

Wednesday, 31 March 2021

(10.00 am)

MS RICHARDS: Sir, just two matters I'm going to pick up from yesterday. Firstly, you asked the question when we looked at the annual returns as to whether there was any apparent correlation between the severity of haemophilia, mild, moderate or severe, and the receipt of more than one type of concentrate or treatment. The answer is, Ms Fraser Butlin having analysed the return data for 1978, 1979, 1980 and 1984, that there's no apparent correlation.

The second point arises out of the documents I referred to yesterday in relation to the proposed exchange in around 1988/1989 between Northern Ireland and Scotland at the time of Z8 usage. The later evidence -- I'm not going to put the documents up on screen -- suggests that that exchange did take place and that there was an exchange of Z8 allocated to Northern Ireland with commercial products supplied by Scotland.

We looked yesterday afternoon at documents relevant to what was or should have been known and understood by those working in clinical roles at the centre about risks of hepatitis. Before I move to do a similar exercise in relation to HIV and AIDS, I just

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inhibitor that would negate the efficacy of their concentrate and finally, to check on their liver function tests and hepatitis status."

So part of the monthly testing for those on home treatment appears to have been according to Dr Mayne not just to look at liver function tests but to expressly consider the question of hepatitis.

Then in 69.3 she says:

"Patients were well versed in this practice and accepted the information given to them about the blood testing and the purposes for which they were being taken. They seemed happy to consent to these arrangements."

What that paragraph doesn't do is spell out what information it is Dr Mayne says was routinely given to patients about blood testing and the purposes for which tests were being undertaken.

If we then go to the --

SIR BRIAN LANGSTAFF: It would imply that what they were told was the checks were for their hepatitis status.

MS RICHARDS: It might well imply that.

SIR BRIAN LANGSTAFF: And the expression "they seemed happy to consent" suggests that there was no active consent. It was an assumption by her that they were happy.

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want to refer to Dr Mayne's most recent statement, and what she says about the information she says was provided to patients. Soumik could we have WITN0736009. Could we go to page 46, please.

This part of the statement is in relation to a series of questions posed by the Inquiry about the process of consent. If we pick it up at paragraph 69.1, Dr Mayne says this:

"The customary practice of the [Northern Ireland] Haemophilia Centre was to check patients' blood at every visit. I must stress that many patients attended at widely spaced intervals, at times six months to a year apart for those that were mildly or moderately affected. Those that were severely affected or were involved in the programme of home treatment were seen and checked more frequently."

And then she refers to forms which those on home treatment completed.

Then at 69.2 she says:

"Thereafter, they" -- I take it those are the home treatment patients -- "were seen at monthly intervals. It was in my view imperative that their bloods were checked to ensure that they had not developed any haematological problems such as anaemia, unduly excessive bleeding or the development of

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MS RICHARDS: Yes.

We'll see similar expression when we look at the question of consent to treatment on the next page. So those questions concerned consent in relation to blood testing. These questions concern consent in relation to treatment. At 70.1 she says this:

"All patients attending the Centre were happy to receive treatment with factor concentrates.

"70.2 In the early days of treatment with concentrates, it was not the practice at the time to obtain written informed consent. Patients, to put it mildly, were overjoyed at receiving concentrate treatment. As the [home treatment] programme progressed, some severely affected patients felt left out and contacted the Centre to request the opportunity of participating in the [home treatment] programme."

And then this:

"Everyone was told of the risk of viral infections associated with all blood and blood products."

Again, what that doesn't identify is what actual information was provided to patients about the risk of viral infections. I should add, sir, having reread every statement received by the Inquiry by or

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1 about a patient treated at the Belfast Haemophilia
2 Centre, that does not accord -- what Dr Mayne says
3 here -- does not accord with any of the evidence that
4 the Inquiry has received from patients or their family
5 members.
6 If we then just go down the page, just to
7 complete what Dr Mayne says, she says at 71.1:
8 "For the purpose of clarification, at the
9 instigation of concentrate therapy, all matters
10 pertaining at that time in respect of risk were
11 conveyed to patients before they commenced on [home
12 treatment]. Discussions included comparison of
13 treatment with cryoprecipitate and treatment with
14 concentrates. No figures were mentioned but patients
15 understood that concentrates came from a large number
16 of donors in comparison to cryoprecipitate."
17 Of course, if that's right, it doesn't follow
18 that they understood and were informed about the
19 relative risks or potential consequences as a result
20 of those risks:
21 "However, the prospect of their lives being
22 revolutionised, the ease of injection, and the ability
23 to undertake reliable dose calculations precluded any
24 obvious reservations about the treatment. No patient
25 favour expressed any reservation to myself or

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1 consent from the patient in all cases and, again,
2 there is evidence that the Inquiry holds from patients
3 which is to the opposite affected and I will refer to
4 that a little later.
5 **SIR BRIAN LANGSTAFF:** If we just go back a page, and 71.1
6 she is speaking in the first sentence of when
7 concentrate therapy on home treatment was begun. It
8 may but probably isn't talking about treatment not at
9 home but in hospital because it refers to "HT".
10 **MS RICHARDS:** Yes.
11 **SIR BRIAN LANGSTAFF:** But it doesn't say that there was
12 any further discussion in respect of the risks as they
13 became better known in the case of hepatitis non-A,
14 non-B or as they were becoming known in respect of the
15 risks of whatever it was that caused AIDS later
16 identified.
17 Is there anything in her witness statement
18 which deals with what she says about the continued
19 conversations that might have been expected in the
20 light of the changed and developing perception of
21 risks?
22 **MS RICHARDS:** I don't think so, sir. I am going to show
23 you in the course of the morning some other parts of
24 her statement where she talks about the provision of
25 information to patients and what she says in

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1 any other member of staff in respect of their
2 treatment."
3 Again, just picking up on some of the evidence
4 from patients and relatives that the Inquiry's
5 received, there are patients who recall, indeed,
6 recall being delighted about factor concentrates.
7 There are patients who describe being left with the
8 impression that these were pioneering treatments is
9 a phrase used in one statement, miracle treatments,
10 wonder drug, although I should say in relation to the
11 latter Dr Mayne has said that's not a phrase she would
12 have used. But those are the recollections of
13 patients. None recount a recollection of being
14 advised of risks of significant health consequences as
15 a potential result of receipt of factor concentrates.
16 Sorry, I should just complete the series of
17 answers by going over the page to the top of the next
18 page. This is in relation to testing and whether
19 patients were tested without their express consent.
20 I'll come on to that later on this morning also but
21 whilst we're in this statement Dr Mayne's answer is:
22 "Absolutely not."
23 That's to the question of were patients tested
24 for HIV or hepatitis or for any other purpose without
25 their express consent. She says she obtained verbal

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1 particular in relation to the question of providing
2 information about HIV and AIDS.
3 I don't think we have any form of narrative
4 about as things became clearer this is what
5 I explained. We do when we get to the mid-1990s, 1995
6 specifically, of course by which time infections will
7 already have occurred. We do have a more detailed
8 account of the weekend that was organised in around
9 1995 to provide information, it was said, about
10 hepatitis C. But I can't recall any account which
11 picks up upon the point that you have just made, but
12 I will check that both so that I can be confident I've
13 given you an accurate answer and, of course, out of
14 fairness to Dr Mayne.
15 Sir, I'm going to move next to documentation
16 and evidence relevant to what was as a matter of fact
17 known in Belfast or what should have been known in
18 Belfast by the clinicians I hasten to add, not
19 patients, about the risk of AIDS and HTLV-III.
20 So if we start if we go back to that same
21 document please, Soumik, WITN0736009 we start with
22 Dr Mayne's witness statement and go to page 25,
23 please. We can see at the top of the page, Dr Mayne
24 says this:
25 "The immune deficiency syndrome which later

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1 became known as HIV/AIDS first came to my notice
 2 during an informal lunchtime discussion with three
 3 colleagues. They were the late Arthur Bloom,
 4 Virologist John Craske and the late Peter Kernoff.
 5 "30.2. John Craske was describing the content
 6 of a paper just published, to the best of my
 7 recollection in the Lancet, but with the passage of
 8 time I cannot be more specific. It described an
 9 account of an immune condition which had occurred in
 10 homosexual males in San Francisco. I enquired as to
 11 the relevance to haemophilia. He reminded us that the
 12 individuals cited in the paper were known to maintain
 13 their lifestyle by being paid blood donors, as was
 14 documented in the World in Action (1975) programme.
 15 Whilst the revelations of that were horrific, I was
 16 unprepared for the shock of the news of a possible
 17 future infection which could affect those in receipt
 18 of plasma derived concentrates, namely, the
 19 Haemophiliac population."
 20 Dr Mayne, perhaps unsurprisingly can't recall
 21 when this conversation took place. There is The
 22 Lancet article that might be the article that's
 23 described at PRSE0004476. I'm not going to go through
 24 the detail of it. You'll see it's a letter to the
 25 editor about something then referred to as "Gay

1 by Friedman-Kien and others, "Disseminated Kaposi's
 2 sarcoma in homosexual men".
 3 In any event, she says:
 4 "Early publications during 1981 (62) and 1982
 5 (63), describing the unexpected outbreaks of the rare
 6 disorders [PCP] and Kaposi's sarcoma in homosexuals
 7 provoked discussion amongst Haemophilia Centre
 8 Directors as early as September 1982."
 9 We'll look at that in a moment.
 10 "At that time particular relevance to
 11 haemophilia care was not yet evident. In July 1982
 12 MMWR ... reported that three haemophiliacs had
 13 developed AIDS, but little evidence had accumulated to
 14 suggest that haemophiliacs of themselves constituted
 15 a special risk group for AIDS."
 16 And then she says at the top of the next page:
 17 "The situation changed with increasing
 18 haemophiliac involvement and towards the end of the
 19 year ..."
 20 So that's towards the end of 1982.
 21 "... they were categorised as a separate
 22 'at risk' population."
 23 And then she goes on to refer to some UKHCDO
 24 interactions which I'll deal with separately.
 25 So, again, there's nothing in Dr Mayne's

1 Compromise Syndrome", and it refers to:
 2 "A remarkable outbreak of opportunistic lung
 3 infections and/or Kaposi's sarcoma in homosexual men
 4 has been reported this year in the United States."
 5 And if so, that's an article in The Lancet,
 6 12 December 1981. So that might fit the bill in terms
 7 of it helping us to date the discussion to which
 8 Dr Mayne refers.
 9 If we go next to Dr Mayne's HIV litigation
 10 report CBLA0000072_024. If we turn to page 32,
 11 Soumik.
 12 So under the heading "The Development of the
 13 AIDS Epidemic", if we go to the bottom of the page,
 14 Dr Mayne says this:
 15 "Early publications during 1981 (62) and 1982
 16 (63) ..."
 17 And the footnoted publications there are --
 18 footnote 62 is a publication in the New England
 19 Journal of Medicine by Gottlieb, Schroff, Schanker and
 20 others about PCP pneumonia, evidence of a new acquired
 21 cellular immunodeficiency. It's a 1981 New England
 22 Journal of Medicine. I don't have the precise date
 23 but we can check that.
 24 The 1982 publication to which she is referring
 25 is in the Annals of Internal Medicine 1982, an article

1 HIV litigation report to suggest that these
 2 developments were unknown to her or unknown to the
 3 Haemophilia Centre Directors members, organisation
 4 members. On the contrary, the implication might be
 5 thought to be she's setting this out precisely because
 6 they were known and were a subject of discussion.
 7 So that's what she says in the litigation
 8 report about the knowledge in 1982. I should just
 9 remind you, sir, although we've looked at it on
 10 a number of occasions, of the UKHCDO records of
 11 discussions in 1982.
 12 We start with HCDO0000410. You will recall
 13 this is the Reference Centre Directors' meeting on
 14 6 September 1982 attended by Dr Mayne and by Dr Craske
 15 as well and by a number of others.
 16 If we go to page 8 we see towards the bottom of
 17 the page the beginning of a verbal report from
 18 Dr Craske about the work of the Hepatitis Working
 19 Party.
 20 Then if we go on to page 11, in the paragraph
 21 halfway down the page beginning, "Professor Bloom
 22 asked":
 23 "Professor Bloom asked Dr Craske if he had any
 24 information about the acquired immune-deficiency
 25 syndrome following reports from the United States and

1 the possible relationship of the syndrome with blood
2 products and hepatitis. Dr Craske said that he would
3 find out more about this and agreed to try to have
4 some information available for the Haemophilia Centre
5 Directors at the Manchester meeting."

6 Then if we go to the Haemophilia Centre
7 Directors' meeting the following week at CBLA0001619,
8 so this is the Manchester meeting of the bigger group
9 of Haemophilia Centre Directors, 13 September 1982.
10 The list of attendees on the second page tells us that
11 Dr Mayne was present and there is a short discussion
12 about AIDS on page 10. Bottom of the page:

13 "The acquired immune deficiency syndrome. The
14 Reference Centre Directors had asked Dr Craske to look
15 into the report from the United States of this
16 syndrome mainly in homosexuals but including three
17 haemophiliacs. It appeared that there was a remote
18 possibility that commercial blood products had been
19 involved."

20 And we considered in earlier hearings the
21 question which will ultimately be for you to resolve,
22 sir, of whether that was a fair or accurate statement
23 given the state of knowledge already by that time.

24 Dr Craske asked the directors to let him know
25 if they had any cases of the syndrome. The working

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1 look at the second page -- sorry, the next page, my
2 apologies, Soumik. Bottom half of the page, we see
3 the passage we've explored before under the heading,
4 "Aetiology":

5 "Several theories have been advanced. It seems
6 likely that this is a 'new' syndrome."

7 And then he sets out the three theories.

8 "Effect of drugs", and says this is not a factor.

9 A second theory is "the immuno-suppressive effect of
10 cytomegalovirus infection", and he says this seems
11 unlikely.

12 Then over the page the third possible cause,
13 "the association with sexual promiscuity, intravenous
14 drug use and possibly the transfusion of commercial
15 blood concentrates", and then he says just below that:

16 "If (3) is the most likely cause, then it seems
17 possible that such an agent might be present in the
18 plasma of hepatitis B carriers used to prepare
19 hepatitis B vaccines."

20 The relevance of that was this was a paper
21 Dr Craske had prepared at that stage for the Medical
22 Research Council's hepatitis vaccine working group.

23 So that's November 1982.

24 If we then go to PRSE0002647, this again is
25 a document that we have looked at on a number of

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1 party was considering the implications of the reports
2 from the USA. So those are the minutes of the
3 September 1982 meetings. Obviously, we don't have
4 a more detailed account of the underlying discussions
5 because the minutes are only, on any view, a summary.

6 What we do know is that in November 1982
7 Dr Craske produced the first version of a report
8 about AIDS.

9 If we go to HCDO0000557, we see a letter from
10 Dr Craske dated 11 November 1982. This letter is
11 addressed to Ms Spooner. We do have copies of this
12 letter addressed to others, including I think
13 Dr Kernoff and at least one other Reference Centre
14 Director.

15 What's not clear from what we have been able to
16 analyse is whether this letter was being sent solely
17 to members of the Hepatitis Working Party, which would
18 not have included Dr Mayne, or whether it was being
19 sent, at this point in time, to the Reference Centre
20 Directors as well, which would have included Dr Mayne.
21 So I'm afraid at the moment we simply don't know the
22 answer to that question.

23 But, in any event, we have over the page the
24 first version of a report prepared by Dr Craske. It's
25 dated 5 November 1982 on its third page, and if we

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1 occasions. It's one of the records of the meeting
2 with Immuno at London Airport or at a London airport
3 hotel on 24 January 1983.

4 If we go to the last page, please, we see in
5 the bottom half of the page the list of attendees and
6 we'll see that they include Dr Mayne.

7 If we go to the page before that, we can see
8 the heading almost halfway down the page, "Acquired
9 immunodeficiency Syndrome", and we see there set out
10 the discussion about AIDS, Dr Craske summarising the
11 current position, giving a clinical description of the
12 AIDS syndrome, and then picking it up towards the
13 bottom of the page reference to the mortality rate,
14 45 per cent mortality, and then in the last paragraph
15 a description of haemophiliacs in the United States
16 affected:

17 "Ten ... affected ... five have died. The
18 youngest was aged 7. All cases have had prolonged
19 treatment with factor VIII but there is no specific
20 implication of one particular product or batch. Other
21 cases involving blood and blood product transmission
22 have included platelets transfused in three cases. In
23 one of these cases, one of the donors was a young
24 New York man in his twenties. A second case was
25 a 20 month old child with rhesus HDN who had received

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1 several units, including platelets known to have come
2 from a homosexual donor who was asymptomatic at the
3 time, but who later died."

4 That's the San Francisco baby case.

5 If we go over the page, the discussion
6 continues with reference to the incubation period:
7 "In the UK, so far only one or two cases have
8 been reported from the communicable diseases centre."

9 There's then reference to, "protocols from the
10 United States [that] are being considered by the
11 Hepatitis Working Party", and a reference to American
12 fractionation companies being "very aware of the
13 problem".

14 Then in the next paragraph a discussion of the
15 editorial, that's the Desforges editorial, in the
16 New England Journal of Medicine, 13 January 1983.

17 So that, it's a matter for you, sir, but may be
18 taken as a guide to what by 24 January 1983 would have
19 been known to Dr Mayne about the latest developments
20 in the state of knowledge in relation to AIDS risk for
21 haemophiliacs.

22 There was then, again in terms of the
23 chronology in early 1983, which is of some particular
24 significance for Belfast patients because of the dates
25 of seroconversion for most of them, which I'll come on

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1 all Haemophilia Centre Directors with appropriate
2 notes regarding the criteria on which a diagnosis
3 should be based.

4 I should note although Dr Mayne wasn't present
5 at that meeting, her HIV litigation report does refer
6 to that meeting, so it may be something that she was
7 aware of, and aware of the discussion, but we can't
8 say that for certain.

9 We do know however that as agreed at that
10 meeting Drs Craske, Rizza and Bloom did write to all
11 centre directors, so that would have included
12 Dr Mayne, in March of 1983. And we can see the letter
13 at HCDO0000517_001. This is the letter
14 of 22 March 1983. Again, we've looked at it before
15 but not, as it were, through the prism of the Belfast
16 Haemophilia Centre:

17 "Dear Director,

18 "Re: Acquired Immune Deficiency Syndrome ..."

19 And then there's reference to:

20 "Recent discussions in both the Hepatitis
21 Working Party and a recent meeting of the Reference
22 Centre Directors ..."

23 And the system being set up:

24 "... for the reporting of possible cases of
25 [AIDS] ..."

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1 to later. So continuing with the chronology, there's
2 then a Reference Centre Directors' meeting in
3 February 1983. That's at HCDO0000411.

4 It's right I should note the covering letter
5 which sends out the draft minutes is 9 May 1983, so
6 it's several months after the meeting on
7 14 February 1983.

8 I mention that because if we look at the next
9 page, we can see that Dr Mayne did not attend this
10 particular Reference Centre Directors' meeting on
11 14 February 1983. We see apologies for absence were
12 received from her.

