do they were a research programme
23	went away when the infection was cleared.	23	to tell whether individual patients had these
24	We tried to think about using Koch's postulates	24	characteristic changes which we saw initially in HIV
25	in relation to this particular problem because, of	25	but were also present in stage 1 hepatitis C, which
20	89	20	90
	03		30
1	I think would have differentiated the virus caused	1	When you took care of patients going through
2	ones from the other causes, depression or brain fog,	2	those interferon treatments, it wasn't surprising that
3	that is unrelated to hepatitis C.	3	their memory had a long-term compromise, really. And
4	But it doesn't answer your question of whether	4	also, if they had rheumatoid arthritis or myxedema,
5	it is causatively related or contributed to. I don't	5	a thyroid condition, these were also made worse
6	think you can differentiate those, except by looking	6	afterwards. So I changed my view during that process,
7	retrospectively as to whether it got better or	7	you know. And when the SCM issue came up, we thought
8	partially got better when the virus was cleared.	8	that virtually anybody who had had interferon should
9	SIR BRIAN LANGSTAFF: Well, I think the magic of the	9	probably get these payments, because there was
10	phrase "caused or contributed" means this covers both.	10	a correlation maybe not causative, but
11	You don't actually have to differentiate between the	11	a correlation which, you know, might mean it was
12	sole cause or one of a number of causes or	12	related to, albeit not in the Koch's postulates way.
13	contributors to a condition.	13	So I don't know if that has helped at all.
14	A. Yes. Many conditions are caused by many for factors.	14	MS RICHARDS: If it assists and, sir, we will no doubt
15	Of course, they can operate in conjunction with each	15	look at this when we look at the current schemes in
16	other as joint causes, yes. I take your point. The	16	May but the current Special Category Mechanism
17	bottom line is that we gave the SCM payments to	17	application form, which I looked up this morning,
18	virtually everybody who applied for that very reason.	18	poses the question in this way of the clinician or
19	The other group that we thought should be given	19	nurse:
20	be these payments were people who during their stage 1	20	"In your opinion how likely is it that your
21	illness had been treated with interferons, which	21	patient's mental health problems are attributable to
22	initially, I thought, wasn't justified, but experience	22	the hepatitis C infection or its treatment or
23	in reviewing these with individuals it clearly became	23	effects?"
24	evident that many people did have the	24	SIR BRIAN LANGSTAFF: It is the same question.
25	interferon-related side effects.	25	MS RICHARDS: It is, although the four potential answers
	91		92 (23) Pages 89 - 92

1		are:	1	ab	out that.
2		"Not likely explained by other causes.	2		If we could go to the last page, we can see the
3		Possible.	3	las	st heading is about "Policy for £10,000 payment [of]
4		Highly likely, and	4	the	e bereaved". Then it is said
5		Definite."	5	SIR BF	RIAN LANGSTAFF: I think it is probably "to the
6		There doesn't appear to be a box for "likely".	6	be	reaved". The T and the O are transposed.
7		But that's a question for the future rather than for	7	MS RIC	CHARDS: I think it probably is "to the bereaved",
8		Professor Thomas.	8	rev	versed to O-T. Then it says:
9		Just before we break for lunch, professor, I	9		"For the purpose of the proposed policy the
10		just have	10	int	ention is that you qualify as 'partner or spouse'
11	A.	I just want to know is it possible to ask what	11	of	the deceased registrant/primary beneficiary if
12		proportion are getting SCM payments? I think it is	12	eit	her of the following applies."
13		virtually 100%, isn't it, of stage 1s, or is it?	13		Then there is a provision as to what amounts to
14	Q.	I think we will be in a better position to know that,	14	aı	partner or spouse."
15		Professor Thomas, when we examine the evidence in May.	15		Can you recall, Professor Thomas, whether there
16	A.	Sorry.	16	wa	as any discussion within the reference group of
17	Q.	I just have one further question about the reference	17		dening the category of people who could receive the
18		group discussions, not on the Special Category	18	be	reavement payment to categories of relatives beyond
19		Mechanism but on a different aspect of the	19	ра	rtners and spouses?
20		discussions.	20		an't really I ended up at one of these sort of
21		If we could just look at DHSC0046884_020, you	21		eetings with as one of the only well, we're
22		will see it is a reference group meeting,	22		ually the only medic present focusing on those
23		16th November 2016.	23	iss	sues, really, and I'm not sure I picked up on this.
24		Again, there is a discussion about the Special	24		o, I can't shed any light on that, I am afraid.
25		Category Mechanism. I am not going ask you further	25		e can
		93			94
1	Α.	Hold on. Yes, I think that was mentioned. Did that	1	dio	dn't feature. I felt that the hepatitis B
2		happen or did it not happen?	2		pulation this is what I am going to say is not
3	Q.	I am just asking you whether you have any recollection	3		ally relevant to those haemophiliacs and those who
4		of discussions about it. We can pick up what then got	4		ceived hepatitis C through a blood transfusion,
5		translated into the scheme with the relevant civil	5		cause don't forget I said earlier, about 95% of my
6		servants in due course.	6		tients with hepatitis C were intravenous drug users.
7	A.			μa	
8		No. The other issue that was raised here was whether	7		nd they deserved good treatment just like everybody
9		No. The other issue that was raised here was whether hepatitis B was mentioned. I know that one or two	7 8	An	nd they deserved good treatment just like everybody se but there was a stigma attached to that group of
		hepatitis B was mentioned. I know that one or two		An els	se but there was a stigma attached to that group of
10			8	An els pa	
	Q.	hepatitis B was mentioned. I know that one or two people mentioned that but I can't remember what the outcome was to be honest.	8 9 10	An els pa ex	se but there was a stigma attached to that group of tients. And my nurses and my staff gave these guys pert care and they were very difficult to manage.
11	Q.	hepatitis B was mentioned. I know that one or two people mentioned that but I can't remember what the outcome was to be honest. You anticipated what was going to be my final question	8 9 10 11	An els pa ex Th	se but there was a stigma attached to that group of tients. And my nurses and my staff gave these guys pert care and they were very difficult to manage. He hepatitis B patients were cross-stigmatised, if
11 12	Q.	hepatitis B was mentioned. I know that one or two people mentioned that but I can't remember what the outcome was to be honest. You anticipated what was going to be my final question before lunch, Professor Thomas, which was just about	8 9 10 11 12	An els pa ex Th	se but there was a stigma attached to that group of tients. And my nurses and my staff gave these guys pert care and they were very difficult to manage. The hepatitis B patients were cross-stigmatised, if ould use that phrase, because people didn't
11	Q.	hepatitis B was mentioned. I know that one or two people mentioned that but I can't remember what the outcome was to be honest. You anticipated what was going to be my final question	8 9 10 11 12 13	An els pa ex Th	se but there was a stigma attached to that group of tients. And my nurses and my staff gave these guys pert care and they were very difficult to manage. He hepatitis B patients were cross-stigmatised, if
11 12 13	Q.	hepatitis B was mentioned. I know that one or two people mentioned that but I can't remember what the outcome was to be honest. You anticipated what was going to be my final question before lunch, Professor Thomas, which was just about hepatitis B. Can I put it more generally than relating to	8 9 10 11 12 13 14	An els pa ex Th I c	see but there was a stigma attached to that group of tients. And my nurses and my staff gave these guys pert care and they were very difficult to manage. The hepatitis B patients were cross-stigmatised, if ould use that phrase, because people didn't ferentiate between hepatitis B and hepatitis C.
11 12 13 14	Q.	hepatitis B was mentioned. I know that one or two people mentioned that but I can't remember what the outcome was to be honest. You anticipated what was going to be my final question before lunch, Professor Thomas, which was just about hepatitis B.	8 9 10 11 12 13 14	An els pa ex Th I c dif	se but there was a stigma attached to that group of tients. And my nurses and my staff gave these guys pert care and they were very difficult to manage. The hepatitis B patients were cross-stigmatised, if could use that phrase, because people didn't referentiate between hepatitis B and hepatitis C. Most people with hepatitis B were Asian, ninese in particular, where 10 or 15% of the Chinese
11 12 13 14 15	Q.	hepatitis B was mentioned. I know that one or two people mentioned that but I can't remember what the outcome was to be honest. You anticipated what was going to be my final question before lunch, Professor Thomas, which was just about hepatitis B. Can I put it more generally than relating to specific conversations within the reference group that	8 9 10 11 12 13 14	An els pa ex Th I c dif	see but there was a stigma attached to that group of tients. And my nurses and my staff gave these guys pert care and they were very difficult to manage. The hepatitis B patients were cross-stigmatised, if could use that phrase, because people didn't referentiate between hepatitis B and hepatitis C. Most people with hepatitis B were Asian,
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11 12 13 14 15 16 17 18 19 20	Q.	hepatitis B was mentioned. I know that one or two people mentioned that but I can't remember what the outcome was to be honest. You anticipated what was going to be my final question before lunch, Professor Thomas, which was just about hepatitis B. Can I put it more generally than relating to specific conversations within the reference group that you may not recall? Work on hepatitis B has formed a significant part of your career over the years. Was the exclusion of people infected with hepatitis B from the Skipton Fund and Caxton Foundation something that ever came up	8 9 10 11 12 13 14 15 16 17 18 19 20	An els pa ex Th I c diff	see but there was a stigma attached to that group of tients. And my nurses and my staff gave these guys pert care and they were very difficult to manage. The hepatitis B patients were cross-stigmatised, if sould use that phrase, because people didn't differentiate between hepatitis B and hepatitis C. Most people with hepatitis B were Asian, ninese in particular, where 10 or 15% of the Chinese appulation were hepatitis B positive. They had quired it from their mother at birth. They often here very sheepish coming to the clinic, because they bought all viral hepatitis was related to intravenous and use.
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11 12 13 14 15 16 17 18 19 20 21 22 23 24		hepatitis B was mentioned. I know that one or two people mentioned that but I can't remember what the outcome was to be honest. You anticipated what was going to be my final question before lunch, Professor Thomas, which was just about hepatitis B. Can I put it more generally than relating to specific conversations within the reference group that you may not recall? Work on hepatitis B has formed a significant part of your career over the years. Was the exclusion of people infected with hepatitis B from the Skipton Fund and Caxton Foundation something that ever came up in any of the discussions or meetings you had over the years with the Department of Health? No. I think it was mentioned at the reference group. As I say, I couldn't remember what the outcome was.	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	An els pa ex Thi I c diff	see but there was a stigma attached to that group of tients. And my nurses and my staff gave these guys pert care and they were very difficult to manage. The hepatitis B patients were cross-stigmatised, if sould use that phrase, because people didn't differentiate between hepatitis B and hepatitis C. Most people with hepatitis B were Asian, ninese in particular, where 10 or 15% of the Chinese equilation were hepatitis B positive. They had equired it from their mother at birth. They often be every sheepish coming to the clinic, because they bought all viral hepatitis was related to intravenous and use. Saying that, I spent a lot of my life looking the people with intravenous drug-related hepatitis. So I am not saying they shouldn't have required but I did think the hepatitis B patients were left.

