

Friday, 2 October 2020

(09.58 am)

DR MARK WINTER (continued)

MS RICHARDS: Dr Winter.

SIR BRIAN LANGSTAFF: Dr Winter, you are still under oath.

Further questioned by MS RICHARDS

MS RICHARDS: Dr Winter, you'd been telling us yesterday about the decision that you made in relation to heat-treated products in the middle of 1984 and in your statement you say of that decision:

"No patient since that time was infected by any virus at our centre."

I just wanted to ask the basis upon which you are able to say that. In relation to HIV -- and you may well be right, I'm not seeking to challenge your conclusion -- what's the basis for your ability to be confident that no-one treated at the centre with heat-treated concentrates from May 1984 was infected with HIV? Because you weren't able to do the historic exercise because there were no stored samples under your predecessor.

THE WITNESS: Yes. So I mean, I'm talking about the major viruses that we were dealing with, hepatitis B, hepatitis C, HIV. I mean, of course that remark is in the context of, as we discussed yesterday, it turned

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on any sort of very solid science, and there are papers we may look at later which later than this date did show that heat treatment did indeed inactivate HIV, as the experimental work had suggested. But it also turned out, very importantly, that this first generation of heat-treated products, which didn't heat for very long or to a very high temperature, in the end did not seem to inactivate hepatitis C.

So this was the first time an attempt was made to make treatment safer, and we now know it did make treatment safer -- really importantly, for HIV -- but it turns out that if you did switch to heat treatment and you at that stage did not have hepatitis C, you might still have been vulnerable to get hepatitis C.

Q. You I think wanted to make some observations about the UKHCDO's publication, the AIDS Advisory Document, in December 1984.

We can put that on screen. Henry, it's HCDO0000270_007.

It should come up before you.

A. So it seems to me this is a really sort of important document because it's coming at this very critical time -- this is December '84?

Q. December 1984?

A. So most centres will have had their HIV results a few

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out that all but one of my patients had HIV already and all of them presumptively had hepatitis C already if they'd been previously exposed to concentrates in the years prior to that, and of course they were screened regularly for hepatitis B and they were vaccinated against hepatitis B.

So there was no patient in our centre and as far as I'm aware -- we were obviously particularly close to St Thomas' and their information as we were part of the same regional network, I wasn't aware of anybody becoming HIV positive or hepatitis C positive, subsequently, who'd previously tested negative at the time of the change. Of course, in that statement it's important to stress there were very few patients left who could seroconvert because most of them had been infected anyway.

I obviously in my statement -- that would not include sort of minor viruses like parvovirus, which we couldn't or didn't test for. I didn't know or wouldn't know whether the heat-treated concentrates transmitted that but that was a pretty low profile virus.

Of course it did turn out -- and this is an important point -- you will understand the reason for the change was based on theoretical concerns and not

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weeks prior to this. We spoke yesterday of the very unexpectedly high level of positivity which nobody had really expected. So there was this very strong sense amongst doctors like me suddenly it's apparent we're in a major health emergency in the haemophilia world, adjacent with what we already know about severe chronic liver disease, the evolving story; so now we have two major problems. This is isn't a minor thing, as some haemophilia doctors had predicted; this is going to be a major healthcare problem and how do we deal with it?

So this is not the whole of the haemophilia directors, this is the Reference Centre Directors. I don't know whether this is -- this could have been a scheduled meeting because they meet every three or four months, and they've got there -- where it says "in consultation", these are some blood transfusion experts and virologists and, in particular, they have got Richard Tedder and John Craske as virologists there.

So they start by reporting the current state of play, that there are three haemophiliacs, and then it stresses to haemophilia doctors the availability of the tests, which now also include the PHLS.

I mean, by now most of the centres should have

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1 done the tests but we know, I think, that that wasn't
 2 always the case.
 3 **Q.** We do know that, yes.
 4 **A.** Can you go next page?
 5 So then, as we've just been discussing, they
 6 then talk about this research evidence, laboratory
 7 evidence, that it seems like HIV might be susceptible
 8 to heat, some "spiked" concentrates. So what that
 9 means is that somebody's taken Factor VIII concentrate
 10 and spiked it in the laboratory with HIV and then
 11 heated it and then shown that the HIV is inactivated.
 12 So that's something that proved to be true. And
 13 then, exactly as I've been saying:
 14 "It is unlikely that this process completely
 15 inactivates Non A Non B hepatitis."
 16 Absolutely correct.
 17 Something we haven't discussed so far, another
 18 problem about heat treated was that you get less
 19 Factor VIII out of the manufacturing process. So not
 20 only was it 50 per cent more expensive but you lost
 21 a bit of Factor VIII in the manufacturing, which was
 22 another sort of slightly minor factor about switching
 23 to heat treated.
 24 Then it talks about the dry heat-treated product
 25 and tells you the price of it. And by now, since the

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1 here, so BPL is being rebuilt, all this money's gone
 2 into it, but it can only dry heat, at that stage,
 3 30 per cent of its output from January 30 -- these
 4 dates are really important. So this is about eight
 5 months after some of us have switched to commercial
 6 dry heat. BPL, eight months down the line, can still
 7 only dry heat 30 per cent but more coming, as
 8 promised.
 9 Then we know about Scotland.
 10 Then they talk about recommendations for doctors
 11 as to what they think they ought to do and, as you can
 12 see here, they're really -- where I'm talking about
 13 options in decreasing order of safety, they are still
 14 recommending concentrate. You know, the haemophilia
 15 directors never prioritised a switch back to
 16 cryoprecipitate at any stage, and in any case we know
 17 that there were not the supplies of cryoprecipitate to
 18 do that. But they do, under option 2, suggest that
 19 you could use some cryoprecipitate.
 20 **MS RICHARDS:** Just pausing there, Dr Winter, we are told
 21 this is in probable decreasing order of safety. So it
 22 does seem as though their first priority was the
 23 heated UK concentrate. But, as you already observed,
 24 comparatively little of that available at this time.
 25 **A.** Yes.

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1 Alpha, which is the one we used, had come in in the
 2 April and May, now you see that last paragraph, under
 3 Factor VIII, there are now several heat treated --
 4 these are all commercial, all American plasma, but all
 5 heated in various ways. There were two ways of doing
 6 it. There was dry heat or wet heat. I'm not quite
 7 sure what the difference was between dry heating and
 8 wet heating.
 9 **SIR BRIAN LANGSTAFF:** I think the difference, as
 10 I understand it, but you may not have understood it
 11 that way at the time, is that wet heat is pasteurised
 12 so you have the virus in solution. Dry heat is after
 13 the product has been freeze-dried and the heat is then
 14 applied to vials of freeze-dried concentrate. I think
 15 there is a third intermediate where the freeze-dried
 16 concentrate is diluted a bit in a solvent so it is
 17 somewhere in between the two. But those I think, as I
 18 understand it, are the three different production
 19 methods available at the time, if that's any help.
 20 **THE WITNESS:** Well, it is. You know a good deal more
 21 about fractionation methods than I seem to, so --
 22 **SIR BRIAN LANGSTAFF:** Well, I'm only taking it from what
 23 I pick up.
 24 **THE WITNESS:** That is very helpful.
 25 Now, the BPL, half way down or towards the end

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1 **Q.** Single donor cryo or FFP is then prioritised in order
 2 of safety, in this document, over imported heat
 3 treated.
 4 **A.** Yes. But we discussed all the problems around cryo
 5 usage and the very significant problems with it, and
 6 we've also discussed the supply problems, certainly
 7 in -- you know, the Tooting -- as we discussed, the
 8 Tooting centre could not put out supplies of cryo to
 9 any significant level, although, as you said
 10 yesterday, in other parts of the country like
 11 Southampton, supplies of cryo appeared to be greater.
 12 But this is an important document because they
 13 are clearly saying to doctors -- reinforcing that it
 14 is better to use heated than unheated.
 15 **Q.** Yes.
 16 **A.** Because this is at a time when an awful lot of centres
 17 have not gone across to using heated. They are
 18 saying, as you would expect, that UK concentrate
 19 heated, if you could get it -- a key phrase -- was
 20 a lot better -- was better than heated imported.
 21 This is a snapshot in time. All this is going
 22 to change radically over the next few months.
 23 Then, again, these key phrases at the bottom:
 24 "Concentrate is still needed; bleeding is the
 25 commonest cause of disability and death."

1 So we've heard of these calls: why could
2 Factor VIII therapy not have been suspended? Well, in
3 the view of the clinicians, it could not have been.
4 They used DDAVP, we've talked about already -- can we
5 go on to -- and then they talk about what used to be
6 called the "virgin" -- the PUPs, how to treat them.
7 That's pretty uncontroversial. And then the using
8 heat treated, and then for haemophilia B -- I'm just
9 reading.

10 The evidence lower down:
11 "The evidence that heated US Factor VIII is
12 safer than unheated NHS is debatable ..."

13 So this was at the core of the argument.

14 After all the things we said yesterday, I got
15 home last night and I remember a meeting --
16 Professor Bloom said to Dr Savidge and I, "You are mad
17 to switch. There will never be HIV in BPL
18 Factor VIII."

19 **Q.** Can I just ask you -- it's very useful evidence to
20 know. Do you have any recollection roughly when that
21 meeting would have been?

22 **A.** It was at a scientific meeting. It was outside of the
23 meeting.

24 **Q.** Yes.

25 **A.** He actually --

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1 sort of 10 to 12 with a totally opposite view. So for
2 the next few months there is this complete -- it's
3 like Brexit, okay, leavers and stayers.

4 **Q.** Then I think if we go on in this document -- well, in
5 fact if we just look there, it says:

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

12 And then the passage you referred to.

13 So it would appear from this document that
14 although this is much more detailed advice than
15 anything previously published by UKHCDO, the idea of
16 clinical freedom which you referred to yesterday still
17 appears to be represented in that passage; would you
18 agree?

19 **A.** Well, I would. I mean, if you read all the
20 haemophilia directors' minutes over the 10 or
21 15 years --

22 **Q.** I have.

23 **A.** -- the phrase "individual directors may wish to make
24 up their own minds" occurs again and again and again
25 and again. Now in medicine, of course, it's not like

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1 **Q.** In the course of 1984?

2 **A.** Yes, he actually -- when he learnt that we were going
3 to switch, he actually came up to us and said, "You
4 are mad to do this, it's completely unnecessary. You
5 know, this is not going to be a problem in BPL
6 Factor VIII", as we'll see from other correspondence
7 of Professor Bloom.

8 So there was this major, major split of
9 haemophilia directors, for all the reasons we talked
10 about. One camp saying, "I'm terribly worried about
11 this data. Haemophiliacs are so vulnerable. We now
12 know it's a virus. Increasing number of patients in
13 the US. Plus by now -- oh no, we don't have the
14 testing data yet -- but we're going to switch".

15 I mean, but we do have the testing data by the
16 time of this document.

17 Then this counter-argument, "This is only
18 a problem for American Factor VIII, it's not going to
19 happen in British Factor VIII. Look at the Germans,
20 they use twice as much as we do, they've had no
21 problems. I'm really worried about inhibitor
22 formation. I'm just going to monitor the situation".

23 So there was this split. Probably, in Britain,
24 20 major treaters, there was about, you know, four to
25 start off with and then a few more, and a hard core of

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1 that. You have standardised protocols which are
2 issued to doctors and they're expected to follow them.
3 But there was this sort of ambience, if you like, of
4 working as a haemophilia director where the function
5 of these bodies was a guidance, which -- steering you,
6 as they are, they are saying what we think, or what
7 the virologists think, but actually at the end, it's
8 down to you.

9 **Q.** I think you have also observed yesterday that there
10 was something in this document about testing, so
11 I don't know if we just carry on further down -- is
12 there anything before we go to the next page --

13 **A.** Yes, so --

14 **Q.** Is there anything before we turn to the last page
15 which deals with testing that you wanted to comment
16 on?

17 **A.** So I'm just looking at section 2 there. We spoke
18 about this, this 50 per cent jump in price and all the
19 problems that that caused. I think again that -- you
20 know, a number of directors would have looked at that
21 and said, "How am I going to get the money, you know,
22 at the start of an NHS financial year? I'm never
23 going to be able to do it". I think that was another
24 deterrent:

25 "Funding will need to be negotiated at local

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1 level ..."
 2 Correct. That's what it was like. I think we
 3 can go to the next page.
 4 So "Antibody testing":
 5 "It is recommended that patients be ... tested."
 6 It does not say anything at all about pre-test
 7 counselling. This was not a concept in clinical
 8 medicine at that time. Then it says, quite rightly --
 9 well, firstly it says:
 10 "... people should be informed ..."
 11 Quite rightly.
 12 Then the use of a very strange word:
 13 "reassured". On what basis did they feel able to say,
 14 "You are testing positive but there's nothing to worry
 15 about"? It seems an extraordinary word to use.
 16 "... counselled regarding transmission to
 17 spouses ..."
 18 Of course that's important.
 19 "This seems to be the most practical method
 20 available."
 21 So here we here, it's clearly saying for the
 22 first time to doctors: You must treat -- you know
 23 most people should have treated already, most of us
 24 had -- and this is the way to do it.
 25 Could we -- is there anything else later on?

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1 that had been there for a year and needed doing but
 2 from which he was not getting major symptoms, you
 3 would be inclined to say to him and the surgeon,
 4 "I really don't think we should go ahead at the
 5 moment. Your symptoms are not major, and I really
 6 think we should put it on hold for a few months and
 7 see what the situation looks like in a few months'
 8 time."
 9 So this was one of the devices, if you like,
 10 that would be used to minimise risk.
 11 **Q.** Now, we know that this document, which is dated
 12 14 December 1984, arose out of a meeting that took
 13 place on 10 December 1984. There is just one issue in
 14 relation to that meeting I wanted to ask you about, so
 15 I'm going to put that on screen. HCDO0000394_117.
 16 It's about the issue of telling patients the test
 17 results. I won't go through the thrust of most of the
 18 meeting. You can see there it was a special meeting
 19 that was arranged on 10 December 1984 to take place at
 20 Elstree.
 21 Henry, could we go to the fourth page, please.
 22 If we go towards the bottom of the page, second half
 23 of the page, after the reference to Dr Jones, there's
 24 a paragraph which says this:
 25 "A long discussion took place on whether persons

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1 **Q.** The rest of it deals with arrangements for the care
 2 of -- if we go on to the heading "Clinical", so it's
 3 personal protective equipment -- a topical issue --
 4 and arrangements for nursing.
 5 Could we just go to the very top of that page,
 6 please, Henry.
 7 We can see there at the top of the page there's
 8 also a point about assessing the need for elective
 9 surgery in the light of supplies of heated
 10 concentrate. This appears to be the first time that
 11 UKHCDO make any reference to that. I think you told
 12 us yesterday that, in your own practice, that was
 13 something you had already considered.
 14 **A.** Yes. I mean, all these changes are happening against
 15 a context of doctors trying to not use concentrate
 16 unless they had to. So you probably talk about
 17 prophylaxis programmes being suspended, making sure
 18 that patients were using concentrates in the home
 19 setting only when it was very strictly needed, making
 20 sure they absolutely understood when they should and
 21 should not be giving concentrate, avoiding concentrate
 22 in mild patients and von Willebrand's, as we discussed
 23 yesterday, and haemophilia carriers, and then also
 24 looking at surgery.
 25 You know, if you had a patient who had a hernia

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1 found to be positive were to be informed. Several
 2 differing views were expressed. It was agreed that
 3 each clinician would decide for each case depending on
 4 the facts of the case, but in general to provide
 5 information if asked for."
 6 Then if we go to the next page, please, Henry,
 7 halfway down there's a passage saying:
 8 "The Chairman [that we know was Professor Bloom]
 9 summarised by saying that testing should be instituted
 10 as soon as possible and that information on the test
 11 results should not be given automatically but if asked
 12 for."
 13 Now, that doesn't appear to have made its way
 14 into the advisory document that we've just looked at,
 15 but just looking at this, I think it follows from
 16 everything you told us yesterday that you would, at
 17 the time, have profoundly disagreed with the view
 18 being expressed here, that it was for a clinician to
 19 decide in every case whether to communicate the
 20 results of the test to a patient. Your view, as I
 21 understand it, was that absolutely every patient
 22 needed to be told?
 23 **A.** Well, I would have very strongly disagreed if I'd been
 24 at that meeting. I mean, I think if a patient has
 25 a blood test, they need the results of it told to them

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1 as a matter of right. But, secondly, there's all the
 2 implications about possible sexual transmission. So
 3 it seems inconceivable, frankly, that a group of
 4 doctors could sit around a table and say, well, you
 5 don't really need to give the results unless the
 6 patient asks for it. I mean, you know, 30 years down
 7 the line, this seems an utterly bizarre meeting.

8 **Q.** You rightly mention the health implications, in terms
 9 of the risks of sexual transmission, if a patient is
 10 positive but does not know. Presumably, in the
 11 context of patients with bleeding disorders -- these
 12 were the cohort of patients being discussed here --
 13 there were further possible health implications -- if
 14 you are having a bleed and a member of your family is
 15 helping dealing deal with that -- transmission of HIV
 16 through that route?

17 **A.** Of course. I'm not sure, by the way, looking at who
 18 was there, why they've got so many BPL people there.
 19 That's an unusual thing to do, to have people from
 20 a company at a meeting of the Reference Centres,
 21 unless there was a major agenda item about BPL
 22 expansion or something.

23 **Q.** I think not specifically, but that may be an issue
 24 that we will need to explore with those who were there
 25 in due course.

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1 is what I think, I'm your doctor."
 2 I mean, many of the patients I had this
 3 conversation with, when I said, "What do you think?"
 4 they said, "You're the doctor. I expect you to tell
 5 me what to do". Now we're in a different world where,
 6 quite rightly, this is a car being driven by patients.
 7 But there was passivity in the air, to a certain
 8 extent.

9 Remember, these people, it's congenital disease,
 10 inherited disease. From their earliest memories of
 11 coming to a hospital, somebody in a white coat gives
 12 them an injection that stops them bleeding, they were
 13 a very different -- by and large, a very different
 14 group of patients, from gay people with HIV who
 15 I looked after who tended to be much more --
 16 I generalise, of course. But, you know, the gay
 17 patients with HIV changed the nature of practice in
 18 the sense that they, in many ways, were a new
 19 generation of patients who came along to doctors,
 20 quite rightly, and said, "Hang on a minute. This is
 21 my life, my illness. I want all the facts, and I want
 22 to do all the decisions," all of which is completely
 23 correct.

24 So I'm just trying to get across to you there
 25 were several patients -- when I had this conversation,

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1 Now, before moving on to events from 1985
 2 onwards, in terms of your own care of your patients,
 3 I want to ask you a few more questions about the issue
 4 of consent and provision of information to patients,
 5 and then a number of questions which the
 6 representatives of Core Participants have raised with
 7 me to explore with you arising out of your evidence
 8 yesterday. So we will be going back to a few of the
 9 topics from yesterday, and then moving on to events
 10 from 1985 onwards.

11 Just dealing broadly with issues of consent and
 12 the provision of information to patients, would you
 13 accept that, as a matter of principle, whether to take
 14 the risks involved in a treatment -- and in this
 15 context, the risks would be the risk of developing
 16 liver disease, or the risk of being exposed to a new
 17 and potentially fatal disease -- or whether to take
 18 the risks of not being treated (which, as you pointed
 19 out in this context, could involve risks in relation
 20 to haemorrhage), that is ultimately a judgment for the
 21 patient; would you accept that?

22 **A.** Yes, but I've said to you already that was the choices
 23 I gave them, and they were choices. You know, okay,
 24 I said to them, "I'm your doctor. This is a very
 25 difficult time. We've got important decisions. This

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1 you can only say they were bemused. They said, "Well,
 2 why are you asking me? Because, you know, I've been
 3 a patient of yours a long time. I've been in the
 4 centre all my life. You know, I don't know what to
 5 do. I rely on you to tell me what to do." And
 6 I would say, "Well, I'm giving you the choice." And
 7 they would say, "Well, I'll do what you think I should
 8 do".

9 **Q.** That choice was so important to give in this context,
 10 and I understand indeed your evidence in particular in
 11 relation to the switch in the middle of 1983 is that
 12 you gave that choice to your patients. But the choice
 13 was so important, even judged against the standards of
 14 the 1980s, because it was their body, their health,
 15 their life, their death.

16 **A.** I agree.

17 **Q.** And, as you've just alluded to, in order to make that
 18 choice, they would need to be given information,
 19 potentially advice, potentially clear recommendations,
 20 but, at the very least, information by their
 21 clinician.

22 **A.** Isn't that what I said to you?

23 **Q.** Yes, absolutely. I'm just trying to establish, as a
 24 matter of principle, even in the '80s -- and we know
 25 that in many respects paternalism and so on --

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1 A. Oh, yes. This is nothing to do with medicine being
2 more paternalistic. These standards should have
3 applied then.
4 Q. Now, in relation specifically to testing now, not for
5 hepatitis C later on, which we'll come to, or HIV in
6 1984, but the array of blood tests that would be done
7 on what I think you described as the regular full
8 review that your patients would have. I'm not going
9 to distinguish here between Guy's and Margate, unless
10 you tell me that there were different practices when
11 you were there.