13 If we go to page 5, Soumik, we can see the
14 discussion about the AIDS syndrome. Professor Bloom
15 reporting it:

16 "... would be discussed at the Stockholm
17 meeting at the World Federation of Haemophilia.
18 Reports from the United States indicated that the
19 incidence of AIDS was higher than at first thought and
20 there was some concern that the haemophilic population
21 of the UK who had received American concentrates might
22 be at risk."

23 Then there is a discussion of a form being
24 prepared for the reporting of cases and Dr Craske was
25 going to draw that up and it would be circulated to

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1 Then the letter continues, this is the second
2 paragraph:

3 "The criteria for reporting cases are given in
4 the accompanying paper AIDS/2."

5 And a request is made to use the form AIDS/3.

6 If we look at the enclosed documents
7 themselves, they are, first of all, we start with the
8 AIDS/1 report. That is HCDO0000517_002.

9 So this is an updated version of Dr Craske's
10 November 1982 report. It's dated at the end of the
11 paper, 1 March 1983. Again, it sets out the growing
12 knowledge at the Communicable Disease Centre in
13 Atlanta of infections.

14 Then if we go towards the bottom of the page we
15 see reference in the last paragraph to delay between
16 initial symptoms and diagnosis.

17 If we go over the page, we see reference, just
18 towards the middle of the page, to mortality rate.

19 And then if we go to the next page, the bottom half of
20 the page -- sorry, I should start with the top half of
21 the page, my apologies. There's reference in the
22 third line:

23 "Since then reported cases of a similar
24 syndrome have been noted in ..."

25 And then there are various now very familiar

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1 categories, including the following:
 2 "... recently in 7 haemophiliacs, 6 of whom
 3 also have no association with drugs or sexual
 4 promiscuity. Three cases have been described in the
 5 UK and one in Spain. All probably acquired their
 6 disease in the USA. However, 4 cases were recently
 7 observed in Denmark ..."
 8 Then if we go further down the page we have the
 9 discussion of aetiology, again in similar terms to the
 10 discussion in the November 1982-version of Dr Craske's
 11 paper. So he discounts effect of drugs in
 12 paragraph 1. He suggests that cytomegalovirus as
 13 a cause is unlikely in paragraph 2. And then if we go
 14 over the page he alights upon (3) as the most likely
 15 cause, so "sexual promiscuity, intravenous blood abuse
 16 and possibly the transfusion of commercial blood
 17 concentrates". This time, below paragraph 3, rather
 18 than referring to the issue of hepatitis vaccines he
 19 says this:
 20 "If (3) is the most likely cause, then it is
 21 possible that such an agent might be present in the
 22 plasma pools used to prepare commercial factor VIII
 23 and IX concentrate manufactured from donor plasma
 24 collected in the USA."
 25 He refers in the next paragraph, if we go

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1 requested the UK Haemophilia Centre Directors to
 2 co-operate with them in a survey by reporting cases of
 3 AIDS possibly associated with transfusion of
 4 US commercial factor VIII concentrate."
 5 He says:
 6 "Cases will also be notified to the
 7 Communicable Disease Surveillance Centre in the UK at
 8 the Central Public Health Laboratory, Colindale,
 9 London."
 10 **SIR BRIAN LANGSTAFF:** Could you just go back a couple of
 11 pages. It says there, six lines down:
 12 "... recently in 7 haemophiliacs, 6 of whom
 13 also have no association with drugs or sexual
 14 promiscuity."
 15 Then if we go over a couple of pages, back
 16 a page, and again I think.
 17 **MS RICHARDS:** There's a reference to ten patients.
 18 **SIR BRIAN LANGSTAFF:** Yes, that's it, it's the reference
 19 to ten.
 20 **MS RICHARDS:** The reason for the difference, sir, is
 21 this -- it only becomes apparent if we look at the
 22 footnotes. So if we go on two pages please, Soumik,
 23 footnote 4 is the source of the seven haemophiliacs.
 24 So that's public reporting and that's in MMWR.
 25 I don't know which without checking. That might be

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1 further down the page, to three patients having,
 2 acquired the disease where the most likely mode of
 3 transmission was blood or platelet transfusions.
 4 He refers then to the incubation period. He says:
 5 "The most recent information ... suggests that
 6 at least ten haemophilia A patients have been reported
 7 with clinical features of the syndrome."
 8 And at the end of that paragraph that five of
 9 those have since died.
 10 There's reference to possibility of sexual
 11 transmission at the bottom of the page.
 12 Then if we go to the next page and we look at
 13 the last -- the first paragraph, the last two
 14 sentences, where he says:
 15 "All the epidemiological evidence is consistent
 16 with the existence of a transmissible agent whose mode
 17 of spread is remarkably similar to that of
 18 hepatitis B."
 19 Then he refers to precautions against
 20 cross-infection and then says:
 21 "It is thought likely that batches of
 22 factor VIII concentrate which might contain the AIDS
 23 agent came into use since January 1st 1980 in the USA.
 24 The Communicable Disease Centre of the US Public
 25 Health Service at Atlanta, Georgia, therefore has

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1 the December MMWR.
 2 **SIR BRIAN LANGSTAFF:** I think December was more than
 3 seven.
 4 **MS RICHARDS:** I think it may well have been an earlier
 5 MMWR. The ten patients -- so Dr Craske goes:
 6 "The most recent information ... suggests at
 7 least ten ..."
 8 That's footnote 8, and he says it's a personal
 9 communication from Dr Dale Lawrence, CDC Task Force on
 10 AIDS.
 11 **SIR BRIAN LANGSTAFF:** Yes, what Dr Mayne has picked up on
 12 in her statement I think is the lower figure.
 13 **MS RICHARDS:** Yes, that might be right. The ten figure is
 14 the figure discussed I think in the January Immuno
 15 meeting at London Airport.
 16 **SIR BRIAN LANGSTAFF:** Yes.
 17 **MS RICHARDS:** We'll check the MMWRs for December. I think
 18 you are right, sir. It may be the ten figure and the
 19 seven figure is earlier.
 20 **SIR BRIAN LANGSTAFF:** I think then it was eight confirmed
 21 cases and -- seven or eight anyway.
 22 **MS RICHARDS:** Yes.
 23 **SIR BRIAN LANGSTAFF:** And then by some time between
 24 January and May it grew to 11, I think, in the States.
 25 **MS RICHARDS:** In the States, yes. Those are cases all in

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1 the States.
 2 So we know Dr Mayne is present at that meeting
 3 at the Excelsior Hotel, Heathrow Airport, 24 January,
 4 and we know that this letter and its attachments were
 5 sent to all Haemophilia Centre Directors.

6 For the sake of completeness I'll just -- as
 7 well as looking at the form, we'll just look at the
 8 other two documents.

9 So if we go to the other two documents that
 10 accompanied the letter. If we go to HCDO0000273_078,
 11 that's, as it were, a note for directors as to
 12 conditions, symptoms and findings to look out for and
 13 report, and we can see from the third page that's also
 14 dated 1 March 1983.

15 Then if we go to HCDO0000517_004, that's the
 16 form that directors were asked to complete in relation
 17 to possible cases and, of course, we've looked by way
 18 of example at the actual form completed by
 19 Professor Bloom in relation to the Cardiff case.

20 Those are the communications from Haemophilia
 21 Centre Directors -- sorry, to Haemophilia Centre
 22 Directors in March of 1983.

23 If we then go to HCDO0000003_008, this is the
 24 special meeting of Reference Centre Directors held on
 25 13 May 1983, and it's right to note that Dr Mayne was

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1 24 June 1983. It refers to the special meeting of the
 2 reference centre directors in the opening paragraph
 3 and then says this:

4 "At the above mentioned meeting on May 13th the
 5 following general recommendations were agreed.

6 "1. For mildly affected patients with
 7 haemophilia A or von Willebrand's disease and minor
 8 lesions, treatment with DDAVP should be considered.
 9 Because of the increased risk of transmitting
 10 hepatitis by means of large pool concentrates in such
 11 patients, this is in any case the usual practice of
 12 many Directors.

13 "2. For treatment of children and mildly
 14 affected patients or patients unexposed to imported
 15 concentrates many Directors already reserve supplies
 16 of NHS concentrates (cryoprecipitate or freeze-dried)
 17 and it would be circumspect to continue this policy."

18 And then it goes on to say that:

19 "It was agreed [at the 13 May meeting] that
 20 there [was] as yet insufficient evidence to warrant
 21 restriction of the use of imported concentrates in
 22 other patients in view of the immense benefits of
 23 therapy ..."

24 Although Dr Mayne was not present at that
 25 meeting it's clear from her evidence that that

27

1 not in attendance at that meeting. It was, however,
 2 obviously a very significant meeting. How the
 3 discussion was communicated to Dr Mayne and when it
 4 was communicated to Dr Mayne, we don't know.

5 Again, we've looked at this on a number of
 6 occasions. If we just go briefly down the page we'll
 7 see Professor Bloom outlined the background to the
 8 meeting and its purpose:

9 "The recent publicity ... had caused
 10 considerable anxiety to haemophiliacs and their
 11 medical attendants as well as to the Department of
 12 Health."

13 If we go over the page -- sorry, it was the
 14 previous page. My apologies. Yes, if we go down. It
 15 says -- this is halfway down this long paragraph:

16 "To date in the [UK] one haemophiliac is
 17 suspected of suffering from AIDS."

18 So that is again, we anticipate, the Cardiff
 19 case that Professor Bloom is there referring to. And
 20 again, Dr Mayne in her litigation report refers to
 21 a knowledge of there being that case.

22 Following that meeting, recommendations were
 23 sent to all centre directors, so that would have
 24 included Dr Mayne, in June of 1983 and the reference
 25 for that is HCDO0000270_004. It's the letter of

26

1 accorded with her own view. She talks on multiple
 2 occasions throughout her various statements of what
 3 she regarded as the immense benefits of treatment with
 4 factor concentrates.

5 In relation to this letter, Dr Mayne's evidence
 6 is this essentially reflected existing practice at the
 7 Belfast Haemophilia Centre. We've looked already at
 8 the position of children and seen that those who were
 9 being treated at the Royal Belfast Hospital for Sick
 10 Children were treated with cryoprecipitates but that
 11 there were two severely affected children treated with
 12 factor concentrate, so I think not entirely correct to
 13 say that it was the policy across the board for all
 14 children.

15 In terms of paragraph 1, suggestion there of
 16 treatment with DDAVP, we've seen from the annual
 17 returns comparatively infrequent reference to DDAVP,
 18 albeit it's right that I note we don't have every
 19 return for the early part of the 1980s.

20 We do see von Willebrand's patients,
 21 apparently, being treated largely with
 22 cryoprecipitate.

23 In terms of mildly affected patients or
 24 patients previously unexposed to imported
 25 concentrates, the position is less clear in relation

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1 to Belfast. I don't think we have any specific
 2 evidence about a particular treatment policy in
 3 relation to previously untreated patients.
 4 In relation to those who were mildly affected
 5 haemophiliacs or those whose haemophilia was of
 6 moderate severity, Dr Mayne addresses this in her
 7 witness statement at WITN0736009. We pick it up at
 8 the bottom of page 17, bottom half of the page.
 9 You'll see reference in the bold print to the
 10 question posed by the Inquiry which refers to the
 11 June 1983 UKHCDO recommendations and she's asked what
 12 the Belfast Centre's policy is, and her answer is as
 13 follows:
 14 "As described above, the policy of using
 15 cryoprecipitate for treating mildly affected patients
 16 and children was adhered to but, at times, proved in
 17 practice to be much more complex than expected."
 18 She then says that:
 19 "Cryoprecipitate, DDAVP and antifibrinolytic
 20 agents were, and are, used for the management
 21 of von Willebrand's syndrome."
 22 Then over the page she sets out in
 23 paragraph 19.1, and we looked at this or a similar
 24 passage yesterday, at the position in relation to
 25 children, but then in relation to people with mild or

29

1 undertaken in the above paragraph.
 2 "... the patients had become used to
 3 concentrate and rejected cryoprecipitate."
 4 She doesn't say what information was given to
 5 the patients to enable them to make an informed
 6 decision as between concentrates and cryoprecipitate.
 7 And then says:
 8 "I have gone into these cases in some detail to
 9 explain that classification of bleeding disorders as
 10 'mild' or 'moderate' in vivo activity is not always
 11 straightforward nor is it a reliable indication of
 12 patients' clotting Factor VIII. Limiting treatment
 13 to, for example, cryoprecipitate is in practice not
 14 always its easy as it might seem in theory."
 15 So it would appear that whilst Dr Mayne is
 16 saying that her general policy in relation to those
 17 who were mildly affected was to treat with
 18 cryoprecipitate and not concentrate. There were cases
 19 of those who were not severely affected who were
 20 treated with factor concentrates.
 21 So that's the position as at June 1983. We
 22 then in terms of Haemophilia Centre Directors'
 23 meetings move to the meeting on 17 October 1983 which
 24 is at PRSE0004440, so the Haemophilia Centre
 25 Directors' meeting 7 October 1983. Dr Mayne is listed

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1 moderate bleeding disorder she deals with that in the
 2 bottom half of this page and says this in 20.1:
 3 "... effective treatment of bleeding disorders
 4 is patient specific and needs to take account of
 5 individual circumstances. Occasionally, it was
 6 necessary to use concentrates for patients whose
 7 bleeding disorders were classified as mild or
 8 moderate. I can best illustrate circumstances in
 9 which this situation arose by reference to specific
 10 examples."

11 Then she sets out in her next paragraph an
 12 example of two brothers who had what might be
 13 described as a typical level for a mildly affected
 14 patient but asserts that clinically they were much
 15 more severely affected and that appropriate doses of
 16 cryoprecipitate proved totally ineffective.

17 If we go over the page, paragraph 20.4 suggests
 18 that in relation to those patients they resorted to
 19 concentrates, and then she gives another example in
 20 20.5 and 20.6 of other patients, and in paragraph 20.6
 21 talks about then the use of concentrate and says this:

22 "Theoretically, I would have advocated the use
 23 of much larger doses of cryoprecipitate, but by the
 24 time these results were available ..."

25 She gives a description of the tests that were

30

1 as present on the second page of attendees, and if we
 2 go to page 10 under the heading "Any Other Business",
 3 this is the meeting at which Dr Chisholm raised the
 4 question of reversion to cryoprecipitate for home
 5 therapy and Professor Bloom is reported as expressing
 6 the view that there was no need for patients to stop
 7 using commercial concentrates because at present there
 8 was no proof that the commercial concentrates were the
 9 cause of AIDS. We've again canvassed in a number of
 10 previous hearings the significance or otherwise of the
 11 phrase "no proof".

12 You will recall, sir, that the discussion goes
 13 on to talk about ease of access to cryoprecipitate as
 14 opposed to difficulty in getting large amounts of
 15 commercial concentrates. In relation to the
 16 Belfast Centre, it doesn't appear there was any lack
 17 of access to commercial concentrates and we've seen
 18 them being used in large measure during the early
 19 1980s, but it also doesn't appear that there was any
 20 lack of access to cryoprecipitate. You will recall
 21 yesterday Dr Mayne saying that there was a sufficient
 22 supply of cryoprecipitate from the Regional
 23 Transfusion Centre itself in Northern Ireland.

24 I should then go to the next page, which is an
 25 update from Dr Craske, under the heading, "Current

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1 situation regarding AIDS", and that sets out the work
 2 he's proposing to do. Then we'll see halfway down the
 3 page -- halfway down that paragraph, sorry:
 4 "There was some discussion regarding the two
 5 cases of AIDS in haemophiliacs in the [UK] ..."
 6 So that by this time is the Cardiff case and
 7 the Bristol case.
 8 "... and Dr Scott gave details about his case."
 9 And that's a reference, we understand, to the
 10 Bristol case.
 11 So that's the position as at 17 October 1983.
 12 If we go back to Dr Mayne's litigation report at
 13 CBLA0000072_024 and we pick it up at page 33 -- sorry,
 14 I have already referred to -- that's it, if we go to
 15 the top half of the page -- I've already referred to
 16 the first sentence which was looking at 1982, and then
 17 we can see Dr Mayne referring to the March 1983 paper.
 18 That's Dr Craske's paper that we looked at a few
 19 minutes ago. You are right, sir, she refers to the
 20 seven haemophiliacs there, rather than the figure of
 21 ten, and if we look towards the bottom of this
 22 paragraph she says:
 23 "The Directors considered it possible that an
 24 infectious agent could be present in blood and
 25 present, in particular in the Factor concentrates used

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1 Desforges article in the New England Journal of
 2 Medicine in January 1983. The White article is a 1983
 3 editorial in the Annals of Internal Medicine. I don't
 4 have the precise date in 1983 but it sounds like it's
 5 early 1983 because she then goes on to say this, after
 6 referring to the White Article:
 7 "Such publications, plus the media coverage of
 8 the syndrome in the press, on radio and television,
 9 caused great anxiety to patients and their haemophilia
 10 centre physicians. Therefore, in February 1983
 11 a special meeting of the Reference Centres was
 12 convened to plan measures which might be undertaken
 13 regarding surveillance of patients and their
 14 treatment."
 15 I've already referred to that meeting. She
 16 describes it in further detail further down. It may
 17 be that she's conflating the February and May 1983
 18 meetings to some extent in her narrative here but she
 19 then talks, bottom of the page, about the
 20 recommendation sent to centre directors in June 1983.
 21 If we go to the top of the next page she refers
 22 to a discussion about AIDS at the World Haemophilia
 23 Federation Congress in Stockholm and says this:
 24 "There was great awareness of the AIDS problem
 25 amongst both the 'users' and the 'treaters' ..."

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1 to treat haemophilia."
 2 So that's Dr Mayne's articulation of what her
 3 understanding was of the views of haemophilia
 4 centre -- Reference Centre Directors, which was the
 5 small cohort of which she was a number at that time.
 6 **SIR BRIAN LANGSTAFF:** So what she's describing is that
 7 giving people who suffer from haemophilia commercial
 8 concentrate was recognised before the end of 1982 as
 9 being -- making them an at-risk group, that the risk
 10 was one which was recognised by her colleagues as
 11 Reference Centre Directors and was known as
 12 a realistic possibility in very early 1983.
 13 **MS RICHARDS:** Yes, precisely. If we pick it up in the
 14 next paragraph, we see Dr Mayne saying this:
 15 "Throughout 1983 publications occurred with
 16 increasing frequency confirming the presence of some,
 17 if not all, the preceding immune abnormalities to be
 18 present in homosexuals, in multi-transfused adults,
 19 children and in some haemophiliac patients."
 20 Then we see she refers to some publications, so
 21 a January 1983 publication by Jones.
 22 Then if we go over the page -- and that's
 23 Dr Peter Jones' publication in The Lancet, "Altered
 24 immunity in haemophilia". If we go over the page, we
 25 see at the top of the page she's referring to the

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1 And she records that:
 2 "Further reports of immunological abnormalities
 3 in Haemophilia were presented. Patients attending the
 4 meeting expressed worry regarding the possible
 5 curtailment of their treatment."
 6 A theme which, sir, you might wish to consider
 7 whether it arises from this part of her litigation
 8 report appears to be a theme of saying this was or may
 9 have been known to patients because of what was being
 10 reported in the media and/or through attendance at the
 11 World Haemophilia Federation Congress.
 12 There's no narrative in the litigation report
 13 of discussions with patients specifically. I'll come
 14 on to what Dr Mayne says on that subject in her
 15 witness statements in a little while.
 16 Then if we go to the bottom of this page she
 17 refers to:
 18 "By September 1983 two haemophiliacs in the
 19 [UK] were suspected of contracting AIDS following
 20 treatment with commercial concentrates."
 21 She suggests that:
 22 "... Haemophilia Centres were circularised
 23 informing them of the batch numbers of the suspected
 24 infected Factor VIII concentrates."
 25 It's not currently clear to me what that's

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1 a reference to at that point in time. But we do know
2 that investigative work was being undertaken by
3 Dr Craske looking at batches, so it may be that's what
4 she's referring to.