Infected Blood Inquiry

1	I spent a lot of my life working on hepatitis C, but	1	lunch?
2	I spent all of my career well, the majority of it,	2	SIR BRIAN LANGSTAFF: Let's do that. So we will take
3	except for the last couple of years working on	3	a break until 2.05. 2.05, professor.
4	hepatitis B. I think it should have been much more to	4	A. That's okay. Yes.
5	the fore in some of these schemes. Some haemophiliacs	5	(1.04 pm)
6	did get hepatitis B.	6	(Lunch break)
7	The other thing to point out, though, in	7	(2.05 pm)
8	relation to hepatitis B and hepatitis C, if you got	8	MS RICHARDS: Professor Thomas, I am going ask you next
9	hepatitis B as an adult or even as a toddler, as many	9	about some aspects of your early involvement with
10	haemophiliacs did, then you had an 80 or 90% chance of	10	issues relating to non-A, non-B hepatitis and
11	getting a circumscribed acute episode with recovery,	11	hepatitis C.
12	whereas the converse was true with hepatitis C. 80%	12	If we could go, first of all, please, Soumik,
13	got chronic infection and all the downsides of risk of	13	to RLIT0001242.
14	cirrhosis and what have you, and liver cancer, related	14	You will see, Professor Thomas, this is
15	to the chronic infection. So I think that may have	15	"Unresolved problems in Haemophilia". And if you go
16	been part of the explanation, although not the	16	to page 3, we can see these are the proceedings of
17	justification, of why the hepatitis B group were left	17	an international symposium held in Glasgow in
18	out, really, but they used to come to our joint	18	September 1980, and you are one of a number of
19	hepatology clinic that we ran at the Royal Free with	19	speakers and attendees.
20	the haemophilia group there with Professor Kernoff and	20	If we can then go to let's find the page
21	CO.	21	I think it is page 33, Soumik.
22	MS RICHARDS: Sir, I note the time. I am going to move on	22	We can see this is a short paper authored by
23	from the financial support schemes now to ask	23	you, Dr Bamber and Dr Kernoff, "Clinical,
24	Professor Thomas some more general questions relating	24	immunological and histological aspects of non-A, non-B
25	to hepatitis. So perhaps we can pick that up after	25	hepatitis in haemophiliacs". I may come back to
20	97	20	
	91		98
1	a couple of your publications around this time in	1	"It is really now a question of how long
2	a little while, but we can see this is the paper	2	just because we have not seen it in this six-year
3	presented at the symposium.	3	period, it does not mean that it will not happen.
4			I think the thinking is that it takes ten or twenty
•	vynat i want to do is take you to the discussion	4	
5	What I want to do is take you to the discussion at that followed the presentation of the paper. We	4 5	vears, or even thirty years, for these lesions to
5 6	at that followed the presentation of the paper. We	5	years, or even thirty years, for these lesions to
6	at that followed the presentation of the paper. We can pick that up at page 42. We can see a question	5 6	progress. I think we have to realise that these are
6 7	at that followed the presentation of the paper. We can pick that up at page 42. We can see a question being posed by Professor Stewart about active	5 6 7	progress. I think we have to realise that these are young patients, with many years ahead, when we are
6 7 8	at that followed the presentation of the paper. We can pick that up at page 42. We can see a question being posed by Professor Stewart about active hepatitis and the question is posed, in particular:	5 6 7 8	progress. I think we have to realise that these are young patients, with many years ahead, when we are considering the significance of these lesions."
6 7 8 9	at that followed the presentation of the paper. We can pick that up at page 42. We can see a question being posed by Professor Stewart about active hepatitis and the question is posed, in particular: "What happens in the haemophiliac?"	5 6 7 8 9	progress. I think we have to realise that these are young patients, with many years ahead, when we are considering the significance of these lesions." Then you go on to contrast that with the
6 7 8 9 10	at that followed the presentation of the paper. We can pick that up at page 42. We can see a question being posed by Professor Stewart about active hepatitis and the question is posed, in particular: "What happens in the haemophiliac?" We can see your answer, and you say this:	5 6 7 8 9 10	progress. I think we have to realise that these are young patients, with many years ahead, when we are considering the significance of these lesions." Then you go on to contrast that with the situation in relation to chronic persistent hepatitis,
6 7 8 9 10 11	at that followed the presentation of the paper. We can pick that up at page 42. We can see a question being posed by Professor Stewart about active hepatitis and the question is posed, in particular: "What happens in the haemophiliac?" We can see your answer, and you say this: "The lesion of chronic active hepatitis, is	5 6 7 8 9 10 11	progress. I think we have to realise that these are young patients, with many years ahead, when we are considering the significance of these lesions." Then you go on to contrast that with the situation in relation to chronic persistent hepatitis, which would have a much better prognosis.
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A. Yes, I think that's spot on, really. I mean, it was one of the reasons for doing biopsies, because we knew by analogy with chronic hepatitis B that if you saw chronic persistent hepatitis, where the inflammatory calls were in the portal tracts and not going into the rest of the liver, then this was essentially a benign condition, whereas if you saw, as the name implies, chronic active hepatitis, then this -- the liver cells in and around the portal tracts would be destroyed and would be replaced by fibrous tissue, which would ultimately result in nodule formation and bands of fibrous tissue, which we call cirrhosis.