12 What were the tests typically that would be
13 undertaken at a regular review of that kind?

14 A. So these would be done about every three months as
15 part of a comprehensive care review, as we walked
16 about, and they would always include a check for this
17 inhibitor. So about 10 per cent of patients with
18 haemophilia develop this antibody which neutralises
19 the Factor VIII. It's a very important and negative
20 development. So that would be number one on the list,
21 would be an inhibitor test. We just do a general
22 blood count to make sure they hadn't become anaemic
23 because of bleeding. We might check their iron levels
24 if there was any suggestion that they had been
25 bleeding significantly. But we would check at that

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1 whether there were abnormal liver function results.
2 If there were, is that something you would expect to
3 discuss with your patient and explain to them the
4 significance or otherwise, as you then understood it
5 to be, of those results?

6 A. Well, yes. But, I mean, it's clear -- it was clear
7 then -- that nearly every patient who had had
8 Factor VIII concentrate from a commercial origin was
9 going to have this non-A, non-B. We had one patient
10 with hepatitis B, but nearly all the other patients,
11 if they were regularly treated, had abnormal liver
12 function tests, and they were aware of that. I told
13 them that, and they knew we were monitoring it, and
14 they knew about the concept of non-A, non-B. But they
15 knew there wasn't a specific blood test, and I would
16 say to them, and the Haemophilia Society would publish
17 that, you know, the presumption is you may have this
18 third virus, and one day we hope that we'd be able to
19 do the blood test.

20 Q. That would feed in then potentially to, as you said
21 yesterday, the lifestyle advice that you might give?

22 A. Yes.

23 Q. Would there be -- this is now talking about testing
24 more broadly; testing for whether it's HIV, or
25 hepatitis B, or obviously later hepatitis C. Can you

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1 stage, you know, depending on which date we're talking
2 about -- I think early 1980s hepatitis B vaccine
3 became available. So we'd be monitoring their
4 hepatitis B status, and if they were hepatitis B
5 negative and hadn't been exposed, didn't have
6 hepatitis B antibodies, we would be offering them
7 vaccine if it was available by then, and then we would
8 be screening them regularly to make sure that the
9 vaccine was still producing antibodies. So that's the
10 hepatitis B part.

11 Then these indirect markers for non-A, non-B --
12 we haven't got a hepatitis C virus to test, or level,
13 so we -- for every visit, we'd be monitoring their
14 liver function tests. But we now know, as we
15 discussed, that the differing results we got actually
16 didn't really help us because they weren't actually
17 a direct sort of predictor of what the state of the
18 patient's liver was like. We'd certainly be looking
19 at their liver function tests. I guess a general sort
20 of wellness check -- the body electrolytes and blood
21 sugar. That would be it.

22 Q. In relation to the liver function tests that you would
23 be looking at -- I mean, leaving aside the fact that
24 you may have learnt later that they weren't the best
25 predictor -- at the time, you were looking to see

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1 think of any circumstances in which you would have
2 thought it right to withhold that test result from
3 a patient for any significant period of time, unless
4 it was a patient who lacked mental capacity, but we're
5 not dealing with patients within that category.

6 From your own perspective as a clinician
7 publishing then, can you think of any circumstance in
8 which you wouldn't be telling a patient that they have
9 tested positive for HIV, hepatitis B or hepatitis C?

10 A. No, I cannot.

11 Q. Can I then just ask you -- these are just a handful of
12 questions about various consent issues as they emerge.
13 We know that -- and you referred to it yesterday --
14 centres sent data to Oxford at the time, later to
15 Manchester, and although we haven't seen it from the
16 documents we've looked at with you, Dr Winter, we've
17 seen from other documents that that data was not just
18 the material we looked at with the overall amount of
19 concentrate but really quite detailed information
20 about individual patients -- patient names, dates of
21 birth, status and so on, in terms of their treatment.

22 That was, as I understand it, material routinely
23 sent by centres to Oxford in the early days.

24 A. It was sent once a year.

25 Q. And that was at the beginning of each year?

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1 A. At the beginning of each year.
 2 Q. I'm not expecting you to be able to speak for other
 3 clinicians in relation to this, but in terms of your
 4 own practice, were your patients made aware by you or
 5 your colleagues that that data was being shared with
 6 Oxford and later with Manchester?
 7 A. The Haemophilia Society had said to patients in their
 8 publications, this data, it's extremely important that
 9 it should be centralised at Oxford, so we have
 10 a national database, and, you know, it's going to give
 11 doctors invaluable information about how many people
 12 with haemophilia did we have in the country, how many
 13 are severe, what percentage have inhibitors, how many
 14 are on home therapy, how many are on prophylaxis, how
 15 much Factor VIII is being used every year.
 16 They published -- you know, when you registered
 17 with the Society as a new patient, this was part of
 18 the information that was given as, you know, "welcome
 19 to the world of haemophilia"; this sort of activity
 20 does go on through the doctors. And they supported
 21 the doctors in that enterprise which was seen as being
 22 very important.
 23 Q. Yes, and I'm not seeking to criticise the exercise,
 24 just to explore what patients would have known about
 25 it at the time.

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1 Brighton, this book would be found, and the doctors in
 2 the hospital would be able to see it and know that
 3 they were a patient with haemophilia. So every single
 4 patient had this booklet, and it had their name and
 5 their registration number in it.
 6 Q. And so are you able to be fairly confident that your
 7 patients were aware that information about them was
 8 being sent on a regular basis to Oxford?
 9 A. I had that confidence for my centre.
 10 Q. One of the observations you made in your evidence,
 11 I think to both Archer and to the Penrose Inquiry when
 12 you were exploring the issue of different medical
 13 culture, clinical cultures of the '70s and '80s, you
 14 made some observations about the way in which
 15 haematologists of an older generation would have been
 16 trained, as compared to haematologists of your
 17 generation and onwards.
 18 Could you just explain to us, please, what the
 19 issue is that you were raising?
 20 A. Yes. I mean, this is an observation that came out of
 21 my Macfarlane Trust, which we may talk about later in
 22 the day, because I had -- my feeling is that I had
 23 insights that other doctors didn't get because I was
 24 having to interact through the Macfarlane Trust with
 25 every centre in the country. So my major role at

27

1 A. It certainly was not the case, obviously. The
 2 patients were not individually approached and asked to
 3 sign anything then -- which in later years they
 4 were -- nor, of course, were they asked to sign any
 5 consent to having Factor VIII. You know, we never --
 6 it was never considered necessary to ask a patient to
 7 give signed consent for that. All of that came later.
 8 Q. In relation then to patients knowing that information
 9 about them was being sent to Oxford for these various
 10 purposes, is it the case that -- did you work on an
 11 assumption that they'd have known that because of
 12 Haemophilia Society publications, or did you have any
 13 conversations yourself with patients about that?
 14 Because I'm conscious most patients may have been
 15 members of The Haemophilia Society, but not
 16 necessarily all, and not necessarily all would have
 17 read material provided to them.
 18 A. Yes. So each patient on diagnosis was registered with
 19 Oxford, given a designated code and was issued with
 20 a book -- a booklet, a small booklet like a diary that
 21 had their name, their UKHCDO registration number, and
 22 they were instructed to always carry this book with
 23 them wherever they went and, most importantly, always
 24 take it wherever they were because if they had a car
 25 crash one day whilst they were on a day trip to

26

1 Macfarlane Trust was: a patient who was a registrant
 2 of the Trust would apply for help -- I need a chair
 3 lift -- and my role was to contact the haemophilia
 4 director and ask for a report. You know, why --
 5 how -- please give the relevant background
 6 information.

7 Plus, you know, going -- running regular
 8 haemophilia residential seminars was a very powerful
 9 experience. You'd sit in a room on a Sunday morning
 10 with ten patients from different centres. You'd be
 11 talking about one topic, and you'd be utterly bemused
 12 by the different way in which ten patients could be
 13 treated by ten different doctors. I mean, it was
 14 astonishing, and something that will surely come out
 15 of this Inquiry is the great variability of care that
 16 patients received.

17 We've already heard how variable was the way in
 18 which haemophilia doctors arranged for testing. We've
 19 already heard about the variability in which
 20 haemophilia doctors told the patients their test
 21 results. We've heard about the variability of
 22 switching to safer treatment and I developed a view --
 23 you should ask this to the doctors that follow me.
 24 I know that some of them don't agree with this view
 25 which I've expressed previously, but I will say it as

28

1 follows: I did feel that you could split the
 2 haemophilia centres, obviously, into centres that were
 3 doing as well as could be expected in a very difficult
 4 time and centres that were doing things that just
 5 seemed inappropriate and not very appropriate. And,
 6 developing this theme, some centres, like St Thomas'
 7 and ours, their philosophy was: haemophilia's a very
 8 rare, complex, specialised disease. We want to know
 9 you, as a patient, every single thing that's happening
 10 to you. So if you've got earache you think it's
 11 nothing to do with haemophilia, but if you go to
 12 accident and emergency, somebody might operate on your
 13 ear without telling us and you'll bleed; or they'll
 14 give you aspirins which will bleed; or they'll give
 15 you an intramuscular injection which will make you
 16 bleed.

17 So we would say, we want to be the filter for
 18 every single thing. Don't go to any other doctor ever
 19 for anything without coming to us. We might say to
 20 you, okay, you've got earache. We'll fix for you to
 21 go and see somebody, and then we'll communicate. So
 22 that's philosophy number one.

23 Some centres, the attitude was: you'd ring up.
 24 I've got earache. Oh, it's nothing to do with your
 25 haemophilia. Go and see your GP. So, if you like --

29

1 first after qualifying. So I was the first -- I think
 2 it was the first year -- about ten of us, we wanted to
 3 be haematologists. We could not go straight into
 4 haematology after the six years of training. We had
 5 to do at least two years of general medicine, and we
 6 had to do this exam, the membership of the Royal
 7 College of Physicians.

8 So the importance of that was, in those two
 9 years, we were working as medical registrars. We were
 10 working with all the things that general medical wards
 11 bring: talking to sick people about very serious
 12 diagnoses; telling people they were going to die;
 13 being with people while they died. So, if you like,
 14 there was a group of us who, for the first time, were
 15 a group of doctors who dealt with the sort of problems
 16 that HIV suddenly brought. The older doctors were
 17 really good laboratory scientists. They were fine as
 18 haemophilia doctors dealing with the haemophilia.
 19 They'd got no experience of saying to somebody,
 20 "I have to tell you this test shows that you've got
 21 HIV, and this is a very serious thing, and your life
 22 might end," and then being with them while they got
 23 ill, and talking to the relatives and all the things
 24 that we've seen that didn't go well in some centres.
 25 So I make that observation.

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1 I don't know if there's a word in the English language
 2 that's the opposite of holistic. Some centres were
 3 holistic. Some centres were not holistic. When you
 4 broke it down, my -- I stress -- controversial view is
 5 that I thought you could, by and large, relate it to
 6 the nature of the doctors. It was down to the doctors
 7 in that centre.

8 And to eventually get around to answering your
 9 question, there was a very important change that
 10 happened in about 1973/74 in the way in which
 11 haematologists were trained. So, before that time, if
 12 you wanted to be a haematologist, you did your medical
 13 training. You did your houseman's year, and then you
 14 went straight into laboratory medicine. So you had --
 15 never had any time on the wards really working as
 16 a doctor.

17 You ran a haemophilia centre. You had patients
 18 who you spoke to about their haemophilia. If they had
 19 to be admitted to the hospital, they were admitted
 20 under a general physician whose name was at the end of
 21 the bed, and the laboratory doctor would go and see
 22 him. In 1974, quite rightly because haematology was
 23 becoming so much more clinical, the Royal Colleges
 24 said, we're completely changing training. If you want
 25 to be a haematologist, you have to do general medicine

30

1 But, you know, please do ask the same question
 2 to the other doctors next week who will probably think
 3 it's not true.

4 Q. I will.

5 There's then just one document I want to show
 6 you. This is a later document. It's from 1995.
 7 There's just an issue about consent that is discussed,
 8 and I just wanted to ask for clarification as to what
 9 you think the issue was. Henry, it's HCDO0000015_005.
 10 Go to the next page, please. It's a meeting in 1995,
 11 September 1995, of the centre directors. Dr Colvin is
 12 now the chair. We can see the bottom of that list
 13 there that you were present.

14 If we go then, please, Henry, to page 5,
 15 paragraph 8. You may have no recollection of this,
 16 Dr Winter, but you are the first person I can ask
 17 about it. It's under the heading "Consent for
 18 treatment". I'll just read it out:

19 "Dr Colvin said this matter had been raised at
 20 the Regional Directors' committee meeting. Agreement
 21 had been reached in principle to formal written
 22 consent for first treatments with concentrates and
 23 also that perhaps further consent should be obtained
 24 when there was a change in the product used for
 25 treatment. There was no uniform agreement about this.

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1 Dr Hill said that consent needed to be informed
 2 consent. He thought there was a need for a standard
 3 form. Dr Colvin said that the Executive Committee
 4 could prepare a form if required to by the AGM, but he
 5 thought it might be difficult as NHS trusts have
 6 differing policies. Dr Ludlam suggested the matter
 7 should be reviewed again [et cetera, et cetera].
 8 Dr Savidge said he felt that legal advice should be
 9 sought about this matter."

10 Then this:

11 "Some directors did not agree that written
 12 consent should be obtained as they felt that this
 13 could be held against them."

14 Then it says:

15 "It was agreed that the directors accepted that
 16 informing patients was important, but there was no
 17 agreement as to whether or not written consent should
 18 be obtained."

19 So we can see the context there is the issue of
 20 whether there should be written consent and standard
 21 consent forms in relation to treatment with
 22 concentrates, either for the first time or change in
 23 product.

24 But I wondered whether you were able to assist
 25 with the suggestion that some directors apparently

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1 process, legalistic formal process, but is a reality
 2 which depends upon the degree of information which is
 3 given and the relationship between the patient and
 4 doctor.

5 A. Yes.

6 **SIR BRIAN LANGSTAFF:** It might see the need for paperwork
 7 and signatures as being consent as simply
 8 concentrating on process rather than reality.

9 A. Yes.

10 **SIR BRIAN LANGSTAFF:** What would be your view on that?

11 A. Well, my only recollection is that, you know, if --
 12 I've not been aware of this view, to my recollection,
 13 and it's not really a view that I can find any empathy
 14 with. It seems to me, if I ask a patient to sign
 15 consent, that's a good thing for me as a doctor. It's
 16 saying, you know, if you like, I have explained this
 17 situation to the patient, and she's put -- or he or
 18 she has put pen to paper saying, "I agree to what
 19 Dr Winter is asking me to do."

20 **SIR BRIAN LANGSTAFF:** The critical thing about that might
 21 be that you had explained it to the patient.

22 A. Yes. That's what I mean.

23 **SIR BRIAN LANGSTAFF:** Rather than simply obtained the
 24 patient's signature.

25 A. Exactly.

35

1 expressed at this meeting that written consent -- they
 2 didn't agree written consent should be obtained as
 3 they felt it could be held against them.

4 Do you know what concern underpinned that? Why
 5 did people think written consent could be held against
 6 them?

7 A. No, I don't. I mean, I do remember these meetings
 8 because it was around this time, you know, with the
 9 changes of medical practice, we began to say as an
 10 organisation we should surely be, you know, getting
 11 signed consent at the start of each process. You
 12 know, when we get a new patient, they should give
 13 signed consent to comprehensive care passages. We
 14 should get signed consent for the first treatment, and
 15 we should get signed consent for the data that was
 16 being sent to Oxford, or then Manchester, and we
 17 should get signed consent for any change of treatment.

18 My recollection was that there was a sort of
 19 consensus but, as usual, there were a few outliers who
 20 had reservations. But I don't recall -- it doesn't
 21 seem intelligible, does it? Why should asking
 22 a patient to sign a consent form be a problem for the
 23 doctor?

24 **SIR BRIAN LANGSTAFF:** There may be a school of thought
 25 that thinks that consent is more than a question of

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1 **SIR BRIAN LANGSTAFF:** Yes, I see.

2 **MS RICHARDS:** Dr Winter, as I said a few moments ago, I am
 3 going to ask you now a handful of questions arising
 4 out of your evidence yesterday which are requests for
 5 clarification or a few further matters to explore that
 6 have been put forward by the representatives of Core
 7 Participants.

8 A. Can I ask you who are the Core Participants?

9 Q. There's a whole range of them. We have the largest
 10 number of Core Participants of any public inquiry,
 11 many of those who were infected, or their relatives,
 12 but also health bodies, Government departments and the
 13 like.

14 **SIR BRIAN LANGSTAFF:** Can I help? Essentially, it's
 15 a question of what's in the rules that govern
 16 inquiries, but a Core Participant is someone with
 17 a very particular interest in the inquiry, either
 18 because they have an interest in the outcome, or
 19 because they played a real part in what took place.
 20 Something along those lines.

21 **MS RICHARDS:** So the first matter I wanted to ask you
 22 about is just the developing state of knowledge, or
 23 the state of knowledge about risks from American
 24 concentrates and the basis for that, and then the
 25 developing state of knowledge about possible risks

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1 from British concentrates.
 2 You alluded to this yesterday and, as I
 3 understand it, there was a general understanding that
 4 American concentrates posed a risk, in terms of
 5 transmission of hepatitis viruses, because of two
 6 factors: pool sizes -- large pool sizes -- and the
 7 paid donors from whom the plasma might be collected.
 8 Is that right? That was the basis of the concern
 9 about the American concentrates.

10 **A.** Yes.
 11 **Q.** For that reason, your preference had been, as between
 12 the two, you'd rather use British concentrate than
 13 American, and you told us yesterday about the supply
 14 problems with Elstree and Tooting that meant there
 15 were shortfalls.

16 **A.** Yes.
 17 **Q.** Then when you were talking yesterday about the
 18 decision-making that you were then taking -- when we
 19 get to 1983 and 1984, you talked about there being an
 20 awareness, certainly for you and Dr Savidge and the
 21 other group who made this decision in 1984, that you
 22 couldn't assume that British concentrates were safe.

23 Could you just explain how that fear, that
 24 concern, developed? What was it that led you to
 25 understand that both sources might pose dangers,

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1 safe. And, of course, if I may say so, we were right,
 2 because it turned out that some British concentrates
 3 did transmit HIV.

4 **Q.** You have talked about how patients had a general
 5 preference for British over American if they could
 6 have that. What was the first time, roughly, you
 7 think that you would have explained to patients that
 8 British concentrates weren't necessarily safe? Would
 9 that have been when you were doing the heat treated --

10 **A.** Yes, that was -- you know, this was a conversation you
 11 always had at these seminars on the weekends. You
 12 talked about the nature of concentrates and where they
 13 came from and commercial and the need for
 14 self-sufficiency. These were a very, very regular
 15 sort of items that on a Sunday morning would be
 16 discussed in one of these workshops.

17 But the key moment for me was this switch to
 18 heat treatment because it was a reversal of the
 19 preferred system.

20 **Q.** Then, looking at the period in the late 70s/early 80s,
 21 where hepatitis is the main concern -- I think you
 22 were candid yesterday, you and your colleagues were
 23 not hepatologists, you were not virologists, you were
 24 haematologists. To what extent, in either Guy's or
 25 Margate, in this period up until sort of late

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1 rather than simply the American?

2 **A.** So let's use hepatitis C as an example and the
 3 knowledge that we later developed about hepatitis C.

4 So here we are. Here's this highly vulnerable
 5 group of patients because of the nature of the
 6 concentrate process. 20,000 donors. If one of the
 7 donors is positive, patients may get infected. So we
 8 now know that in the 1970s the incidence of
 9 hepatitis C in US plasma was, what, 1 per cent? So
 10 let's do the maths. If you were a British
 11 haemophiliac attending a British haemophilia centre on
 12 regular treatment in the 1970s after the concentrate
 13 had become available '73/'74, a doctor gives you an
 14 injection of Factor VIII from paid donors in America,
 15 1 per cent of whom have got hepatitis C, and it comes
 16 from 20,000 blood donors, you're probably getting
 17 maybe 200 different hepatitis infections.

18 We now know that the incidence of hepatitis C
 19 infection in British blood donors was much less than
 20 that but it was still about 1 in a thousand. So,
 21 instead of being exposed -- getting 200 doses of
 22 hepatitis C each injection, you might be getting 20,
 23 so -- which is no better than 200. So this was our
 24 major concern. We accepted that British Factor VIII
 25 was likely to be safer than American but still not

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1 70s/early 80s was advice sought from hepatologists or
 2 virologists by centres such as yours?

3 **A.** Well, it was sought. I mean, the UKHCDO, as you said
 4 yesterday, they did have a liver working party at that
 5 time, so they were doing those interactions and taking
 6 advice, and they would have passed down anything to us
 7 in terms of specific recommendations.