5 "Surveillance and collation of data was
6 undertaken by the Hepatitis Working Party."

7 Then she refers to the report by Dr Daly and
8 Dr Scott which was in The Lancet in late 1983,
9 November 1983, the first death of a UK haemophilic
10 from PCP, and she records that:

11 "At that time the world statistics indicated
12 that some 26 Haemophilia A patients and two
13 Haemophilia B patients had been reported to CDC as
14 having AIDS."

15 She then goes on over the page -- I'm not going
16 to go through this part in detail -- to talk about the
17 identification of HTLV-III and various publications in
18 that regard in the course of 1984.

19 At the bottom of the page she reports -- she
20 refers to an article about patients having antibodies
21 to HTLV-III and then says:

22 "During the same month" -- I need to check
23 which month that is, sir, because I don't think --

24 **SIR BRIAN LANGSTAFF:** Well, that's the article in I think
25 September in The Lancet, isn't it, Popovic et al,

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1 all patients."

2 And then she says this:

3 "Thus, the recommendations to revert to
4 cryoprecipitate unfortunately would have been too late
5 to prevent infection."

6 Given that those recommendations appeared in
7 amongst other things the New England Journal of
8 Medicine in January of 1983, how logically it could be
9 said that that recommendation would have been too late
10 to prevent infection if 1983 is the major year of
11 infection, well it simply doesn't follow
12 chronologically.

13 Then it's perhaps worth reading Dr Mayne's
14 observations in the following paragraph. She says
15 this:

16 "The foregoing paragraphs indicate that the
17 growing awareness of the grave threat of infection to
18 haemophilic patients through AIDS."

19 I think there must be a verb missing there.

20 She refers to:

21 "... during these years 1982-85 dramatic
22 developments in medicine received worldwide publicity.
23 Medicine is both a science and an art. Scientific
24 research forms the basis for advances in treatment.
25 The art is the appropriate application of the science.

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1 which talks -- it's Cheingsong-Popov, I think it is.

2 **MS RICHARDS:** The Popovic article that she refers to is
3 a publication in Science in 1984 and without checking
4 I can't recall, I'm afraid, the month, and then the
5 editorial in the BMJ that she says accepted that AIDS
6 was transmitted by blood products is an editorial
7 entitled, "Infection, immunity and blood transfusion",
8 the author being given as Bruce-Chwatt, which again
9 I will need to check the month.

10 **SIR BRIAN LANGSTAFF:** Yes.

11 **MS RICHARDS:** And then reference to the Danish study that
12 was in The Lancet. Again, without checking I can't
13 recall off the top of my head which month it was.

14 Well, in fact, so that I needn't go back to it
15 if we go to the next page and look at the bottom half
16 of the page she says this -- this is obviously looking
17 generally in the United Kingdom and not specifically
18 at Belfast because this was a report for the HIV
19 litigation to the Department of Health, but she says
20 this:

21 "The results of antibody testing of the UK
22 haemophiliacs accumulated during 1985, it was found
23 that 44 per cent were positive. 1983 was found to be
24 the major year of infection, established from the
25 availability of retrospective testing for some but not

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1 Members of the medical profession and laymen are
2 entitled to express public opinions regarding the
3 state of the art at any time. Media reporters are
4 particularly adept in this respect. However, in the
5 light of subsequent scientific knowledge the expressed
6 opinions may require revision."

7 Then she says:

8 "Such opinions are documented in paragraph 63."

9 To understand that we need to look at which
10 version of HIV litigation Statement of Claim she's
11 referring to. But she says this:

12 "Their expression was based on the then
13 available evidence and reflected the element of doubt
14 which existed regarding the magnitude of the AIDS
15 problem in haemophilia and its causation. They did
16 not unduly underestimate or understate the position
17 during the year 1983, a feeling which now might be
18 construed by the aid of the retrospectroscope."

19 So it's not entirely clear what is being said
20 in that. It appears to be suggesting that there
21 should be the avoidance of retrospective reflection or
22 any application of hindsight possibly.

23 **SIR BRIAN LANGSTAFF:** At the moment what I'm inclined to
24 do, but obviously it's subject to any submissions
25 I may later receive at the end of the Inquiry, that

40

1 what she appears to be saying is that the position
2 during the year 1983 was indeed understated and
3 underestimated. However, that is what appears now
4 looking back. At the time, the science had not
5 advanced sufficiently to allow for those conclusions
6 properly to be drawn.

7 **MS RICHARDS:** That may be what she is saying and, of
8 course, you have the benefit of being able to look
9 yourself at the contemporaneous materials from 1982
10 and 1983 to assess that claim.

11 **SIR BRIAN LANGSTAFF:** It's not a question of what was the
12 cause, what was the problem, was it understated. It's
13 a question of whether it should have been stated in
14 a different way is the question I think she's
15 addressing.

16 **MS RICHARDS:** Yes, what was understood as a risk, what
17 action could and should have been taken, what
18 information could and should have been provided to
19 patients to enable informed judgments to be made by
20 those whose health and lives were potentially being
21 placed at risk.

22 Going to then, just in terms of UKHCDO
23 meetings, refer to one further meeting on this topic.
24 It's the December 1984 meeting at Elstree, at
25 HCDO0000394_117.

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1 LOTH0000080_007. This is a rather later letter. It's
2 August 1993, so it's three years on from the
3 production of the litigation report and obviously
4 a decade on from the key events in 1983 but it's
5 a letter Dr Mayne wrote to the editor of The Lancet
6 about what had happened in relation to
7 Professor Allain in France, and she says this in
8 the -- picking it up in the second sentence:

9 "This action [that's the imprisonment of
10 Professor Allain] instilled a feeling of dismay and
11 grave concern over the fate of such a respected
12 colleague; one who I know personally and for whom
13 I have the highest regard for his scientific
14 contributions to the field of Haemophilia and for his
15 humanitarian attitude to the entire problem of HIV
16 infection contracted by Haemophiliac patients through
17 the receipt of blood products."

18 Then she says this:

19 "The evolution of the HIV problem within the
20 haemophilia population has caused immeasurable
21 distress to patients and to all physicians treating
22 them. The doctors concerned were guilty of one fault,
23 namely that of ignorance. The imposition of a prison
24 sentence in these circumstances seems illogical."

25 Now I draw attention to that not particularly

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1 Again, we've looked at this on a number of
2 occasions but not for the purpose of highlighting
3 Dr Mayne's attendance. So it was the haemophilia
4 Reference Centre Directors' meeting held at BPL
5 10 December 1984 to discuss what should by now be
6 done, and we can see from the list of attendees
7 Dr Mayne there along with a range of other
8 representatives.

9 I'm not going to go through the detail of the
10 meeting. There is no particular contribution to the
11 meeting from Dr Mayne that's identified in the
12 minutes. You will recall, sir, it records the
13 Reference Centre Directors' discussion about what
14 should now be done both in terms of testing patients
15 and in terms of ceasing to use commercial
16 concentrates.

17 We can see Dr Mayne writing about the meeting
18 in brief terms at BPLL0010480. She writes to Dr Lane
19 at BPL on 12 December 1984 thanking him and his staff
20 for the hospitality at the meeting and says this:

21 "The meeting was certainly beneficial if indeed
22 somewhat depressing."

23 Just perhaps picking up on the issue of
24 reflection as set out at the end of that section of
25 Dr Mayne's litigation report, if we go to

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1 because of Dr Mayne's views in relation to the fate of
2 Professor Allain but because of what she suggests as
3 a more general point, "the doctors concerned", which
4 would encompass presumably not only those in the
5 position of Professor Allain but all those involved
6 with treating haemophiliac patients with blood
7 products, so all Haemophilia Centre Directors,
8 including herself, guilty only of ignorance she says.
9 No doubt for you to decide whether that is an accurate
10 characterisation of the position.

11 If we turn next, on the issue of the extent of
12 HIV infection in the Northern Ireland haemophilia
13 community, to one of Dr Mayne's witness statements.
14 It's at WITN0736006, so it's one of her statements
15 from last year. If we pick it up at the bottom of the
16 page, "Statistics", she says this:

17 "... it is not difficult to recall the data for
18 the overall UK percentage of treated Haemophilia
19 patients who became infected with HIV. I believe it
20 to be 44.5 per cent. Some regions in England and
21 Wales attained figures greater than 70 per cent. The
22 comparable figure for Northern Ireland (NI) was
23 14.5 per cent, clearly anomalous. I well recall
24 presenting the [Northern Ireland] data to a meeting of
25 the [UK] Haemophilia Directors Organisation (UKHCDO)

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1 in Autumn 1985. Some colleagues, not unsurprisingly,
2 were politely sceptical about the veracity of the
3 results. Further testing was carried out by all
4 centres. In [Northern Ireland] I organised for all
5 samples to be tested in duplicate and simultaneously
6 in the Belfast Virology Laboratory and in the
7 Middlesex Hospital (London). The [Northern Ireland]
8 results were unchanged."

9 If we go to, I think it's the next page -- yes,
10 if we pick it up in paragraphs 8 and 9, this is where
11 she derives her figures from:

12 "Of the 110 annually treated patients, 43 were
13 on Home Treatment. Of this group 15 became HIV
14 positive. The patients had received comparable
15 amounts of Factor Concentrate to those in the rest of
16 the UK. The 16th positive HIV patient was a spouse
17 within the [home treatment] group. There were no
18 positive patients in the [non-home treatment] group
19 and no children seroconverted. The number 16 is
20 accurate however, the final number included in the
21 [home treatment] group may be 43 or 47, my memory
22 eludes me."

23 **SIR BRIAN LANGSTAFF:** Just pausing there, of those who
24 were on home treatment, which one -- would tend to be,
25 one would expect, serious, severe haemophilia A

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1 "... and home treatment impracticable."

2 Again, whether it's correct to characterise it
3 as "impracticable" as opposed to "less practicable" is
4 a matter for you.

5 "The advent of Factor VIII Concentrate in small
6 vials and with accurate dosage revolutionised life for
7 the Haemophilic patient.

8 "Furthermore, an alternative explanation might
9 have a straightforward numerical basis. Each company
10 utilised approximately 25,000 donors. If, due to
11 large patients numbers, financial constraints or
12 problems relating to product availability any one
13 patient could be treated with 2, 4 or even up to
14 6 different products, thus their exposure could be
15 increased even to 125,000 donors, leading to the
16 possibility of increased viral conversion.

17 "Regardless of underlying reason, there seems
18 to be a definite pointer to the fact that patients do
19 better on one product."

20 Just picking it up over the page, she refers
21 to, paragraph 10:

22 "... one severely affected patient was treated
23 with a batch of a new concentrate which was
24 contaminated by HIV. ... Armour ... informed me after
25 it had been used. The patient was in the [home

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1 patients, largely, it's just over a third.

2 **MS RICHARDS:** Yes, it is. So, as always with statistics,
3 it depends what you are presenting and what you are
4 looking as your overall group. But that's absolutely
5 right, sir. A third of those on home treatment became
6 HIV positive with one infection from a spouse or
7 partner as well.

8 There is then what Dr Mayne in fairness
9 characterises as conjecture in the following
10 paragraph. She says:

11 "A conjectural conclusion may be appropriate;
12 I speculate that repeated injections of treatment
13 regardless of plasma source may induce a degree of
14 immune tolerance, perhaps mediated through alteration
15 within the Complement system? It does not seem to
16 matter whether the treatment is Cryoprecipitate, or
17 Concentrate sourced in Scotland, Europe or the USA."

18 Not entirely clear what is meant by that.

19 "Figures from Scotland and NI would indicate
20 the Cryoprecipitate may well have been the safest
21 product available at that time. However, it was
22 cumbersome to use, accurate dosage was impossible ..."

23 Whether that puts it too high, given what else
24 we've seen about cryoprecipitate usage, is a matter
25 for your judgment, sir.

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1 treatment] group and thankfully did not seroconvert."

2 So we don't, I'm afraid, sir, I think have
3 sufficient data in relation to every year throughout
4 the first part of the 1980s to look at the individuals
5 who were infected with HIV and to trace whether they
6 were treated with more than one product, and if so
7 which products, and that's because we don't have the
8 returns data for some of the key years. So in
9 relation to the -- we've got the Bull returns for
10 example for 1983 but not the detailed breakdown of
11 individual patients that we have, for example, for
12 1984.

13 So I'm afraid we can't, at least on the
14 information currently available, verify the
15 correctness or otherwise or the plausibility or
16 otherwise of Dr Mayne's conjecture.

17 That's what she says in her statement in
18 relation to rates of infection. Sir, perhaps given
19 the time -- I'll just show you one more document which
20 just picks up on her last point about the
21 communication she received about an HTLV-III
22 contaminated batch. That's at ARMO0000382, so it's
23 a letter 10 May 1985 from Armour to Dr Mayne. She
24 refers to -- sorry, the letter refers to:

25 "... one donor, whose plasma was incorporated

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1 into pools from which our [Factor VIII] was produced,
2 has developed [AIDS]."
3 And then in the third paragraph:
4 "Only one batch in the [UK] is implicated.
5 Fortunately this is a heat-treated batch ..."
6 And he gives the batch number.
7 "This small heat-treated batch was distributed
8 in December 1984 in January 1985 to a few centres
9 only, of which yours is one, and we anticipate the
10 product has already been used."
11 And then a suggestion that if it hasn't been,
12 it should be returned and there will be reimbursement
13 or replacement. So that's, I think, the communication
14 to which Dr Mayne was referring in her statement.
15 Sir, there's some more to say in relation to
16 HIV and AIDS, so perhaps we could pick that up after
17 the break.
18 **SIR BRIAN LANGSTAFF:** Yes. Let's take a break now until
19 11.45.
20 **MS RICHARDS:** Thank you.
21 **(11.15 am)**
22 **(A short break)**
23 **(11.45 am)**
24 **SIR BRIAN LANGSTAFF:** Yes.
25 **MS RICHARDS:** Sir, I'm going to refer now to various parts

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1 treatment available to the physicians in charge of the
2 patient: the personal in possession of all the
3 information regarding the patient's needs."
4 Now, I emphasise those sentences because they
5 may be relevant to any assessment you make, sir, about
6 Dr Mayne's views as to the patient-physician
7 relationship.
8 **SIR BRIAN LANGSTAFF:** It is not, as I read it, consistent
9 with the view which was clearly expressed to us by the
10 expert ethicists who emphasised, I think, the person
11 in possession of all the information regarding the
12 patient's needs, in the broad sense, is usually the
13 patient.
14 **MS RICHARDS:** Precisely.
15 **SIR BRIAN LANGSTAFF:** Although how best medically to
16 resolve the needs is a matter upon which the doctor
17 has very valuable information to give in the light of
18 what he understands the individual patient's needs to
19 be.
20 **MS RICHARDS:** Precisely.
21 **SIR BRIAN LANGSTAFF:** Have I summarised their view
22 properly?
23 **MS RICHARDS:** Absolutely, and this appears to show
24 a different concept of characterisation of the
25 patient-physician relationship, with the physician

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1 in documents authored by Dr Mayne relevant to issues
2 relating to what action was or was not taken in
3 response to the risk of AIDS reflection or absence of
4 reflection and what information was or wasn't provided
5 to patients.

6 If we can start with the litigation report at
7 CBLA0000072_024 and if we go to page 40, this is the
8 last substantive page of the report. What follows is
9 simply the footnoted or end note references. This is
10 under a heading "The duties of care and breaches of
11 the duties of care", and then there are some
12 observations from Dr Mayne in relation to hepatitis
13 risk and then AIDS risk and she says this:

14 "The earlier sections of the report affirm that
15 haemophiliacs were at risk from hepatitis through the
16 medium of their treatment ..."

17 She then refers again to what must be matters
18 set out in one of the versions of the HIV litigation
19 Statement of Claim about alternative measures and she
20 says:

21 "In general, they are impractical but in
22 particular [she refers to one of them] denies the goal
23 of haemophilia treatment, namely to minimise pain and
24 disability and to prolong life. Its conjectural
25 implementation would have restricted the choice of

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1 essentially being the person in charge.

2 **SIR BRIAN LANGSTAFF:** This is a justification of
3 paternalism I think.

4 **MS RICHARDS:** Yes. Then she continues:

5 "The alternative treatments; cryoprecipitate,
6 Desmopressin and animal concentrates have already been
7 discussed and found wanting for the universal
8 treatment of severe haemophilia."

9 Again pausing there, it may be that those are
10 treatments that would not suffice for universal
11 treatment. It doesn't necessarily follow they
12 couldn't be used for treatment for some at least
13 severe haemophiliacs. Then she says this:

14 "The risk/benefit ratio of non-treatment versus
15 treatment could not be upheld" -- and I guess that
16 begs the question of by whom -- "in the light of the
17 plight of haemophiliacs in the era before infusion
18 treatment became available. A return to bed rest,
19 immobilisation and analgesia for joint bleeds would
20 have been untenable."

21 So strong terms there used by Dr Mayne to
22 characterise what she says was the option, treatment
23 versus non-treatment, and her identification and
24 characterisation of the risk benefit ratio predicated,
25 it would seem, upon at least on one reading of this

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1 document an assumption that that's ultimately
2 a balancing exercise for the physician rather than the
3 patient.

4 In relation to AIDS she then deals with it
5 shortly by saying:

6 "Comments of a similar nature apply to the
7 paragraphs ... relating to AIDS."

8 So that's the HIV report.

9 If we then go to Dr Mayne's main witness
10 statement, at WITN0736009, and if we turn, please, to
11 page 30, we look at the question at the bottom of the
12 page, and it's a question that the Inquiry has posed
13 to most of the clinicians from whom it's requested
14 statements, who were haemophilia clinicians practising
15 at the relevant time:

16 "Do you consider that your decisions and
17 actions, and those of the Centre in response to any
18 known or suspected risks of infection were adequate
19 and appropriate? If so, why? If not, please explain
20 what you accept could or should have been done
21 differently."

22 Then Dr Mayne's response at the top of the
23 page:

24 "The two words 'could' and 'should' often
25 suggest that today, with the benefit of hindsight, it

1 come on to.

2 So that's the evidence for you to assess from
3 patients -- from people who were infected or from
4 their family members.

5 In terms of Dr Mayne's witness statement, if we
6 stick with the document on screen but go first of all,
7 please, to page 28, bottom of the page is the
8 question:

9 "Did you take steps to ensure that patients
10 were informed and educated about the risks of
11 hepatitis and HIV? If so, what steps?"