So the initial biopsies suggested that chronic

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

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

hepatitis B. You say:

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

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

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

Then you say this:

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

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

Then you say in the third paragraph:

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

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

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

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

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

Page 45, please, Soumik, of this.

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

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

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

Then there is a reference to the analogies with

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

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

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

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

(26) Pages 101 - 104

1		In fact, the percentage with cirrhosis,	1	(NANB) Hepatitis: A Controlled Blind Study". We can
2		I always remember it by saying: every ten years there	2	see from the bottom of the page it was accepted for
3		is another 10% who have cirrhosis. So, you know, when	3	publication August 27, 1981 and it was published in
4		some of the young people for instance, there was a	4	the Journal of Medical Virology in the course of 1981.
5		haemo plasmapheresis cohort in Germany who got	5	If we can just go up to the bottom of the
6		infected because of infected plasma, you know, when	6	page again, we can see what the study entailed:
7		that group of people, who were several hundred	7	"Liver biopsies from 12 patients with chronic
8		I think, would work through, then up to, you know,	8	non-A, non-B hepatitis, 7 with hepatitis B surface
9		20%, 30% would have cirrhosis. And a significant	9	antigen positive chronic liver disease, 1
10		number of those, as I have said, who were 2% to 3%	10	[hepatitis B] positive normal carrier, and 4 patients
11		per year at risk of liver cell cancer. And, something	11	with non-viral liver disease, were examined by
12		I haven't mentioned yet, 2% to 3% per year die of	12	electron microscopy for cytoplasmic and nuclear
13		liver failure and require the only treatment for	13	changes."
14		that is liver transplantation. So add all these	14	Then if we look at the introduction just
15		things up and it looks like a big problem on the	15	a little further down, you and your fellow authors say
16		horizon, not to mention the problem from the patient's	16	there:
17		point of view, because cirrhosis is not a pleasant	17	"Following the development of diagnostic
18		condition.	18	serological tests for hepatitis A and B infection, it
19	O	So that's September 1980, that symposium. Then I want	19	became apparent that there were additional unknown
20	uę.	to just ask you a little about a paper that you and	20	viruses causing hepatitis in man and these were been
21		others published in 1981.	21	named the Non-A, Non-B group"
22		Soumik, that's RLIT0000497.	22	So that's the background.
23		This is a paper which I think we haven't looked	23	If we can go over the page, I am going to ask
24		at yet within an Inquiry hearing. It's	24	you about the first patient group that you describe,
25		"Ultrastructural Features in Chronic Non-A, Non-B	25	under the heading "Patients and methods". You say:
20			25	106
		105		100
1		"Three patient groups were studied."	1	up.
		"Three patient groups were studied." The first is those with non-A, non-B chronic		up. These patients came in with significant liver
1 2 3		"Three patient groups were studied." The first is those with non-A, non-B chronic liver disease.	1 2 3	These patients came in with significant liver
2		The first is those with non-A, non-B chronic liver disease.	2 3	These patients came in with significant liver test abnormalities. The first thing we required to
2 3		The first is those with non-A, non-B chronic liver disease. Before I do that if we just look at the top of	2	These patients came in with significant liver test abnormalities. The first thing we required to know was whether it was an acute episode, having
2 3 4		The first is those with non-A, non-B chronic liver disease. Before I do that if we just look at the top of the page, just so we can understand the purpose of	2 3 4	These patients came in with significant liver test abnormalities. The first thing we required to know was whether it was an acute episode, having excluded hepatitis A and B, or whether it was acute
2 3 4 5		The first is those with non-A, non-B chronic liver disease. Before I do that if we just look at the top of	2 3 4 5	These patients came in with significant liver test abnormalities. The first thing we required to know was whether it was an acute episode, having excluded hepatitis A and B, or whether it was acute non-A, non-B, or whether it was already chronic
2 3 4 5 6 7		The first is those with non-A, non-B chronic liver disease. Before I do that if we just look at the top of the page, just so we can understand the purpose of this study and this paper, which is about ultrastructural features, there's reference there to	2 3 4 5 6 7	These patients came in with significant liver test abnormalities. The first thing we required to know was whether it was an acute episode, having excluded hepatitis A and B, or whether it was acute non-A, non-B, or whether it was already chronic non-A, non-B, with chronic active hepatitis, which
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1 turned out to be hepatitis C. non-A, non-B, with one with a short incubation and one 2 So what we wanted to do is to take biopsies 2 with a long incubation. So to get some other basis 3 3 where we knew the diagnosis, which was hepatitis B, for separating out the two, long and short incubation, 4 4 we needed another marker. So this was a study, and then take a similar number of biopsies, which had 5 5 really, to look at that issue -been done for routine care reasons and look at them 6 6 all under the electron microscope really to see how Q. Then if you --7 many had these changes, which at least in animals, in 7 A. -- and it turned out that these studies suggested it 8 8 chimpanzees, had been shown in the literature to be was a fairly uniform disease in most non-A, non-B. 9 9 due to non-A, non-B. Q. If we just look at the next page, and this relates to 10 10 It was a way, if you like, of showing whether the specific patient's group, of those with non-A, 11 this was one disease or several diseases and really 11 non-B hepatitis. Picking it up in the first main 12 trying to get at least on one basis a diagnosis. So 12 paragraph, so the second line on the page: 13 13 "Eight haemophilia and 4 nonhaemophiliac that's why it was done. 14 It turned out that these electron microscopic 14 patents underwent liver biopsies at between 6 and 36 15 changes, intranuclear particles and changes in the 15 months after either an episode of acute [non-A, non-B] 16 parts of the cell where proteins are made, called the 16 hepatitis (7) or the first detection of abnormal liver 17 17 function tests (5)." endoplasmic reticulum, these were similarly present in 18 18 human patients as they were in the animal studies, the Then we can see the results there: 19 chimpanzees, mainly from NIH in the United States but 19 "Four of the haemophiliac patients demonstrated 20 some done here in the UK, in the London School of 20 chronic active hepatitis ... and 4 chronic persistent 21 Hygiene. 21 hepatitis ..." 22 22 So it was really to see if we could get I appreciate the numbers are relatively small, 23 a histological basis for saying "This group have 23 as with all of these biopsy studies, but you have 50% 24 a type of non-A, non-B". At that stage the people in 24 with chronic active hepatitis there: 25 the United States said that there were two types of 25 "Of the 4 nonhaemophiliac patients, 1 had 109 110 1 [chronic active hepatitis] with cirrhosis, 1 [chronic 1 continue and represents a chronic lobular hepatitis. 2 2 active hepatitis] without cirrhosis ..." So chronic lobular hepatitis isn't that helpful 3 So again 50% of those four with chronic active 3 in determining who is going to go on to cirrhosis. It 4 4 hepatitis: is a group really where you need to integrate their 5 "... and 2 had chronic lobular hepatitis." 5 biopsy with the temporal sequence of what has been 6 Just so we don't get confused about terminology 6 happening to the liver function tests. Have 7 7 is chronic lobular hepatitis to be equated with I explained that all right? 8 8 chronic persistent hepatitis or is it something else? Q. Yes. Thank you. So in relation to this group of 9 9 A. No, it's a third condition. It means that eight patients, the biopsies showed 50% of them with 10 10 inflammation is distributed throughout the liver chronic active hepatitis; is that correct? 11 lobules. So the whole liver is full of cells. You 11 A. Yes, yes, yes. 12 can't tell acute lobular hepatitis from chronic 12 Q. I think we can see from the next paragraph that of 13 lobular hepatitis, apart from by knowing the temporal 13 those who were within the haemophiliac group of the history, in other words how long the patient has had 14 eight patients one had received only cryoprecipitate 14 15 15 but seven Factor VIII concentrate of a mainly an elevated transaminase, which would indicate that --16 16 if at some stage during that chronic elevation of the commercial source. 17 transaminases there has been a biopsy, and you see 17 I then want to ask you about two studies that 18 a lobular hepatitis, then that is chronic. If the 18 you have referred to in your report to the Penrose 19 patient has had abnormal LFTs for, let's say, two or 19 Inquiry. I am not going to ask you any detail about