8 I think there was a feeling that, you know,
 9 hepatitis B we could identify and we knew about that,
 10 we were monitoring the liver function. We believed,
 11 at that time, that we could see whether somebody was
 12 clinically well, fine, and we had a belief --
 13 subsequently untrue -- that we could monitor
 14 somebody's liver function by looking at their poorly
 15 named "liver function tests", which don't, we now
 16 know, reflect liver function.

17 We had the theory, as we talked about, of non-A,
 18 non-B, and then the liver biopsy findings of
 19 Professor Preston. But there was no therapy. I think
 20 this is a key issue in answering your question. There
 21 was no great move at that time to have people
 22 automatically reviewed by a liver specialist -- that
 23 came later -- and that was driven by the advent of
 24 Hep C testing but most especially by the availability
 25 of treatment, because haemophilia doctors did not have

40

1 the expertise to make a decision, "Should this patient
2 have interferon?" which was the first of the hepatitis
3 treatments.

4 So no, I don't think there was. If I had
5 somebody who was jaundiced and who wasn't well and
6 their bilirubin was getting worse, I would, of course,
7 refer him to a liver specialist.

8 **Q.** When you gave your evidence yesterday, after I played
9 that first extract from the 1988 documentary, your
10 comment was that you didn't have any regrets about
11 having said that, and I have been asked by a number of
12 people to ask what you meant by that, about not having
13 any regrets about what you said. Was there some form
14 of criticism of you for making those comments?

15 **A.** You will have to remind me what I said.

16 **Q.** I'm going to have to remind myself. I think the first
17 extract was an extract in which you talked about the
18 knowledge about American concentrates and the
19 potential risks from an American concentrate and the
20 general state of knowledge in relation to that.

21 **A.** Yes. That sounds all right, doesn't it?

22 **Q.** Yes -- no, absolutely. I've been asked to ask you
23 what you meant by saying "no regrets"; do you mean
24 that's still your view?

25 **A.** I've listened to myself, looking much younger,

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1 have -- was it your assumption then, do you think,
2 that many or most of your patients had non-A, non-B or
3 was it just a concern that they might have?

4 **A.** I thought from the moment I -- you know, from about
5 '78 onwards, that every single patient of mine who had
6 had Factor VIII concentrate had Hep C, for all the
7 reasons we've just discussed about the risk of being
8 exposed to donors with -- you know, we had all this
9 data by this stage of infectivity rates of American
10 donors.

11 I mean, indeed, going back to Garrett Alan, the
12 late 1960s, of all the risks of commercial donations
13 compared with voluntary donations in the US. So I was
14 completely signed up at a very early stage that -- you
15 know, I was working on the assumption that any patient
16 who had had Factor VIII had Hep C or had -- had non-A,
17 non-B.

18 **Q.** I know when I asked you about this yesterday you
19 couldn't recall what you told patients about the risks
20 of that, although you agreed that they should have
21 been told but you couldn't recall what you'd said to
22 patients over 40 years ago. Do you recall whether you
23 told patients that you thought they probably had
24 non-A, non-B hepatitis? Did you use that term with
25 your patients --

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1 30 years later, and I've listened to what I've said
2 and I don't -- I haven't looked at it and said, "Oh,
3 I wish I hadn't said that."

4 **Q.** Thank you.

5 **A.** I'm, you know, obviously reassured to find that what
6 I said sounded reasonable.

7 **Q.** Then I just wanted to ask you about the phrase you
8 used yesterday and again this morning about
9 "presumptive non-A, non-B hepatitis". What did you
10 mean by that?

11 **A.** Well, again we've talked this. We didn't know -- we
12 invented that phrase but we didn't know what it meant.
13 I mean, we -- theory number 1, which turned out to be
14 true, was that it was just hepatitis C. But there was
15 a lot of talk about could it be several viruses. You
16 know, we subsequently got hepatitis E and whatever.
17 So we didn't know whether we were dealing with --
18 whether it was all one disorder or could it be
19 several, is what -- that's why I've used that word.
20 Because in theory it could have been one virus, Hep C,
21 or it could have been an array of viruses, all of
22 which were non-A, non-B.

23 **Q.** Was it your assumption by the late 1970s that -- and
24 I'm looking at what you knew at the time rather than
25 what you now know, with the greater knowledge that you

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1 **A.** Very much so, because we've talked about the
2 monitoring of liver function and part of that package
3 was to say to the patient, "As you know, you know,
4 your blood tests include these liver functions which
5 are abnormal and this is because, as you know, you
6 haven't got hepatitis B or A, you've got this third
7 virus". And in the early years that would have been,
8 you know, accompanied by a phrase, "You're very well,
9 and you're doing very well and I know you're very
10 pleased with the concentrate treatment and we're
11 monitoring it". And then later on, after the
12 Sheffield data, we'd have started to qualify that
13 with, you know, "We are looking significantly at this
14 because we're, you know, there's some evidence that
15 some people might be getting or might get sick in the
16 future with this hepatitis virus."

17 **Q.** I asked you yesterday about --

18 **SIR BRIAN LANGSTAFF:** Just before we move on, can I just
19 be clear about your use of your word "presumptive",
20 because it seems to me at the moment you may have used
21 it in one of two different senses or both.

22 In your answers to counsel, what you have said
23 is that it was presumptive non-A, non-B, presumptive
24 Hep C, because there might be other viruses, and so
25 one presumed it was an entity: non-A, non-B.

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1 Presumptive in that sense.
 2 The other "presumptive" was your reflection on
 3 what the patient might have, your assumption that
 4 whatever non-A, non-B was, one or more viruses, they
 5 had it?
 6 **A.** Yes.
 7 **SIR BRIAN LANGSTAFF:** Now which one was it or was it both?
 8 **A.** There's something going on with the loop system.
 9 I think you're --
 10 **SIR BRIAN LANGSTAFF:** My fault. Which one was --
 11 **A.** You've cured it. Yes, I've heard you. There's just
 12 a lot of interference suddenly.
 13 **SIR BRIAN LANGSTAFF:** My fault.
 14 **A.** No, that's fine.
 15 I think what I was trying to say to a patient
 16 was, "Your blood tests show a pattern suggestive of
 17 viral hepatitis. Number 1. 2, that hepatitis is not
 18 hepatitis A and it is not hepatitis B, so here's the
 19 presumption: you have a third type of hepatitis which
 20 we're calling non-A, non-B but we don't really know
 21 anything else about that virus or viruses at the
 22 moment."
 23 That was the presumption.
 24 **SIR BRIAN LANGSTAFF:** And the assumption was that most
 25 patients had it because they had had -- if they'd had

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1 frustrated about the nature of that link, because we
 2 had wanted and expected that that medical link would
 3 go back to the DoH and put a bomb under them
 4 basically. We expected they would go back and say,
 5 "There's a very serious situation in haemophilia and
 6 there are some very important things we need to do.
 7 One of them is absolutely putting as much funds as
 8 quickly as possible towards self-sufficiency, the
 9 other thing is making sure we've got communication
 10 networks open with transfusion centres and also that
 11 we're issuing appropriate directives to haemophilia
 12 doctors on a much more formal basis."
 13 So I think that all the time I was a haemophilia
 14 doctor by and large we were always very frustrated by
 15 the lack of DoH involvement. These doctors changed
 16 regularly. I'm sorry to say they didn't seem
 17 particularly interested or motivated. You know, we
 18 went to them with all sorts of issues: could we have
 19 more cryoprecipitate? We need more funding for
 20 concentrate. We want to switch to heat treatment.
 21 What's going on with self-sufficiency? Where's the
 22 recombinant Factor VIII? And each time the response
 23 was nothing like as dynamic or helpful as we would
 24 have wished.
 25 Again, Dr Colvin, next week, who was Chairman of

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1 commercial concentrates?
 2 **A.** Yes, on two bases. Firstly, for all the sort of
 3 statistical reasons we've discussed, if they had had
 4 Factor VIII it would be extraordinarily unlikely that
 5 they wouldn't have it. But then, secondly, if they
 6 had abnormal liver function tests for no other reason,
 7 they didn't have hep A or B and they weren't an
 8 alcoholic, that would make you even more certain.
 9 **SIR BRIAN LANGSTAFF:** Thank you very much.
 10 **MS RICHARDS:** I'd asked you yesterday about Chief Medical
 11 Officer guidance, and I'll come back at a later stage
 12 today to the absence of overarching guidance in more
 13 detail, but specifically in relation to Chief Medical
 14 Officer guidance, we know that, from time to time the
 15 Chief Medical Officer, for example, issued what were
 16 called "dear doctor letters".
 17 **A.** "Dear doctors", yes.
 18 **Q.** Was the expectation at the time that if the CMO issued
 19 a dear doctor letter that doctors would comply with
 20 whatever was being said?
 21 **A.** No, I don't think we worked at that level. I think --
 22 you see, we had -- the Department of Health had
 23 a doctor who was designated to attend UKHCDO meetings;
 24 so we had a link, a formal link. I think it would be
 25 fair to say we were always, I'm sorry to say, pretty

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1 the organisation, he would have had those links more
 2 closely than I, and I would wish to have his view.
 3 **Q.** I absolutely understand that as a matter of fact there
 4 was potentially limited guidance coming out of the
 5 Department of Health, but in general terms dear doctor
 6 letters from the Chief Medical Officer, were they, as
 7 far as you can recall -- I know there weren't any on
 8 the issues that we're talking about --
 9 **A.** Yes.
 10 **Q.** -- but were they generally materials that doctors
 11 would expect to comply with?
 12 **A.** Oh, very much so. If the Chief Medical Officer wrote
 13 a dear doctor letter and it was an area of medical
 14 activity that you were involved with, you would be
 15 expected to follow it.
 16 **Q.** Thank you.
 17 Then a very specific question about a particular
 18 form of test that we have seen some evidence that some
 19 patients underwent in 1983, possibly 1984. Some have
 20 recounted to the Inquiry in their evidence that they
 21 were given some form of skin prick test in the late
 22 1980s in relation, in some respects, to monitoring for
 23 signs of AIDS.
 24 Do you know what that would have been or is that
 25 a practice that you were familiar with?

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1 A. I'm not familiar with it. This seems to be something
2 very inappropriate but there's a -- you could test for
3 somebody's -- it was perceived that you could test for
4 somebody's immune function. There's a limb of immune
5 activity called cell immunity and, as I recall, you
6 could assess somebody's cell immunity by some sort of
7 patch test on the skin where you provoked -- like
8 allergy testing. The gay patients who had originally
9 presented with AIDS, they had some of these features
10 of suppressed immune function, hence the pneumocystis
11 pneumonia as well.

12 I've never heard of that being done for people
13 with haemophilia. It was not at all a good idea. It
14 was certainly not going to give you any accurate
15 information and it was certainly not going to tell you
16 whether you had this virus or not.

17 Q. Thank you.

18 Then moving to you taking up your post in
19 Margate, do you know why your predecessor,
20 Dr Sterndale, was leaving? Was it just routine
21 retirement or were there other --

22 A. Yes, he was retiring.

23 Q. Yesterday when you were talking about providing
24 information and advice to your patients who had tested
25 positive for HIV, you talked about the sexual health

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1 this wasn't an extra blood test, it was while these
2 routine bloods were being taken some centres -- I'm
3 sure without saying anything to the patient -- took --
4 just filled up an extra ampoule and froze it and held
5 it in deep freeze for long-term usage, for a research
6 purpose.

7 Q. Do you know -- and if you don't, please feel free to
8 say so -- but do you know whether any of those
9 research purposes included any work on development of
10 the hepatitis B vaccine?

11 A. I've never heard of that but I've certainly heard it
12 used for other purposes which we'll talk about.

13 Q. Which were what?

14 A. Well, Dr Kernoff's work. Do you want me to talk about
15 that?

16 Q. Yes, please.

17 A. So the Royal Free with 100 positive -- so let's go
18 back to where we started this morning: the balloon's
19 gone up; the world has changed; it's October 1984,
20 late October; the results are in. So at the
21 Royal Free -- you are going to get Professor Christine
22 Lee who was part of that team, you can ask her. They
23 have got at least 100 positive patients. At the
24 Royal Free, they did what we talked about. They had
25 stored blood.

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1 advice that was given, the risk of transmission, and
2 said that was the first time haemophilia clinicians
3 had to give such advice to their patients.

4 What about sexual transmissibility of
5 hepatitis B? Because that was known to be a risk. Is
6 that something you were aware of and had had to
7 counsel patients?

8 A. Well, I only had one patient who had hepatitis B and
9 I had spoken to him.

10 Q. About that, the sexual transmission?

11 A. Yes.

12 Q. Are you aware of any practice, in any centre of which
13 you have any direct knowledge, of taking blood samples
14 from patients with bleeding disorders for the purposes
15 of research into either the development of the
16 hepatitis B vaccine or any other forms of research?

17 A. I am aware -- I was taught by my professor at the
18 Middlesex always a good idea to take an extra vial of
19 blood and store it. You never know what it might be
20 useful. He did with that all of his patients. He had
21 a vial of Winston Churchill's blood, I remember.

22 That was a practice that was followed in a small
23 number of centres and, as in one particular instance
24 at the Royal Free, came to provide extremely important
25 information. But there were some centres that did --

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1 So the director at the time or co-director,
2 Professor Peter Kernoff, did the obvious thing in the
3 terms of he then retrieved from the deep freeze the
4 samples on all of the patients who were positive and
5 tested them for HIV. So this was an -- you can argue
6 about the morals and the ethics of he should have told
7 the patients he was doing it or whatever, but this was
8 a quite extraordinarily important exercise because
9 there were two very major observations.

10 Firstly, when he started to do the retrospective
11 testing, all his 100 patients positive in October 84
12 all of them had been positive for at least three
13 years. This was not a new virus in the blood supply:
14 this virus had been in the blood supply for three
15 years; the patients had been infected for three years;
16 if you extrapolate that to other patients round the
17 country, the haemophiliac (unknowingly) had not been
18 taking any precautions; the doctors and nurses in the
19 hospital had not been taking any barrier precautions,
20 they didn't know the patients had this unknown virus.
21 So that's was first extraordinarily important
22 observation.

23 The second extraordinarily important observation
24 was when he got as far as back I think as 1980/1979
25 the tests were negative. So this was the second --

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1 I can't stress the importance of this work. It told
2 us HIV seems to have entered the blood supply around
3 1979 to 1980. Now, this has got immediate major
4 references to Dr David Owen's initiative. I might as
5 well go on to say this now.

6 **Q.** Yes.

7 **A.** I might as well go on to give my whole sort of
8 overview of the virus changes over the years. If you
9 look at -- we've just been talking ten minutes ago
10 about the chances of getting hepatitis C in American
11 donors compared to British donors in the 1970s, and
12 I've said to you even if Dr Did Owen's initiative had
13 been successful, let's say it's 1978 and we've gone
14 from a high hep C incidence (1 in 100) to a low hep C
15 incidence (1 in 1,000), for concentrate manufacture
16 it's voluntary donation, it's still 1 in 1,000. So if
17 you're a British haemophiliac in the 1970s on
18 self-sufficiency, voluntary donated, you are still
19 going to get hep C.

20 So my major conclusion number 1: the two
21 epidemics I see as being different. I see the
22 hepatitis C one if you were a regularly treated
23 patient, it was inevitable that you got hepatitis C.
24 You probably got many hepatitis C infections the first
25 time you ever had Factor VIII and that lasted all the

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1 been self-sufficient at a time when HIV entered the
2 blood supply, we wouldn't have been relying on a high
3 HIV infection pool, we'd have been relying on a low
4 HIV infection pool like the Scots.

5 So I think it is tempting -- this is all
6 medicine's dangerous retrospectively -- but it is
7 tempting to speculate that if Dr David Owen's
8 initiative had worked, the experience in England would
9 have been similar to Scotland and we would have had
10 maybe 10 per cent, same as Scotland, instead of the
11 catastrophic 90 per cent.

12 So that's my generalised overview obviously when
13 I was thinking of the things that I would wish to say
14 to you in giving my evidence. These are some of the
15 most particular things I would wish to say to you.
16 I think these two virus epidemics, which were both
17 catastrophic, are different. You should look at them
18 in different ways. I think the hepatitis C was
19 generally, for most patients, unavoidable. I think
20 that -- very poignantly, I think if Dr David Owen's
21 initiative had worked, you have to think things could
22 have been very different.

23 **Q.** Thank you, Dr Winter. Sir, I note the time and I have
24 run over in my questions into the break, so is this
25 a convenient moment to take the break?

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1 way through, even if you then went on to British only
2 and even on the first generation of heat treated.
3 They all transmitted hepatitis C.

4 So until about 1985/1986 when the second
5 generation of heat-treated concentrates came through,
6 if you were a haemophiliac patient in Britain and you
7 had had Factor VIII once, it was extraordinarily
8 likely that you would have hepatitis C. So the major
9 conclusion from that is I do not believe, from my
10 experience, the hepatitis C epidemic was avoidable in
11 regularly treated patients -- a key phrase. If you
12 were a patient who had hardly had -- you know, it's
13 1985 and it's your first ever injection, that's
14 different. But for regularly treated patients with
15 severe haemophilia, this catastrophe could not have
16 been avoided.

17 With HIV, my own view is the situation is
18 different because Dr Kernoff's work tells us that HIV,
19 reported as a disease in 1981, doesn't seem to have
20 been in the blood supply until 1979/80.

21 We now know from the Scottish experience,
22 self-sufficiency, when HIV broke they had very little
23 HIV infection, less than 10 per cent. So if
24 Dr David Owen's initiative had worked, as it was
25 tantalisingly close to doing, if in 1979/80 we had

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1 **SIR BRIAN LANGSTAFF:** Yes, it is. We'll take a break now
2 until 12 o'clock.

3 (11.15 am)

4 (A short break)

5 (12.00 pm)

6 **MS RICHARDS:** Dr Winter, just a couple of points on the
7 issue of self-sufficiency. Lord Owen told us when he
8 gave his evidence that the pledge he had in mind
9 encompassed self-sufficiency on the basis of use of
10 factor concentrates for home treatment but not
11 prophylactic treatment.

12 Do you know whether that was the understanding
13 of clinicians such as yourself that what was meant by
14 Lord Owen in relation to self-sufficiency at least
15 excluded prophylaxis?

16 **A.** I was only a trainee doctor at the time of Dr Owen's
17 initiative but our understanding of self-sufficiency
18 was always that it would encompass all aspects of
19 haemophilia treatment.

20 **Q.** Thank you. Then the second point is not necessarily
21 a question for you, Dr Winter, but it's just a point
22 I have been asked by some Core Participants to raise.

23 In relation to the position in Scotland, I'm
24 asked to point out that commercial concentrates were,
25 as a matter of fact, being used in parts of Scotland

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1 in the early 1980s. But, as I say, I don't think
2 that's really a question for you, it just arose out of
3 your evidence.

4 **A.** But they did end up in a situation where not only were
5 they were self-sufficient, they had extra capacity,
6 I believe, and there was even a suggestion that some
7 of this -- that, you know, they might provide
8 Factor VIII for some English patients.

9 **Q.** Yes. Then you told us yesterday, when we were talking
10 about telling children about their HIV diagnosis, and
11 we referred to the talk that you had given expressly
12 on that subject, and you mentioned a Scottish group
13 who delivered a talk on the possibility of not telling
14 children their diagnosis.

15 Who was that Scottish group?

16 **A.** I honestly can't remember. I mean, they would have
17 been from one of the major centres. They were
18 counsellors and nurses, I think, from one of the major
19 centres, which would be Glasgow or Edinburgh or Dundee
20 I guess.

21 **Q.** What did you understand their main counter-argument to
22 be? What was the reason being advanced by them for
23 not telling children?

24 **A.** I think their main argument was that whilst the
25 children were well this would only distress them and

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1 that until we had more knowledge it was perhaps best
2 not to tell them. All these years later, it's
3 difficult, but I do remember it as being quite
4 a powerful occasion because of the two divergent views
5 in front of really quite a large audience who, again,
6 were very split as to whether you should tell or
7 whether you shouldn't tell, and, again, you know, no
8 agency saying to us, "This is what you should do". We
9 had Dr Craske saying, "You could tell but maybe you
10 don't need to, and each director must do what they
11 think is best". The familiar thing.

12 So, again, it was another moment of great
13 uncertainty.

14 **Q.** Do you remember when -- the particular occasion that
15 you're talking about where there was this discussion
16 and your talk was delivered, do you remember when that
17 was, very roughly?

18 **A.** Well, obviously it was -- so we're talking, I'm
19 thinking it must be -- at the very end of 1984 the
20 results would have been through and people are working
21 out what to do with the results, and one of which was
22 to say, "Should we tell children?" I'm tempted to say
23 very early '85.

24 **Q.** Thank you.