12 "[Answer] I do not think I can expand usefully
13 to answer this question other than as already answered
14 previously."

15 In terms of what is previously set out it's not
16 clear what Dr Mayne is there referring to in the
17 statement. There's little that I can see which talks
18 about the provision of information to patients in the
19 earlier part of her statement. There is a discussion
20 which I'm going to come on to about what was done in
21 response to the risk of AIDS, but that all appears to
22 be at a later stage but be that as it may that's
23 Dr Mayne's answer to that question?

24 **SIR BRIAN LANGSTAFF:** Is she possible referring to other
25 witness statements which she gave earlier?

1 may cause alteration of decisions or changed actions.
2 Like everyone else, I wish that none of my patients
3 had been infected as a result of blood products.
4 However, after careful appraisal I remain convinced
5 that the course of action pursued by both myself and
6 my colleagues was measured and appropriate for that
7 time in light of the information and the state of
8 knowledge at the time."

9 So that is Dr Mayne's response. Then in answer
10 to the next question, "What decisions or actions by
11 you and/or by the Centre could and/or should have
12 avoided, or brought to an end earlier, the use of
13 infected blood products?", she refers to that answer.

14 In terms of the question of whether it patients
15 were warned or provided with information or advice
16 about the risks of HIV so that the patients could make
17 an informed decision, that's obviously a matter for
18 you to determine. You will recall the evidence that
19 the Inquiry has already received and heard from
20 patients themselves or from their relatives, which is,
21 I think I'm right in saying, universally to the effect
22 that they were not provided with specific advice,
23 warnings or information about risks of AIDS from
24 factor concentrates prior to the group meetings that
25 took place probably in January 1985 and which I'll

1 **MS RICHARDS:** It is possible and I'm going to go through
2 where I can find reference in her statements to this
3 issue. I can't guarantee that I necessarily refer to
4 every single statement that she refers to it and no
5 doubt you will be reading them all again in due
6 course, sir. But it is absolutely possible that she
7 may be referring to earlier statements.

8 In relation to this statement, if we go to
9 paragraph 43.1, I'm looking here for passages which
10 deal with information provided to or discussions held
11 with patients, so it's page 31. She was asked about
12 reversion to treatment with cryoprecipitate and her
13 answer is this:

14 "Theoretically a return to using
15 cryoprecipitate would have been appropriate for some
16 patients. However, it was neither a practical nor
17 realistic option. Following lengthy explanatory
18 discussions, during which the possibility of reverting
19 to cryo was raised, I was greeted by an emphatic
20 refusal from the patients concerned. Patients had
21 become used to carrying their concentrate/pack with
22 them to school, to college or their workplace. The
23 presence of that pack had become life changing.
24 A return to being dependent on the availability of
25 a fridge freezer and to the lengthy process of thawing

1 and preparing cryoprecipitate was just not acceptable
2 to them."

3 Unfortunately, what that paragraph doesn't tell
4 us is when it is said such conversations took place or
5 what information was provided about risks to enable
6 a judgment to be made by the patient.

7 I should say I don't think we've seen anything
8 in individual statements from people who were infected
9 or their relatives which reports any such
10 conversations but assuming for the purposes of debate
11 in Dr Mayne's favour she had them, it doesn't tell us
12 when she had them and whether it was at any stage
13 prior to the group meetings in January 1985.

14 If we then turn over the page and go to the
15 bottom half of the page, so this is under a series of
16 questions relating to the provision of information to
17 patients, she's asked the general question:

18 "What information did you provide or cause to
19 be provided to patients with a bleeding disorder ...
20 about the risks of infection in consequence of
21 treatment with blood products ... prior to such
22 treatment commencing?"

23 The answer is:

24 "No local leaflets/printouts were available.
25 Discussions with patients were held if and when

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1 What she says by way of response is:

2 "An annual meeting for patients, relatives and
3 members of staff was held as part and parcel of the
4 activities of the Northern Ireland Group of the
5 National Haemophilia Society. Over time,
6 a multiplicity of experts was invited to be speakers.
7 Each gave an opening talk on aspects of haemophilia
8 and then the afternoon was open to patients and their
9 relatives to ask questions of the experts - questions
10 about treatments, about the risks, about advances in
11 therapy, changes in scientific research etc."

12 And then she gives a list of some of those who
13 spoke over the years.

14 So, again, that doesn't answer the question,
15 the actual question asked, which is what the
16 discussions were, what's the basis for saying that
17 patients were aware of risks of hepatitis. That
18 doesn't address the content of any communications at
19 these what was said to be annual meetings rather than
20 the fact of them.

21 If we go to the next paragraph, Dr Mayne says:

22 "Patients also had their own magazine/journal
23 originally started by me but then passed on to the
24 patients. ... entitled 'CLOTT'."

25 Again, it doesn't provide us with any

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1 possible. Each patient was provided with information
2 provided by the national Haemophilic Society. There
3 were few occasions when concentrate was given to
4 patients other than those with haemophilia or allied
5 disorders. I recall rare incidents when concentrates
6 were given to counteract the excessive effects of
7 Warfarin anti-coagulation. It was also used for
8 patients with advanced liver disease."

9 She refers, top of the next page, to instances
10 where concentrates were used erroneously on an
11 emergency basis within the ICU.

12 So, again, that doesn't actually tell us what
13 information was provided. It merely says leaflets or
14 information from The Haemophilia Society was provided
15 and discussions were held with patients, but the
16 content of that information remains unclear.

17 If we go to the next page -- sorry, stick where
18 we are, Soumik. Paragraph 47.1, you'll see the
19 question that's been posed of her, and by reference to
20 the HIV litigation expert report, was picking up on
21 her assertion that patients became aware of the risks
22 of hepatitis during the mid-1970s.

23 She's asked what the factual basis for that is
24 and what discussions she had with patients in the
25 mid-'70s.

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1 information -- I don't say this in pejorative terms,
2 just as a matter of fact -- it doesn't provide us with
3 information about what the content of any such
4 articles might be.

5 If we go over the page we then see the
6 assertion at 47.4:

7 "Therefore, the patients in the 1970s onwards
8 would have been aware of all aspects of haemophilia
9 treatment and research, if they attended their local
10 society and read its magazine."

11 That's, well, sir, a matter for you as to
12 whether that's an adequate substitute for information
13 being provided directly to patients by their
14 physician.

15 If we go further down the page there's then
16 a question about what information was provided before
17 the commencement of home therapy and there's a more
18 detailed answer about the process of training families
19 in relation to home therapy.

20 In terms of risks of infection, what we see is
21 at the bottom of the page, it's just said in last
22 sentence on the page:

23 "At all times patients were advised regarding
24 the risks of disease, any then-known risk of using
25 concentrate and were encouraged to have discussions

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1 any time they had a problem."
 2 Again, there's a sharp contrast between what
 3 Dr Mayne says and what those who have provided
 4 statements to the Inquiry say in relation to being
 5 warned of risks.
 6 Then we have the question at 50.1:
 7 "When did you first discuss AIDS or HIV ...
 8 with any of your patients?
 9 "50.1 At this distance in time, I cannot
 10 recall the details but I have no doubt I had informal
 11 discussions with the patients at clinical
 12 appointments. The minutes of the UKHCDO meeting in
 13 December 1984 have been brought to my attention.
 14 I note that I attended; however, I cannot recall
 15 attending or the meeting itself. I assume that the
 16 decision to hold the 1985 meetings ..."
 17 So those are the group meetings held for
 18 patients in January or thereabouts.
 19 "... was influenced by this meeting. It was
 20 then decided to have formal meetings. I arranged for
 21 three meetings to take place in early 1985."
 22 And she refers to those being described in her
 23 earlier witness statement.
 24 So in terms of any dates, we have the
 25 January 1985 meetings, which obviously is too late in

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1 previously untreated patients.
 2 Then she's asked the question:
 3 "Did you continue to use blood products to
 4 treat patients, after becoming aware of the possible
 5 risks of infected with HIV? Why?"
 6 And she says this:
 7 "Within my response to [question] 33 I have
 8 indicated that I continued to use concentrates. Even
 9 with the benefit of hindsight, I cannot envisage
 10 otherwise. In reality, the choice was stark -- stop
 11 treatment with concentrates with all the risks and
 12 disruption that would entail for patients or continue
 13 with treatment in light of the information then
 14 available."
 15 In common with some others who have provided
 16 evidence to the Inquiry from a clinical perspective or
 17 from some of the material we've seen in
 18 contemporaneous documentation, the choice is posed as
 19 this stark choice between essentially no treatment or
 20 continuation of treatment rather than a potential
 21 spectrum of choices.
 22 She refers in the next paragraph to the special
 23 meeting of Reference Centre Directors, and that's
 24 I think an accurate reflection of what -- the outcome
 25 of the Reference Centre Directors' meeting in May

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1 terms of providing information in advance of treatment
 2 or in the course of treatment programmes, and then we
 3 have the general statement that she has no doubt she
 4 had informal discussions with patients at clinical
 5 appointments but we're not told what the content of
 6 those discussions were. And, again, the evidence from
 7 individual patients or their family members is to the
 8 effect that information about the risks was not
 9 communicated to them.

10 So that's what she says in her statement about
 11 information provided to -- in that statement about
 12 information provided to patients.

13 If we go back in this statement then to
 14 page 28, she's asked the question, so this is now
 15 "What actions did you take in response to the risk of
 16 AIDS", she's asked the question in 35:

17 "What, if any, actions did you take to reduce
 18 the risk to your patients of being infected with HIV?"

19 She says:

20 "[She] followed the recommendations issued by
 21 UKHCDO in June 1983 which reflected my existing
 22 practice in any event."

23 We've already explored that. That's the
 24 June '83 letter and the UKHCDO recommendations in
 25 relation to children, mildly affected patients and

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1 of 1983.

2 I should draw your attention to a previous set
 3 of answers on page 26, where Dr Mayne is asked the
 4 question:

5 "What, if any, enquiries and/or investigations
 6 did you carry out or cause to be carried out in
 7 respect of the risks of transmission of HIV or AIDS?
 8 What information was obtained as a result?"

9 The way in which Dr Mayne has answered that is
 10 to look at the process of testing patients for
 11 HTLV-III and what happened thereafter, so there's not
 12 a suggestion in her answer of enquiries or
 13 investigations prior to the actual point of testing
 14 which seems to have commenced at the beginning of
 15 1985. We can see that because she -- that talks in
 16 paragraph 33.3 about what her expectation was as to
 17 how many patients would be HTLV-III positive. She
 18 poses a rhetorical question about immunity in
 19 paragraph 33.4.

20 If we go down the page, she says that -- this
 21 may be in relation to an earlier period in fairness --
 22 she says:

23 "The treatment policy was kept under review.

24 Discussions and many conversations took place with the
 25 patients."

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1 Again, that doesn't reflect the evidence that
2 individuals who were infected or their family members
3 has provided to the Inquiry so those are factual
4 issues that will be for you, sir, to consider.

5 She says a return to cryoprecipitate was
6 offered and was turned down. Again, there's no
7 information as to when she says that offer was made or
8 to whom and she says patients were asked to reduce
9 their usage if possible.

10 There's certainly a later letter, from the late
11 1980s when there's a request for reasons of financial
12 constraint, for patients to reduce their usage.
13 There's no documentary evidence of patients being
14 asked to reduce usage that the Inquiry has found in
15 the first half of the 1980s; so relevant to the risk
16 of AIDS.

17 She then refers to offering testing to staff.
18 That again puts this into the either very end of 1984
19 or 1985 period. She refers then in the next paragraph
20 to regular patient testing continuing and where
21 appropriate testing of partners being carried out.
22 Again, that puts what she's talking about squarely
23 into 1985 or thereafter.

24 If we go to the next page, the measures she
25 then sets out I think on a fair reading of the

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1 the anti-HTLV-III seroconversions from negative to
2 positive are as follows."

3 Sir, I should say what flows from this and is
4 acknowledged by Dr Mayne in her statements is that, in
5 common with some other haemophilia centres, samples of
6 sera were stored I think in the Regional Virus
7 Laboratory primarily, possibly exclusively. To what
8 extent that was with the knowledge or informed consent
9 of patients I think is probably unclear on the state
10 of the evidence but, as a matter of fact, there were
11 stored sera samples and that enabled this exercise to
12 be undertaken for a number of those who had been found
13 to be positive for HIV and the dates are significant.

14 First one, last negative result January '84,
15 first positive result July '84, so seroconversion
16 within the first half of 1984. Second one is last
17 negative result October '84, first positive result
18 April '85, so seroconversion in the last months of '84
19 or the first months of 1985. The third suggests
20 seroconversion in the period between February and
21 October of 1983; the next August 1983 and
22 January 1984; then January '83 and January '84; then
23 November '83 and June '84; September '83 and February
24 '84; February '83 and November '83; September '83 and
25 March '84; September '84 and July '85; August '83 and

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1 statement all relate to the period from 1985 onwards,
2 at least that seems the likeliest reading. So she
3 talks out paragraph 33.8 about needing to disseminate
4 information because of misconceptions relating to
5 stigma. She talks in paragraph 33.9 about speaking on
6 the radio/TV, attending a range of meetings to offset
7 and counteract incorrect rumours regarding infection
8 with HIV.

9 She then talks about increasing staffing levels
10 in 33.10, and in 33.11 liaising with colleagues from
11 other disciplines. So that's looking I think then at
12 how to treat and care for those infected with HTLV-III
13 HIV rather than the prior question of what steps were
14 taken to consider and the best response to the risks
15 in advance of those risks actually being fulfilled.

16 Sir, that's I think the most relevant part of
17 Dr Mayne's main witness statement. If we then look
18 again at information about the circumstances of
19 infection and dates of seroconversion, we pick it up
20 at BHCT0000484. This is a letter dated
21 15 October 1985. It's from the Regional Virus
22 Laboratory at the Royal Victoria Hospital to Dr Mayne
23 and it says:

24 "We have completed the retrospective study on
25 our stored sera from your patients. The results of

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1 March 1984.

2 Then there are four patients listed for whom we
3 have a first positive result, the earliest of those
4 dates being February 1983 and one being February 1984,
5 but no earlier stored serum samples. So what we can
6 see from that list is no apparent seroconversions
7 prior to 1983. The earliest date of a last negative
8 result is January 1983 and the majority of the last
9 negative results are later than that. That obviously
10 raises the question of whether, given what was known
11 in late 1982 and by the beginning of 1983, these were
12 avoidable seroconversions.

13 So that's information about the patients who
14 were found to be HIV positive. As Dr Mayne's
15 statement says there is also one spouse or partner who
16 was infected with HTLV-III.

17 You will recall Dr Mayne's statement saying
18 that there were no children who seroconverted.
19 However, that might depend upon one's definition of
20 a child. If we go to BHCT0000846_004, if we go to the
21 next page, so this is a letter from Dr Mayne to
22 Dr Machin in the Haematology Department of the
23 Middlesex Hospital, 18 October 1985. Obviously, the
24 patient details are redacted but you can see -- sorry,
25 if we go up the page -- the date of birth is 1971.

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1 This is a letter written in 1985 so it refers to
2 a 14-year old. For the avoidance of doubt I confirm
3 it does refer to one of the patients listed in that
4 letter we looked at a few moments ago.

5 We can see from this it refers to a "moderately
6 severe haemophilic", so not severe, moderate
7 severity, and if we go to the bottom of the page we
8 can see this paragraph:

9 "The most significant problem with [him] is the
10 fact that the human material given in January [so it
11 would seem that's January 1985, given what's set out
12 in the rest of the letter] produced seroconversion on
13 10 July 1985 with a positive HTLV-III
14 result confirmed. I have not told the patient this
15 result, nor his family, at the present time ..."

16 Again, the letter is October 1985, so three
17 months further on:

18 "... the reasons are due to the precarious
19 family base of the patient."

20 The letter continues over the page but there's
21 nothing material for present purposes in that letter.

22 So that would suggest that a 14-year old was
23 infected, and infected at a late stage, and the fact
24 of his infection with withheld from him and his family
25 for a period of time.

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1 affected patients in the UK is 54 per cent, with some
2 centres having ratings of 75 to 80 per cent."

3 I think we have seen 44 per cent cited
4 elsewhere, but in any event.

5 "In Northern Ireland only 16 patients have been
6 shown to be antibody positive. This is equivalent to
7 25 per cent of the most severely affected patients and
8 16.5 per cent of all treated patients in the
9 Province."

10 Then she goes on, and we looked at this
11 yesterday, to suggest that that may be explicable upon
12 the basis of the policy of using a single concentrate
13 and I've explored the extent to which that was in fact
14 adhered to in practical terms yesterday.

15 If we go to HCDO0000 --

16 **SIR BRIAN LANGSTAFF:** Just before you leave this, if we
17 can just go back to page 1. It is a completely
18 different point. No, sorry, forget that.

19 Forget that.

20 **MS RICHARDS:** If we go to HCDO0000524, these are the
21 minutes of a meeting of the AIDS Group of Haemophilia
22 Centre Directors. That was a group established
23 I think at the beginning of 1985. This is the sixth
24 meeting, October 1985, and Dr Mayne was a member of
25 that group.

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1 If we go to BHCT0000860 and go to the next
2 page. Again, this is picking up upon the suggestion
3 in Dr Mayne's statement that no child was infected.
4 This says "Surveillance of paediatric HIV infection
5 and AIDS follow-up", and if we look further down the
6 page we can see:

7 "Has the child received treatment for HIV?

8 "Yes", and we can see that the child has
9 received AZT. If we go over the page -- sorry, we're
10 back to the first page, I should say. We see there
11 reference to this patient having HIV-related symptoms
12 and details are there given.

13 Sir, again, obviously patient identifying
14 details are redacted by the Inquiry but it appears
15 from the information we have that relates to the same
16 person, that same patient as we looked at in relation
17 to the previous letter.

18 If we then go to one of the other documents
19 authored by Dr Mayne, again looking at seroconversion
20 rates, it's RHSC0000067_002. We've looked at this
21 previously. It's Dr Mayne's March 1988 report. If we
22 just pick up on something she says on page 4, under
23 the heading "HIV Positivity", at the bottom of the
24 page, she says:

25 "The HIV antibody positive rate for severely

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1 If we just go to page 4, we can see at the
2 bottom of the page Dr Mayne making the same point
3 suggesting that the incidence of positivity in her
4 patients was low probably because all her home therapy
5 patients were kept on one product and, as I say, that
6 doesn't appear to be correct, although the individual
7 patient data we have doesn't clearly distinguish home
8 therapy and hospital therapy. Some had only received
9 one product for ten years and then there's
10 a discussion amongst directors of the variable
11 incidence of positivity between centres.

12 It's not, I think, clear that it's accurate to
13 say that the patients -- if this is what Dr Mayne was
14 saying, that the patients who seroconverted were all
15 severely affected patients. We've looked at one
16 example already of someone who was described as
17 moderately severe.