> under a heading of "The changing perception of Severity of [non-A, non-B] hepatitis". Just pick it

> > 112

the evidence you gave to Penrose. Rather than look at

the underlying studies, it's probably quicker just to

PRSE0004640. If we go to page 9, please, this is

go to your report and take it from there. So it is

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three months and you see a lobular hepatitis, in that

time-frame you would say it is probably acute

hepatitis, but until you follow that patient, you

abnormalities for six months, that lobular hepatitis

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seen in the first two to three months is presumed to

won't know, because if he goes on to have

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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 11 12

Sherlock's book which you have already referred to. Then we see two studies there set out. One is a study of which you are a co-author, Bamber, Sherlock, Scheuer and Thomas, 1981, Journal of Clinical Pathology, "Clinical and histological features of a group of patients with sporadic non-A, non-B hepatitis". We have that if we need to look at but I think we can take it from here. You record that study as:

"... showing that biopsies from patients with chronic [non-A, non-B] hepatitis 'covered the whole spectrum of acute and chronic hepatitis and 1 patient had cirrhosis' ..."

Then you referred to a US study entitled "Non-A, non-B post-transfusion hepatitis: disaster after decades?" If we just go over the top, at the

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as present and you are there for Professor Dame Sheila Sherlock?

A. Yes.

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Q. Then if we can go to the third page, we just pick up the heading, in the top of the page "Non-A, non-B Hepatitis", we can see there:

"As previously reported the Department was anxious to encourage research directed towards establishing the extent of the problem in the UK and the development of tests for the agent(s) of non-A, non-B hepatitis."

There is reference to the medical research council's interest in relation to that. The next paragraph:

"Dr Dane proposed that clinicians should be reminded of the importance of reporting all cases of post-transfusion hepatitis including those which were hepatitis B negative."

Then there is reference to studies that Professor Zuckerman wants to undertake and then if we look at the penultimate paragraph in this section:

"Dr Vandervelde/Mrs Supran said that the arrangements for the notification of post-transfusion jaundice cases were deficient, as anicteric individuals do develop chronic liver disease and these

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top of the page we can see that is a 1982 publication. You say:

"... also reflected this changing view and pointed out that [non-A, non-B] was a silent and slowly progressive disease which ultimately did result in cirrhosis in a proportion of cases."

Without going to the detail of those two papers, is it fair to say what you were reporting and what was reported in the American publication in 1981 and 1982 respectively is essentially consistent with the message you had given at the symposium in 1980 and, indeed, the work from Sheffield and Professor Preston, published in 1978?

A. Yes, yes. They were all in accord really.

Q. Thank you. We can put that away. Next I am going to ask you just about a handful of the various working groups and committees that you were involved with in the late '70s and early '80s.

The first is the advisory group on testing for the presence of hepatitis B surface antigen. If we could go to CBLA0000931, we can see if we look at the top of the page this is "Note of the 2nd meeting of reconvened advisory group on testing for the presence of hepatitis B surface antigen and its antibody". The 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 RTDs [so regional transfusion directors] and hospital staff to the possibility of non-A, non-B hepatitis, and urge notification and reporting of suspect cases. sample materials being sent to Professor Zuckerman. Disseminating this information could be via medical journals, eg the BMJ and Lancet. This would be brought to the attention of Regional Transfusion Directors at their next meeting."

It would appear from this, Professor Thomas, that both the Department of Health and the specific attendees at this meeting were particularly concerned by this time, April 1979, about non-A, non-B hepatitis and keen to ensure that there was a proper notification of non-A, non-B hepatitis cases. Is that a correct understanding of what we see here?

A. Yes. Just to briefly re-state it, the only way we could record post-transfusion hepatitis before was jaundice screening, which was really the extreme end. So if the patient went yellow after a blood transfusion, then you knew they had post transfusion hepatitis. But, of course, we know that most cases of non-A, non-B hepatitis are anicteric, they don't cause

jaundice, and those cases wouldn't be picked up by

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Infected Blood Inquiry

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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,

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please, Soumik, the bottom half the page, we can see,

paragraph is an update from Professor Zuckerman about

the Medical Research Council Working Party. Then the

under the heading "Non-A, Non-B Hepatitis", the first

those meetings.

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Could we next go to a third working party, the Working Party on Post-Transfusion Hepatitis. That's NHBT0000068_049. So we can see if we look at the top

using radio labelled convalescent sera from haemophiliacs ..."

> Then further details given, and it says: "Further work was needed with this test."

Can you assist us with what the efforts were that were being made that you were involved with to develop and RIA test for non-A, non-B hepatitis? A. Yes, I did publish that data. It was from a Chinese

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second paragraph says this:

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

Then if we go to the last paragraph there: "It was agreed that all cases would be notified to the PHLS [so the Public Health Laboratory Service] as well ..."

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

A. That is correct, yes.

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

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

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

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

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where there had been a transaminase elevation. He prepared an immunoglobulin from it, which is the antibody containing a fraction of blood. Then he used that antibody to coat microtitre wells and then he took another specimen and produced the globulin from it and radio labelled that, in the hope that he would then have what's called a sandwich immunoassay.

He then went to the haemophilia patients. The antibody from one of the specimens was stuck to the microtitre plate. If the serum in that contains the antigen to which that antibody was reactive and then you put on the radio labelled antibody from another patient's residual serum, then you would see a signal, in other words, there will have been binding of the radio label. This he applied to, I think, I don't know, 50 or so from the haemophilia unit, 50 from the renal unit, 50 from my lab staff, 50 alcoholics, in the hope that he might be able to -- he might see a higher prevalence of the antigen in the groups that we knew developed non-A, non-B, and that would be the haemophilia patients. The renal unit also had a high proportion but we hoped not to see it in hepatitis A and hepatitis B or in alcoholics, nor indeed in the laboratory staff populations. This he found, he found that this antigen, which was being detected by these

undertaking work with Dr Janossy on diagnostic tests and working with Dr Dane on a radioimmunoassay test for non-A, non-B hepatitis. Are those all separate pieces of work?

A. No. They were all -- because I was developing new assays and trying to find non-A, non-B, I had a collaboration going with Dr Janossy in which we would try to produce most monoclonal antibodies to the components of hepatitis A and hepatitis B, so that we might improve on the existing assays which Abbott produced and which involved sheep antiserum produced by inoculating a sheep with, let's say, hepatitis B surface antigen.

In order to make that reproducible monoclonal antibody technology had been developed by Cesar Milstein. I had shown an interest in that, as had George Janossy, as Professor of Immunology. I purified viral antigens, in particular hepatitis B surface antigen and hepatitis B core. We immunised mice with those antigens and produced monoclonal antibodies, which are pure antibodies. Do you understand? Sorry, I am not being rude but do you understand the monoclonal antibody term?

Q. In fact, one of the questions I have been asked by Core Participants to ask you, which was going to be my

antibodies, was present in anonymised serum from these various groups.

Then we wrote that up in -- I have forgotten the publication, but you have got it -- which showed that, yes, there was an antigen in the patients from the haemophilia unit and the renal unit but not in alcohol or hepatitis A or hepatitis B cases. We thought "Well, this could be then a component of the non-A, non-B virus", which it turned out it wasn't actually. It was an antiglobulin, but that's why the experiments were done.

The experiments, as I say, were done with serum that was left after we had tested for hepatitis A and B, which was part of the diagnostic service that my laboratory provided in diagnosing non-A, non-B, excluding hepatitis A and hepatitis B. So we kept the residual serum from those cases, which was usually about half to 1 millilitre of serum in the hope they would be of use in the future. We would throw them out after six months when the freezer -- we had two freezers -- when those freezers became full. So that's what that study was about and I think it was Dr Luo -- L-U-O, I think -- of which you have his paper. I alluded to that assay in the Glasgow meeting.