25 Then can I clarify one aspect or ask you to

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1 clarify one aspect of your evidence in relation to
2 how -- or your approach to the treatment of severe
3 haemophiliacs, severe regularly treated haemophiliacs,
4 in the period from early 1983, when you're aware of
5 the risk of HIV, through to May 1984, when you made
6 the switch to the heat-treated product, was your
7 approach and your advice to carry on as normal with
8 heat-treated product -- sorry, with unheated product,
9 or was it advice to treat only when necessary and to
10 try to reduce the amount that you received?

11 **A.** Yes, it was the latter. It was to say: we're
12 increasingly -- we have increasing concerns, firstly
13 because of the hepatitis data, secondly because of
14 this new disorder which seems to be in the blood
15 supply, we're trying to reach a situation where
16 Factor VIII might be treated to make it safer, but in
17 the meantime you should only use concentrate when you
18 need to. I guess was a core phrase and a core belief
19 that we had round the centre, and that extended, as
20 we've discussed, to restricting operations and
21 restricting prophylaxis, et cetera.

22 **Q.** Then I've been asked to ask you to clarify your
23 references to being a trainee doctor when you were at
24 the Middlesex and Guy's because obviously the precise
25 way in which different categories of doctor are

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1 described may not be universally known and understood.

2 **A.** Yes.

3 **Q.** So what was your qualification and what did you mean
4 by saying you were a "trainee doctor" at that time?

5 **A.** So I'm -- obviously I was a qualified doctor. That's
6 five years of training. Then everybody has to do
7 a year's houseman, house physician. So that's -- then
8 you are registered. So I was a registered doctor.
9 But then if you're going to work in a hospital you
10 enter speciality training, so you are a trainee in
11 that speciality even though you are a registered
12 doctor. So that was what I meant by that phrase.

13 **Q.** So that period at the Middlesex and then Guy's, you
14 were a senior registrar or a registrar?

15 **A.** A senior registrar for seven years in further
16 training.

17 **Q.** As a haematologist?

18 **A.** Yes.

19 **Q.** Thank you.

20 **A.** And then you end up with this other exam, the MRCPATH,
21 and at that -- they now formally call it
22 accreditation, and then you are enabled, you are
23 qualified to become a specialist.

24 **Q.** Thank you. Then, in terms of the communications you
25 had with patients, and I'm not going to go back over

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1 the detail of what was being said to patients at
 2 different times, the question I'm asked to ask you is
 3 about the extent to which in the period we've been
 4 looking at, late '70s, first half of the '80s, to what
 5 extent would this kind of discussion be recorded by
 6 you in the patients' notes?

7 **A.** I stress yet again, you know, I was in training and
 8 not responsible for policy but my general recollection
 9 would be that -- hospital notes are a variable feast,
 10 firstly. Some doctors write, you know -- no doctor
 11 writes very voluminous notes because you are doing
 12 a busy clinic with lots of patients and you don't have
 13 time to write a great deal. Some patients, for
 14 a clinic visit, would write a very brief, "All well,
 15 no new symptoms to report, three months", and our
 16 little initials.

17 It would be, in those days, I think unusual for
 18 in the notes, where the doctors actually got to hand
 19 write it, to say, "I have counselled this patient
 20 against the situation concerning the latest evidence
 21 for hepatitis infection". What would be much more
 22 likely, and I've seen some of my own correspondence
 23 from the time, is that when we actually wrote a letter
 24 to the GP at the end of the clinic, into a Dictaphone,
 25 it was much easier to give more detail, and the

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1 **A.** Yes. To complicate matters, obviously in some cities,
 2 like with Great Ormond Street or Birmingham
 3 Children's, there wasn't even a standard age of
 4 transition to the adult centre. So this was another
 5 area of not contention but there wasn't
 6 standardisation of practice.

7 **Q.** Now, I want to ask you to look a document that has
 8 been shown to you this morning. It's a Haemophilia
 9 Society publication.

10 Henry, could we have DHSC0001228, please.
 11 Thank you.

12 So this is The Haemophilia Society letter of
 13 4 May 1983 which sets out advice from Professor Bloom
 14 that was then sent out by The Haemophilia Society to
 15 its members. The reason I am asking you about this,
 16 Dr Winter, is because you talked about information
 17 from The Haemophilia Society as one of the sources of
 18 information for patients.

19 Do you know whether you read this or would have
 20 been likely to have read this at the time?

21 **A.** No, I remember in particular covering this letter in
 22 detail at the two previous inquiries.

23 **Q.** In that case, can I invite you to set out what you can
 24 recall about this letter and what your view is of the
 25 advice that's contained within it.

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1 letters to the GP would be much more likely to say,
 2 "I've reviewed your patient, he's perfectly well, I've
 3 brought him up to date with the evolving situation
 4 concerning possible hepatitis infection in haemophilia
 5 patients", or something like that.

6 **Q.** Thank you. And then in the first half of the '80s but
 7 in particular 1982 to 1983, did you -- and I'm
 8 conscious at this time you are not a consultant -- did
 9 you put forward any of your patients, in particular
 10 mild haemophiliacs or those who were virgin
 11 haemophiliacs, PUPS, for any clinical trials?

12 **A.** No.

13 **Q.** We talked about the approach to children. Can I just
 14 ask you to clarify up until what age, for the purposes
 15 of the discussion that we've been having, would you
 16 regard someone as a child for the purpose of the
 17 treatment decisions?

18 **A.** Well, I think for the -- you know, there's semantic
 19 discussions as to what is a child. When I said to you
 20 to my best recollection of my 30-something there were
 21 15/16, I would have included up to the age of 18.

22 **Q.** In terms of the guidance that came from UKHCDO, for
 23 example, in the middle of 1983 about how clinicians
 24 might want to treat children, would that be pretty
 25 much all children, up to the age of 18?

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1 **A.** Well, here's a doctor looking at an evolving situation
 2 and with the best of intentions, trying to be helpful.
 3 Professor Bloom was an awfully gentle, charming man
 4 who, you know, always tried to do his best. But he's
 5 given advice here to the Haemophilia Society which has
 6 gone on to patients which has turned out to be
 7 completely wrong.

8 Some of his phraseology, given that it's in
 9 a state of great uncertainty, with the evolving
 10 numbers of patients -- and indeed, we should say, was
 11 it not almost exactly the same date that the patient
 12 in his own centre was diagnosed with this disease,
 13 which he thinks isn't going to be a problem to people
 14 with haemophilia -- so when he says the cause of AIDS
 15 is "quite unknown", if "quite" means completely, which
 16 I assume it does, that was a strange use of phrase
 17 because any sentient doctor looking at the data would
 18 have to say there must be a very high chance it's due
 19 to a transmissible agent in blood and, if it's in
 20 blood, the haemophiliacs will be the most affected.
 21 So that's a very strange choice of phrase.

22 And:

23 "... it has not been proven to result from
 24 transmission ..."

25 Well, there are patients with haemophilia with

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1 the disorder. So that's a strange choice of phrase.
 2 Then it's interesting -- I haven't seen this
 3 before -- I was talking yesterday about the German
 4 experience. Here he is again putting out to some
 5 people with his views did, "This is -- you know, this
 6 is an American problem. If anything, it's not going
 7 to occur in British donated plasma, and look at the
 8 Germans, they use twice as much as us and they had no
 9 problems."

10 Can we look lower down the letter?

11 **Q.** Certainly.

12 **A.** Yes, so that's the phrase, isn't it, that stands out
 13 as being so very inappropriate. You know, one wonders
 14 why he didn't say, "We're monitoring the situation
 15 very closely and we're trying to get as much
 16 information as we can as to whether this might be an
 17 evolving issue for patients with haemophilia and as
 18 soon as we have more information we'll get it to you".
 19 You know it's the sort of certainty of saying the
 20 cause is quite unknown. Well, there were significant
 21 clues.

22 **Q.** Dr Winter, was this a communication that you saw at
 23 the time? I don't know whether you can answer that,
 24 but --

25 **A.** I would have been -- yes, I mean, I read the -- I had

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1 a chance to talk to the sort of people who would have
 2 granted such a licence to commercial concentrate.

3 **SIR BRIAN LANGSTAFF:** The next passage which I would
 4 invite your comment on -- I appreciate it is only a
 5 comment, and you may be considering this for the first
 6 time, though you have looked at this letter before --
 7 is, the very last sentence:

8 "We should give those experts who are
 9 responsible a chance to continually assess the
 10 situation."

11 At that time, what experts did you see as being
 12 responsible for the quality of the factor product
 13 given from the States to individuals in this country?

14 **A.** Well, I think, obviously, in terms of the licence,
 15 it's the agency that will grant the licence. They
 16 surely must have had criteria to use behind the
 17 licensing of any blood product or drug. But I think
 18 what he actually means is -- he really means the other
 19 haemophilia doctors are going to continually to assess
 20 the situation. He is actually not referring to the
 21 agency. I think he means that doctors like him are
 22 keeping a very close eye for any sign of their
 23 patients getting this new disease.

24 **SIR BRIAN LANGSTAFF:** So it's "leave it to us"?

25 **A.** That's what I think he means.

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1 been a member of The Haemophilia Society myself since
 2 the late 1970s, so I would have been sent this
 3 document.

4 **Q.** Do you have any memory of reading it and reacting to
 5 it?

6 **A.** Not at the time as a registrar. I mean, I must have
 7 read it and thought, that's a strange thing to say.

8 **SIR BRIAN LANGSTAFF:** Just before we leave that letter,
 9 the third from last sentence:

10 "In addition, the importation of licensed blood
 11 products has always been strictly monitored and
 12 controlled."

13 Is the -- would you understand the implication
 14 of that as being, well, the product must be safe
 15 because, otherwise, it wouldn't be let into the
 16 country?

17 **A.** Well, that's another big issue, isn't it? You know,
 18 what factors does -- are taken into account when
 19 a product is licensed? And did the people or the
 20 agencies in Britain granting that licence -- were they
 21 aware of the sort of events that had been portrayed in
 22 the World in Action documentary? Because, surely, if
 23 they had, would they not have had major reservations
 24 about granting a product licence?

25 I don't know if the Inquiry has as yet had

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

2 Dr Winter, I'm going to move on now to ask you
 3 about various matters from 1985 onwards.

4 Can I have up on screen, please, Henry,
 5 ARMO0000409, please. This is a letter from Armour to
 6 you, June 1985:

7 "Heat Treated Factorate, Batch No. Y69402."

8 It thanks you for the information given in your
 9 letter of 10 June. I don't think we have that letter,
 10 I'm afraid, so we only have what is set out here.
 11 Then it says:

12 "In view of the fact that all three patients
 13 were HTLV 3 positive prior to receiving [that] batch
 14 ... any symptoms will be virtually impossible to
 15 relate to the Factorate batch in question ...

16 "Nevertheless, in the generation of an overall
 17 picture of all patients treated with the batch, the
 18 subsequent progress of these patients will be of
 19 interest."

20 Just two questions arising out of this,
 21 Dr Winter. The first is: do you recall why you were
 22 writing to Armour about that particular batch?

23 **A.** So this is quite a common occurrence in haemophilia
 24 treatment. As a standard practice, if a doctor gives
 25 a patient a product and there is a problem with that

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1 administration of the treatment of any kind, the
2 doctor informs the company, for obvious reasons, so
3 that they can look at the batch and make sure that
4 other hospitals who have received that same batch are
5 not getting the same problems. That would range from,
6 at the extreme end, the development of an inhibitor --
7 you would notify the company. Maybe in the
8 manufacture of that batch something had happened, and
9 the batch was more antigenic than other batches. That
10 would be an extreme example.

11 Almost certainly what this related to was that
12 the patients were getting some sort of side effect
13 during administration of the sort of type that we were
14 talking about with cryoprecipitate. So I expect these
15 patients came to me -- they were probably all on home
16 therapy -- and said, "Actually, I've got the shivers
17 and the shakes with this one," which could happen with
18 concentrates, and I felt obliged to report this.

19 The reply is rather curious. I don't know
20 why -- I've obviously informed them. I would not have
21 given the names of the patients, obviously. I would
22 have said, "Three patients under my care," and then
23 I would have given brief -- I would have said,
24 "They've got severe haemophilia, and they are HTLV-III
25 positive, and they've got these clinical signs, and

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1 some NHS product.

2 Was there any particular thinking behind the
3 continuing with the Alpha product as your predominant
4 mode of treatment in the second half of the '80s?

5 A. Well, firstly, as a principle, you try not to change
6 treatment in haemophilia. It's not considered to be
7 a good idea. There are practicalities. The
8 patient -- all the Factor VIIIs are drawn up in rather
9 a different way according to the packs that the
10 company provide. So the patients didn't like
11 changing. The nurses didn't like changing. So it
12 was -- you weren't going to change unless there were
13 a reason.

14 Of course, from May 1984, I was greatly
15 reassured because I knew my patients were -- well,
16 I had hoped -- I didn't know -- at least I'd got my
17 patients on to a heat-treated product, and I had
18 reason to believe that was likely to be safe against
19 HIV, which turned out to be true. I didn't know
20 whether it was going to protect them from hepatitis,
21 which turned out not to be true, but nearly all my
22 patients had hepatitis anyway.

23 So, if you like, there was no clinical pressure.
24 I could get the supplies. That was a major issue.
25 Here's a time when Elstree in its new shape and form

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1 they have obviously then had some event under the
2 treatment, and I'm just letting you know as a courtesy
3 in case it's a problem that's being seen in other
4 patients". But quite why he's talked about their
5 positivity and lymphadenopathy, I don't know.

6 Q. Okay.

7 A. But this was a perfectly standard thing, and there
8 will be lots of letters like this.

9 Q. It talks about -- in the next paragraph it says:

10 "The subsequent progress of these patients will
11 be of interest."

12 Was that normal for a pharmaceutical company to
13 ask for an update about the progress of particular
14 patients?

15 A. I think he's just being courteous. No, it wouldn't.
16 You wouldn't. You're just reporting the adverse
17 event. You wouldn't expect to write further to the
18 company.

19 Q. Okay, thank you.

20 Now, I don't think I need to put the document up
21 on screen, but we've got a sample of your returns from
22 1986, 1988, 1989. What they show is you are
23 predominantly using Alpha product, as you had been
24 since the middle of May 1984 -- though, obviously, it
25 may move on to further generations of that -- with

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1 after all the funding is taking off. It's still not
2 firing on all cylinders. There's a lot of demand for
3 Elstree product, as ever, for the new heat-treated
4 product. So I'm -- you know, through the early part
5 of the years from 1984, together with Dr Savidge,
6 we're pretty comfortable with where we are.

7 What happens then is new generations of
8 heat-treated products come in, where you heat them for
9 longer and to a higher temperature. Then we move into
10 a yet further generation of what's called
11 monoclonally-treated, where there are antibodies in
12 the preparation which pick out any viruses or proteins
13 or whatever, and they were generally perceived as
14 being -- remember our conversations yesterday -- not
15 only safer but purer. So you move into a different
16 generation of products which turn out, for the first
17 time, to inactivate hepatitis, which the first
18 generation heat-treated don't do, but are also much
19 purer. And remember my comments of "purer" might also
20 mean "safer".

21 So I'm thinking that around '87/'88, you're
22 going to say that I moved across to -- away from Alpha
23 to using other drugs like Monoclate and things like
24 that. These are the third generation
25 monoclonally-derived Factor VIIIIs. In other words,

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1 this first generation dry heat, like the Alpha and the
 2 other ones, major breakthrough, safe from HIV, but
 3 turned out not to inactivate hepatitis, and also not
 4 very pure. So they were soon replaced by more
 5 sophisticated concentrates.

6 **Q.** Then could we have up on screen, please, Henry,
 7 BAYP0000071_001. We'll see this is a Bayer internal
 8 document, 1 August 1991. It's headed "Koate HP study
 9 0101". It encloses documents which we don't currently
 10 have. It says:

11 "I currently have all case record folders from
 12 Dr Winter in-house, and I'm hoping to collect the
 13 remainder from St Thomas' at the end of August.
 14 I feel that a meeting would be useful to discuss the
 15 reporting of this study involving both Drs Savidge and
 16 Winter."

17 Do you have any recollection of what this study
 18 was about?

19 **A.** Well, I don't. I've looked at this. It was almost
 20 certainly a PUP study, and I think in '91, I just
 21 wonder whether we'd -- the very, very early stages of
 22 being -- to get a recombinant product, although
 23 perhaps it's a little early for that. But this is --
 24 we were not involved. It says "Phase 1 analysis",
 25 et cetera. We were never involved in multi-centre

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1 **Q.** In terms of your own practice, if you had a patient,
 2 whether a previously untreated patient or otherwise,
 3 who you thought might be a suitable candidate for
 4 a study, what information would you provide to that
 5 patient? I ask that question, you will understand,
 6 because we've heard evidence of people being involved
 7 in studies of which they were unaware.

8 **A.** Yes. So any research study of this type has two major
 9 levels of control. Firstly, this would have been
 10 a study done with other centres, and there would be
 11 a lead investigator, perhaps Dr Savidge. And he would
 12 go to a centralised ethical committee in London called
 13 MREC, and this is the first phase of getting ethical
 14 committee approval for this study.

15 It's absolutely impossible for any sort of
 16 research activity like this to take place without
 17 these two committees having given their approval, and
 18 the first hoop is MREC. An absolutely central part of
 19 MREC is that they have lay representatives, and the
 20 lay representatives, quite properly, would be greatly
 21 exercised at the information produced for patients.
 22 Is it understandable, comprehensible, pitched at the
 23 right level? Is the patient fully aware of their
 24 responsibilities? Does the patient or the parent have
 25 the ability to come out of the study at any time?

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1 evaluations of established products because we were
 2 a -- you know, we weren't an academic centre. I
 3 didn't have research registrars, but we did do a small
 4 number of PUP studies. So I'm tempted to think this
 5 must have been one of the new generation of
 6 monoclonal, or an early recombinant. I was working
 7 very closely with Dr Savidge who was in an academic
 8 centre with large numbers of research registrars. He
 9 would have said to me, you know, it may be a good idea
 10 if we consider putting some patients into this because
 11 this new product looks to be a very good one, and it
 12 will be good if we could, you know, evaluate it and
 13 get some patients on to it as soon as possible.

14 Of course, there was great interest and concern
 15 amongst the patients. Everybody knew about the advent
 16 of the Holy Grail recombinant Factor VIII that wasn't
 17 from blood donors, and there was a period of time
 18 where the only way you could get recombinant was to go
 19 into a research study. So it's possible that -- you
 20 know, the dates seem a little early for me because I'm
 21 thinking '93/'94 would have been the earliest for
 22 recombinant, but, anyway, I'm just making the point
 23 some patients were very happy to enter, or parents
 24 were, because they -- it was the only way of getting
 25 this perceived better product for their child.

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1 These are very extensive procedures.

2 Once you've got through the MREC, the individual
 3 investigators, like me in Kent -- I would have to do
 4 a similar thing with my local ethical committee. So
 5 I would go to them in Canterbury and Margate and say,
 6 "I'd like to take part in this study." If I said,
 7 "I haven't yet got MREC approval," they would say, "We
 8 can't look at this until you have." If I said, "I've
 9 got MREC approval," I would go through exactly the
 10 same process with them. There'd be two or three --
 11 I would have to go and physically present it, and the
 12 local lay representatives, who would be lawyers or
 13 whoever, local people of influence, would say, "We
 14 absolutely want a detailed look at all the patient
 15 information, and we've got some comments to make.
 16 We'd like you to make some changes, and we'd like you
 17 to come back at our meeting next month." They would
 18 be very particular about consent forms -- what was the
 19 patient actually consenting to -- and all these things
 20 are, of course, right and proper.

21 So these are very exhaustive processes. So for
 22 studies like this which are multi-centre with a new
 23 form of Factor VIII coming in, there isn't any way
 24 a patient could be entered into the study without
 25 being aware of it.