18 If we then go to BHCT0000612, this is a letter
19 from Dr Mayne dated 23 August 1994 to Ms Spooner in
20 Oxford and she says this:

21 "Further to your query regarding [patient]
22 there has been no documentation of his receiving
23 treatment since 1974 because that is the state of his
24 hospital records both here and in a peripheral
25 hospital. Agatha Christie or otherwise known as

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1 Dr Elizabeth Mayne found out that he had been given
2 two bottles of Edinburgh Factor IX on the day his
3 niece was born. It was never written down by the kind
4 Doctor who administered the dose and it led to much
5 consternation for the patient, his family and myself.
6 The sad and ironic aspect of the whole performance was
7 that the patient did not need the Factor IX. He has
8 mild Christmas Disease and does not suffer from
9 Haemarthrosis. The Doctor who saw him either forgot
10 or did not realise these facts and [he] now sadly has
11 full-blown AIDS."

12 Again, the patient cross-referencing between
13 the documents available to the Inquiry identified
14 there is, it would appear, one of the patients listed
15 in that letter, that list of seroconversions. So
16 there we have an account of a patient with mild
17 haemophilia B, even on Dr Mayne's account, having been
18 given Factor IX, not I should say according to this
19 letter by Dr Mayne but elsewhere, completely
20 unnecessarily. It's not clear from this or from the
21 other material the Inquiry has I think which hospital
22 that treatment was administered at.

23 That obviously raises an issue that we've seen
24 explored elsewhere in relation to other centres within
25 the United Kingdom of systemic problems with hospitals

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1 January to March 1984 as the dates --

2 **SIR BRIAN LANGSTAFF:** 1985.

3 **MS RICHARDS:** 1985, sorry -- when these meetings occurred.

4 If we then go to WITN2658002, go to the second
5 page, we see that this is the report entitled
6 "A synopsis of haemophilia re Mr Malachy Devlin", and
7 we explored the evidence relating to Mr Devlin in the
8 oral hearings in Belfast.

9 If we go to page 12 and we pick it up at the
10 bottom of the page, bottom half, we can see Dr Mayne
11 saying this under the heading "December 1984":

12 "During December 1984 plans were laid to
13 interview all of the patients attending the Northern
14 Ireland Haemophilia Centre. It was felt that the
15 opportunity should be afforded to all to have frank
16 discussions regarding the possibilities of becoming
17 infected or already being infected by the AIDS virus."

18 There's no reference to any earlier meetings in
19 this document as I recall.

20 "At that time a test was available to measure
21 antibody to the HIV virus. There was no test
22 available to test for the presence of the actual virus
23 i.e. there was no antigen test available. Therefore,
24 it was not possible to predict the consequences of
25 finding a positive result. The arrangements took

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1 which were not full haemophilia centres or doctors who
2 were not knowledgeable about risks providing treatment
3 where it wasn't required.

4 If we then look at the question of the meetings
5 that were held in January 1985 and -- we can take that
6 down, Soumik -- I'm sure you will recall, sir, from
7 the Belfast hearings some very vivid testimony about
8 those meetings at the hospital. I'll have to dart
9 between different statements I think in order to see
10 what's said about those meetings by Dr Mayne.

11 So if we start with WITN0736001 and we go to
12 page 7, so this is Dr Mayne's statement in response to
13 a number of individual statements from people who were
14 infected, a number of whom were giving evidence at the
15 oral hearings in Belfast, and in paragraph 2.6 she
16 says:

17 "... categorically, there was no HIV testing
18 carried out before the meetings that were convened in
19 January to March 1985 at the Royal Victoria Hospital."

20 So that assists, if that's correct, in telling
21 us that there was no HIV testing in the course of
22 1984. We know of course that there were HIV tests or
23 HTLV-III tests carried out in relation to samples from
24 1983 and 1984 and possibly earlier, but she says there
25 was no HIV testing and she gives that window of

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1 several months to complete, as patients were requested
2 to come to the Centre in small groups to allow
3 sufficient time for discussion and debate. Actual
4 testing of samples commenced on 2 January 1985. Each
5 sample was coded. The prefix was BV (Belfast virus)
6 and each patient's sample was allocated a sequential
7 number commencing at BV1 up to and including BV396.
8 When the results were available, they were entered
9 into a confidential notebook retained by Dr Mayne and
10 kept in a locked filing cabinet drawer in her office.
11 Access was permitted only to two other people, the
12 Chief MLSO in the Haemophilia Laboratory and
13 Dr Mayne's personal and confidential secretary."

14 Then although --

15 **SIR BRIAN LANGSTAFF:** Just pausing there, this is not
16 consistent with what you've just referred me to at
17 page 7 of WITN0736001 where she said no testing was
18 carried out before the meetings in January to March of
19 '85. Here it's saying testing did begin, isn't it,
20 upon the previous page?

21 **MS RICHARDS:** She's saying the actual testing began on
22 2 January.

23 **SIR BRIAN LANGSTAFF:** Yes. How does that fit with what
24 she said at page 7?

25 **MS RICHARDS:** So that's WITN0736001.

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1 **SIR BRIAN LANGSTAFF:** Page 7.
 2 **MS RICHARDS:** Sir, unless there was a meeting --
 3 **SIR BRIAN LANGSTAFF:** It may just be relating to
 4 Mr Kilpatrick, but it seemed to be more generally
 5 expressed --
 6 **MS RICHARDS:** Yes.
 7 **SIR BRIAN LANGSTAFF:** -- because it's talking about
 8 meetings, so it looks as though it's wider: no HIV
 9 testing carried out before the meetings in January to
 10 March '85, i.e. none before March 1985 meeting.
 11 **MS RICHARDS:** Yes. Well, that's obviously not consistent
 12 with saying that the actual testing commenced on
 13 2 January 1985.
 14 **SIR BRIAN LANGSTAFF:** I just wanted to confirm that was
 15 so.
 16 **MS RICHARDS:** Yes.
 17 **SIR BRIAN LANGSTAFF:** Thank you.
 18 **MS RICHARDS:** Then in terms of the meetings themselves, it
 19 seems from trying to piece together the evidence that
 20 there were a series possibly of three meetings.
 21 You'll recall I'm sure, and I'll just put it up on
 22 screen briefly, one of the oral accounts you have
 23 heard from an attendee at the meeting WITN1371001.
 24 This is from the statement of Louise Marsden. If we
 25 go to the fifth page, bottom of the page, the date

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1 held in an alternative venue. This was because a
 2 terrorist episode had necessitated the occupation of
 3 all bed space in the hospital.
 4 "The alternative venue was unsuitable for
 5 severely affected patients as the seating was not
 6 appropriate for patients with severe joint
 7 disabilities. Therefore, proceedings were
 8 foreshortened and perhaps not as much information as
 9 previously was presented. I seem to recall that on
 10 this occasion Professor John Bridges, Head of Academic
 11 Haematology and Consultant Clinical Haematologist
 12 attended as a support for myself as I had been up all
 13 the previous night on emergency hospital business. It
 14 was neither practical nor possible to carry out long
 15 consultations on an individual basis but the situation
 16 was addressed as far as possible when the person was
 17 having the test carried out."
 18 So that's Dr Mayne's account of the meetings in
 19 this statement and obviously raises a question about
 20 the appropriateness of having both patients and
 21 members of portering, catering and cleaning staff all
 22 in attendance together.
 23 If we then go to WITN0736006, this is another
 24 of Dr Mayne's witness statements, and if we go to the
 25 last page, please, Soumik, Dr Mayne says this:

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1 that's given for the open meeting is 1983, which
 2 appears to be unlikely to be correct but it's the
 3 characterisation of the meeting that's of value here.
 4 So it refers to the open meeting where Dr Mayne
 5 announced everyone would be tested for HIV.
 6 "She gave the Haemophiliacs present the choice
 7 of whether they wanted to know the result of their HIV
 8 test."
 9 And she says:
 10 "I found that bizarre."
 11 If we look at one of Dr Mayne's responses at
 12 WITN0736005, and if we go to -- this is in response to
 13 the Marsden statements. If we go to page 10 I think
 14 it is, you'll see Dr Mayne giving this description in
 15 this statement. She says:
 16 "Three open meetings were held regarding the
 17 problems of HIV infections. Two were held within the
 18 confines of Ward 37, [Royal Victoria Hospital]. In
 19 addition to patients attending the meetings, RVH
 20 members of portering, catering and cleaning staff were
 21 all invited to attend and express their worries and
 22 queries about HIV infection. The staff expressed much
 23 gratitude at having all their problems aired and
 24 clarified. Unfortunately, the meeting to which the
 25 witness and his wife attended had per force, to be

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1 "Later within the deposition of Louise Marsden
 2 she referred to the 1985 HIV meeting as bizarre. She
 3 was completely correct in her description. I agree.
 4 The explanation is as follows. I had been up all the
 5 previous night dealing with the unclottable blood of a
 6 patient in the Intensive Care Unit. The hospital was
 7 full to capacity. Therefore, the normal venue for the
 8 meeting was unavailable. It had been commandeered for
 9 emergency bed space. I think the full capacity was
 10 related to an increased incidence of influenza and
 11 pneumonia."
 12 That's a different reason. It may be nothing
 13 turns on it but, in any event, I just observe that.
 14 "However, the only available space for the
 15 meeting was the historic Old Surgical Extern Theatre.
 16 It was unsuitable in every respect. The space was
 17 confined; the seating was unsuitable for disabled
 18 patients and the general impression inhibitory. It
 19 was not possible to cancel the meeting as transport
 20 had been arranged for the disabled patients and others
 21 were coming from far afield ..."
 22 And she gives some examples.
 23 "Professor John Bridges attended as support.
 24 He was concerned that I might pass out from fatigue.
 25 I have not discussed this aspect of the meeting

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1 previously as it seemed irrelevant. However, in view
2 of Louise Marsden's apposite description I thought
3 I should enlarge on the detail to the Inquiry."

4 Then if we go to WITN0736001, again this is
5 another of Dr Mayne's statements and if we look at
6 page 11, please, bottom half of the page, this is in
7 response to a recollection of the meeting described by
8 Mr Hamilton, and Dr Mayne says this:

9 "... when the possibilities of viral infection
10 became known, in 1984, towards the end of that year,
11 meetings were planned to meet with all patients who
12 had received treatment. They began in January 1985.
13 Routinely, they were scheduled to take place in
14 Ward 37, block A, [Royal Victoria Hospital].
15 Initially, Mr Hamilton's description of a hexagonal
16 room caused bewilderment. After two weeks
17 consideration, I remembered that Ward 37 was not
18 available for one of the scheduled meetings due to an
19 influx of emergency admissions the previous evening.
20 The only hospital venue available, therefore, was the
21 Sir Ian Fraser Lecture Theatre which was located off
22 the main hospital corridor. It was a historical venue
23 as it was the old anatomy and surgical theatre for
24 teaching medical students. It was in the form of
25 a rotunda, with a glass ceiling and tiered seats which

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1 individual taking of samples rather than the group
2 meeting; I don't know:

3 "All samples were tested and labelled
4 anonymously by a code."

5 And then -- well, I might as well read this so
6 I don't have to come back to it. I'm going to look at
7 the process for giving patients their diagnosis in
8 a moment. She says:

9 "Patients plus relatives were invited to come
10 back to receive their results. If negative, at first,
11 it was thought a letter might be a good idea but this
12 was rapidly rejected. All but two families returned
13 for results and both received a home visit. The
14 situation was dire and all members of the Centre's
15 staff did the best they possibly could. Only
16 16 adults tested positive but for each and every one
17 of them it was then a disaster. All patients accepted
18 the invitation to be tested, but some deferred the
19 appointment to a more convenient time."

20 So that's the further description we have from
21 Dr Mayne of the group meetings and the arrangements
22 for testing. I should say that in the evidence the
23 Inquiry has received from individuals, whilst it's
24 absolutely right that there is evidence of patients
25 being informed of their diagnosis in person, there is

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1 were very uncomfortable. It had old fashioned heavy
2 wooden doors which clanged shut when closed. It had
3 been refurbished and was used for weekly physicians
4 meetings and post graduate seminars. Sadly there was
5 no facility for tea and coffee."

6 I refer to that because this meeting was
7 obviously a very significant event in the memory of
8 a lot of individuals and it seemed important to draw
9 out what information we have from Dr Mayne about it.
10 She then continues:

11 "I cannot recall how the subsequent blood
12 testing was [arranged]."

13 So it sounds as though there was testing
14 undertaken on this account immediately following the
15 meeting:

16 "It may have been necessary for the attendees
17 to walk to a nearby ward. I do not remember. I can
18 certainly remember that the room was not locked.
19 There was absolutely no justification or reason to
20 take such a step."

21 Then perhaps in contrast to the other accounts
22 she says here:

23 "As much time and space was given for
24 discussion as was necessary."

25 That may, of course, be a reference to

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1 also evidence of patients being informed of their
2 diagnosis, both negative and positive in some cases,
3 by letter. So that again may be an area where there
4 is a factual conflict that you, sir, may wish to
5 consider in due course.

6 One of the themes that has emerged from the
7 statements of those who were infected or from their
8 family members is as to the adequacy of the
9 information that was provided when patients were told
10 their HIV diagnosis and again you'll recall, sir, it's
11 a theme that the Inquiry has heard both in relation to
12 evidence relating to Belfast and in relation to
13 evidence relating to a number of other centres,
14 criticisms or concerns expressed about the adequacy of
15 the information that was provided. It has been to
16 some extent, perhaps, a fairly typical clinician
17 response to say much was uncertain and the information
18 that was provided was the information that was known
19 at the time.

20 There is some evidence from individuals
21 suggesting that their impression was that they were
22 given no choice about whether to be tested for HIV,
23 only as to whether they wished to know the results.

24 If we look at WITN2658009, these are the terms
25 of a letter written to one patient, Mr Devlin, and

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1 again we looked at a lot of the material relating to
2 his tragic case in the oral hearings in Belfast, but
3 this is a letter 25 March 1985. It helps gives some
4 context as well and a chronology to the period of time
5 over which testing was being undertaken. This is late
6 March and Dr Mayne is writing saying:

7 "... we ... have serum for the antibody to the
8 virus. A positive test does not mean that the person
9 will be developing AIDS but it is important to carry
10 out this test ..."

11 And she says:

12 "... I want to know the antibody status of all
13 patients before receiving heat-treated material."

14 So that would suggest that as at 25 March 1985
15 patients were still receiving unheated concentrates
16 and the change had not taken place or at least not
17 taken place for all patients. Then it's a "please
18 come for a simple straightforward blood test". So it
19 could I think in fairness to Dr Mayne be said there's
20 no compulsion there, but equally it could be said in
21 fairness to some of the criticisms that have been
22 expressed that there's no statement there that it's
23 a choice for the patient to make.

24 **SIR BRIAN LANGSTAFF:** It sounds a bit like rationing the
25 heat-treated material, presumably because of

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1 side of caution'. However at the time of actually
2 testing, the patient was invited to give consent and
3 if they had any difficulty in doing it the test was
4 easily postponed until a future date or not carried
5 out at all in accordance with the patient's wishes.
6 Several patients postponed testing but none refused.
7 It seemed only right and proper that they should be
8 given the opportunity to know or not know the results.
9 One of the secretaries took a note of the names of
10 patients who did not wish to know the result."

11 And then she deals with the individual patients
12 in question, or the individual patient and his spouse
13 in question.

14 Then I should I think perhaps point out the
15 next answer. This is dealing with the more general
16 question about the suggestion that not sufficient
17 information was provided about HIV at 2.10.1

18 Dr Mayne's response is:

19 "... each patient when tested received the
20 maximum amount of knowledge available and was offered
21 appointments at any time to discuss important issues
22 relating to HIV."

23 So again it doesn't really tell us what
24 information was routinely provided to patients at this
25 point in time. I can check whether any more detail is

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1 a shortage, I do not know, but -- yes, as to the
2 question of were people -- did think they were obliged
3 to have a test or not, does she ever deal with the
4 question of why would you give people a choice as to
5 whether they wanted to know the results if they had
6 had a choice as to whether they should be tested in
7 the first place?

8 **MS RICHARDS:** I'm going to check that because I'm
9 confident Dr Mayne does deal with it somewhere.

10 This might be one of the places, WITN0736005.
11 If we go to page 5 and we look at the bottom of the
12 page, you'll see this is in response to an individual
13 witness statement, and reference is made to the
14 witness W1371's statement describing the meeting and
15 the witness saying that Dr Mayne said all
16 haemophiliacs in the room would be tested for HIV
17 because she was erring on the side of caution, and so
18 Dr Mayne is invited to comment on the patients only
19 being given the option to choose whether or not they
20 wanted to know the results of the testing. This is
21 Dr Mayne's response:

22 "HIV testing was offered to all those who had
23 been in receipt of blood factor concentrates. The
24 witness is correct, because in carrying out such
25 a widespread testing it probably was 'erring on the

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1 given elsewhere but that's Dr Mayne's response in this
2 statement to the question that you raised, sir.

3 **SIR BRIAN LANGSTAFF:** Yes, it doesn't really deal with the
4 point at all, which is really a question of argument,
5 I suspect, and it may simply be she was offering
6 people not only a test but if they didn't want to know
7 the result, they didn't want to know the result, but
8 it seems rather curious that you would expect people
9 to go for a test without wanting to know the result
10 one way or the other.

11 **MS RICHARDS:** Yes. I can't --

12 **SIR BRIAN LANGSTAFF:** It's just an observation and it may
13 simply be misplaced because of the nature of the times
14 and the difficulties that she was facing. But I can
15 be addressed on that in due course if it's regarded as
16 important.

17 **MS RICHARDS:** Yes, I should I think probably just refer
18 you to two other passages in Dr Mayne's other
19 statements that deal with this issue. I don't think
20 they cast any further or additional light on the
21 matter but for the sake of completeness if we go to
22 WITN0736001, page 13, top paragraph, and again this is
23 in response to the statement of Mr Simon Hamilton, she
24 says:

25 "... it was decided that all patients who had

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1 received Factor treatment whether in the form of
2 cryoprecipitate or freeze-dried concentrate should be
3 offered testing for HIV. Patients and their relatives
4 were invited to a succession of meetings to update
5 them on all known risks and information about the
6 virus."

7 Again, that still doesn't tell us what the
8 information was that was provided.

9 "The meetings took place between January and
10 March of 1985 at the Royal Victoria Hospital.
11 Patients were invited to be tested; it was a matter of
12 choice whether they wished to do so. No-one was
13 compelled to participate."

14 Then she says -- I'll just find the reference
15 WITN0736009, page 35, paragraph, 51.1, so bottom half
16 of the page:

17 "I have set out previously that I arranged
18 a number of special meetings in 1985 with the
19 patients. At that meeting they were invited to be
20 tested. Their express consent was invited for that
21 testing and prior to such testing had no knowledge of
22 whether a patient was infected with HIV. I only
23 became aware after the test results were received."

24 What's not clear, and we saw the date of the
25 letter inviting Mr Devlin to come and be tested, which

1 undertaken then. That may of course be a reflection
2 of not all patients attending the meetings. Again,
3 that remains unclear.

4 In terms of the process then for telling
5 patients their results, I've indicated that there's
6 some evidence of patients saying in their statements
7 or their relative's statements to the Inquiry that
8 they were told the results by letter. There isn't
9 evidence to suggest that that was a universal practice
10 I should make clear.