Q. The documents from the early '80s also refer to you

next question, was if you could tell us what you mean by "monoclonal antibodies"?

A. Well, what Mr Milstein showed, with Greg Winters, wh

A. Well, what Mr Milstein showed, with Greg Winters, who was at Imperial, and Alan Fish, if you immunise a mouse with, let's say, hepatitis B surface antigen, then that mouse will produce a heap of antibodies to different parts of the viral protein. So there might be 100 or 200 different antibodies all binding to different parts of the viral antigen. So you immunised a mouse with the antigen and then you took the spleen cells from that immune mouse and fuse them in a myeloma cell, which is a malignant antibody producing cell. Then the progeny from that fusion, so-called hybrids, would have the joint function of or the joint property of being malignant, so they kept on producing the antibody, and each hybrid would produce a different single antibody, because we cloned them

So monoclonal antibody is a malignant cell line producing 100% pure antibody to a particular epitope. An epitope is just a part of an antigen. Remember, I just said an antigen might have 100 or more epitopes, fragments of the antigen to which the antibodies bind. Those antibodies are very useful to produce radioimmunoassays or enzyme immunoassays.

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

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

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

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

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

You probably know that the Blood Transfusion

story.

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

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

A. Right.

A. Well, as well as producing antibodies to hepatitis B surface antigen, which is the envelope of hepatitis B, we also produced antibodies to what is called the core, the centre of the hepatitis B virus. We then were able to -- it doesn't matter the detail -- but we produced that monoclonal antibody to produce a very sensitive and reproducible assay to mention antibody

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

to hepatitis B core. Everybody who was infected, either acutely or chronically, and the acute ones that get better, all of this group will have antibodies to hepatitis B core, okay? So it was a good indication

22 self-cured or persistent -- for hepatitis B.

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

of infection, acute or chronic, cured or persistent --

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

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

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

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I gave him the telephone number of Peter Karayiannis, who was an academic colleague in the department, telling -- or asking Brian McClelland to bring him if he wanted to take up that offer, and Peter would have sent him the antibody. But I think for some reason or other it didn't happen. Q. You said in the statement that your view was that anti-HBc and ALT surrogate, non-A, non-B screening of blood donations should have been introduced. Is that correct? A. Yes. I thought it was -- we should have introduced it. But at least we should, having heard the counter argument, which we were going to get a lot of false positives -- which was reasonable -- I mean, I took that on board. I thought that it could be reasonable

That's why -- if we could reduce the cost with free anti-core, which was the expensive component of that trial, then it might make it more plausible -- or possible, rather, not plausible.

post-transfusion non-A, non-B, and then we could work

then to do a trial, just to see how many units we lost

and whether we did reduce the incidence of

on a much better basis.

Q. Then can I then just turn to the question of screening for hepatitis C once an antibody assay was available?

"In this paper, the argument for 'Blood transfusion services should have begun screening for hepatitis C when an" -- if we go to the top of the next column -- "antibody assay first became available' will be developed by examining what is known about the serology of hepatitis C to determine (i) how many donations would be excluded by screening for anti-C100, (ii) how many cases of [post-transfusion hepatitis] could be avoided by eliminating blood products positive for anti-C100 and (iii) how many cases of [post-transfusion hepatitis] would not be prevented by such a screening programme."

I am not going to go through the detail of the arguments, but we just pick up your conclusion, bottom of the next page. Under the heading "Conclusion", very bottom of the page:

"The introduction of an HCV screening programme for blood products using the anti-C100 assay would cost about £6-25 million/year, would result in the loss of", top of the next page, "12,500 to 25,000 donations/year and prevent between 2,500 and 5,000 cases of [post-transfusion hepatitis] per year.

Between 1,250 and 2,500 cases of chronic liver disease ... [per] year and 250-500 cases of cirrhosis/year could be prevented, but a similar number of cases

I am going to direct your attention to an article you wrote with a colleague, Dr Brown. It is NHBT0088770.

This is published in Medical Virology. It is entitled "Blood Transfusion Services Should Have Begun Screening for Hepatitis C When an Antibody assay First Became Available". For, so in favour of that proposition, Dr Brown and you. And then against, Dr Barbara from the Colindale Blood Transfusion Centre.

Then if we can just look at the bottom half of the page, I want to pick up in the left-hand column, three paragraphs up from the bottom it says:

"In the early 1980s it was shown that the incidence of [non-A, non-B hepatitis] could be almost halved by the exclusion of donors with antibodies to hepatitis B core ... or abnormal liver function tests ..."

I think that was the issue you were addressing a few minutes ago. Then:

"The presence of these surrogate markers for [non-A, non-B] hepatitis resulted in a loss of only 4% of the donors."

Then you refer to the identification in 1989 of the hepatitis C virus.

Then you say at the bottom of the page:

would still occur because of the 50% sensitivity of the test."

Then you go on to say:

"Patients with CLD [chronic liver disease] will consume NHS resources as they develop the complications of portal hypertension; the cost of 250 liver transplants is about £8.75 million. It would seem to us therefore that there are financial as well as ethical considerations in HCV screening. Clinicians tend to underestimate the magnitude of the problem as 75% of PTH cases are anicteric; if we are not doing everything possible to prevent NANB PTH we may find ourselves in a difficult situation when the first group of cirrhotics in the anti-C100 era become litigious."

Then we have Dr Barbara's counter argument in the rest of the article.

I think you said in your statement, Professor Thomas, you don't have really anything to add to that, but it is a perspective that we have not yet explored and I wanted to ask, in addition to publishing this article, whether you were involved in any meetings or discussions with the Department of Health or Blood Transfusion Service as to whether this screening should have been introduced?

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A. Well, it was my view that we should introduce it. I should say in the context of this article that I guess -- the editor of this journal was Professor Paul Griffiths, who was the Professor of Virology at the Royal Free, and he had just set up this journal and he was looking for someone to write in favour of this, as opposed to a member of the Blood Transfusion Service, whom he knew would be able to write against it. It was almost -- as I think I said at the Penrose Inquiry, this was the sort of adversarial format -- or, not an adversarial format but a --where -- a bit like barristers, you know. One would present one case, one aspect of an argument, I suppose

with populations of patients and economic issues.

So I thought it would be useful for Jonathan

Brown to work this through -- he was a registrar in my
department -- so I asked him to do this. We sat down
and talked about how we might do it and that's how it
came about.

Service and epidemiologists are much more concerned

the defence, and another would produce the defence

(sic), you know. So I -- because I was a physician,

individual patients, whereas the Blood Transfusion

and physicians in the main are interested in

hadn't been introduced and that we were going to wait until, I think, 1991, September, for the second generation assay, which had got rid of a lot of the false positives, which was more acceptable to the Blood Transfusion Service because they would lose a smaller number of units of blood.

And, you know, it's a proper concern, isn't it? That, you know, if you are involved in a blood traffic accident or you are going to have cardiac surgery, you will expect the Blood Transfusion Service to provide enough blood for you to get through that quite safely. So he presented the argument for that and I presented the argument for the number of patients who might die by not using the first generation assay. So that's the situation.

Clearly then it went internal into the health service and -- into the health service and someone somewhere decided that they wouldn't introduce it.

Q. The next and, for present purposes at least, the last lot of questions I have for you, Professor Thomas, relate to a study which Dr Kernoff was involved with and in which you were involved.

If I can pick it up in your witness statement at WITN3824007, and if we can go to -- can we try page 10, Soumik. Mine is in a slightly different

I can't -- I mean, there was this discussion, not only about ALT and anti-core screening, as I alluded to, which was in the context of blood transfusion, but there were discussions also on -- which I think I was present at -- you know, looking at whether we should go with the stage 1 or the first available assay of anti-core or whether we should wait for the second format, which was likely to be ready in a year and would get rid of a lot of the false positives.