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1 Q. You would be having that dialogue directly with your
 2 own patients?
 3 A. I was obliged to, under the terms of the ethical
 4 committee.
 5 Q. Can I ask you next about HCV testing for your
 6 patients?
 7 Do you recall when you began hepatitis C
 8 testing?
 9 A. I'm thinking -- my recollection would be HCV was
 10 isolated about 1989, maybe. And I'm thinking the test
 11 was -- about 1991, we got access to the test. I'm
 12 thinking that sort of date.
 13 Q. Do you have any recollection of over what period of
 14 time you undertook the test? Was it something that
 15 went on for a prolonged period of time, or was it the
 16 test is available, and much as you describe with the
 17 HIV, you take the blood samples, and you send it off?
 18 A. Yeah. So I was reflecting on this overnight. I think
 19 there was a difference in practice here. With HIV, as
 20 we discussed, there was great anxiety. We were really
 21 concerned to have the test. We didn't know what the
 22 results would show. We were astounded by the results.
 23 With the hep C test, we had wanted to have it.
 24 We weren't expecting it to tell us anything we didn't
 25 really presumptively know. I've already said to you,

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1 invariably in person at an appointment?
 2 A. Always -- yes, always.
 3 Q. Can you recall what kind of information you provided
 4 at that early stage to those who tested positive about
 5 hepatitis C?
 6 A. Well, it was really, you know, a confirmation of all
 7 the previous advice that had been given: that we now
 8 definitely know that this non-A, non-B we had been
 9 talking to you about for 15 years for severe regular
 10 patients aged 40-something under long-term treatment,
 11 we've always said to you we think it's hep C and we
 12 now know for sure it is hep C. That doesn't change
 13 the nature of our advice to you about healthy living,
 14 about avoidance of alcohol.
 15 There was very little, if any, data at all
 16 (unlike HIV) about sexual transmission, which was an
 17 area of difficulty, and something that happened that
 18 came out of the availability of hep C testing around
 19 this time there was availability for treatment with
 20 this interferon.
 21 Now, by then we were in an area where
 22 haemophilia doctors were outside of their expertise.
 23 So when I was looking after my patients I was looking
 24 after the haemophilia. As it happened, I was an HIV
 25 physician so I was looking after their HIV. Many

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1 I'd already told my patients, "I think you've got this
 2 new virus". So I was expecting -- I wanted to have
 3 the patients tested but I was expecting that all the
 4 regularly treated patients would test positive. So
 5 I decided I would not send for them immediately, like
 6 I did with HIV, where I was so concerned to know.
 7 These are all patients that had upcoming appointments.
 8 I knew I was going to be seeing them within the next
 9 few weeks. So when they came in to their routine
 10 appointments, I said to them, "We now have this test
 11 available and obviously, you know, I hope you agree,
 12 we should get this test done". Then -- you know, then
 13 I said to them what I've just said to you. I said,
 14 "Probably, unless you're anxious, we could pick up the
 15 results of this test the next time you come. If
 16 you're really concerned you know we can make another
 17 arrangement to get the test result to you more
 18 quickly, but you know I really am expecting it is
 19 going to confirm kind of what we already know, is that
 20 you've got hep C."
 21 Q. So your patients, you told them or you invited them to
 22 be tested, they weren't tested without their
 23 knowledge?
 24 A. No.
 25 Q. When you communicated the results to them, was that

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1 other centres would have sent their patients across to
 2 a different unit for HIV care but I was not
 3 a hepatitis specialist, of course, and I didn't have
 4 detailed knowledge about a whole range of things
 5 evolving around hepatitis C now that it had been
 6 identified. I didn't really know about advice about
 7 how common was sexual transmission and I didn't know
 8 whether a patient, now that hep C had been confirmed,
 9 I didn't know what criteria would be used to determine
 10 whether they ought to have interferon treatment,
 11 I didn't know whether the patient should be advised to
 12 have a liver biopsy.
 13 So all of these patients in the fullness of time
 14 would have been referred to our liver specialist, to
 15 Dr Frank Muller -- we didn't do formal combined
 16 clinics but patients were referred to him for his
 17 assessment and he would see them and write back to me
 18 and say, you know, "This is what I think and, you
 19 know, we're going to" -- he would then monitor
 20 their -- he would then take over the formal management
 21 of their hepatitis, he would do all the measurement of
 22 the liver function tests, he would advise me about
 23 liver biopsy, he would advise me about evolving
 24 treatment. Sometimes the patients were sent up to
 25 King's College in London for evaluation for liver

1 transplantation. He, from that point in time, took
 2 over all that sort of hepatitis management and that
 3 would have been a very sort of commonplace thing
 4 across haemophilia centres.
 5 **Q.** In terms of the prescription of interferon, and we
 6 have heard some horrific accounts of the side effects
 7 of interferon from patients, would that have been his
 8 responsibility then rather than yours?
 9 **A.** Completely. I've never as a doctor prescribed
 10 interferon.
 11 **Q.** There is some reference in documents -- I don't think
 12 particularly in light of your last answer I need to
 13 take you to them -- in the course of the '90s to there
 14 being difficulties in securing funding in your local
 15 area for interferon and ribavirin for patients. Did
 16 you have any involvement or recollection in that --
 17 **A.** I had no involvement but I -- we had no -- nobody ever
 18 said to me that funding had not been obtained. So if
 19 Dr Muller, my colleague, he would write to me and say
 20 we're going to start this patient on interferon and
 21 ribavirin, they started. And the patient would turn
 22 up for their next appointment with me and would say,
 23 "Have you heard from Dr Muller, and I would say, "Yes,
 24 I hear you're on the treatment", and he would say,
 25 "Yes, I've started."

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1 hep C. That wasn't my direct responsibility but other
 2 doctors would quite often talk to me and say, "You
 3 know, who should we be screening and looking at?"
 4 **Q.** So in terms of your patients, your haemophilia or
 5 bleeding disorder patients, who had hepatitis C, was
 6 that all of the severe regularly treated haemophiliacs
 7 who'd -- there may, I suppose, have been a handful of
 8 new patients who had only received the later
 9 generation but --
 10 **A.** I didn't have anybody -- as I've said to you, there
 11 was nobody -- I had two or three patients who only
 12 ever received heat treated. They were just either
 13 children born '84 or they were milds having their
 14 first, and none of those got hep C. Even though we
 15 now know that heat treatment wasn't terribly effective
 16 mercifully they didn't get hep C.
 17 But I tested obviously -- there was quite a big
 18 group of people who had had Factor VIII once or twice,
 19 even some haemophilia carriers, very sensitive
 20 situation, and there was quite a big list of people
 21 who tested negative.
 22 **Q.** In terms of the treatment of your patients who had
 23 HIV, and I'm talking here about the bleeding disorder
 24 patients, I know you had a wider cohort of
 25 HIV patients as well, did you have any difficulty in

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1 **Q.** Your statement says it was approximately 50 patients
 2 under your care who were confirmed to have hepatitis C
 3 when the testing came in. Are you able to recall what
 4 proportion of your patients at that time, 1991 or so,
 5 did not have hepatitis C?
 6 **A.** So now we're entering a sort of wider group from the
 7 HIV group because you're picking up people with, say,
 8 mild haemophilia who have only had, say, one or two
 9 lifetime treatments. Mercifully, they've escaped HIV
 10 but inevitably, as we've been discussing, because they
 11 have had Factor VIII before 1985/6, they have got
 12 hep C. So that's why we've got this wider group of
 13 people with hep C.
 14 So I would have -- I would have tested everybody
 15 under my care who had ever had a commercial
 16 concentrate: the Factor VIII patients, the Factor IX
 17 patients. Some people had a sort of pooled plasma
 18 given to them, patients in the hospital given pools of
 19 plasma to reverse anticoagulant therapy. So this has
 20 been a big issue, hasn't it, about hidden cases of
 21 hepatitis C in hospitals. There were cases of anti-D
 22 immunoglobulin, particularly in Ireland. So we were
 23 in a different territory then of also looking for
 24 patients who had been through the hospital, who had
 25 never had Factor VIII or Factor IX, who might have had

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1 obtaining funding for their treatment which was under
 2 your direct responsibility?
 3 **A.** No, no, I didn't.
 4 **Q.** Can I ask you then about counselling. You mentioned
 5 yesterday there came a point in time when you had
 6 a full-time counsellor at the centre. Roughly when do
 7 you think that was?
 8 **A.** Well, I remember it was at a time just after we had
 9 been telling patients, and I remember going with her
 10 to other meetings where we discussed with other
 11 doctors telling patients, so I'm thinking she probably
 12 started about '85, sometime '85. And she was
 13 full-time based in our centre, which was a big thing
 14 to be able to have -- because there were very few --
 15 it was at a time when hospitals were losing social
 16 workers, they were all going into the community, and
 17 it had been very difficult to obtain funding to get
 18 counsellors. Hospital counsellors were few and far
 19 between. And somehow, again, I managed to find the
 20 money to get her and she was an absolutely invaluable
 21 part of the service when the whole of the patient
 22 community was in such distress.
 23 **Q.** What kind of counselling was she able to offer? Was
 24 she a trained psychologist?
 25 **A.** She was a counsellor, a trained counsellor. She

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1 wasn't a psychologist.

2 **Q.** And if patients wanted it, was there a facility for

3 them to have counselling with her on an ongoing,

4 long-term basis or was it a one-off?

5 **A.** No, it was very long-term. As I say, she was based in

6 the centre. She had a suite in another part of the

7 hospital. So she was employed by the centre, so she

8 was responsible and accountable to me, she was one of

9 my staff, she was based in another part of the

10 hospital, and we would strongly recommend that

11 everybody with HIV saw her. You know, even if you

12 don't think it's necessary we said, "We just think

13 it's a good idea if you have a talk to this person."

14 Most people found her extremely helpful, and

15 then most people would go on on quite a long-term

16 basis. I mean -- and some patients went on for

17 several years. They would come in and say, "Is Juliet

18 around today? I'd really like to see her". Then, of

19 course, that service was extended to other patients

20 who didn't have HIV who also had problems. So yes,

21 she had a number of patients on a very long-term

22 basis.

23 **Q.** Was that a facility that continued at your centre,

24 whether it was her as an individual or a successor, up

25 until the time of your retirement in 2011 or did there

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1 bit more context and background for that. We've seen

2 different practices to some extent in different areas,

3 so in relation to your area, what were the problems

4 with the coroner and with the undertaker that led to

5 not usually including the term on the death

6 certificate?

7 **A.** So this was an issue that caused very great distress.

8 AIDS was not a notifiable disorder. However, as

9 a doctor, I was obliged to inform a coroner of any

10 death that was not natural. And of course it was not

11 natural for a person with haemophilia to die as

12 a result of HIV.

13 So when I had a patient who died of AIDS who was

14 not a haemophiliac, I did not need to inform the

15 coroner. When I had a patient who died who was

16 a haemophiliac with AIDS, I did need to inform the

17 coroner. I had no choice. I did it very reluctantly.

18 The coroner, in response, felt obliged to hold an

19 inquest.

20 There was very intense correspondence along the

21 lines -- from myself, and The Haemophilia Society got

22 involved -- along the lines of, "This is going to

23 cause the family, who are already greatly distressed,

24 even more distress, and if the purpose of an inquest

25 is to establish the medical cause of death, that is

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1 come a point where the counsellor post ceased?

2 **A.** No, that's still gone on. So we opened the new centre

3 in Canterbury in 1995 and she transferred and was

4 still working there when I left the service.

5 **Q.** Then I wanted to ask you about a paragraph in your

6 witness statement. I don't know if you have it to

7 hand, Dr Winter?

8 **A.** Yes.

9 **Q.** It's paragraph 112 of your statement, page 16. It's

10 very short so I will read it out for those who don't

11 have it.

12 **A.** Okay.

13 **Q.** You say there:

14 "AIDS was not a notifiable disease.

15 "Because of the stigma surrounding this

16 diagnosis it was not usual to use this term on

17 a patient's death certificate as it had caused

18 significant problems with the coroner, and with

19 undertakers."

20 And then you say:

21 "No such stigma surrounded patients dying of

22 hepatitis."

23 You were addressing there a particular question

24 you had been asked to address.

25 Can I just ask you to provide us with a little

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1 already known. We know why this patient died. They

2 had haemophilia, they were given contaminated blood

3 and they died of AIDS. So why do you have to hold an

4 inquest?"

5 The coroner would not be moved. To make a bad

6 situation even worse, that meant that at the inquest

7 I was commanded to attend, describe the cause of

8 death, which would then be reported in the local

9 press; on one occasion "Bad blood kills boy" on the

10 front page, together with the name and address of the

11 child.

12 So this was -- well, you'll gather, it was

13 a very, very distressing episode, and it couldn't --

14 every time we had a death we had to go through this

15 exercise.

16 **Q.** So your concern -- you talked your reluctance -- was

17 because of the impact on families and what the

18 families wanted?

19 **A.** It didn't serve me as a doctor any benefit because

20 I had known why the patient died. All it had served

21 to do was to cause very great distress to a family who

22 were already greatly distressed.

23 **Q.** What was the particular problem with undertakers?

24 **A.** The problem with undertakers is you would inform them

25 about the HIV infection, which I think you had to do,

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1 but they would turn up wearing space suits. Which was
2 inappropriate.

3 **Q.** You said no such stigma surrounded patients dying of
4 hepatitis. It may be because of the evidence you have
5 given about hepatitis care being under the control of
6 one of your colleagues that you're not in a position
7 to answer this but were there referrals to the coroner
8 if a patient infected with hepatitis as a consequence
9 of blood products or blood transfusion subsequently
10 died as a result of the hepatitis, liver cancer or
11 whatever the cause was, were those notified to the
12 coroner?

13 **A.** That would have been handled by the hepatitis team, to
14 my recollection. I don't remember any personal
15 issues.

16 **Q.** If the term "HIV" or "AIDS" was not going to be used
17 on the death certificate, what term was used instead?

18 **A.** Oh, you'd use a term like "pneumocystis pneumonia",
19 and then, you know, under 2, "haemophilia".

20 **Q.** And then -- sorry, I put the statement away but I have
21 a different question about a different paragraph in
22 your statement.

23 Paragraph 94, please. Page 15 of your
24 statement. This is a question about research.

25 You have touched on the process of seeking

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1 the process.

2 **Q.** Can I then ask you about the issue of recombinants.
3 Your statement says that you switched to recombinant
4 Factor VIII in about 1997, but I've seen from other
5 documents, correspondence meetings, materials which
6 I know you've seen, that the availability or
7 non-availability of recombinant continued to be
8 a significant issue over the following years. You had
9 meetings. It was raised within UKHCDO. I think you'd
10 at least one meeting if not more with Government
11 ministers in relation to this issue.

12 We can look at the document in detail if we need
13 to but I suspect you can probably give us an account.
14 What was the issue with recombinant in terms of the
15 inability to give it to all patients?

16 **A.** So here we go again with the very familiar story.
17 A major change in therapy to the benefits of patients.
18 Was it controlled by the DoH? No. Did the DoH have
19 any influence over how we were going to switch to
20 recombinant? No. Had the DoH secured funding for
21 haemophilia directors to switch to recombinant? No.

22 The usual situation: a licence is given,
23 haemophilia doctors all over the country and the
24 patients want to use it, and you have to fight your
25 own battles. Each doctor has to go, as I recall, to

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1 ethical committee approval so I don't propose to ask
2 you about that. Just a couple of questions again that
3 I've been asked by others to raise in relation --

4 **A.** Which number?

5 **Q.** I'm so sorry. It's paragraph 94. It starts at the
6 bottom of page 14 but it continues on to page 15.

7 So it's just some general questions about
8 research. To some extent you have already answered
9 them perhaps, when we looked at that Bayer letter.
10 Any research involving your patients, there would have
11 been, I think your evidence earlier, patient consent
12 and knowledge. Were any of the research projects with
13 which you were involved in relation to patients with
14 bleeding disorders funded or initiated or prompted by
15 pharmaceutical companies from whom you purchased
16 products?

17 **A.** Nearly all of them would have been.

18 **Q.** How would it come about that you might be involved in
19 that or that your centre might be involved in it?
20 Would the approach come from the pharmaceutical
21 company via Dr Savidge or directly to you?

22 **A.** They would approach usually one of the sort of leading
23 clinicians who had experience at conducting clinical
24 trials such as this, and he would then invite other
25 directors to participate in the study. That would be

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1 their own finance and say, "I want to spend even more
2 money on your favourite disease, haemophilia, that you
3 already have a low opinion of because it's high cost,
4 low volume and unpredictable, we need to push the boat
5 out even more". Some finance departments were more
6 sympathetic than others.

7 There was not enough supply to go round in the
8 immediate changeover. Do I not recall that
9 St Thomas', I think, started to switch '94 or
10 something. I think we were a bit behind them.
11 Anyway, there was -- the point I'm making is there was
12 a gradual change across the country, depending on how
13 active the doctor was and successful the doctor was in
14 negotiating the change in getting the funding.

15 What then happened, I recall, is that quite soon
16 after '97 there was a major problem I think with the
17 Bayer plant. So there were only two or three
18 recombinant manufacturers, in California, and one of
19 them had a major lock-down because it had failed an
20 inspection. So suddenly the bottom fell out of an
21 already slightly insufficient supply. So I think
22 you'll find that some patients maybe even had to
23 switch back from recombinant to the best of the plasma
24 products until the problem was righted. I'm sure that
25 problem went on for several months at least.

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1 Q. Then, in terms of variant CJD, what can you recall
 2 about how and when you learnt of the risk of
 3 patients -- of transmission for patients with bleeding
 4 disorders of variant CJD, and what can you recall
 5 about your involvement in the notification process,
 6 telling patients of this?
 7 A. I've lost track of dates, but the variant CJD story is
 8 of interest because it gives the feel for the sort of
 9 continuing problems that doctors like me were having
 10 to deal with, and it was yet another Covid moment
 11 because we absolutely didn't know what the data meant.
 12 So whenever it was the year that some small number of
 13 people in Britain started to get variant CJD, there
 14 was evidence that it was due to an abnormal protein,
 15 that that protein was in the blood supply -- well,
 16 I remember a period of two or three months where, if
 17 you like, we were straight back to 1983.
 18 I remember talking to Dr Savidge and saying,
 19 "This could be AIDS part 2. How do we -- you know,
 20 new disease in blood, one or two other
 21 non-haemophiliacs with it. How do we know in six
 22 months this is not going to be AIDS part 2, in
 23 addition to everything else?" So it was yet another
 24 worry. So that was a real difficulty.
 25 Secondly, we had no way of testing. No way of

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1 a doctor and a patient, the patient must have felt,
 2 well, thank you very much. That's actually
 3 reassuring.
 4 I remember vividly one patient said to me,
 5 "Mark, that's the fifth time in 20 years you've sat me
 6 down and told me I've got a virus. You told me I've
 7 got Hep B, Hep C, HIV, parvovirus, and now here's
 8 another thing." And he said, "I thought this was very
 9 good. You obviously don't know anything about it.
 10 It's just going to get parked with the other four, and
 11 we'll see how we get on."
 12 The point I'm making was, if you believed in
 13 telling patients about everything, it was a very
 14 difficult and awkward and unsettling conversation.
 15 Any patient would have gone away from that and gone
 16 home to his family and said, "Dr Winter's told me
 17 this", and they would have said, "Well, we don't like
 18 the sound of that." I mean, mercifully, it didn't
 19 evolve into a major problem, but I didn't know that,
 20 and the patient didn't know that.
 21 Q. We've seen examples of notification letters which --
 22 to some extent, there seems to have been some form of
 23 standard form, but in the case of your patients, you
 24 had conversations with them directly?
 25 A. I didn't send them a letter. I spoke to them.

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1 monitoring. Then you enter a series of, how can
 2 I describe this? What am I going to tell my patients?
 3 Should I tell my patients? You're going to tell me
 4 there was very varied stuff. I'm absolutely sure in
 5 some centres patients were never told, but let's walk
 6 through. I'm having a conversation in my centre with
 7 one of my patients. So I sit him down and I say,
 8 "I've got something else to tell you. You've heard of
 9 mad cow disease? And you may have heard that some
 10 patients, a very small number of patients, have got
 11 this variant of mad cow disease and died of it." And
 12 maybe I even said, "We now know that some of the
 13 Factor VIII you had in the past 15 years ago came
 14 from -- because we had -- nominated batches
 15 occasionally came from a patient who has now developed
 16 variant CJD and died. Fifteen years ago, you had
 17 Factor VIII from him, so I'm just telling you this.
 18 I haven't got a test which tells me whether you've got
 19 this or not. I haven't got any way of monitoring you
 20 as to how you're getting on. Don't worry. You'll
 21 probably be all right."
 22 I mean, all the things that's been thrown at
 23 doctors in the past few years tell the patient
 24 everything, quite rightly, which I always believed in.
 25 Here's an example where the interchange between

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1 Q. There's one other issue, a miscellaneous issue this
 2 one, but one of practical importance about
 3 prescription charges I wanted to ask you about.
 4 HCDO0000264_155, please, Henry.
 5 This is a letter sent by you to all haemophilia
 6 centre doctors, May 2002, and I know you are familiar
 7 with this, Dr Winter:
 8 "Prescriptions for haemophiliacs infected with
 9 HIV and/or hepatitis viruses. You'll be aware that
 10 a particularly iniquitous situation exists where in
 11 patients with haemophilia who have been infected with
 12 HIV and/or hepatitis viruses through the use of
 13 contaminated coagulation factor concentrates
 14 prescribed on the NHS currently have to pay for
 15 prescriptions for the treatment of these conditions.
 16 This has understandably caused great resentment
 17 amongst patients with haemophilia, particularly as
 18 patients attending GUM clinics who have acquired HIV
 19 through other means are traditionally ascribed a code
 20 which allowed them to have free prescriptions."
 21 Then you go on to say:
 22 "The Macfarlane Trust has been in dialogue with
 23 the Department of Health about this situation, but
 24 whilst a strong agreement that the situation is wholly
 25 unreasonable, there is no immediate prospect of being

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1 able to create an exemption clause for haemophiliac
2 patients as part of the national prescription form."
3 Then you said there was going to have to try and
4 be some kind of local solution which, as I understand
5 it, is the reason why you were writing to Haemophilia
6 Centre Directors.