11 If we look at WITN0736005, and we go to
12 page 10, please, if we look at the bottom half of the
13 page, paragraph 3.10.1, now this is in relation to
14 relaying a negative test result:

15 "There was no intention to" -- so the question
16 is -- the criticism that Dr Mayne is being asked to
17 respond to is the appropriateness of informing
18 a witness of their test result by letter. Dr Mayne's
19 response is:

20 "There was no intention to relay this
21 information but the secretarial staff had a difficult
22 job to complete and they would have assumed despite
23 the clipboard entry [I think that's a reference to
24 where they've taken information about how people
25 wanted to be told their results, but that may be

1 was late March 1985, what's not clear is why it took
2 a period of time for the testing to be undertaken.
3 There may be plenty of explanations as to why but
4 obviously every day, week or month that goes past
5 potentially puts patients or their relatives at risk
6 and so we've seen example in another case of a patient
7 being tested for example in July 1985, so the testing
8 process seems to have taken a period of months. That
9 may simply be a reflection of what the facilities were
10 that were available and the numbers that had to be
11 tested.

12 It's not clear whether there was any particular
13 sequence chosen in terms of testing first particular
14 cohorts of patients and then testing other cohorts of
15 patients at later stage. We don't know one way or
16 another those kind of details.

17 **SIR BRIAN LANGSTAFF:** I thought you made a suggestion
18 a few minutes ago that at at least one of the meetings
19 those who were there understood they were to go down
20 the corridor and have a test, unless they wanted to
21 defer it.

22 **MS RICHARDS:** That's certainly what Dr Mayne says about
23 one of the meetings. I don't think we have the same
24 detail about the other two meetings and we know from
25 other references that certainly not all testing was

1 wrong] that you would be pleased to know the
2 negativity of the result. It was the policy of the
3 Centre not to send positive information via a letter.
4 Either patients were told when they came to the
5 Department or else I myself visited them to discuss
6 the positive results."

7 You will recall again we looked at this during
8 the Belfast hearing but I think it's probably worth
9 referring to again in the context of the issues we are
10 currently exploring. It was a letter BHCT0000896.
11 This is October 1985 and I'm sure you will recall this
12 letter, sir, because of the evidence you heard about
13 the relative's concern about the language in which it
14 was expressed. So this is not a communication of the
15 outcome of the first test. It's a communication of
16 the outcome of the investigations into dates of
17 seroconversion:

18 "You will be glad to know that you became
19 positive some time between February 1983 and
20 October 1983. We have no sample between those two
21 dates but I imagine that you became positive some time
22 during the summer of 1983. Therefore you have more
23 than passed the two-year point."

24 I should then show you what Dr Mayne said in
25 response, because she accepted that the use of the

1 word "glad" would seem to be appalling. If we look at
 2 WITN0736001 and we go to page 10, paragraph 4.2, this
 3 was Dr Mayne's account of telling this particular
 4 patient how she communicated the result to him and
 5 that she did so in person by visiting his house and
 6 then she explains towards the end of the paragraph the
 7 context of the letter and what she says the seemingly
 8 appalling use of the word "glad", because she says it
 9 was in response to him asking if she could find out
 10 exactly when he was infected and him saying he would
 11 be glad if she could find and let him know.

12 So that's communication by letter of
 13 seroconversion dates. It's obviously not the same as
 14 communication by letter of the positive result itself
 15 but, as I say, there is some evidence the Inquiry has
 16 received which suggests that that was the position.

17 We've already looked at a letter in relation to
 18 one patient, the patient who was 14 or thereabouts,
 19 and the fact that that patient and the patient's
 20 family had not yet been told the positive HTLV-III
 21 result.

22 If we look at BHCT0000846_003, you'll see this
 23 is a letter of 18 October 1985 to a school. Before we
 24 look at what's there set out it's a letter of the same
 25 date of the letter that was being written to a doctor

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1 Then it refers in the next paragraph to
 2 retrospective samples being sent off and then a
 3 suggestion that other family contacts come in to be
 4 tested. Now, again, it's unclear I think from the
 5 information we have as to whether the communication of
 6 that information by letter to family members was done
 7 with the patient's consent or not.

8 Then in terms of just a further example on the
 9 issue of communication of test results, go to
 10 WITN0265001. This is -- if we go to page 14, I think,
 11 and pick it up in paragraph 50, it says this:

12 "In 1985, prior to telling me that I was HIV
 13 positive, Dr Mayne had come to the house when I wasn't
 14 there and told my parents that me and my two brothers
 15 had HIV. When I went to see her, I told her that I
 16 had not wanted my parents to be informed but she said
 17 it was better for them to know."

18 So obviously highly material evidence there in
 19 relation to HIV diagnosis.

20 **SIR BRIAN LANGSTAFF:** How old was that patient?

21 **MS RICHARDS:** They were an adult -- in 1985 would have
 22 been in their 20s. I'm afraid I don't know the
 23 brothers' ages.

24 Then if we go to WITN2658008, again, I think we
 25 probably looked at this when we heard the testimony

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1 in London, so a doctor in London is being told the
 2 positive result for a particular patient in October
 3 '85 in circumstances where the patient and their
 4 family has not been told. What we see here appears to
 5 be, or hints at, Dr Mayne wanting to let the school
 6 know. That's an inference that you could draw from
 7 the letter. It's not clear. She asks for a personal
 8 conversation with the person to whom the letter's
 9 addressed at the school by telephone in the second
 10 letter. So it raises the possibility that others were
 11 being told of diagnosis but not the patients
 12 themselves or their record. We can take that down.

13 Again, there are a number of different accounts
 14 the Inquiry's received. There are patients who have
 15 no recollection. There's a patient who has no
 16 recollection of being tested or being told of the test
 17 result, which was negative, only discovering being
 18 tested on receipt of their medical records. Again, to
 19 try and get some understanding of the dates when
 20 testing was being undertaken, if we look at
 21 WITN2607004, this is a letter 12 February 1985 and it
 22 says:

23 "I'm sure that, by now, you have heard that
 24 [X]'s blood sample was positive for the AIDS related
 25 virus."

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1 relating to Mr Devlin at the oral hearings in Belfast
 2 but, again, it just provides a little further light on
 3 the process of telling patients their results. So
 4 this is August 1985 to a GP:

5 "The problem of testing for response to the
 6 AIDS virus is well-known throughout the media and my
 7 policy has been to ask each patient when they are
 8 being tested if each individual wishes to know the
 9 result or not. At the meeting, Malachy himself
 10 declared that he did not wish to know the result,
 11 therefore I have respected his wishes and have not
 12 informed him."

13 But then Dr Mayne says that she's written to
 14 the patient's spouse and, of course, that in itself
 15 may ultimately give rise to the inference of the
 16 patient themselves being infected.

17 Again, these are bits and pieces of jigsaw
 18 information relating to individual patients which may
 19 assist you in forming an overall view, sir.

20 Dr Mayne has responded to that in her
 21 statement. I'm sorry, I don't have the reference
 22 noted down but I note the time and I can pick that up
 23 perhaps at 2 o'clock. There are a handful of further
 24 references and documents to look at on this issue but
 25 they will take longer than minute or so, so perhaps we

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1 could adjourn for lunch now.

2 **SIR BRIAN LANGSTAFF:** Very well. 2 o'clock.

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

4 **SIR BRIAN LANGSTAFF:** 2 o'clock.

5 (1.01 pm)

6 (Luncheon Adjournment)

7 (2.00 pm)

8 **MS RICHARDS:** Sir, if I can just go back to the documents

9 we were looking at before lunch, Soumik, WITN2658008,

10 I had been about to say before lunch that there was

11 a response from Dr Mayne to this letter. That's

12 incorrect. What I had in mind was Dr Mayne's

13 explanation within the letter.

14 She describes her policy about asking patients

15 if they want to know the result, and then a reference

16 to her practice in relation to spouses being tested.

17 Then she says in the last paragraph:

18 "I have been trying to keep the panic situation

19 at the minimal level throughout the Province's

20 haemophilic population, hence this practice."

21 Quite how that's an explanation of the policy

22 or practice is unclear but I just wanted to make clear

23 that's what Dr Mayne says in the letter itself as

24 opposed to any particular statement.

25 More generally, it is apparent from materials

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1 being able to listen to conversations and that we

2 should be careful about what we say over the

3 telephone ..."

4 And a suggestion of staff education also being

5 directed toward telephonists so they are aware of the

6 importance of confidentiality.

7 More generally in her witness statement, at

8 WITN0736009, at paragraph -- sorry, page 36 she talks

9 at the bottom of the page, last paragraph:

10 "Lack of knowledge within the general

11 population and the limited experience of many

12 individuals led me to suggest that patients should not

13 publicise their results unnecessarily."

14 Again, that chimes with some of the oral and

15 written testimony the Inquiry has received. I should

16 also note, if we look at the next page, I omitted to

17 take you earlier to a rather more detailed explanation

18 or account of the January 1985 onwards meetings from

19 Dr Mayne in this statement. So I will, if I may, just

20 invite you to look at the bottom half of this page and

21 then over the page. She says this at paragraph 54.1:

22 "When the HIV/AIDS tragedy was evolving in the

23 1980s, to be told of a positive HIV test was in

24 essence a death sentence. There was no treatment.

25 Patients were terrified. Likewise, relatives and

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1 that the Inquiry has examined that Dr Mayne was alive

2 to the issues relating to confidentiality and stigma,

3 and we can see that, for example, from BHCT0000981.

4 This is a letter from January 1986 to a GP

5 about an individual infected with HTLV-III, but if we

6 just look at the bottom of the page and what she's

7 written in handwriting at the very bottom:

8 "Phone call to GP re extreme need [of

9 confidentiality."

10 We can see that also in RHSC0000040_050. This

11 is the meeting of something called the HIV Advisory

12 Group of the Eastern Health and Social Services Board.

13 It's their second meeting, in October 1986, and we can

14 see that Dr Mayne is one of the attendees.

15 If we go to page 3, picking it up in the fourth

16 and fifth paragraphs, we can see the discussion refers

17 to:

18 "The confidentiality of information on AIDS

19 patients is an important matter ... the media are only

20 entitled to historic information, eg at six-monthly

21 intervals about the number of cases and the number of

22 deaths ..."

23 And then in the next paragraph Dr Mayne is

24 recorded as:

25 "... [raising] the possibility of telephonists

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1 friends were bewildered and frightened. I gave much

2 thought to the planning of how to achieve the

3 essential HIV testing. Finally, I agreed to have

4 group meetings, three in total. All patients who had

5 been treated were invited to attend with the exception

6 of the paediatric patients who were looked after by

7 their haematologist.

8 "The prime aim of the meetings was to provide

9 information about the global situation, and secondly,

10 to inform patients of the local situation. In

11 particular, the mode of transmission from person to

12 person and its effect on the day-to-day living of

13 those concerned, information about care about was

14 given to friends and relations. It was suggested to

15 be careful as the general public was not well informed

16 about modes of transmission and infectivity."

17 So, again, that's the suggestion of keeping

18 these matters confidential. And then she says in

19 terms:

20 "Finally, there was a need to address

21 confidentiality, lack of which gave great concern to

22 patients.

23 "The format of the meetings was that I gave an

24 introduction. Thereafter, there was time for an

25 informal chat over a cup of tea ..."

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1 Again, that's not consistent, I think, with
2 some of the accounts we have of at least -- including
3 Dr Mayne's own account, of at least one of the
4 meetings.

5 **SIR BRIAN LANGSTAFF:** That was the third meeting in the
6 old lecture theatre.

7 **MS RICHARDS:** Precisely:
8 "... and finally the testing would take place."

9 So that again suggests that the expectation was
10 that those who were present at the meeting would
11 immediately be tested:

12 "My sources of information regarding HIV
13 infection were multiple; the UKHCDO AIDS working
14 party, chaired by Dr Rizza, provided copies of all
15 publications as and when they appeared. This
16 information was invaluable."

17 Now, I will need to double-check, sir, but my
18 recollection is that the UKHCDO's AIDS group was set
19 up for the first time or met for the first time in
20 January 1985, so it's unlikely that there had been
21 much produced by that stage. Of course, as the months
22 went on, the AIDS group did meet on several occasions
23 during 1985 so more might have been produced. She
24 says:

25 "This information was invaluable. Secondly,

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1 offered testing. At this point in time, testing was
2 not mandatory. Patients could say yes or no. I had
3 anticipated that most people would accept the
4 opportunity to be tested. They all did. The reason
5 for couching the invitation for testing in this manner
6 was to permit patients to be in full control of their
7 lives - circumstances which, sadly, would change
8 radically if the tests proved to be positive. They
9 were told that no names would be used, that a coding
10 system would be applied and that for confidentiality
11 purposes the results would be logged into
12 a confidential notebook. They were asked if they
13 wished to know their result. Contrary to my
14 expectations one patient declined to hear the result.
15 His response posed a problem. Rapidly, I had to
16 consider the action I would take if this particular
17 patient tested positive. It was recognised that all
18 patients who tested positive would require
19 a confirmatory test. Apart from taking his routine
20 treatment, sexual transmission was the only other
21 means of transmission. Therefore, a short delay
22 before his confirmatory test would not constitute a
23 public health issue.

24 "After the testing was completed, I then had
25 a concluding address with the patients. I was acutely

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1 information gained through combined monthly meetings
2 with colleagues in Scotland and, thirdly, in an
3 informal manner through conversations with my
4 colleagues with whom I had worked in the USA,
5 Australia and Europe. In a different context, I also
6 had regular discussions with my STD colleagues."

7 She then refers in the next paragraph to going
8 from time to time to London for meetings. Again,
9 I think that's potentially looking forward in time.

10 Then in paragraph 54.5 she returns to the
11 format of the group meetings at the hospital. She
12 says:

13 "... I presented and explained to patients and
14 relatives the characteristics of the HIV virus.
15 Inside the body cavity in the blood stream, it was
16 lethal. However, outside the body the virus was
17 extremely vulnerable. It could be destroyed by
18 a simple wipe of bleach and certainly, heat treatment
19 removed its activity ... Therefore, apart from IV,
20 i.e. through treatment, blood transfusion, dirty
21 needles between drug users, there was no way that it
22 could be transmitted except by sexual intercourse. It
23 was easier to transmit it by what could be described
24 as vigorous sexual intercourse.

25 "After my introduction, the patients were

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1 aware of the difficulty of imparting unpleasant news
2 to patients. I had been much involved in telling
3 individuals that either they, or their close relative
4 was suffering from acute leukaemia and all the
5 problems associated with chemotherapy. I well knew
6 from experience that the audience for this type of
7 introductory session would perhaps remember as much as
8 25 per cent of what they were told and it was unlikely
9 that they would remember more than 50 per cent.
10 Therefore, it seemed important to me to reiterate to
11 them exactly how their lifestyle might change in the
12 future if they had experienced transmission of the
13 virus. I also asked them to refrain from sexual
14 activity before they came back for their results.
15 They were aghast, and there was some laughter at this,
16 but the purpose was to protect spouses and
17 partners and the general public."

18 So that's Dr Mayne's more detailed account of
19 her recollection in her most recent witness statement
20 and then over the page -- so questions were asked
21 about why she -- about her decision to tell patients
22 their test results only if they wished to be told, and
23 she refers back to the answer above.

24 She's then asked in question 56 about the
25 policy in relation to testing partners and family

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1 members and she says there:
2 "Following the confirmation of a positive
3 result spouses/partners were tested by mutual
4 agreement."

5 Then she's asked about what, if any,
6 information or advice was provided to partners or
7 family members and the response is to say that all
8 relevant information was relayed, either in the centre
9 or at home during home visits but it doesn't tell us
10 what information or advice was, as a matter of fact,
11 relayed. That's, as I say, to complete the picture in
12 terms of Dr Mayne's evidence on that issue.

13 I've referred to Dr Mayne's statement that
14 15 patients were infected with HIV as a result of
15 treatment. In fact, if we go back to BHCT0000484,
16 there are 16 patients listed, and then of course there
17 is the one additional case of a partner who became
18 infected, so 16 cases of direct infection and one of
19 infection via sexual transmission presumably, or
20 indirect infection, however one wants to term it. So
21 a total of 17 cases in that regard.

22 Just then two further documents in relation to
23 the testing process. If we look at BHCT0000158, this
24 is a communication, 21 August 1985:

25 "The results of our latest test for

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1 There is reference in later statements to arrangements
2 being made for some form of joint clinic or joint
3 arrangement with an infectious diseases specialist,
4 but that looks to be from around 1999 onwards or
5 indeed a little later than that during Dr Anderson's
6 tenure.

7 If we go to WITN3082020, we can see an article
8 in the Ulster Medical Journal. We looked at one
9 yesterday which was about hepatitis B infection in
10 Northern Ireland. This is "[HIV] infection in
11 Northern Ireland 1980-1989", and it's published in the
12 Ulster Medical Journal in April 1991.

13 If we go to the second page -- I should say,
14 Dr Mayne is identified as one of the authors -- under
15 the heading "Methods", the second paragraph tells us
16 that:

17 "The Regional Virus Laboratory began anti-HIV
18 testing in May 1983 (*sic*) and the Northern Ireland" --

19 **SIR BRIAN LANGSTAFF:** '85.

20 **MS RICHARDS:** I'm so sorry:

21 "... 1985 and the Northern Ireland Blood
22 Transfusion Service in October 1985."

23 So there is evidence of some test results
24 earlier in 1985 and it may be that those were tests
25 that were undertaken elsewhere. We've seen one

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1 anti-HTLV-III in your patients are as follows ..."

2 And then there are two identified as positive
3 and then a series identified as not positive and then
4 down the bottom of the page is:

5 "We have no sera in store from ..."

6 And then there are two patients there
7 identified. So it would appear that the testing
8 process was ongoing for a period of time.

9 If we look over the page -- sorry, not over the
10 page. If we look at BHCT0000161, there's a later
11 letter, 12 September 1985. Again, it provides results
12 of anti-HTLV-III tests in the centre's haemophiliac
13 patients. The first three, who are listed as
14 positive, two of those are identified as having
15 already been tested, one by the regional virology lab,
16 which is where this letter emanates from, one by
17 Dr Tedder, but the second of the three is what appears
18 to be a new result. So again, it would appear that
19 the testing process was still ongoing as at
20 September 1985. And then there's a whole list of
21 patients who are anti-HTLV-III negative.

22 If we can then -- just turning to the question
23 of how those patients with HIV were treated, it would
24 appear as though the process for treatment for
25 their HIV was that they were treated by Dr Mayne.

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1 reference to a test, for example, by Dr Tedder. So it
2 may be that sera were sent off to be tested elsewhere.
3 It's not clear. But, in any event, in terms of the
4 Regional Virus Laboratory there's no reason to doubt
5 what's said here, that their process began in May of
6 1985.

7 We can also see from the next paragraph that it
8 says that:

9 "Retrospective testing of haemophiliacs was
10 done on available sera which had been stored at
11 minus 20 degrees centigrade in the Regional Virus
12 Laboratory and fresh sera were obtained from the
13 Department of Haematology, Royal Victoria Hospital."