So in answer to your question, this is how I felt about it. I thought it would be useful to work it through economically, because that would give solid facts, but there is an ethical issue as well, and Dr Barbara genuinely thought they would be losing large numbers of units of blood and they wouldn't be able to supply enough blood because of all the false positive blood that would be lost. I could see that argument as well. We were both friends and would we said, "Well, let's do the best and write the arguments for and against", and that's what we did.

I mean, it must have been taken up subsequently, but I didn't hear any more about it, you know, as to whether it had been introduced or not at the time until it came through and it turned out it

format. Yes.

So if we pick it up at the top of the page, you refer there to a:

"... prospective study of 30 patients recording the incidence of abnormal LFTs and persistent abnormalities after infusion of cryoprecipitate, NHS factor VIII And IX or USA factor VIII concentrate ..."

Then you refer in brackets to the article itself:

"... (High risk of [non-A, non-B] after first exposure to volunteer or commercial Factor VIII ...)."

We will look at that in a moment.

Then you say:

"This was done because abnormal liver tests had already been reported in USA and it was important to know in each case whether the abnormality had been there before treatment in which case it would not be due to [post transfusion non-A, non-B] hepatitis ..."

You refer a little further down to the study being:

"... supervised by the Haemophilia Unit and Professor Kernoff states in the paper that the study was approved by the RFH Ethics Committee and all patients gave verbal consent."

You say your contribution, as a hepatologist,

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1	was to provide advice on management of the liver	1	Are you I don't know whether, as I say, you
2	abnormalities.	2	can assist with this, but if, as your witness
3	I am going to ask you to look at the paper.	3	statement suggests, this study was undertaken because
4	I have some questions I have been asked to ask you.	4	of concern over reports of abnormal liver function
5	I don't know whether you are going to be able to	5	tests from the USA, what was the justification for
6	assist with casting further light on this but you will	6	Royal Free Hospital patients being moved from
7	appreciate they are not questions I can pose to	7	cryoprecipitate to factor concentrates?
8	Dr Kernoff.		A. Well, I think the context of this was that I mean,
9	So if we go to PRSE0003439.	9	all the patients that went into this study had come
10	So this is the paper you have referred to in	10	into the haemophilia unit at the Royal Free either
11	your witness statement:	11	with a bleeding episode or, latterly I am not sure
12	"High risk of non-A, non-B hepatitis after a	12	whether the second group I am going to mention were
13	first exposure to volunteer or commercial clotting	13	involved here, but or, latterly, when Factor VIII
14	factor concentrates"	14	concentrates were used prophylactically. In other
15	And then we can see the authors there: Kernoff,	15	words, the haemophilia population found, you know, the
16	Lee, Karayiannis and you.	16	concentrates very patient-friendly, if I can put it,
17	Then we see the summary:	17	to a patient, but, you know because we didn't know
18	"After a first exposure to factor VIII	18	about any of the problems that were being transmitted.
19	concentrates, 9 [out of] 9 British patients treated	19	But, you know, if you had a painful haemarthrosis,
20	with USA-derived commercial products, and 10 [out of]	20	bleeding into your joint, which your doctors would
21	12 treated with British volunteer (NHS) products,	21	tell you would cause fibrosis and deformities, then
22	developed acute non-A, non-B hepatitis. Hepatitis	22	an injection of this material stopped that. And very
23	following commercial products was more severe, and of	23	soon after it was a natural extension of this to ask,
24	shorter incubation."	23	"Well, if we took this three times a week, would it
25	Et cetera.	2 4 25	
20		25	prevent having haemarthrosis and muscle bleeds and
	137		138
1	things?" So these young, in the main, boys, in the	1	episode, they would be in the middle of the night
2	first few years of life, could then actually play and	2	often they would be given concentrate. And I think
3	develop normally as normal children.	3	what Peter Kernoff decided to do, with the agreement
4	So the use of these concentrates at this stage	4	of the ethics committee and the consent of the
5	was very important. People wanted to have them.	5	patients, randomly allocate them to whether they
6	I think what shouldn't have happened, and the	6	received NHS or commercial material. And they were
7	haemophilia directors, of which Peter Kernoff was one,	7	also following transaminases at this time, to see
8	had argued that only if you had severe haemophilia,	8	whether, you know, patients did get ALT abnormalities,
9	with virtually I am not a haemophilia doctor	9	and essentially virtually 100%, whether it was an NHS
10	virtually a total deficiency of the Factor VIII in	10	concentrate or commercial concentrate, got
11	your blood, would you need these concentrates. If you	11	abnormalities.
12	had mild haemophilia, you could be treated with	12	That was predictable in a way, because the
13	cryoprecipitate, which was derived just from	13	incidence of hepatitis non-A, non-B was something like
14	eight units of blood. And already it was known that	14	0.5% in human in British donors and about 2 or 3%
15	the risk of getting non-A, non-B hepatitis after	15	in American commercial donors. And since something
16	cryoprecipitate use was much less than if you used	16	like 1,500 litres or donations of blood were used for
17	concentrates. And there was an agreement with the	17	each preparation, every single preparation would be
18	haemophilia directors that you know, what the	18	expected to contain the virus. And indeed this is
19	cut-off would be, which patients would get	19	what turned out to be the case.
20	vasopressin, which released any remaining Factor VIII	20	So what this study showed, in patients who
21	globulins from the patient's liver cells, or could be	21	should have all had severe Factor VIII deficiency
22	treated with cryoprecipitate rather than the higher	22	and I don't know whether any of them are there any
23	risk concentrates.	23	in the list of patients who had mild disease? Because
24	Of the group who had the more severe	24	if there were, then those people shouldn't have had
25	haemophilia, when they came in with a bleeding	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 24 25

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

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

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

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

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

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

- Q. You said, Professor Thomas, that Dr Kernoff discussed matters with the patients and consent was given. Do you have any first-hand knowledge yourself of what was said to the patients who were participating in this study?
- A. No, but -- I mean, Peter Kernoff was an obsessive individual. I mean, he ran the unit with a rod of iron. And the reason occasional patients may have got concentrate when they should have had cryo, if it was mild haemophiliacs, was related to the fact he would set up the rules and the patients who came in in the middle of the night would be looked after by a registrar or a haemophilia nurse, who would be, in the middle of the night, looking for a concentrate in

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

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

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

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

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- A. So that was the background to all of that. And the trial was successful in the non-haemophiliac patients and that was published in the British Medical Journal.
- Q. Just sticking with the study that we see here, as a hepatologist involved with this study, was it your expectation that the patients who were being enrolled in it and participating in it should have been advised of the risks of developing non-A, non-B hepatitis from the factor concentrates with which they were going to be treated?
- A. Yes. I mean, these patients were drawn from the haemophilia clinics, and I think Peter and Christine say that they were asked for informed consent and the ethics committee of the Royal Free were asked to comment on it. Does it not say that in that text?
 - Q. It says they were asked to give consent but doesn't provide full details of what that consent process would have entailed.

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

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

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

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

That is quite a complicated issue really, and

22 . 23 **Q**. Y

Q. Yes. I am not going to be asking you about HIV. Just two further questions in relation to this study. Do you recall how soon after the commencement

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patients who were being asked to participate in the study to have included an explanation of the high probability, if not near certainty, of developing 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.

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

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

- 3 A. You mean after this --
- 4 Q. In the course of this study --
- 5 A. Yes.
 - Q. -- how soon after the study commenced were abnormal liver function test results being reported to you? 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

with haemophilia might be immunosuppressed, one of

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

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

12 Q. As it became -- sorry.

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- A. So that was my role, to look at what was happening andwhy the patients had got abnormal ALTs.
- Q. As it became apparent that the patients enrolled in this study were developing post transfusion
 non-A, non-B hepatitis, was it, in your view, ethical to continue with the study?
- A. Well, luckily I wasn't involved in that situation.
 I suppose if they were seeing an equal incidence of
 abnormal transaminase in both groups, then I don't
 know -- was this -- I have forgotten now. Was this
 blinded; in other words, did they know which group
 were getting which product?
 - Q. I am afraid I don't know without checking, professor,

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

- A. Well, it wouldn't have been of value. Had they had abnormal ALTs before, then you wouldn't have been able to determine anything.
- SIR BRIAN LANGSTAFF: The object of the study is to take people who had not shown any signs of non-A, non-B hepatitis and administer to them a product which it was hypothesised might give them less hepatitis if it was NHS-made and give them a lot more risk of it if it was commercial, on the basis that probably one or the other would provide it. There would have to be some therapeutic reason for the treatment.