7 Can you just give us a little bit about the
8 background to it and how at all it was resolved?
9 **A.** You will see that this is -- I am writing this as
10 a Macfarlane Trust trustee as the doctor. This,
11 again, is a very classical NHS story where, if you
12 look at the back of a prescription sheet, some groups
13 of patients are exempt from prescription charges.
14 It's a very curious selection of patients. How
15 anybody came up with those conditions, it's very
16 strange.

17 Here was a situation that was clearly unfair.
18 If you went to a sexual transmitted diseases clinic,
19 you turned out to have HIV, you were given a code,
20 somebody took your prescription to a pharmacy, and
21 your drugs came back, and you didn't pay. My patients
22 with haemophilia, I wrote a prescription with their
23 name on. They went to the pharmacy. All these
24 patients were on five, six, seven drugs. There would
25 be a bill for £35. You then work your way up. You go

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1 their NHS treatment, and they were being asked to pay
2 for it. So, actually, quite rightly, the patients
3 felt very resentful about this.

4 **Q.** Do you know whether it was resolved on a national
5 level ever, and if so, when?

6 **A.** No.

7 **Q.** You don't know, or it wasn't resolved?

8 **A.** I don't know.

9 **Q.** I've got some questions to ask you about the
10 Macfarlane Trust, but I see the time, and they'll take
11 -- they won't take a huge amount of time, but they
12 will take longer than a few minutes, sir, so is this
13 a convenient moment to break for lunch?

14 **SIR BRIAN LANGSTAFF:** Yes, it is. We'll take a break
15 until 2 o'clock.

16 (1.04 pm)

(Luncheon Adjournment)

17 (2.00 pm)

18 **MS RICHARDS:** Dr Winter, just before I come to the
19 Macfarlane Trust just a couple of other matters, if
20 I may.

21 The first is to ask you specifically in relation
22 to haemophiliacs who were mild or moderate but not
23 severe and regularly treated haemophiliacs. You
24 talked earlier about the natural history of
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1 to the local pharmacy in the hospital, the district
2 pharmacy, the regional pharmacy, the Department of
3 Health, everybody says, "I completely agree with you.
4 This is a completely unfair situation." "So what are
5 we going to do it about it?" says I. And nobody -- I
6 mean, essentially, they would have to rewrite the back
7 of the standard prescription charges.

8 **Q.** It doesn't sound terribly difficult.

9 **A.** Well, it was very difficult for them -- far too
10 difficult for them.

11 So, in the end, you can see the sort of note of
12 exasperation. This has been going on -- I'd
13 discovered -- when I went and chatted up my pharmacy,
14 I said, "How would you feel if I gave you a list of my
15 patients with haemophilia and HIV, their names, and we
16 gave them a code? So if I sent you a prescription
17 from my clinics with a code, you know it's one of
18 these registered names, exactly like you are getting
19 from STD clinics, and you could issue them with free
20 prescriptions." And they said that's fine. So that's
21 why I've -- it's the only thing I've come up with to
22 bypass this incredibly frustrating and bureaucratic
23 and very -- actually, very important problem.

24 These patients had to pay a lot of money to
25 resolve to treat an infection that they'd got through

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1 haemophilia, dying of cerebral bleeding in the
2 early 20s. Is that the same for mild or moderate
3 haemophiliacs or is that data that relates to severe
4 haemophiliacs?

5 **A.** That would only be for severe. So a moderate
6 haemophiliac we would sort of classify as someone who
7 had a Factor VIII level of between 1 and 5 per cent of
8 normal. That doesn't sound very much but day-to-day
9 that would probably not cause them any great problems
10 but they would bleed significantly if they had
11 accidents or had surgery without cover. They wouldn't
12 get the very serious, sometimes spontaneous, episodes
13 of bleeding into joints and muscles of severe
14 patients.

15 Now, mild haemophiliacs, I mean, it's quite --
16 sometimes seen in centres, somebody will come in at
17 the age of 45 who has been very healthy and have
18 a routine surgery and bleed and been found to have
19 mild haemophilia. So mild haemophilia you could live
20 to be a good age, depending on your health
21 experiences, before you were diagnosed.

22 **Q.** Then just a second point perhaps slightly related to
23 that. You talked about the knowledge that haemophilia
24 patients might acquire through family members having
25 had haemophilia or because of the close-knit community

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1 or attendance at Haemophilia Society meetings and so
 2 on, and no doubt that may be true for some people.
 3 Would you accept, though, that's not an assumption
 4 a clinician can make about everyone, that they will
 5 necessarily have that acquired knowledge?
 6 **A.** Yes.
 7 **Q.** In particular those who, for example, are mild
 8 haemophiliacs or moderate haemophiliacs, who haven't
 9 required regular treatment, may not have had that same
 10 interaction with others?
 11 **A.** No, I mean, I recall that of the information that we
 12 did give to patients, if we had a new patient with
 13 significant haemophilia, Peter Jones from Newcastle
 14 (who you may or may not be going to interview), he had
 15 written a book called Living with Haemophilia --
 16 **Q.** Yes.
 17 **A.** -- and that had been made available by some sort of
 18 arrangement. So we had lots of copies of that book
 19 and that book was written by Dr Jones for patients
 20 with haemophilia and we would give that book to
 21 patients with significant haemophilia. We probably
 22 wouldn't have given it to a mild haemophiliac because
 23 if we saw somebody with mild haemophilia we would
 24 register them with our centre and with Oxford and we
 25 would instruct them to come to us if there were any

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1 How can we help you in your community? You know, what
 2 could we do to make a difference to your centre? And
 3 the nurses would say, "Well, it would be great if you
 4 could run a weekend for our patients about
 5 prophylaxis" or the nurses would say, "It would be
 6 great if we could have some improved home treatment
 7 kits" or "it would be great if we could have
 8 a pamphlet on variant CJD".
 9 The NHS was really good at sort of -- once you'd
 10 got it -- the core funding. What was very difficult
 11 on the NHS was what you might call providing the
 12 frilly, but actually they weren't so frilly, bits for
 13 patients. So we might talk later about the
 14 Haemophilia Alliance. Well, we wrote a National
 15 Service specification. I could never have got funding
 16 for that document through the NHS but I was able to
 17 get funding from a commercial company for this
 18 document, which was an important one for patients.
 19 We wrote and published a home diary to collect
 20 Factor VIII usage. One of the really big issues in
 21 haemophilia care is home therapy is a great liberation
 22 for patients but it was essential for the centre to
 23 get good records of what the patients were doing. And
 24 if doctors are different, so are patients. Some
 25 patients weren't very good at keeping records of what

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1 problems with bleeding or any surgical or dental
 2 planned, but we would then only see them once a year
 3 for follow-up, very briefly, just to make sure they
 4 were okay. We probably wouldn't have given them that
 5 book. But any haemophilia that was significant in
 6 addition to the things that you're talking about, the
 7 patients would have been given this really quite
 8 substantial book to read -- no internet in those days,
 9 obviously.
 10 **Q.** Thank you.
 11 Then I just wanted to ask you about
 12 relationships with pharmaceutical companies. You use
 13 the phrase in your witness statement that there was an
 14 element of symbiosis in the relationship between
 15 centres and pharmaceutical companies. I wonder if you
 16 could just elaborate what you mean by that.
 17 **A.** So there were only, at any one time -- like all
 18 industrial companies, companies were forever changing
 19 and merging and changing their name, but at any one
 20 time there probably weren't more than four or five
 21 main providers of American, Japanese, Spanish, French
 22 origin that we would be buying concentrate from if we
 23 weren't using BPL.
 24 They would come to us outside of the contractual
 25 arrangements. Firstly, they would come to us and say:

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1 happened in the home. So we wrote this diary it was
 2 like -- it was called the Filofactor. So it was the
 3 age of the Filofax, and on each page was information
 4 about Factor VIII and space: Have you had Factor VIII
 5 today? That was funded by a commercial company.
 6 I took 100 haemophiliac children to Disneyland
 7 in Paris as a sort of bonding exercise. That was
 8 funded by a commercial company.
 9 They would sponsor the residential weekends for
 10 the patients that we've been discussing. The
 11 Haemophilia Society did not have their own funds
 12 sufficient for that. The Haemophilia Society would
 13 approach the companies and say, "How would you like to
 14 fund this residential weekend in Coventry, and you
 15 could come along and have a stand", so patients can
 16 come and say hello to you. The companies were only
 17 too happy to do that.
 18 So it was those sorts of activities, really,
 19 that they did. BPL never did any of that, to my
 20 recollection. I mean, I had limited interaction with
 21 BPL but at the start we kept saying to BPL, "It would
 22 be good if actually you started to do the things that
 23 commercial companies did, because haemophilia centres
 24 have needs outside of Factor VIII and it's very
 25 difficult to satisfy those needs through NHS funding

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1 and the companies are doing things which actually are
 2 very helpful."
 3 Sometimes the companies might pump prime a post.
 4 If a centre said, "I really need a physiotherapist",
 5 the centre would say, "We will fund that post for
 6 a year", and the director could then go to the Trust
 7 and say, "You know, we've been talking about getting
 8 a physiotherapist, I've got funding for the first
 9 year". That was a sort of big help. And the Trust
 10 might then say, "Fine, let's go ahead with that post."
 11 So there was a whole range of, from our point of
 12 view, beneficial things that they were doing for the
 13 haemophilia community at large and very much, you
 14 know, for the patient groups.
 15 **Q.** I understand from the description that you give of
 16 those kind of facilities and services what the benefit
 17 might have been for patients and the centre. What was
 18 the benefit for pharmaceutical companies? What -- put
 19 crudely, what were they getting out of it?
 20 **A.** Well, I think they got a sort of closer relationship
 21 and understanding of the way in which haemophilia
 22 centres worked and I think there was a feeling that --
 23 I've no evidence for this and nobody ever said this
 24 but maybe they felt that by providing these icing on
 25 the cake services -- but they were regarded as very

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1 Haemophilia Society; four by the Secretary of State."
 2 I think that changed over the years. Then:
 3 "The trust deeds specify that one of the
 4 Secretary of State's appointments should be the
 5 director of a haemophilia centre."
 6 Your name was put forward as a replacement for
 7 Dr Mayne, who had hitherto had that role. So you were
 8 appointed by the Department of Health, but were you in
 9 any respect answerable to the Department of Health?
 10 **A.** Not in any way, no. Nobody from the DoH ever
 11 communicated with me and asked me how I was getting on
 12 as a Macfarlane trustee in the 12 years or so. Plus,
 13 we should explain the Eileen Trust was a parallel
 14 trust for patients who got HIV from blood
 15 transfusions. It was very, very small, 20 to 30
 16 patients only, compared with 1,300 or so with
 17 Macfarlane Trust.
 18 **Q.** Now, your role as a trustee -- you had, I think, the
 19 general role that a trustee had in taking decisions
 20 and attending board meetings, but you had a particular
 21 role as medical trustee. Could you just explain what
 22 that was.
 23 **A.** Yes. Well, as you say, I attended the regular
 24 meetings which did have a medical element. You know,
 25 the Trust would be forming policy on what to do with

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1 welcome by the centres -- maybe that would make it
 2 more likely that they would get the contract from the
 3 hospital for the following year for Factor VIII.
 4 **Q.** They're private companies, not altruistic foundations,
 5 so ultimately they wanted your business?
 6 **A.** I think they wanted our business, of course, and they
 7 said to themselves this would be a way of making it
 8 more likely that they would get our business.
 9 **Q.** Did that influence your decisions as to what --
 10 **A.** Well, no. I mean, I've said to you we fell over
 11 backwards not to change product.
 12 **Q.** The Macfarlane Trust then: you were a medical trustee
 13 of the Macfarlane Trust and the Eileen Trust '96 to
 14 2009. I'll just look at the letter appointing you,
 15 just so that we can see how the appointment system
 16 worked. It's DHSC0003431_002. We can see from this
 17 it's a letter the end of 1995 addressed to you from
 18 the Department of Health:
 19 "The Haemophilia Society have put forward your
 20 name for consideration for appointment by the
 21 Secretary of State as trustee of the
 22 Macfarlane Trust."
 23 Then we can see -- then in the next paragraph,
 24 it said:
 25 "There are ten trustees: six appointed by The

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1 bereaved people or partners or establishing
 2 information. So there was a number of occasions at
 3 each meeting where they would need medical input which
 4 I provided. But my specific function was to deal with
 5 individual requests.
 6 So the registrants they were called, rather than
 7 patients, they received a regular monthly payment from
 8 the Trust, but they also had the ability to lodge an
 9 application for an individual grant. If they had
 10 a problem and they -- something that was -- would be
 11 of great benefit to them, they could put in an
 12 individual application from the Trust.
 13 The Trust needed, you know, medical background
 14 information as to how poorly the patient was, and why
 15 they needed to have this change to their life, and why
 16 should the Trust fund it. So I would read the
 17 patient's application, and then I would, with the
 18 patient's permission, get in touch with the centre
 19 that looked after the patient and say, "This patient
 20 has applied to the Macfarlane Trust for a chair lift
 21 or whatever. Please could you give me the background
 22 medical information as to, you know, how severe is the
 23 haemophilia, how is the state of the general health,
 24 what's happening with the HIV treatment." And I would
 25 send, obviously, the director a signed consent from

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1 the patient giving consent for the director to give
 2 that information to me.
 3 Then, in those days, the meeting was in two
 4 parts. So the first part of the Trust meetings were
 5 the sort of general agenda and then, later in the day,
 6 we would go on to hearing these individual requests
 7 and, for each request, I would then give, you know,
 8 "I've spoken to the centre, this is the medical
 9 background", and on that basis the Trust could form
 10 a decision.
 11 **Q.** Were there occasions in which the centre was -- or the
 12 clinicians at the centre were less than forthcoming
 13 and you had to chase to try and get the information
 14 that was required to assess the application?
 15 **A.** I think most people were pretty good, but some were
 16 a little harder than others to get communications
 17 from, but generally they were pretty good.
 18 **Q.** Could we look at BHCT0000873, please, Henry. So this
 19 is a letter from the Macfarlane Trust to Dr Mayne,
 20 June 1996. We can see that it's a letter to her in
 21 her capacity as the haemophilia clinician for
 22 a particular patient who has made an application, and
 23 there's an explanation here of intended process:
 24 "The trustees have decided that the anonymous
 25 case summaries which they receive in advance of their

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1 there's consent from the patient.
 2 The doctor writing it back to me or the Trust
 3 would never have said, "This patient's actually, you
 4 know, very well and I don't recommend that you give
 5 this grant." You know, the doctors knew all their
 6 role was to give the Trust, through me as the trustee,
 7 medical information. Maybe the sensitivity was that
 8 a doctor might -- you know, if the original report to
 9 the doctor had said, "This patient would like a chair
 10 lift," if the doctor wrote back and said, "The
 11 patient's perfectly mobile. Why would they need
 12 a chair lift?" Maybe the Trust didn't want the
 13 patient to see that. But in my experience, the
 14 doctors never did write back like that. They wrote
 15 back to say, "As I have requested, this patient's got
 16 mild or moderate haemophilia. They've got HIV. This
 17 is their medication, and this is their state of the
 18 health".
 19 **Q.** In your statement, you talk about you raise
 20 a number of concerns about the Trust's actions and
 21 decisions. You say, first of all, that you initially
 22 had issues with the Macfarlane Trust because the board
 23 spent more time discussing finances rather than
 24 discussing the needs of registrants. Can I invite you
 25 to explain a bit more about that, please.

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1 meeting should contain up-to-date health information
 2 gathered in a consistent fashion. To meet this aim
 3 where the health information held on the particular
 4 patient is older than six months, a doctor's report
 5 will be requested."

6 Then it's said that -- information in the next
 7 paragraph about how often that's likely to be
 8 requested. Then the next paragraph:

9 "All information contained in the completed
 10 report will be treated as given in confidence to the
 11 Trust and will not be shared with the patient
 12 concerned. Information provided of a complex
 13 technical nature will be drawn to the attention of our
 14 medical trustee, currently Dr Winter from Canterbury,
 15 who will translate it for the other trustees."

16 I just wanted to ask you about the first part of
 17 that paragraph I've looked at, that the report that
 18 was being requested here would not be shared with the
 19 patient concerned. Do you know why the Trust adopted
 20 that policy?

21 **A.** No, and I can't think why they would have done because
 22 the process -- you know, this letter sort of supports,
 23 doesn't it, what I said to you about the way the whole
 24 sort of single grant process worked: it was
 25 health-related; there was a report from the doctor;

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1 **A.** Yes. I'm not -- I presumably made those comments in
 2 a previous inquiry because I was asked to. When
 3 I first joined the Trust, the meetings did have the
 4 aura of a board meeting of Shell or something. You
 5 would spend a significant amount of time talking about
 6 the state of the investments of the Trust, and this
 7 I found rather bemusing. And there seemed to be
 8 nothing like as much time as I would have liked
 9 talking about the needs of patients.

10 I mean, eventually in each meeting, they would
 11 get around to talking about some matters, but I didn't
 12 really personally see the need why all these financial
 13 matters had to be discussed in a meeting that should
 14 really have been talking about: how can we provide the
 15 best possible service to the registrants? You know,
 16 the Trust deed said we're to relieve suffering in the
 17 haemophilia community. That's why I was a trustee;
 18 obviously to the help out with that general
 19 philosophy.

20 So I was disconcerted, would be a good word, at
 21 the sort of aura of the meetings at first. This was
 22 partly due to the personnel who were senior trustees
 23 at the time, and that did change as those personnel
 24 changed.

25 **Q.** You also talk in your statement about trust executives

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1 seeming to follow a position of providing generalised
2 welfare support where the culture was for registrants
3 to be passive recipients, and your experience was that
4 wasn't what patients wanted. Again, can I just invite
5 you to elaborate upon that?

6 **A.** Yes. We went from one extreme to the other, really,
7 where there did seem to me to be a culture -- which
8 was very well intentioned, and these people were very
9 caring and compassionate -- and it was a time when,
10 you know, many people were dying, a lot of people
11 were ill. The culture seemed to say to the
12 registrants -- you know, it was like the Welfare
13 State: we're here to look after you, you're not
14 expected to do anything. You know, your role is to
15 make applications to us for extra support, and that's
16 fine and we will do what we can do give you all that
17 extra money that we have at our disposal.

18 I learnt from talking to patients, particularly
19 at residential weekends, as the treatment improved,
20 particularly the advent of what we call
21 protease inhibitors in about 1995, until then people
22 with HIV would have been on two drugs, which were sort
23 of quite effective but not very, and then the addition
24 of this third drug was a major step forward, and for
25 the first time it became possible to clear HIV from

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1 suddenly the doctors are telling me they've cleared
2 HIV from my bloodstream and I might survive. And
3 that's great but I've got to rejoin the human race.
4 I've got to think about the hole in my roof, I've got
5 to get the fridge sorted out and I've got to get my
6 life back on track."

7 So this was a very -- it wasn't -- if you
8 thought that patients were in a state of, you know,
9 emotional improvement, it was much more complex than
10 that. It came on a background of -- everybody kept
11 using the word "worn out". They'd lived with the
12 virus, their partners had had to live with the virus,
13 all the drama, people they knew had died, all the
14 media exposure, having no money, everything -- you
15 know, people had had such a difficult time and it was
16 very hard for them. Yes, it was great they weren't
17 going to die -- if you got as far as 1995, you were
18 pretty unlikely to die of HIV. Nearly all of my
19 patients died between '84 and '95. If you got to '95,
20 most of those patients are still alive, but getting
21 lots of problems with hepatitis now, but that's
22 a different issue.

23 Anyway, this was all part of this retraining and
24 a change of emphasis of the Trust to get people back
25 on their feet again.

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1 the bloodstream, people started feeling much better,
2 and people said, quite rightly, "In any case, I don't
3 want to be a passive recipient of largesse. You know,
4 I want to rebuild my life. I want control and, now
5 that I'm feeling so much better, I'd really like the
6 trust to help me take my life forward. I'd like to go
7 on a course. I'd like to retrain".

8 So there was, from people like me, an
9 encouragement to sort of change the emphasis to what
10 you would call a partnership. We even set up
11 a partnership group where we met regularly with some
12 registrants to see what they wanted. And the culture
13 was, you know, "Let's not expect you to do nothing and
14 we'll give you money when we can, let's work together
15 to help you rebuild your lives".

16 This wasn't easy because for -- people had lived
17 for a long time with HIV. I remember giving a talk at
18 a World Federation meeting called "The Problems of
19 Survival", and patients were saying, "You know, I'd
20 expected to die, I'd been told I was going to die and
21 I'd not planned to live, so I've got no money, my
22 relationships are worn out, there's a hole in my roof,
23 I never worried about that, the washing machine's
24 bust, I haven't got a job, I didn't worry about any of
25 that because I knew I was going to die, and now

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1 **Q.** You I think identify in your statement a particular
2 problem with the treatment of widows and the lack of
3 financial support for them. How do you recall that
4 arising and being considered by the Trust?