14 Then if we go to the next page, and we look at
15 the third paragraph it says:

16 "The 16 haemophiliacs ... identified as
17 infected with the virus in 1985 ..."

18 So that doesn't include the one partner.

19 "... when HIV antibody testing became available
20 have been cared for by the Northern Ireland
21 Haemophilia Service. Of the 55 remaining persons 49
22 ... have been cared for by the genito-urinary
23 services. The remaining six ... have been cared for
24 by other agencies."

25 So that would appear to confirm that the

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1 responsibility for the consequences of their HIV
2 infection was retained within the haemophilia centre.
3 If we go two pages further on under the heading
4 "Testing", the second paragraph refers to testing of
5 patients with coagulation defects, so it says:
6 "One hundred and twenty-three patients with
7 coagulation defects who had received treatment with
8 blood products were tested and 16 were positive
9 (13.8 per cent). If only severely affected patients
10 ... are included this rises to 25 per cent."

11 It's not entirely clear why you would include
12 only severely affected patients in one sense because
13 we have seen two examples of patients who were not
14 severely affected who were infected with HIV.

15 "Stored sera were available on 11 of the 16
16 positive patients and when tested showed that
17 seroconversion occurred between 1983 and 1985. The
18 source of seroconversion in one patient in 1985 was
19 traced to a batch of heat-treated factor VIII which
20 was found retrospectively to be contaminated with
21 HIV."

22 **SIR BRIAN LANGSTAFF:** Do we know if that's the same as we
23 looked at earlier on today, where there had
24 been heat-treated Factor VIII, it had been reported as
25 a batch from Armour where there had been a contributor

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1 you will recall in the course of today at a letter
2 which refers to an identification of a patient
3 seroconverting in 1985. Whether it's that patient or
4 a different patient, given that we also know there
5 wasn't an immediate switchover, it would appear, to
6 heat-treated products, is unclear.

7 **SIR BRIAN LANGSTAFF:** Yes.

8 **MS RICHARDS:** But in any event, as we see there, evidence
9 that one seroconversion was from heat-treated
10 Factor VIII.

11 If we turn over then to page 9 please, Soumik,
12 and look at the second paragraph, this is the position
13 set out in the second paragraph as at the date of this
14 report:

15 "Of the 16 haemophilic patients infected,
16 three have died, one by suicide, one from liver
17 failure unrelated to HIV infection, and one in whom
18 HIV infection was contributory."

19 Then if we go over the page and look at the
20 heading "Management", we'll see how patients other
21 than haemophiliacs with HIV infection, how their care
22 was managed:

23 "... mostly been managed as outpatients by the
24 Genitourinary Medicine Service at the Royal Victoria
25 Hospital ..."

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1 who subsequently developed AIDS and the comment made
2 by I think Dr Mayne was that thankfully there had been
3 no seroconversion?

4 **MS RICHARDS:** The comment made by Dr Mayne, as
5 I understand the position, relates to a patient whose
6 identity I think is known to the Inquiry who was not
7 as the matter of fact infected with HIV. I think
8 that's right.

9 **SIR BRIAN LANGSTAFF:** So this is another episode where --

10 **MS RICHARDS:** It may be the same batch --

11 **SIR BRIAN LANGSTAFF:** -- (*unclear: multiple speakers*)
12 product might have been -- well, was in this case
13 implicated?

14 **MS RICHARDS:** Yes, I don't think we've seen anything other
15 than that single letter from Armour so it may be that
16 it was a batch used for more than one patient.
17 I don't know. But there is some evidence --
18 Dr Mayne's evidence, as I recall, relates to
19 a particular patient who was not infected with HIV.
20 This is I think no reason to doubt what is said here
21 in a journal co-authored -- article co-authored by
22 Dr Mayne in 1991, so only a few years after the event,
23 which tells us that there was one heat-treated
24 seroconversion.

25 Who that was, we don't know. We have looked as

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1 Some are recorded as attending clinics
2 elsewhere:

3 "These patients have open access to the clinics
4 and the counselling and social services provided at
5 these centres. A designated HIV clinic is in
6 operation at the Royal Victoria Hospital. In-patient
7 management has mostly been handled by the
8 genitourinary medicine physicians, with close
9 co-operation with relevant specialists, mostly
10 gastroenterology, immunology, neurology and
11 respiratory medicine."

12 So there would appear to be a contrast between
13 the multidisciplinary care that appears to have been
14 available to patients other than haemophiliacs with
15 HIV infection in contrast with those who were
16 haemophiliacs whose care was retained within the
17 haemophilia centre.

18 If we go next to WITN0736010, again we've
19 looked at this yesterday for different purposes. It's
20 a 1991 report of activity of the Northern Ireland
21 Regional Centre.

22 If we go to the second page, this is authored
23 by Dr Mayne and we look at the bottom of the page,
24 Dr Mayne says this:

25 "It is noteworthy that the visits of HIV

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1 positive patients for counselling by the director of
2 the Centre averages ten visits per month and many of
3 these visits last up to two hours in duration."

4 So a description there of Dr Mayne undertaking
5 counselling, but what she means by "counselling" and
6 what might be meant more generally by "counselling"
7 may be different matters.

8 "Initially there were 16 HIV positive
9 Haemophilic patients in Northern Ireland. They were
10 all adults."

11 I have already drawn attention to the fact that
12 one at least seems to have been 14 at the date of
13 testing.

14 "By 1991 three had already died."

15 We have seen that picked up in the Ulster
16 Medical Journal. Go to the top the next page:

17 "During that year [so 1991] a fourth patient
18 died of salmonella septicaemia directly related to his
19 HIV condition."

20 That is an update as at 1991 that four of the
21 16 had already died.

22 In terms of what Dr Mayne says about the
23 arrangements for the care of those with HIV, if we
24 turn to WITN0736009, this is her main statement again,
25 and we go to page 27, if we look at the third and

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1 halfway down, she talks about -- sorry, Dr Mayne talks
2 about her next visit to London hoping to:

3 "... have some further consultations with
4 experts there in the dermatological manifestations of
5 HIV infection."

6 And then there's a discussion about what
7 treatment the patient should receive. We see that
8 continuing in the next paragraph, discussion about
9 what treatment the patient should be on.

10 So, again, it's one example. There are other
11 examples in the bundle of Dr Mayne essentially being
12 the primary clinician in relation to the haemophilic
13 HIV patients.

14 If we go to HSOC0010892 and we go to the third
15 page, there's a letter from Dr Mayne dated March 2,
16 1994, which contains her comments on AZT. She says:

17 "The advent of AZT was a therapeutic advance in
18 the management of HIV. At the time of granting of its
19 licence, I remember being particularly concerned about
20 its side effects."

21 She sets out what she thought those would be,
22 and then says:

23 "Despite these reservations, I have found it to
24 be effective in treating HIV positive patients whose
25 CD4 counts were falling. I would admit, however, that

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1 fourth paragraphs she says:

2 "The staffing levels in the Centre were
3 augmented by an E grade nurse, a full-time secretary
4 and a scientific officer. The letter was to help with
5 the laboratory side of the situation and possible
6 future research."

7 It's not entirely clear how that assisted with
8 HIV care but this her answer in response to a series
9 of questions -- a question about what enquiries or
10 investigations were undertaken in respect of the risks
11 of transmission of HIV.

12 Then paragraph 33.11:

13 "Measures were taken to liaise with colleagues
14 from other disciplines as and when necessary.
15 A Dermatologist, a Neurologist, and an Infectious
16 Disease expert were all briefed, and were willing to
17 and did attend patients in the Centre. In respect of
18 general assistance, a liaison was also formed with the
19 Sexually Transmitted Disease Department. They had
20 many more HIV patients."

21 Then if we turn to BHCT0000609, go to the next
22 page. This is a letter in relation to one patient.
23 It's from June of 1994. I'm not proposing to go
24 through the detail of it.

25 We can see in the first paragraph, just over

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1 I have never utilised the maximum recommended dose.
2 Most patients in this Centre have been treated
3 intermittently, rather than with permanent
4 prophylaxis.

5 "I think patients can be reassured that the
6 drug has a well established role in treating certain
7 aspects of HIV and AIDS."

8 And she carries on.

9 So again it would appear decisions relating to
10 use of AZT from a clinical perspective were taken by
11 Dr Mayne. There is a description by Dr Anderson
12 picking up the picture a little later on in her
13 witness statement, as I indicated a few minutes ago,
14 of care being shared with an infectious diseases
15 consultant and, again, Dr Benson I think will be able
16 to assist tomorrow in relation to the position as at
17 2008 and since in that regard.

18 Turn then to the information that the Inquiry
19 has about the process of testing for hepatitis C and
20 informing patients of their diagnosis. The themes
21 which emerge from the evidence which the Inquiry have
22 received from people who were infected with
23 hepatitis C or their relatives has a number of common
24 themes. Some, not all but some, describe being
25 unaware of being tested for hepatitis C. A number of

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1 them draw attention to there being an apparently
2 significant delay between date of testing, whether
3 with the first test or a second generation test, and
4 the patient themselves being informed of their
5 diagnosis. Some recount an experience of only being
6 told effectively when there's a significant event
7 going on and they are attending the Haemophilia Centre
8 and then, as it were, are told almost as an
9 afterthought about the hepatitis C diagnosis.

10 A further theme that emerges from this
11 statement is of insufficient information being
12 provided in terms of the nature of the virus, its
13 likely consequences, treatment options and the like,
14 and a final theme which emerges from the witness
15 statements, some of the witness statements, is of
16 a degree of false reassurance or perhaps I should say
17 over-optimistic reassurance about the nature of the
18 condition.

19 I want to start then, if I may, with looking at
20 Dr Mayne's various accounts of the position in
21 relation to hepatitis C testing. So if we go, first
22 of all, to WITN0736001 and if we go, first of all,
23 to -- in fact, if we go first of all to page 6, if we
24 look at paragraph 2.2, this is in fact on a slightly
25 different point but whilst we are looking at this

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1 a corridor. She says she doesn't recall:

2 "It would not be my clinical practice to
3 discuss patients' health in a corridor."

4 Then more generally in relation to hepatitis C
5 testing she says this:

6 "Precise laboratory testing for Hepatitis C
7 became the norm in 1992-1993, the virus having been
8 identified in 1991."

9 That latter date, obviously, is not correct.

10 **SIR BRIAN LANGSTAFF:** No, it was 1988 but not published
11 I think in detail until 1989.

12 **MS RICHARDS:** Yes. And there is evidence of testing
13 having been undertaken at the Centre in 1991 as well
14 as 1992 to '93.

15 **SIR BRIAN LANGSTAFF:** Yes. This talks about the norm, but
16 it was introduced across the board apparently from
17 1 September 1991.

18 **MS RICHARDS:** Yes. She says:

19 "It was not my clinical practice to test
20 patients for Hepatitis C without their consent. All
21 patients attending the centre, after receiving blood
22 products, were checked physically and had laboratory
23 investigations."

24 Then she goes on to talk about liver function
25 tests but, in any event, that's the general statement

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1 statement I should have drawn attention to it. So
2 I referred earlier to the individual statements giving
3 a near-universal account of not being told about the
4 risks of viral infection from their treatment, and to
5 some recalling receiving the impression of it being
6 a wonder drug or pioneering or a miracle treatment.

7 You will see here Dr Mayne responds to one
8 individual witness statement. She says this:

9 "... no warnings, apart from vein care and
10 aseptic techniques, were given because at that
11 time ..."

12 And we will have to look back at
13 Mr Kirkpatrick's statement to check the particular
14 time.

15 "... I believed the treatment was both
16 effective and safe. I certainly do not recall being
17 asked about risks. The words 'wonder drug' may have
18 emanated from others but not me. I doubt if I would
19 have dared to utter such words."

20 So I should have referred to that. Then
21 returning then to the issue of hepatitis C testing, if
22 we go on two pages, Soumik, we look at paragraph 3.2,
23 I should refer probably back to 3.1. This is in
24 response to an account of a patient being -- having
25 their hepatitis C diagnosis communicated to them in

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1 in relation to the testing process.

2 I should also draw attention to paragraph 3.4.
3 Dr Mayne says in the first sentence:

4 "... there was no specific test for Hepatitis C
5 available in 1987."

6 That obviously is correct, and then she
7 describes hepatitis C as not a prevalent concept in
8 '87:

9 "It merely referred to the existence of
10 abnormal liver function tests designated by the UKHCDO
11 Hepatitis Working Party as non-A, non-B hepatitis."

12 Well, I think the term "non-A, non-B hepatitis"
13 is not attributable to UKHCDO's hepatitis C working
14 party but had been in common usage since at least the
15 mid-1970s. But in any event, we see then she says --
16 in response to the patient saying she was not advised
17 until 1993 of her hepatitis C diagnosis, Dr Mayne
18 says:

19 "Precise laboratory testing for Hepatitis C
20 [only became available] in 1992-1993."

21 If we then turn on four pages, I think, Soumik,
22 to paragraph 5.4, this is part of Dr Mayne's response
23 here to an individual witness, here to the statement
24 of Mr Nigel Hamilton. Dr Mayne says:

25 "... the diagnosis of hepatitis C was difficult

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1 as nearly all patients had evidence of abnormal liver
2 function tests ..."

3 She refers again to it being given the title
4 non-A, non-B hepatitis, and then says:

5 "Definitive tests for Hepatitis C were not
6 available until 1992-1993 ..."

7 It may of course turn on the use of the word
8 "definitive", but obviously there were tests available
9 prior to that.

10 So that's that witness statement. If we then
11 go to WITN0736005, if we go to the bottom of the
12 second page we can see in paragraph 2.1.1 there's
13 a description in the second half of that paragraph to
14 what was said to be the practice of the virology
15 laboratory to keep a sample of serum to be retested in
16 the future.

17 She then, in paragraph 2.1.2, says:

18 "The Hepatitis C virus became isolated in
19 1991."

20 We've already dealt with the incorrectness of
21 that date.

22 "Tests became available to detect HCV antibody
23 around that time but tests for active HCV infection
24 were not available until 1993. As far as I can
25 recall, I believe the original 1976 sample was

1 testimony overall from patients treated at this
2 centre, there is evidence in medical records of tests
3 being undertaken in 1991 but of patients not learning
4 the results until some considerable time later,
5 sometimes in 1992 or 1993 but sometimes much later.
6 We've given a number of examples in the written note
7 and I'll refer to a handful of them.

8 If we look at the bottom of this page, we can
9 see confirmation by Dr Mayne of there being testing in
10 1991 because in relation to again another individual
11 witness's account she says:

12 "The test in 1991 demonstrated that the witness
13 had 'met' the Hepatitis C Virus at some time. It
14 showed that he had antibody but not active infection
15 at the time of testing. He was clinically well."

16 Top of the next page:

17 "Therefore he was not informed about this
18 particular result. It was thought it might cause
19 undue anxiety and worry. At that time, it was unclear
20 what the future would hold for someone with such
21 a result. By 1993, a test became available which
22 could detect active Hepatitis C infection. It took
23 time before the test came into routine use. The
24 witness' definitive result of active infection was
25 obtained in March 1996 and confirmed in August 1996.

1 re-tested in 1991. In 1991 a further sample was taken
2 and tested and a further sample was taken and tested
3 in 1993, making three tests in all. The customary
4 length of time elapsed between testing and results
5 becoming available. Patients were seen as soon as
6 possible after their results were received for
7 consultation and discussion.

8 "Present day practice would require oral or
9 written permission to carry out viral blood tests. At
10 the time in question, locally, nationally and
11 internationally, expediency seemed paramount and
12 specific consent was often not obtained. Quite unlike
13 the situation relating to HIV testing, when no test
14 was ever carried out without consent of the patient.
15 Refusal to have any test was acceptable at all times."

16 Again, there may potentially be much to unpick
17 in that paragraph. Specific consent often not
18 obtained, but it's then said refusal to have any test
19 was acceptable at all times. Of course, if a patient
20 doesn't know what they are being tested for it may be
21 a little difficult for them to exercise a right of
22 refusal to the test.

23 Picking up upon the dates given at the top of
24 the page, you will no doubt recall, sir, from the
25 hearing in Belfast and from the oral and written

1 It was now felt important that he should know the
2 findings hence the invitation to come and meet with
3 the staff."

4 So there is an example, but a fairly striking
5 example in terms of the dates, of a patient tested
6 in 1991, using the tests then available, a positive
7 result, but the patient learning for the first time
8 about a positive result following further testing
9 five years later, in 1996. That's, as I say, one of
10 a number of examples.

11 Whilst we're looking at this witness statement,
12 if we go to the paragraph a little further down,
13 2.4.1, again a theme from the -- a theme from the
14 evidence has been Dr Mayne's manner in providing
15 information and diagnoses, and she responds here to
16 a statement that described her as patronising and as
17 not providing answers or the information that the
18 patient was requesting. She says:

19 "There was a considerable degree of confusion
20 at this time caused by lack of precise knowledge as to
21 how HCV would ultimately affect patients. I was fully
22 aware of the situation, as I travelled on a monthly
23 basis to meetings in Scotland and also to other
24 meetings in the UK and Europe. Specifically, I tried
25 to bring back knowledge to Northern Ireland and relay

1 it to the patients. It was not always easy to answer
 2 the patients' questions. It was felt better not to
 3 speculate about what might or might not happen in the
 4 future. It is regrettable that the witness found the
 5 presentation of the paucity of information
 6 patronising."
 7 **SIR BRIAN LANGSTAFF:** When she says "it was felt better
 8 not to speculate", is she describing there her
 9 understanding of general practice derived from
 10 Scotland, Europe, et cetera, or is she describing her
 11 own practice by adopting the third person?
 12 **MS RICHARDS:** Grammatically, it could be either. I don't
 13 think we've heard evidence more generally to suggest
 14 it would be the former and there's no particular
 15 material relating to Scotland, UK or Europe which she
 16 refers to. You obviously, sir, have encountered
 17 evidence of a range of different practices and
 18 approaches taken by clinicians at this time.
 19 **SIR BRIAN LANGSTAFF:** Do I have to take into account in
 20 looking at this my understanding of what was generally
 21 known about the prospects for those who had chronic
 22 infection?
 23 **MS RICHARDS:** Yes, absolutely.
 24 **SIR BRIAN LANGSTAFF:** As they were understood, at any
 25 rate, at the start of the '90s?