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

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

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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.

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

- Q. That's the inference, professor, yes, not least
 because these are patients who were being exposed to
 concentrates for the first time, as the study tells
 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?
- A. Well, presumably. Did they have ALTs beforehand?I think they did.
- SIR BRIAN LANGSTAFF: Well, if they did and they were
 entered knowing that they were suffering from

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

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

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

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

21 MS RICHARDS: Yes.

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

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Infected Blood Inquiry

1		was to work out why they had abnormal liver function	1	you any further.
2		tests after these concentrates, and you might say	2	MS RICHARDS: Sir, those are the questions I have for
3		"Well, surely it would be obvious?", but, as I say	3	Professor Thomas.
4		and I think in other studies that were published at	4	We obviously need to give an opportunity to
5		this time, some patients had hepatitis B and C at the	5	Core Participants and their legal representatives to
6		same time. Some had hepatitis B and had delta virus	6	suggest any further questions arising out of
7		infection as well, and there were other patients who	7	Professor Thomas' evidence today. So if we could take
		had other, you know, problems. So, you know, we were		a break at this stage to enable me to receive and
8			8	•
9		trying to, at that stage, also look at patients who	9	consider any questions, and obviously to give
10		had persistent abnormalities to see whether or not	10	Professor Thomas a break as well.
11		they should have whether they needed a liver biopsy	11	SIR BRIAN LANGSTAFF: Yes, absolutely.
12		to determine this issue of whether they had chronic	12	Just by way of explanation, professor, there
13		persistent or chronic active hepatitis. In the main,	13	are quite a number of people who plainly aren't here
14		I think this was after we had already determined that	14	at the moment they are also remote who are
15		they had not had chronic active hepatitis, so I don't	15	watching, who are entitled to ask, through counsel,
16		think any of these did have liver biopsies. But you	16	questions which they have in their minds arising out
17		really need to ask the haemophilia unit what was going	17	of what you can say.
18		on. I saw them afterwards, after it had happened.	18	Counsel will receive and field those questions
19		But that's all I can say about that at the moment,	19	and ask those that are appropriate to you when we come
20		unless you want me to read it again, because I	20	back, which will be at 4.10.
21	SIR	BRIAN LANGSTAFF: No, no. I think you have answered	21	A. Okay. Thank you very much.
22		very fairly in saying that, in essence, the study was	22	(3.36 pm)
23		one which was organised by the haemophilia unit, and	23	(Short break)
24		we have already asked Professor Lee about this general	24	(4.10 pm)
25		area and about her study. So I think I don't trouble	25	SIR BRIAN LANGSTAFF: Yes.
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1	MS	RICHARDS: Professor Thomas. I have some various	1	which operated at the time treatment was given. These
1 2	MS	RICHARDS: Professor Thomas, I have some various guestions, so we will dot around from topic to topic	1 2	which operated at the time treatment was given. These
2	MS	questions, so we will dot around from topic to topic	2	policies changed over the period of the study"
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research reasons to see what the frequency would be, but also in terms of management of the patient, because there were lots of causes of abnormal AST, as I mentioned non-A, non-B being the main one but some people had hepatitis B and there were other causes, chemical toxicity in the liver.

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

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

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

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

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

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

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

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

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

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

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

"Hepatitis after blood transfusion was quite

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 --

- A. Sorry. The US study was the basis -- there was an NIH study, National Institute of Health study at Bethesda where I think that was -- well, Jay Hoofnagle was involved and they were looking prospectively at doing ALT screens after blood transfusion, the percentage that were abnormal, and I think it was around about 10%. The other name to pick up is Blaine Hollinger from Texas. He also did a post-transfusion hepatitis incidence study.
- Q. We can take that down. Thank you. The next question I am asked to ask you relates to stage 1 Skipton decisions, intravenous drug use. How would you have dealt with a case where there was evidence to suggest that there was a route of transmission through transfusion of hepatitis C, prior to evidence of intravenous drug use, and then evidence of intravenous drug use post transfusion? Is it the case that the record of intravenous drug use would still have been enough to lead to the claim being rejected?
 - A. I think if you could be sure that the hepatitis was noted before drug use, then, of course, you could say that it was due to the blood transfusion, but how you

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

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- **Q.** Was there ever in relation to Skipton decisions, whether stage 1 or stage 2, a policy of deliberately delaying or deferring decisions in borderline cases to see if the virus would progress or clear?
- A. No, I certainly didn't know of any instances of that really. Whether it was an acute episode -- 20 or 30% would have cleared -- or whether it was an established chronic episode, where 1% might clear after six months, you know, we never waited or -- we just took it at face value and looked at the statistical probability, but the former was much more common than
- Q. Still with stage 1 Skipton applications, I want to ask you about this hypothetical scenario. If you had an applicant who was known to have had a particular operation, if there was evidence of, say, 10 or 20% of

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

So that's the situation I took but, as a director of the Skipton, of course, we did get serial, you know -- at each yearly, Annual General Meeting of the Board of Directors we were given sort of things. So whether it has a subconscious effect, I don't know, but we didn't consciously go in to try to limit the spend.

from the applicant's own clinician setting out their view that the patient was cirrhotic, why was there ever a need to look behind that, rather than Trust the

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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 committee, I would have let it through. What I am 11 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

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

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

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

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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 1989/1990, that 20% or so of people cleared the virus, 4 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 former wouldn't actually have qualified by the rules.

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

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

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the same individual's spleen or liver.

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

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

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

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

- 21 A. Not that we are able to demonstrate.
 - Q. The next two questions, I think, relate to hepatitis B. As part of your work over the years on hepatitis B, did you come to any conclusion about the efficacy of the screening for hepatitis B that had

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

So, you know, that natural history of the serology was evident in the 1991/92 period and is the 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?

- A. In the general population or in the haemophiliac population?
- Q. I am afraid I am simply asking a question as articulated to me. So ...
- A. Well, perhaps let's interpret in as in the context of infected blood. I mean, all blood was screened for hepatitis B surface antigen from -- I don't know -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.

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

Q. I think that does answer the question, thank you. Did 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

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

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

MS RICHARDS: Sir, those are the additional questions that I am proposing to ask.

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

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

13 **A**. Yes

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

Hepatitis B wasn't identified until -- well, the

earliest, the Australia antigen, is about 1966.
Hepatitis C had to wait until 1988 and 1989 before there was any full record of what had been cloned in '88.

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

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

did transmit B as well as C. We wrote one such case
up. Another concentrate transmitted hepatitis B plus
delta and C. So there was all sorts of -- carrier for
all sorts of viruses in that concentrate, many of
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.

Do you think it is possible you may have been applying a scientific standard higher than balance of 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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SIR BRIAN LANGSTAFF: And infectious hepatitis is what we 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 65 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.