5 **A.** One of the chief executives brought this to my
6 attention. The widows, under the terms of the Trust,
7 were supported for six months only after the death of
8 the patient with haemophilia. So there was obviously
9 a very distressing situation where the wife had often
10 given up work for 6/12 months to look after her dying
11 husband, who had then passed on, and then after
12 six months of support from the Trust, which wasn't
13 very substantial anyway, she would be left with no
14 support at all, and having not worked for 18 months or
15 so. So we felt that widows were particularly hard
16 done by.

17 You have provided me with papers reminding me of
18 the regular meetings we had with various ministers.
19 I remember meeting Hazel Blears and people like that
20 each time, and we regularly I think flagged up that we
21 would really like to do more for widows. Coming out
22 of that, the Trust had set up a bereavement group and
23 that, you know, put a lot of energy into trying to
24 support bereaved women.

25 **Q.** I think this is right, that the position in terms of

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1 financial support for widows didn't change during the
 2 time that you were there?
 3 **A.** That's my understanding.
 4 **Q.** Then you also set out your view that registered
 5 patients with the Trust, in your view were not
 6 receiving the level of financial support via lump sums
 7 to which they should have been entitled, considering
 8 the very serious viral infections they'd acquired
 9 through NHS treatment. You observe in your statement
 10 the financial support was significantly greater in
 11 other countries such as in Ireland. Again, can you
 12 just perhaps help us with how you formed that view and
 13 to what extent it was considered by the Trust?
 14 **A.** Well, I don't know how society puts a value on
 15 somebody with a very unpleasant life-long blood
 16 disorder got infected with HIV and hepatitis from
 17 their NHS treatment which either killed them or made
 18 them very ill. How do you put a sum on that?
 19 But what you could do is compare the funding,
 20 the grants that people in the UK had got compared with
 21 other countries. I made the Irish comparison.
 22 In Eire, I think if you had hepatitis alone -- they
 23 had a lot of cases through anti-D -- I think the
 24 patients who were infected were given something like
 25 the equivalent of about -- it was certainly well over

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1 obviously, who wasn't an MP but he was always
 2 extremely supportive and helpful.
 3 There was collaboration with The Haemophilia
 4 Society and we did have these regular -- it was,
 5 I think, a regular event that once a year maybe there
 6 was a little group that was taken off to the DoH to
 7 meet the minister. That was always top of the list
 8 when it came to the Trust's part of the meeting, would
 9 be to say, "Well, Minister, we've come to see you
 10 today, we really are very concerned that, you know,
 11 we're charged by the DoH with offering this level of
 12 support and we can't do it."
 13 So I do think the Trust did try very hard to get
 14 extra funds and usually each time we went, the DoH did
 15 give some extra money but it was always sort of given
 16 with, you know, the caveats of, "We're under great
 17 pressure, and other competitive grants, and we've
 18 managed to find another 50,000 for you but that's all
 19 we can afford for this year and maybe we could review
 20 it next year".
 21 That was the sort of response that we got. So
 22 it was like a sort of chronic drip-feed of minor
 23 improvements.
 24 **Q.** Could we have up on screen, please, Henry,
 25 HSOC0029628_002.

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1 £200,000. That was way, way, way in excess of what
 2 patients with hepatitis in Britain were given and the
 3 general level of support was less than in other
 4 countries. I think that was the point I was trying to
 5 make.
 6 **Q.** One feature of the documents, Trust minutes and so on,
 7 and we've given you a sample of them to look at, was
 8 the Trust not having enough money and asking the
 9 Department of Health for more financial assistance,
 10 for more money. Do you think, from your perspective
 11 as a trustee, attending the trustee meetings when this
 12 issue came up, sometimes attending meetings with the
 13 Department of Health as a trustee, do you think
 14 there's more that could have been done and should have
 15 been done by the Trust, first of all, and then,
 16 secondly, by the Department of Health?
 17 **A.** I think the Trust, you know, had the -- were always of
 18 a view that they would like -- you know, given the
 19 task in front of them, they didn't have enough funds
 20 to provide the level of support for the registrants
 21 that they would have wanted. I think they did really
 22 try hard to increase that funding.
 23 There were two or three politicians who we
 24 interacted with who were always very supportive.
 25 I can't remember who they were now -- Lord Morris

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1 This is the minutes of one meeting of the
 2 trustees. It's actually one you didn't attend, but
 3 I'm hoping I can still ask you about it.
 4 So we can see it's 23 January 2006. We can see
 5 who is there: Mr Stevens and others. Apologies from
 6 some, including you.
 7 Could we go to page 4, please, Henry.
 8 I just wanted to ask you about this entry here
 9 under "Department of Health", and if you have any
 10 recollection of the issue that comes up here.
 11 So we have the chair reporting on a meeting with
 12 department officials on 5 December. The main area of
 13 business discussed was the funding bid.
 14 "The Chief Executive was asked to pursue the
 15 possibility of a ministerial meeting to discuss the
 16 business case."
 17 Then there's reference to Lord Morris having
 18 tabled written questions.
 19 Then it says:
 20 "The board were of the view that as many
 21 contacts as possible should be exploited to further
 22 the case for the increase in funding such as the
 23 [All-Party] Parliamentary Group on Haemophilia ... and
 24 the All-Party Parliamentary Group on HIV ..."
 25 Then the chair talks about having established

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1 good relations with the local MP and the possibility
 2 of a meeting with the Shadow Secretary of State for
 3 Health.
 4 Then we have Mr Spellman saying this:
 5 "Mr Spellman urged that caution in respect of
 6 overt lobbying should be followed for the following
 7 reasons:
 8 "(a) That the business case supported itself in
 9 terms of the requirement.
 10 "(b) Overt lobbying might prove
 11 counter-productive.
 12 "(c) If the business case is declined, the full
 13 board of trustees should be given the opportunity to
 14 debate a 'next steps' programme.
 15 "(d) Further political activity might not help
 16 the situation."
 17 Then we see it records the chair agreeing that:
 18 "... no political activity should be undertaken
 19 which might impede a positive response from the
 20 Department."
 21 Now, the impression that those minutes give is
 22 that some on the board were suggesting: maximise the
 23 opportunity, maybe undertake some form of campaigning,
 24 lobbying. Then there's a counter-voice on the board
 25 saying, "Well, no, let's not do overt lobbying".

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1 is a rather curious thing which I think we can ignore.
 2 **Q.** We'll, no doubt, be able to ask those working for the
 3 Trust and schemes full-time about that.
 4 Just two further matters on the
 5 Macfarlane Trust, Dr Winter. The first is about the
 6 Trust's policy in relation to funding for aspects of
 7 assisted fertility -- sperm washing and the like.
 8 Now, there are a number of references to that in the
 9 minutes of meetings. I'm not proposing to go through
 10 them, unless that would assist you in terms of your
 11 memory. But it does appear that the question of the
 12 extent to which the Macfarlane Trust should fund such
 13 treatment was something the Trust considered over
 14 quite a number of years before it finally settled on
 15 a policy, and I wondered what you can recall about
 16 that.
 17 **A.** So you get this familiar story from me now. If you
 18 work for the NHS and you have problems, here's yet
 19 another issue where everybody listens to you and says,
 20 "I fully agree. I completely understand." And then
 21 when you say, "Well, how are we going to fix it?"
 22 nobody has any idea.
 23 There was another evolving area of concern. The
 24 Trust had a number of registrants it was supporting
 25 who were girls who had caught HIV from their

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1 What can you recall about any discussions about
 2 the kind of stance the Trust should take?
 3 **A.** So, I mean, I wasn't at the meeting, and I actually
 4 can't remember who Mr Spellman was. He must have been
 5 a trustee, but he certainly wasn't a major figure in
 6 the trust.
 7 So the first part of this document reinforces
 8 everything I've said to you. They've got contacts
 9 with the Society, they've got Lord Morris, and now
 10 that I read this, I mention the MPs. There used to be
 11 an All-Party Parliamentary Group. It had disbanded
 12 sort of spontaneously, and through encouragement from
 13 The Haemophilia Society and the Trust, it had got
 14 going again through Michael Connarty. I remember
 15 meeting him. So these were all the things I was
 16 saying to you, this sort of different pronged approach
 17 which was all very appropriate, and then these rather
 18 curious comments at the bottom, which I obviously
 19 don't agree with. But I -- you know, all of the
 20 meetings that I recall, the Trust, to my eyes, as
 21 someone who was -- you know, I'd done a lot of work
 22 with the Society and getting the publicity to get the
 23 Trust set up. I'd been to meet -- I'd been to the
 24 House of Commons with other patients and given talks,
 25 and I knew political influence was everything. This

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1 haemophilic husbands, some of whom had died. The
 2 Trust also had a small number of orphans where both
 3 the mother and father had died of HIV. So this was --
 4 you know, the importance of doing anything you
 5 possibly could to minimise any more haemophilic men
 6 infecting their wives and partners was obvious.
 7 It was -- you could make a little bit of
 8 difference by ovulation testing, by asking the girls
 9 to keep exact dates, but that was only a minor thing,
 10 and you had no reassurance that the girls would be
 11 safe. Ovulation testing was in increasing clinical
 12 usage across the country, and we were very keen for
 13 our patients to have it. The patients were -- well,
 14 a small number of patients were very keen to try. The
 15 particular issues about ovulation testing where -- the
 16 treatment took form of a cycle, and each cycle only
 17 had about a 10 per cent chance of leading to
 18 pregnancy, and each cycle cost about £1,000. Those
 19 were the issues.
 20 So the issues were: how do I get any money at
 21 all? And if I get 3,000 and it hasn't worked, how do
 22 I get the next 3,000? So you know what I'm going to
 23 say: no centralised policy; no centralised funding;
 24 every centre director must do what they can. I am
 25 sure there's correspondence from me, is there not, to

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1 haemophilia directors about this matter encouraging
 2 them to approach their own trusts. And, again, the
 3 variable response: some trusts were helpful; some
 4 trusts were not so helpful. My own trust in Kent were
 5 very supportive. I had one patient in particular who
 6 they funded and which led to a successful pregnancy
 7 and safe, and then repeated again two to three years
 8 later.

9 Now, I think the Trust -- the problems with the
 10 Trust was, it was brought to the Trust's attention by
 11 a trustee. He said, "We are obliged to follow the
 12 Trust deed which says you must alleviate suffering."
 13 And this trustee said, "Does that include providing
 14 funding for this sort of activity?" There was, you
 15 know, considerable discussion about that.

16 Then, of course, there was discussion -- well,
 17 if the Trust supported somebody for £3,000 and the
 18 registrants came back at said, "Well, thanks very
 19 much. It hasn't worked. Could I have another 3,000?"
 20 What would they do? These were the sort of
 21 conversations, as I recall.

22 What I do remember -- and I'm pretty sure about
 23 this -- is that the Trust did eventually, as you say
 24 after a long and protracted correspondence and
 25 discussion -- I'm pretty sure they agreed to consider

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1 individual grant scheme was always going to be
 2 a problem because you had large number of people.
 3 Some people would hardly apply for anything. I mean,
 4 I had patients who were very sick, very disabled. I'd
 5 say to them, you know, "Have you thought about
 6 applying to the Trust for ... ?" "No, I can't be
 7 bothered." So some sick people never applied. Some
 8 people applied for huge numbers of things, some of
 9 which were, frankly, well over the top. I won't give
 10 you examples, but there were some you just couldn't
 11 believe what they were applying for.

12 So that sort of scheme where people could apply
 13 for individual grants was always going to cause
 14 difficulties, I think, and, you know, I think we even
 15 discussed was it a good idea to have an individual
 16 scheme? But then we thought, well, some people can
 17 have unexpected financial needs, and we probably
 18 should have some mechanism for the registrants to come
 19 to the Trust on an individual basis. But it did cause
 20 exactly those sort of problems.

21 **Q.** I want to ask you about the Skipton Fund briefly.

22 Henry, could we have HCDO0000242_050, please.

23 This is a letter from you, December 2004, to
 24 Dr Hill, who was then the Chairman of UKHCDO. The
 25 subject matter, as I think you know -- we see it from

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1 funding if the local trust had already provided some
 2 cycles of treatment which had not been effective. My
 3 recollection is the Trust did eventually, somewhat
 4 reluctantly I think, fund some treatment of this
 5 nature.

6 **Q.** The Inquiry's heard evidence from a number of
 7 individuals who, either as relatives or as people who
 8 were themselves infected, made applications to the
 9 Trust. We've heard expressions of unhappiness and
 10 dissatisfaction -- it's not the universal account, but
 11 it's certainly the account from a lot of people --
 12 things like feeling they had to go with a begging bowl
 13 was the sense that some have described.

14 Does that surprise you, or do you understand
 15 that perspective, as someone who was a trustee for
 16 a number of years?

17 **A.** Well, that's exactly what I said to you. Patients
 18 would say, "I don't want to be the passive recipient
 19 of the Trust's largesse. I want to have a more active
 20 role, and I want to rebuild my life." So I do
 21 recognise that, and that's why I did welcome this
 22 eventual sort of change of policy of the Trust, to put
 23 more money into training and teaching programmes and
 24 getting people back to work.

25 I mean, I -- you know, the -- you see, the

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1 the next page -- is a letter you were drafting about
 2 the criteria for assistance under the Skipton Fund.
 3 But it was this phrase I wanted to ask you about:
 4 "As the Skipton Fund is only the servant of the
 5 DoH -- and does not set policy -- on reflection, I
 6 think it would be better to direct the correspondence
 7 directly to the DoH with copies going to Peter Stevens
 8 and Martin Harvey at the Skipton Fund."

9 Can we look at the second page, Henry, briefly,
 10 so we can contextualise this. We can see the draft
 11 letter there is something that had been discussed by
 12 Haemophilia Centre Directors, and it was about the
 13 criteria for the scheme. I don't need to ask you
 14 about the detail of that, but if we just go back to
 15 the first page, what did you mean by the Skipton is
 16 the servant of the Department of Health?

17 **A.** So I think what I meant was -- this is all about who's
 18 going to qualify to be a registrant on the
 19 Skipton Fund and the issue, as set out in the second
 20 letter, is if you've got hepatitis C antibody, in
 21 theory, you could have been exposed to it and cleared
 22 it or something. You might not have live virus. So
 23 one school of thought said, well, maybe we shouldn't
 24 treat as registrants people who are just antibody
 25 positive. Maybe we should want them also to have

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1 abnormal liver function tests because that would
 2 indicate they have got active virus. Whereas other
 3 people said, well, why don't we just do it with the
 4 antibody positives anyway?
 5 So I think what I'm referring to here is -- I
 6 mean, the Skipton Fund obviously does set policy, once
 7 it's up and running. This was about who could the
 8 Skipton Fund accept as a registrant.
 9 **Q.** And you didn't, I think, have any formal involvement
 10 with the Skipton fund?
 11 **A.** No.
 12 **Q.** Did you have much experience of its decision-making in
 13 your capacity as centre director between 2004 until
 14 your retirement in 2011?
 15 **A.** No, beyond, you know, being asked -- I mean, I'm
 16 assuming there must have been a separate medical
 17 trustee for the Skipton Fund. Occasionally, I might
 18 have been asked for a medical report on one of my
 19 patients, but beyond that, I wasn't involved.
 20 **Q.** Then leaving the Trust and schemes and just coming
 21 back to a handful of the more general issues that
 22 you've alluded to in your evidence so far, you've
 23 talked on a number of occasions during your evidence
 24 about the lack of national guidance, advice,
 25 decision-making.

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1 issues. I mean, we all agree this was the greatest
 2 medical disaster ever to befall the NHS. Where was
 3 the DoH in all of this? Surely they should have been
 4 much higher profile working with the haemophilia
 5 directors to make sure that doctors like me and my
 6 colleagues were giving the best possible care. That's
 7 the core of my comment.
 8 **Q.** Are there actions that you think the UKHCDO could or
 9 should have taken in that period that you've
 10 identified, 1978 to 1985, during these very sea
 11 changes that we've discussed, to promote safer care?
 12 **A.** Well, if it was happening now, there's no way those
 13 type of documents could be written. All this stuff
 14 was, "Well, on balance it would be good to do this but
 15 every doctor must make up their own mind", that would
 16 never happen now, and, you know, in many ways it
 17 wasn't helpful, was it, because it opened the door to
 18 variability. That should not have been -- you know,
 19 it should have been done by a document saying: We're
 20 in a very difficult situation, we, the following, you
 21 know, directors of the major centres in Britain, this
 22 is what we think is best practice at this time and we
 23 strongly recommend that you do this.
 24 Any doctor receiving a document like that would
 25 have been very wary of not following it. He would

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1 Could I ask you to identify for the Inquiry some
 2 of the particular issues that you think could and
 3 should have been usefully addressed at a national
 4 level which weren't?
 5 **A.** Well, I think that the DoH generally should have taken
 6 much more of an active interest in the evolving
 7 crisis, as a starting comment. As I've said to you,
 8 it was -- from a practical point of view, even though
 9 they had a doctor at our meetings, it seemed very hard
 10 to get them to take this as the very, very serious
 11 healthcare crisis that it became. I think that at
 12 times of all this variability that we've seen (about
 13 how to test patients, how to tell patients), that
 14 could have been much better handled if there'd been
 15 a DoH doctor at senior level working with the
 16 haemophilia directors, writing to haemophilia
 17 directors on behalf of the DoH about this very serious
 18 issue and this is the way in which it is recommended
 19 that you should handle the following issues, and we
 20 can go from how to test your patients; how to tell
 21 your patients; what treatments you should be giving at
 22 a time when we don't yet have sterilised treatment;
 23 how to switch to safe treatment; how to switch to
 24 recombinant treatment.
 25 It seems to me these were such serious medical

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1 have said, or she, "If I don't follow that and then
 2 something goes wrong, I'm dog meat for a legal case."
 3 Once you get a letter saying, "Well, you could
 4 do this or you could do that but every doctor must
 5 make up their mind", a comment that seems to be in
 6 almost every communication, then the doctor might say,
 7 "Well, I've read that but this is what I think and
 8 it's not quite the same thing and I seem to be given
 9 carte blanche to deviate". And I obviously don't
 10 think that was a good thing.
 11 **Q.** In your witness statement, your statement to the
 12 Inquiry, you say this:
 13 "It has always been my view that the level of
 14 care offered to some patients in some centres was not
 15 what those patients had a right to expect, even by the
 16 standards of the day."
 17 Now we've obviously alluded or you have alluded
 18 to some of those in the course of your evidence but
 19 can I invite you to set out to the Inquiry what
 20 particular aspects of care that you think was provided
 21 to patients in some centres that was not what they had
 22 a right to expect by the standards of the day?
 23 **A.** Well, I think most particularly about testing and most
 24 particularly about the telling, and I've heard so many
 25 examples of the way in which that happened to patients

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1 that I think was terribly wrong. I think some centres
2 just didn't do well in supporting the patients
3 generally.

4 You know, I've heard patients from centres say
5 it almost felt like they had been rejected by the
6 centre. They would ring up and say, "I'm not feeling
7 well, I'm short of breath", to be told, "Nothing to do
8 with the haemophilia, ring this other hospital."

9 The patient would say, "You know, I've been
10 infected by you, through treatment in your centre, and
11 now you are rejecting me, you're saying go and see
12 somebody else."

13 So I think it sort of reflects back to the sort
14 of way in which some centres were holistic and some
15 weren't, and the way in which some centres worked was
16 in such a manner that patients I think did feel
17 rejected. You know, if there was any problems to
18 do -- that wasn't to do with the haemophilia, they'd
19 say, "Nothing to do with us, go to somebody else", and
20 I think that went down badly with patients.

21 **MS RICHARDS:** Sir, I know you have a couple of questions
22 you would like to ask Dr Winter. One of them relates
23 to a Lancet article which Dr Winter hasn't yet had the
24 opportunity to fully read.

25 **A.** Well, I've probably read enough.

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1 **A.** The Lancet is a must-read, yes.

2 **SIR BRIAN LANGSTAFF:** So on 1 September 1984 -- now the
3 importance of that might be the date -- your memory is
4 that your tests conducted by the Middlesex came back
5 to Thanet sometime the end of October/beginning
6 November. Is that about right?

7 **A.** Yes, for certain -- see, on this list of authors is
8 Dr Tedder from the Middlesex, he was the virologist,
9 and it was his test that was made available to the
10 haemophilia directors. And it's my recollection --
11 which fits with this -- this is the very early
12 evaluation of actually two tests.

13 **SIR BRIAN LANGSTAFF:** Yes.

14 **A.** I can't remember which one we were offered or which
15 Dr Tedder did. But anyway, it was very, very short,
16 very early October that we got the news that the test
17 was available and then, as we've discussed, it's a few
18 weeks later that the process is finished.