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

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

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1	at jaundice after their transfusions when the	1	casualties which are looked at in the Boer War and all
2	Americans had reverted to doing transaminases	2	
	afterwards.	3	these, it would say, you know: "Killed in action"
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4	SIR BRIAN LANGSTAFF: I was going to ask, at what stage	4	I don't know. Just for argument's sake:
5	did transaminases liver function tests come in,	5	" 10.
6	roughly?	6	"Killed by dysentery/infectious
7	A. Oh, you mean as being available in every context?	7	hepatitis: 100."
8	SIR BRIAN LANGSTAFF: As being used to determine what	8	So ten times more. So the outcome of these
9	problems of a hepatitic sort in the liver?	9	wars was purely dependent on, you know, how well they
10	A. I don't know the answer to that. They must	10	could keep their soldiers. You know, very few were
11	SIR BRIAN LANGSTAFF: We can find that out from somewhere	11	hit by bullets or whatever else.
12	else. But it was at some stage during the 50s	12	So I think, you know, they were very much aware
13	presumably, was it?	13	of all this, and I suspect there were transaminase as
14	A. Yes. I think it would be before probably before	14	well as those crude measures of jaundice being used at
15	the war actually, but they were still talking about	15	that time, but I don't know for certain.
16	serum and infectious hepatitis during the war. There	16	SIR BRIAN LANGSTAFF: The nature of hepatitis which might
17	were some major outbreaks in the soldiers in Singapore	17	develop after a transfusion, would that lead in quite
18	area, really massive outbreaks, and it was deemed to	18	a number of cases to cirrhosis?
19	be a major factor on who won any battle there, the	19	A. Yes. I mean, the big issue would have been, at that
20	number of soldiers that went down with hepatitis,	20	stage, how many are due to alcohol. But the fatty
21	infectious hepatitis, at that time, because of the	21	liver related to type 2 diabetes, which is in the next
22	terrible conditions. It was a major proportion.	22	year predicted to overtake alcohol as the major cause
23	If you go through my hobby is going through	23	of cirrhosis alcohol was before, the last few
24	reading the war plaques in the cathedrals, and if you	24	years, that was certainly thought to be the most
25	read them, most of the if you look at the	25	common cause.
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1	Hepatitis B in the context of the UK was pretty	1	SARS SARS-CoV-2. It is too long a name.

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Hepatitis B in the context of the UK was pretty unusual, but the Chinese, of course, as soon as the Australia antigen became available, they noted that 10 or 15% of their population were chronically infected with hepatitis B and they had acquired at birth from their mother. And since immunising at birth, the incidence of primary liver cell cancer, which is in the Far East mainly due to hepatitis B, that has gone down massively once the hepatitis B vaccine was used extensively. And the main cause of primary liver cell cancer now, reflecting the fact that the major cause of cirrhosis -- which is, if you like, the pre-malignant condition -- is now hepatitis C, because hepatitis B has been controlled by vaccination.

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We still do not have a vaccine for hepatitis C. It is same problem as we are having with this current pandemic. All of these viruses, hepatitis C and the Covid 2 virus, the SARS virus, they are what we call swarms of viruses. So with hepatitis C there may be, you know, 10,000 or 100,000 virus particles, all slightly different in their genetic structure. And as the immune pressure comes on the virus, then one or two virus particles will find they have an advantage, they can break through the natural antibody response or the vaccine response. And the same is true now of

That is a mixture of different virus particles, and when you apply an antibody immune pressure to the virus, you will select out variants, which is going to be our problem with the current vaccines and Covid 2. I don't want to be too pessimistic about it, but I think that will happen.

We were able to show this in the context of hepatitis C by looking at agammaglobulinemics. The envelope of hepatitis C varies massively over to hyper-variable regions, to variable regions in the envelope. This is in a person with a normal antibody response. But if you look at somebody with agammaglobulinemia, who can't produce antibodies, there is no variation in the envelope. So it is the patient's antibody response which selects out the variants.

The same will be happening with SARS-CoV-2. You know, as we put different antibody pressures on the virus, you will be selecting out different variants. And because we have a bigger proportion of our population immune now, then we are selecting out different variants, and hence we had the distinction of having the UK or Kent variants named after us, where we -- because we've had a lot of vaccine, we're

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1 seeing variants come through. outside the sexually promiscuous and intravenous drug 2 I must say, this is a retired armchair ex 2 users, then the transmission of hepatitis B is not 3 3 virology clinician's view of the world, so ... that great in the general population and, you know, 4 SIR BRIAN LANGSTAFF: Just taking that same retired 4 I think, therefore, at the earlier stage, probably 5 armchair clinician's view of the world, you mentioned 5 introducing a hepatitis B vaccine wasn't cost 6 6 a moment or two ago, and earlier you were asked by effective. 7 counsel questions about hepatitis B, you mentioned the 7 I think a lot of -- there is now a hepatitis A 8 8 effectiveness, at least so far, of hepatitis B plus B vaccine. I think, for instance, when 9 9 vaccine. That, as we understand it, was introduced university students are going on walkabout, you know, 10 only as a universal vaccine for children in this 10 on their gap year, then we recommend they are all 11 country in 2017. 11 vaccinated. So as behaviour changes, then the vaccine 12 Do you have a view or did you have a view as to 12 strategies change. 13 whether that, in line with your views about testing 13 SIR BRIAN LANGSTAFF: Thank you very much. That's all 14 for hepatitis C and surrogate testing earlier, should 14 I am going to ask. 15 15 have been introduced earlier? MS RICHARDS: Sir, I should have confirmed 16 16 A. Well, it was introduced in the medical and nursing Professor Thomas's counsel has no questions that she 17 17 profession, because it is -- the major incidence, seeks to ask. 18 18 I think, is related to blood contamination either Professor Thomas, is there anything further you 19 through needle use or because of sexual activity, and 19 would wish to add to your evidence? 20 I think we do have an extensive programme where people 20 A. Not really. I think -- I don't think -- I have had 21 attending sexually transmitted disease clinics are 21 three different experiences as a clinician really: 22 22 immunised against hepatitis B. That was something this one on non-A, non-B, where I did get the 23 that came to the advisory group on hepatitis that 23 impression that the NHS was short of money and was, 24 I was involved in. We pushed really to get control of 24 you know, trying to make it go as far as possible; and 25 that mechanism of transmission in our community. But 25 then, of course, I was on the new and emerging Virus 177 178 1 Committee when the Swine Flu thing started, and there 1 more on the health service so that there was a better 2 2 the mathematical modellers said we were going to lose level of preparedness really, but then you are going 3 millions of people and I think we lost about 18,000 in 3 to say, "What are you not going to spend money on?" 4 4 the end. The recommendation that I and others was So that's a problem as well, but otherwise I don't 5 involved in on this committee was we ought to buy 5 have anything to say. 6 a lot of drugs. There were two drugs which were --6 MS RICHARDS: Thank you. Sir. 7 7 SIR BRIAN LANGSTAFF: You described yourself just shortly might work against flu, and, of course, that didn't 8 8 come about. So the Department of Health bought a lot ago as a clinician first and a scientist second. 9 9 of drugs that they didn't need. I think certainly you have shown us a huge amount of 10 10 Then most recently I think, you know, it's been both sides of what you have to say, but you also have 11 a question of, you know, the vaccine versus drugs to 11 indicated a third side, which is I think demonstrated 12 treat people. I happen to be working in a little 12 by the lectures which you have told us you gave from 13 biotech company really making drugs for hepatitis --13 time to time, in which you explain some of the making drugs for SARS-CoV-2 with Porton Down, and, you 14 intricacies of science, and you have helped us to 14 15 15 explore some of those intricacies in a clear and know, again the focus has been on the vaccine and not 16 16 the individual really, but I think the driver to all helpful way and given us access to some of the 17 of this is that we have never been particularly 17 information which, if I can say, has probably filled 18 prepared in the UK, because we don't have any spare 18 a few gaps, for me certainly, and I am grateful, very 19 capacity in our hospitals, and this isn't original. 19 grateful, for that. 20 I mean, everybody has said this, and I think it was 20 You have told us, so far as the Skipton is 21 true right from the word go with non-A, non-B, where, 21 concerned -- given us the detail of how you saw your 22 22 you know, treatment was expensive and there were role and the way in which you applied what, to 23 23 financial constraints, and it is the same true today a lawyer, is familiar territory: the burden of proof 24 really, but otherwise money is always the root of the 24 on the balance of probabilities. 25 problems. I would like to see that we spent a lot 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	INDEX
2	experience of giving this type of evidence over	2	PROFESSOR HOWARD CHRISTOPHER THOMAS
3	a number of occasions. So thank you for being	3	(sworn) Questions by MS RICHARDS
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	Questions by SIR BRIAN LANGSTAFF
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	
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