19 **SIR BRIAN LANGSTAFF:** The authorship, if we just look at
20 the top of it, there's Rachanee Chengsong-Popov is put
21 as the first author but then -- was it
22 Professor Weiss? I don't know if you have come across
23 his name before but he -- as I understand it, on
24 behalf of the Chester Beatty Laboratory, was
25 developing the test which was proposed by him and by

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1 **MS RICHARDS:** But, in any event, I should also find out
2 from recognised legal representatives if there's
3 anything further they --

4 **SIR BRIAN LANGSTAFF:** You are asking me for a break.

5 **MS RICHARDS:** I am suggesting it might be suitable to just
6 have a short break -- we wouldn't necessarily need a
7 long one, or as long as you want, sir -- just so that
8 I can undertake that and Dr Winter can --

9 **SIR BRIAN LANGSTAFF:** We will make it long enough, shall
10 we, for people to think a cup of tea if they want and
11 I hope it might be available. So shall we say --
12 shall we come back at 3.30 if that's long enough.

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

14 (2.53 pm)

(A short break)

16 (3.29 pm)

17 **MS RICHARDS:** Sir, I have no further questions for
18 Dr Winter but I think you have a couple of matters
19 that you want to ask him about.

Questioned by SIR BRIAN LANGSTAFF

21 **SIR BRIAN LANGSTAFF:** Just a handful of questions, if
22 I may.

23 Can I begin with the article from The Lancet.
24 You read The Lancet -- you read The Lancet at the
25 time?

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1 Tedder as a test to be rolled out across the country.
2 And I think the Inquiry may hear later from various
3 documents that the proposal was made perhaps in July,
4 certainly by August there was a test, and it was this
5 test which, from what you say, was used for your
6 patients in due course.

7 Now it's a very -- fairly impressive list of
8 authors, isn't it? It includes Pinching from
9 St Mary's, Craske from Public Health Laboratory and
10 Dr Barbara from the North London Transfusion Service?

11 **A.** Yes. There aren't any haemophilia doctors but they
12 are just one of the subgroup of patients. But this is
13 a distinguished list of HIV specialists. Ian Weller
14 was head of the group eventually at the Westminster,
15 I think, and the Middlesex, and Tony Pinching was
16 obviously a leading light, with Weber, of the very
17 large St Mary's HIV treatment centre.

18 **SIR BRIAN LANGSTAFF:** So if I can just draw one or two
19 aspects of it to your attention and then ask some
20 questions about it, if one looks at the summary --
21 left-hand column, very bottom, Henry -- the results
22 were that testing those who were haemophiliacs --
23 doesn't tell you here how many there were --
24 34 per cent --

25 **A.** There were 184 on one of the tables.

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1 **SIR BRIAN LANGSTAFF:** Yes, I was going to take you to
2 that, but you've answered that question.
3 So 34 per cent. That's 68 out of 184
4 haemophiliacs receiving pooled clotting factors tested
5 positive. So roughly a third, very nearly a third,
6 which, as far as this cohort was concerned, was rather
7 less than you recollect in due course it was reported
8 to you that Professor Kernoff's research had found in
9 the Royal Free.

10 **A.** Well, the interest at this paper is this is just
11 immediately before the haemophilia directors are about
12 to test and find that 80 to 90 per cent of regularly
13 treated patients are HIV positive.

14 So, against the context of Professor Bloom's
15 remarks, "This isn't going to be a big problem", this
16 might perhaps be an indication that the percentage of
17 people affected is much greater than we had
18 anticipated.

19 I mean, it's surprising the figure's only
20 34 per cent. But I just make the comment, looking at
21 the patients they've got, patients were drawn from the
22 Middlesex, Mary's and St Stephens. St Stephens
23 actually isn't a haemophilia centre at all. The other
24 two are small centres. And we're just told they'd had
25 Factor VIII, including commercial. So that really --

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1 clotting factors, appeared to have seropositivity --
2 and this in The Lancet, which is required reading for
3 most if not all doctors -- what was the reaction to it
4 in the haemophilia doctors' community?

5 **A.** You see, I think if we were testing beginning of
6 October, I think we had already been told about this
7 test and that it was going to come to us, because we
8 would have had to line up the patients and write to
9 them. If I was testing October, I must have written
10 to them earlier than that. So I'm thinking that we
11 already knew about what this survey had shown and that
12 we had already been informed that the test was coming
13 our way. So our attitude was: Dr Tedder, who we knew,
14 has got this test. We're about to be able to do it,
15 here's a preliminary report indicating the antibody
16 positivity. And, you know, all the more reason for us
17 to do our tests.

18 But it's rather slipped under the radar, this
19 paper, because we've jumped from Professor Bloom and
20 the theories of "this isn't going to be a problem" to
21 our 80 to 90 per cent, this is a bit of a middle
22 ground one, which I think has rather got -- rather got
23 hidden.

24 **SIR BRIAN LANGSTAFF:** The introduction, on the right-hand
25 column -- just the very beginning of that if you

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1 to me, I'd like to know a lot more about those
2 patients. They may not have been very heavily
3 treated, very regularly treated.

4 **SIR BRIAN LANGSTAFF:** I think it says they were regular
5 recipients. I think that's in the --

6 **A.** It does say "regular clotting factor replacement
7 therapy".

8 **SIR BRIAN LANGSTAFF:** So that would suggest that they were
9 not necessarily mild or moderate.

10 **A.** But my main comment is one is surprised that the
11 percentage of positive people was not greater than
12 34 per cent, given the results that are about to
13 emerge the next month using the same test.

14 **SIR BRIAN LANGSTAFF:** Might it be that the picture varied
15 across the country?

16 **A.** Well, that wasn't a feature. I think wherever you
17 were looking in England you found that all the major
18 centres had very similar levels of incidence of HIV
19 positivity.

20 **SIR BRIAN LANGSTAFF:** I think we'll have a look at that in
21 the Inquiry and just see what they were reporting but
22 thank you for that.

23 The next part I wanted to ask you about was,
24 given that this said a third of all haemophiliacs
25 receiving regular clotting factors, of commercial

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1 please, Henry, if you can highlight that:

2 "The likelihood of the acquired immunodeficiency
3 syndrome (AIDS) being caused by an infectious agent
4 has been apparent for some years."

5 That's what the virologists appear to be saying.

6 "The exponential rise in the number of cases of
7 this disease has been restricted to certain
8 well-defined risk groups in a pattern that strongly
9 suggests an agent transmissible by sexual or blood
10 contact."

11 I think you would, from what you have said,
12 agree that that's a fair summary?

13 **A.** Well, it was. I wouldn't have used a phrase like "for
14 some years", but you'd certainly, as I've previously
15 given evidence -- by the time you've got the
16 haemophiliacs, in the summer of '82 in the US, the
17 San Francisco baby at the end of '82, you would have
18 to, in my view, strongly suspect. So I think I might
19 have written, you know, the likelihood of it being
20 caused by an infectious agent has been apparent since
21 at least December 1982, which was less than two years
22 after the paper was actually published. But it's
23 a fair point.

24 **SIR BRIAN LANGSTAFF:** Then it says:

25 "Case-clustering supports this hypothesis."

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1 So that would be an epidemiological construct,
 2 would it?
 3 **A.** That would be in relationship to the sexual contact.
 4 **SIR BRIAN LANGSTAFF:** I see.
 5 So, if you like, further support for that
 6 hypothesis. If one needed one now, because by now, in
 7 September '84, it would be generally accepted,
 8 I think, that the cause was a virus and generally
 9 accepted it was to be known as HTLV-III or, for that
 10 matter, NAV.
 11 **A.** Yes, HTLV-III was the initial terminology at that
 12 stage.
 13 **Q.** I think the only other thing I need to ask you about,
 14 at page 480 -- it's the fourth page in, Henry, if you
 15 please, that's the page -- and the second paragraph
 16 beginning "high prevalence of":
 17 "It says this:
 18 "The high prevalence of HTLV-III antibodies in
 19 haemophiliacs found in this and other studies ..."
 20 And it sets those out below. I think it cites
 21 just one, at footnote 12, it's probably a Danish
 22 study, Melby and others:
 23 "... has to be set against the relative low
 24 incidence of disease in this risk group so far ..."
 25 So the prevalence of HTLV-III antibodies set

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1 If I may say, taking a general view, asking
 2 something rather more general than specific to this
 3 article now, if I may, what you've described as
 4 a healthcare crisis and a treatment disaster in the
 5 course of your evidence, you've given me the
 6 impression that it is something which has caused, at
 7 the time and since, deep concern to you that it should
 8 have happened at all?
 9 **A.** Well, of course. I mean, here's a disease,
 10 haemophilia, which is pretty unpleasant, and
 11 life-long, and my take on the whole thing, over a long
 12 period of years, is that decisions were made in the
 13 mid-1970s that were clearly, at the time, wrong, and
 14 that other countries looked at the same situation and
 15 made the correct decision, which was: it is not
 16 sensible, in terms of safety of patients, to be using
 17 clotting factors that have come from paid blood donors
 18 in the US. You know, no doctor would have signed up
 19 to that idea in the mid-1970s.
 20 So those decisions are unfathomable, really, to
 21 a clinician. How could the body have looked at the
 22 evidence and said that's a perfectly sensible thing to
 23 continue to do?
 24 So as a result of that decision, 1,500 people
 25 died.

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1 against the relatively low incidence.
 2 And:
 3 "This high antibody prevalence also shows the
 4 retrovirus or its antigen, is present in pooled blood
 5 products, especially factor VIII concentrates."
 6 Then this:
 7 "The likelihood that infection resulted from
 8 commercial rather than National Health Service
 9 factor VIII concentrates is increased by our failure
 10 to detect HTLV-III antibody in over 1,000 blood donors
 11 from the North London Blood Transfusion Centre. This
 12 finding is also reassuring as to the low risk at
 13 present of acquiring HTLV-III infection or AIDS by
 14 blood transfusion in Britain."
 15 **A.** So this is very important re-affirmation of my point
 16 about, if Dr Owen's initiative had been successful,
 17 these are the sort of donors who would have been
 18 giving blood turned into Factor VIII in Britain. And
 19 in the 1,000 donors there's no HIV in it. So, you
 20 know, we would have moved from a high-risk population
 21 of donors with HIV to a low incidence of HIV and that
 22 might have made -- might -- a difference.
 23 **SIR BRIAN LANGSTAFF:** Yes, I see that entirely. And
 24 I thought it would support what you had been saying to
 25 us throughout.

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1 **SIR BRIAN LANGSTAFF:** So if I were to ask: what do you see
 2 as -- amongst the various different contributory
 3 causes for different parts of what we have been
 4 discussing, what you would see as the single most
 5 important cause, either by taking action or failing to
 6 take action --
 7 **A.** Yes.
 8 **SIR BRIAN LANGSTAFF:** -- would that be it?
 9 **A.** If you were only allowed to have one witness for this
 10 Inquiry, it would have been David Owen, because
 11 everything revolves around that moment in time.
 12 I have already given evidence that I don't think
 13 the hepatitis epidemic could have been affected by
 14 becoming self-sufficient, but Dr Owen was so close,
 15 even had a press conference to announce
 16 self-sufficiency. We were so close in getting to be
 17 where Scotland was in being, effectively, more or less
 18 self-sufficient. If that had happened, given all that
 19 we've then learnt about the incidence of HIV in
 20 American plasma compared to British plasma -- this is
 21 retrospective speculation -- always dangerous in
 22 medicine -- but I've always thought -- hepatitis could
 23 not have been changed, by and large, but it always had
 24 been a matter of great concern, given all the people
 25 who lost their lives, would it have made a difference

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1 if David Owen had not become Foreign Secretary and
2 stayed for another year and got it through, as I'm
3 sure he would have done.

4 **SIR BRIAN LANGSTAFF:** For some of the -- amongst the
5 perhaps then lesser causes, you have identified
6 a structural problem, if I can call it that, in the
7 way in which advice was given, rather than direction,
8 that you wanted to know what to do and no-one would
9 tell you, except it was your decision -- words to that
10 effect.

11 How would you have wanted the system to work?
12 It goes back to your discussion of clinical freedom
13 which you described -- well, you first mentioned it
14 yesterday as dangerous.

15 **A.** Well, I've already expressed a view that, in
16 retrospect, I think the UKHCDO, faced with a mix of
17 opinions, issued guidelines to doctors that were too
18 flexible. They should have been firmer, should have
19 said: we think you should do the following. This is
20 a very complex moment in time, but this is our best
21 advice. We think you should do the following.

22 There should never have been phrases like "but
23 every clinician must make up their own mind", because
24 that was an invitation to flexibility and an
25 invitation for doctors to carry on doing what they

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1 Dr Savidge always said, was an informal gathering of
2 haemophilia doctors with no constitution. We just all
3 got together and did what we thought was best. We
4 didn't have a constitution.

5 If the DHSS had issued advice, that would have
6 made it of more stature, and I think that could have
7 been very helpful. To be honest, they could have had
8 a wider group, looking at all aspects of the crisis.
9 Are we doing everything that we possibly can to
10 improve the production of clotting factor concentrates
11 in this country? Is it happening fast enough? Is the
12 funding sufficient? Is the staffing sufficient? What
13 is getting in the way of this country producing more
14 concentrate and stopping us having to import
15 concentrates from America made from the sort of human
16 beings we saw in the World in Action documentary.

17 **SIR BRIAN LANGSTAFF:** I think it is probably allied to
18 that, but let me introduce the question in this way,
19 that those who listened to counsel's presentation
20 about Dr Bloom and the Cardiff Centre may have been
21 struck by the number of different committees relating
22 to the healthcare crisis, as you have described it,
23 upon which Professor Bloom found himself sitting, all
24 of which seemed to be discussing similar aspects of
25 the same problem, perhaps -- that may be a comment

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1 wanted, which was a whole variety of different things.
2 So I think that was -- I think it was well-intentioned
3 but unfortunate.

4 As you will gather, I would very much like to
5 have seen the Department of Health having a much
6 stronger, more overt role in the whole crisis, which
7 was apparent, and working together with UKHCDO to take
8 matters forward. And I would have also liked to have
9 seen Elstree and the transfusion services be much more
10 politically active and doing much more, frankly, to,
11 you know, improve the provision of clotting factor
12 concentrates for people with haemophilia in this
13 country. I think, you know, their activities were
14 also a relevant part of what happened.

15 **SIR BRIAN LANGSTAFF:** So you would have wanted the
16 department to have been more proactive?

17 **A.** Yes.

18 **SIR BRIAN LANGSTAFF:** In what ways in particular?

19 **A.** Well, I think they could -- as I've said, they had
20 a nominated doctor who attended our meetings. It
21 would have been all too easy for this doctor to say to
22 UKHCDO, "This is a serious healthcare problem. We
23 should work together. I would like a senior figure in
24 the DHSS to be issuing this guidance to doctors, to
25 make it more formal", rather than a -- UKHCDO, as

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1 which may be wrong, but I can be addressed for that in
2 due course -- and perhaps not always speaking with
3 entirely the same voice.

4 Did that represent your view of what was
5 happening at the time?

6 **A.** Not particularly. I think a lot of these other
7 committees were sort of virological, and we were
8 rather remote from that. You gather, what I would
9 have liked, if you like, is a sort of SAGE. You know
10 we have SAGE now. We would have liked a haemophilia
11 SAGE. Let's get all the interested parties in, bang
12 everything together and sort it out, instead of which,
13 as you're implying, there was sort of an individual --
14 you know, one agency was doing something, another
15 agency was doing something else. This was a serious
16 enough healthcare problem for us to want a much more
17 co-ordinated approach. It should have been the DHSS
18 leading that, I think.

19 **SIR BRIAN LANGSTAFF:** So some authoritative body speaking
20 directly to Government, through Government?

21 **A.** Yes, exactly.

22 **SIR BRIAN LANGSTAFF:** I see.

23 The next one -- the last thing I think I want to
24 ask you about is in respect of your particular --
25 you're in a particularly good position to deal with

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1 this because you are, in your thinking, the only or
2 one of the only doctors who combined haemophilia
3 treatment with HIV treatment.

4 Do you think that's been an advantage to your
5 treatment of those with haemophilia who had HIV?

6 **A.** Well, I'd like to think so. I mean, I think it was --
7 it worked out well that I was able to look after their
8 haemophilia and their HIV. Quite a lot of patients,
9 they -- I've described already -- they would ring up
10 the centre and be told -- many patients were going to
11 different hospitals; some of them not even in the same
12 town. So they were at haemophilia centre X, they went
13 for their HIV care to another centre or hospital Y,
14 and they went to a third place, Z, for their hepatitis
15 care. So they were all over the place.

16 I think it was -- or I hope, you know, my
17 patients felt it was good that at least they had the
18 haemophilia and the HIV under one centre, and the only
19 thing they had to move sideways to in the same
20 hospital was for the hepatitis consultant, you know,
21 in the out-patient clinic just around the corner. So
22 it was all centralised. You know, I hope they found
23 that helpful.

24 **SIR BRIAN LANGSTAFF:** Was there a reason you didn't do
25 combined clinics?

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1 point that this sense of rejection that was spoken
2 about was sort of reinforced by: not only can I not go
3 to the centre that gave me the treatment that gave me
4 the infection, I've actually got to travel to
5 a different hospital for my HIV, and another hospital
6 for hepatitis, and a GP. I've got four sets of
7 doctors in four different places. For someone who's
8 not very well, that's far from ideal.

9 **SIR BRIAN LANGSTAFF:** Yes. Well, that's all that I wanted
10 to ask you myself.

11 Ms Richards?

12 **MS RICHARDS:** No further questions from me, but Dr Winter,
13 is there anything else that you would like to add that
14 we haven't covered?

15 **A.** I had a long list when I came in yesterday morning,
16 but I'm extremely happy to say we've covered
17 everything.

18 **MS RICHARDS:** Good.

19 Then that's it for today, sir.

20 **SIR BRIAN LANGSTAFF:** Well, not quite it, because I would
21 like to say something to you personally, if I may.

22 It's never easy, I think, to give evidence, and
23 particularly when we might have had every right to
24 think that you would have given it in a rather jaded
25 manner, having done it twice before to two other

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1 **A.** I think they now happen. Now, eventually I was
2 replaced as an HIV physician, when the work got too
3 much, and I did then start to do combined clinics with
4 this new HIV physician on HIV. I think the number of
5 people being referred to Dr Muller, my hepatology
6 colleague, was not enough and not regular and frequent
7 enough to warrant regular clinics. But he was
8 terribly helpful, and he saw the patients very quickly
9 and dealt with them very promptly and communicated.
10 So that was fine.

11 **SIR BRIAN LANGSTAFF:** Going back to the problem for the
12 individual who is suffering from the condition of
13 haemophilia, first of all, but the troubles that come
14 with HIV infection, and possibly with AIDS, and the
15 problems which come with infection with hepatitis,
16 they might also have needs for physiotherapy, or needs
17 for counselling. It might be thought that it would be
18 an advantage to them, ill as they are, to have that
19 all in one place. Would you agree with that or think
20 that would have been difficult to organise?

21 **A.** Well, that would have been ideal, and that's what
22 we -- we had a physiotherapist in our centre and we
23 had a counsellor in our centre. So we ticked all
24 those boxes, apart from the hepatitis one.

25 All I've been trying to do is just to make the

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1 inquiries, but you've shown absolutely no sign of
2 that. I may say that I am very glad that we heard you
3 first of the clinicians and that you had such a fluent
4 recollection and an astonishingly good memory for
5 dates and events and recollections.

6 But, in particular, I'd like to thank you for
7 your frankness. You tell it like it is, I think, from
8 your perspective, and that is really valuable for
9 me -- that's as I see it, anyway -- and given us
10 a valuable insight, a number of valuable insights,
11 into what it felt like to be a haemophilia doctor in
12 this most difficult of times, particularly coming into
13 it, as you did, in the end or the start of
14 December 1983 as a consultant and then having your
15 responsibilities.

16 I suppose you would have left some of us
17 wondering if they could bottle your secret for getting
18 money out of your local finance director because that
19 might be very useful to other people.

20 **A.** Yes. I'm still not sure how it worked.

21 **SIR BRIAN LANGSTAFF:** But it didn't seem to work on the
22 DoH.

23 **A.** No. That was a different matter.

24 **SIR BRIAN LANGSTAFF:** Thank you much.

25 **A.** Pleasure.

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1 **MS RICHARDS:** Sir, we reconvene on Tuesday to hear the
2 evidence of Dr Brian Colvin.

3 **SIR BRIAN LANGSTAFF:** Ladies and gentlemen, that's it for
4 this week. Thank you very much for your attendance.
5 I have already thanked Dr Winter myself. If you are
6 travelling home and going any distance, travel safely.
7 But, in any event, stay safe, and those of you who are
8 coming back next week, I look forward to seeing you
9 then. If not, I may see you -- I am sure I will see
10 you -- later. Thank you.

11 **(3.58 pm)**
12 **(Adjourned until Tuesday, 6 October at 10.00 am)**

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