1 "This paragraph underlines the need for the
 2 witness and her husband to have discussed these
 3 matters with experts. During the early 1990s,
 4 concerns regarding the implications of having HCV
 5 infection grew by leaps and bounds. Clinical symptoms
 6 were developing and the most common complaint was of
 7 extreme lethargy, therefore, in 1995 a residential
 8 weekend for all patients and Centre staff was
 9 arranged."
 10 Then she provides details of the location, says
 11 it was fully sponsored by nine international
 12 pharmaceutical companies and she describes a number of
 13 experts, including virologists, coming to address the
 14 conference and they made themselves available to
 15 individuals.
 16 She says in the next paragraph:
 17 "I do not remember the witnesses being present
 18 at the residential weekend, at least I do not remember
 19 seeing or speaking with them on that occasion. If
 20 they were not present it was sad as they might have
 21 received much help and advice."
 22 There's no evidence that we've thus far
 23 uncovered of any -- for those potentially majority of
 24 patients who didn't attend this particular conference,
 25 and there may of course be multiple reasons why

1 **MS RICHARDS:** Yes. Well, at the start of in the course of
 2 the 90s because I don't --
 3 **SIR BRIAN LANGSTAFF:** That's why I said the start of the
 4 '90s. It covers the whole period.
 5 **MS RICHARDS:** Yes. I don't know without checking witness
 6 1371's statement what the particular date was of this
 7 consultation.
 8 Then if we go a little further down the page we
 9 just see the issue being raised at 2.6 and 2.61 about
 10 risks of HCV transmission during sexual intercourse.
 11 The witness records Dr Mayne saying that there was no
 12 risk of HCV transmission during unprotected sexual
 13 intercourse. Dr Mayne's response is to say:
 14 "I do not recall this part of our conversation
 15 but the witness is probably correct that at that time
 16 I did not feel it was likely that HCV would be
 17 transmitted through unexpected intercourse."
 18 Again, there may be a difference between saying
 19 no risk and the question of whether it's likely or
 20 not.
 21 Then if we go to the top of the next page, this
 22 is again in response to a witness expressing concern
 23 about an absence of openness and transparency in the
 24 information provided about hepatitis C.
 25 Dr Mayne's response is to say:

1 patients would either not want to or not be able to,
 2 we've seen no evidence of the material from that
 3 conference being gathered and disseminated to
 4 a non-attendees.
 5 Then if we go to -- go on another three pages,
 6 Soumik. Sorry, back one page. My fault. Bottom of
 7 this page, this is in response to a witness saying
 8 that they were not told about their HCV infection for
 9 five years and a reference to blood samples being
 10 regularly taken in visits to hospital. Dr Mayne says:
 11 "Regular blood samples were taken from patients
 12 at all visits to the Centre. This was to ensure that
 13 they had not developed an inhibitor to their own
 14 specific clotting factor as this would alter their
 15 future management to a significant degree. As
 16 previously stated in earlier responses, samples from
 17 the 1970s were retained as was customary in the
 18 protocols of the Northern Ireland Virus Laboratory."
 19 Then this:
 20 "The patient's final diagnosis of active HCV
 21 was not made until after the 1993 test was in routine
 22 use, i.e. in 1996. Prior to that time he was
 23 designated as having Non-A, Non-B hepatitis."
 24 Now, it's not clear why a test which Dr Mayne
 25 describes as being available from 1993 was not

1 seemingly in routine use, to use her phrase, in the
2 Belfast Centre until 1996.
3 Then if we go -- no, we've looked at the next
4 passage I was going to refer to already today. If we
5 then turn to WITN0736007 this is a further statement
6 from Dr Mayne in response to individual witness
7 statements. If we go to the second page, paragraph 5,
8 so again Dr Mayne repeats the error about when HCV was
9 identified. Then she says:

10 "Tests for antibody were available in 1993
11 [again, that doesn't appear to be right], but not
12 indicative of active clinical infection. Tests for
13 RNA viral load were available in 1994/95. The patient
14 visited in 1995 and therefore was not involved in any
15 particular delay. He was seen as soon as possible in
16 rotation with his fellow patients."

17 She says he was informed that the source of
18 infection was his treatment. The evidence more
19 generally suggests that there was no programme for
20 calling patients in to be tested specifically for
21 hepatitis C or calling them back in to be informed of
22 their test results as soon as those test results were
23 available or as soon as practicable after those test
24 results became available.

25 The evidence suggests that once hepatitis C

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1 dire'."

2 Top of the next page Dr Mayne says this:
3 "Many of the clinicians, myself included, could
4 not in 1995 foresee how complex, disastrous symptoms
5 and complications of the virus would develop, sadly."

6 Again, you will need to assess that by
7 reference to what you, sir, conclude a clinician could
8 or should have understood in or by 1995.

9 If we then go to WITN0736009 and we go to
10 page 41, we pick it up at the bottom of the page, at
11 62.1 Dr Mayne asserts that:

12 "... patients infected with [non-A, non-B]
13 hepatitis were informed of the existence of their
14 abnormal liver function tests. At the time the
15 condition was termed Non-A Non-B. At that time
16 although patients had raised liver function tests they
17 were otherwise well."

18 It doesn't say that they were told that they
19 had non-A, non-B hepatitis. It doesn't say that they
20 weren't, but what it says that they were informed of
21 the existence of the abnormal liver function tests.
22 Then next paragraph she says:

23 "It was not possible to inform patients of
24 active hepatitis C infection until the specific blood
25 test for this virus became available ..."

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1 testing was in use it would be when the patient
2 attended for a routine appointment that they might be
3 tested. Again, there is some evidence from
4 individuals of them being -- occasional evidence of
5 being called in when there was special -- in some
6 individual special circumstances, but more generally
7 that appears to have been the case and then not being
8 told the result for some considerable period of time,
9 and I think Dr Mayne suggested it would have been at
10 the next routine appointment, but certainly there were
11 no special arrangements made for communicating the
12 diagnosis prior to the patient's next general
13 attendance, at least as a matter of general practice.
14 There may of course have been individual symptoms.

15 If we look at the bottom of this page, we can
16 see a response from Dr Mayne to the observation by
17 a witness that she did not offer any support or
18 counselling after informing him of the HCV diagnosis.
19 She says:

20 "Neither support nor counselling were
21 available. At that time it was significantly
22 problematic trying to establish a good clinic for
23 hepatitis patients to attend. Additionally, as the
24 witness' wife mentioned in her statement ... 'we,
25 rather naively, thought that Hepatitis C was not so

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1 If we go over to the top of the next page she
2 says:

3 "It had been suspected for many years that
4 regularly treated patients were likely to have the
5 virus previously known as Non-A Non-B hepatitis,
6 subsequently known as hepatitis C. Patients had been
7 attending the Centre regularly for many years and
8 receiving advice before the confirmation of their
9 diagnosis. They were informed that they had a chronic
10 viral infection of the liver that was causing
11 inflammation."

12 Again, there is evidence to contrary effect
13 from some of the patients in their written statements
14 to the Inquiry, and then she refers to advice about
15 alcohol consumption and diet.

16 If we then go further down the page, she says,
17 to the date given here in paragraph 63.1, that:

18 "The Centre began testing patients for
19 Hepatitis C in 1993 when the test became available."

20 So we do have a range of different tests --
21 a range of different dates, of course, there were
22 different tests being developed. She says in the next
23 paragraph:

24 "All patients were routinely assessed for liver
25 function and for unknown viruses, up until the

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1 definitive test for active Hepatitis C became
 2 available in 1993."
 3 Then towards the bottom of the page, picking it
 4 up -- well, perhaps halfway down that paragraph it
 5 says:
 6 "Patients were surprised at the clinical
 7 examination but the abnormal test results were
 8 explained, they were told they did not have
 9 Hepatitis B, a condition of which patients were well
 10 aware."
 11 Just pausing there, some statements relate
 12 patients not being aware that they had had
 13 hepatitis B:
 14 "Likewise, they knew they did not have any
 15 symptoms of Hepatitis A, therefore they were not
 16 surprised when they were told that they probably had
 17 a condition called Non-A Non-B hepatitis."
 18 Then if we go over the page she continues in
 19 that paragraph her views about the seriousness or
 20 otherwise of non-A, non-B hepatitis and then 63.3 says
 21 this:
 22 "Some 3-4 years prior to 1993 tests for
 23 Hepatitis C antibody became available. That test, if
 24 positive, only indicated that the individual had met
 25 the virus at some time. In a similar way, adults, if

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1 we look at the third paragraph, 65.3 -- sorry, the
 2 third paragraph under the question in 65 she says
 3 this:
 4 "With regard to HCV, the tests were done in
 5 batches to facilitate the effective management of the
 6 laboratory. The patients were informed at their next
 7 routine clinic visit. That may have been some time
 8 later."
 9 And the evidence certainly suggests also in
 10 many cases a very significant gap of time in that
 11 regard. She says in 65.4:
 12 "It is important to state that a positive
 13 antibody test required no action at this time.
 14 Positivity merely showed that, at some time in the
 15 past, the patient had been exposed to the virus ..."
 16 And she develops that theme.
 17 Then the last paragraph on this page:
 18 "The antibody tests were explained to patients
 19 at the next routine visit. The timing of routine
 20 reviews depended on the severity of the patient's
 21 condition. Those on Home Treatment or severely
 22 affected were seen on a monthly basis. The moderately
 23 severe were seen theoretically on a six-monthly
 24 basis -- I say theoretically because if they had no
 25 problems they would cancel for perhaps a further

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1 tested, would show the presence of anti-measles
 2 antibody although of course they had no clinical
 3 evidence of the condition. During discussion with
 4 patients they found it difficult to understand the
 5 explanation of having HCV antibody. Some were worried
 6 that I was keeping secrets from them."
 7 Just pausing there, again a common theme from
 8 the witness statements is that they were not given
 9 this information about the results of early tests.
 10 Dr Mayne continues:
 11 "When the specific tests became available in
 12 1993, the results indicated in many cases active
 13 disease. Even in 1993 it was difficult, even
 14 impossible, to give any precise prognosis or details
 15 of how the diagnosis may play out in time. As
 16 developments progressed viral load testing became
 17 capable of the estimation of infection. Likewise,
 18 different subtypes of the virus were accurately
 19 diagnosable. At this time a special liver clinic was
 20 established."
 21 And she gives a little more information about
 22 that.
 23 If we go over the page, in response to the
 24 question how many patients were infected with
 25 hepatitis C her answer is in excess of 100. Then if

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1 3-6 months. The very mildly affected were seen
 2 annually."
 3 So the Inquiry has evidence of patients who
 4 were not seen even annually. Now, that may have been
 5 a matter of patient choice, of course, but there
 6 doesn't appear to have been any arrangement for
 7 bringing those patients in for a period of testing,
 8 and we see some examples of testing a number of years
 9 later.
 10 Top of the next page what Dr Mayne says is
 11 that:
 12 "At a later date from late 1993 onwards, if
 13 their definitive test showed active disease the
 14 patient was contacted and seen as soon as possible.
 15 Then management would proceed, after discussion, to
 16 the Liver Clinic and possible treatment with alpha
 17 interferon."
 18 It's not clear what's meant by "their
 19 definitive test [showing] active disease", because
 20 there are individual accounts and I think not disputed
 21 in Dr Mayne's responses to them of patients, for
 22 example, not being told their hepatitis C results
 23 until 1996 in some instances.
 24 So that's the account, the main account in
 25 Dr Mayne's most recent and most detailed statement.

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1 We've looked at the example referred to in one of her
2 earlier statements of testing in 1991 patient being
3 informed on 1996. We've given further examples in the
4 written note and of course, sir, you have all the
5 individual statements available to you to consider.
6 Perhaps one or two further examples may be worth
7 looking at for present general purposes.

8 If we go to WITN257001, this is an example, if
9 we go to the third page -- WITN257001, sorry.

10 If we go to the second page of that, first of
11 all. So if we pick it up at paragraph 5, towards the
12 bottom of the page, this is an example of a patient
13 account, of them being invited to go in for screening
14 because of a brother's diagnosis of hepatitis C. And
15 then if we go to the next page we can see in
16 paragraph 4.1 patient saying that they were given
17 their diagnosis in 2003, after, I think it was, the
18 brother's death in 2002. So that's one example.

19 There are then accounts that we have and,
20 again, we've sought to summarise them in our written
21 note, of some witnesses only becoming aware of
22 relatives' hepatitis C infections after the patient
23 had died or some only becoming aware in recent years
24 of hepatitis C infections and we may hear some
25 relevant evidence from Dr Benson in relation to that

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1 another account of -- and it may, I think, be
2 a sibling potentially of one of the statements we have
3 already looked at but I'm not sure of that, but we see
4 again an invitation in paragraph 4, at the bottom half
5 of the page to being screened following a brother's
6 death from hepatitis C.

7 If we go to the next page, at paragraph 4.1 the
8 witness says in the second line:

9 "There was a time when I didn't attend hospital
10 for a number of years and that was because I wasn't
11 sent for. I think this was between 1997 and 2003.
12 Hepatitis C was only mentioned to me after my
13 [brother's] death."

14 Then if we go over two pages, top of the next
15 page:

16 "I wasn't offered any support or counselling at
17 the time of being diagnosed. I think if I had been
18 offered counselling in how to manage this infection,
19 I doubt I would be suffering with depression now. The
20 only information offered was not to share my razor.
21 I was informed of my diagnosis in a clinical manner
22 and felt there was little empathy for me."

23 Then if we just look at a couple of letters
24 from Dr Mayne on the issue of hepatitis C, so first of
25 all WITN2655002, this is a letter from Dr Mayne,

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1 tomorrow.

2 If we go to WITN1382001 and, again, these are
3 just examples of some of the broader themes that
4 emerge, and we go to the fourth page, I've referred
5 already to a theme about patients not being given what
6 they regard as sufficient or adequate information or
7 being given overoptimistic reassurance. We see in
8 paragraph 18 -- I should say this is an example of
9 a patient asking to be tested and being tested and
10 being told their diagnosis in 1992, so tests clearly
11 were available earlier than the dates that Dr Mayne's
12 other statements might suggest.

13 Then in paragraph 18:

14 "I was told by Dr Mayne that despite my
15 Hepatitis C, I would probably have a long and normal
16 life and that it was just a risk of having
17 Factor VIII. Dr Mayne did not discuss any of the
18 potential health issues; she just brushed over it very
19 quickly. She did not discuss any treatment, although
20 there wasn't any available then, or provide any advice
21 on how to manage and understand the infection. She
22 simply told me that I had it and it would do me no
23 harm."

24 So that's one example. Then if we go to
25 WITN2569001 and we go over the page. So this is

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1 April 1992, about a particular patient,
2 Richard Lowry -- and you will no doubt, sir, I'm sure
3 remember the evidence of his widow in Belfast --
4 mildly affected haemophiliac.

5 If we look at the bottom of the page, we can
6 see Dr Mayne saying in the last four lines:

7 "... he has had elevation of his liver enzymes
8 for a number of years. This is related most likely to
9 infections with Hepatitis C virus. His results vary
10 between two and three times the normal range of
11 values."

12 So, April '92, Dr Mayne feeling able in this
13 case to articulate a diagnosis or likely diagnosis of
14 hepatitis C.

15 Over the page she says in the second line:

16 "Hepatitis C is an unknown quantity to some
17 degree, between 80 and 90 per cent of treated
18 Haemophiliacs are known to be positive, all are
19 clinically well. From liver biopsy specimens obtained
20 in some centres it would appear that a small
21 percentage of patients may ultimately develop
22 cirrhosis or chronic active hepatitis."

23 Perhaps a particularly difficult letter to read
24 now in light of what we know happened to this
25 gentleman.

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1 **SIR BRIAN LANGSTAFF:** Yes.
 2 **MS RICHARDS:** But there's Dr Mayne setting out her
 3 apparent understanding of the condition in April 1992.
 4 If we then turn to WITN1382003, second page, this is
 5 a letter at the end of 1992, 21 December 1992. It's
 6 in relation to one of the witnesses whose statements
 7 we looked at who said she was led to believe that the
 8 hepatitis C wasn't a problem and this, I think, would
 9 appear to confirm the accuracy of her recollection
 10 because, if we look at the bottom paragraph, it says:
 11 "I have explained to Anne that there are
 12 several viruses which cause positivity to Hepatitis C.
 13 Generally it is thought that it is very unlike
 14 Hepatitis B infection and it may not have any serious
 15 sequelae for liver function in the future. Presently
 16 Professor Eric Preston and other Colleagues in the
 17 Haemophilia Centre Directors Organisation are carrying
 18 out an assessment of the benefit received by a 6-month
 19 course of Alpha Interferon. The results to date are
 20 quite promising and if Anne's tests suggest that she
 21 should fit into this category I will discuss it
 22 further with the patient and with yourself."
 23 So that is apparently Dr Mayne's understanding
 24 in December 1992 of the nature of hepatitis C.

25 **SIR BRIAN LANGSTAFF:** Well, it's what she wrote but it

1 input and if we go to -- this is in relation to
 2 hepatitis C -- if we go to WITN0736001 and we go to
 3 paragraph 6.2, which is page 13 I think, and we pick
 4 it up in paragraph 6.2 so this is a response to Simon
 5 Hamilton's witness statement, she says in 6.2:
 6 "... up until the Hepatitis C virus was
 7 identified in 1991 no-one really knew what to expect."
 8 Et cetera.
 9 "Always I had an ominous feeling about the
 10 virus ..."
 11 She says, and then she refers to the weekend
 12 meeting in 1995 and exhibits a programme for that.
 13 Then she says in the last sentence:
 14 "Thereafter, [so at some point after the
 15 weekend in 1995] a combined Haemophilia/Hepatitis
 16 clinic was established in the Centre under the egis of
 17 Dr ME Callender, Consultant Hepatologist in the Royal
 18 Victoria Hospital."
 19 There's also reference if we go to WITN0921001.
 20 This is the statement of Dr McNulty. Go to page 5 --
 21 no, sorry, page 7. We know Dr Mayne retired in 1999
 22 and we've seen the reference to her setting up the
 23 joint venture clinic.
 24 If we look at paragraph 3.16 in Dr McNulty's
 25 statement -- thank you -- we can see she's referring

1 doesn't quite fit with what she wrote on
 2 15 April '92 --
 3 **MS RICHARDS:** No.
 4 **SIR BRIAN LANGSTAFF:** -- in that last letter about
 5 Richard Lowry.
 6 **MS RICHARDS:** Yes, and it doesn't quite fit with what we
 7 have heard more generally about the position.
 8 **SIR BRIAN LANGSTAFF:** No, it doesn't easily reconcile with
 9 that.
 10 **MS RICHARDS:** Then just picking up on the point in
 11 relation to interferon, we can see from this that that
 12 was again, just as we've seen HIV infection being
 13 treated by Dr Mayne, we see in the early years at
 14 least in the 1990s Dr Mayne taking responsibility for
 15 the treatment of those of her patients who had by that
 16 time been diagnosed with hepatitis C.
 17 We see the letter in relation to Richard Lowry
 18 that we looked at also refers to her offering
 19 interferon treatment as at April 1992. So she was
 20 taking it upon herself at that stage as, indeed, we've
 21 heard other haemophilia clinicians were doing,
 22 I should make that clear, to be the treating clinician
 23 in relation to this virus.
 24 We saw the reference in one of Dr Mayne's
 25 earlier statements to seeking a degree of specialist

1 in the last sentence:
 2 "There were many discussions between me and
 3 Dr Jones" -- and he took over as acting director when
 4 Dr Mayne retired -- "at that time as we were trying to
 5 set up a regular joint hepatology/haemophilia clinic
 6 and were in regular contact with the hepatologists to
 7 press our case."
 8 So the position in relation to when such
 9 a clinic was established is not entirely clear.
 10 Dr Anderson in her statement describes when she
 11 arrived there being limited hepatology input only and
 12 that being a particular concern of hers and she's
 13 described that in some considerable detail in her
 14 witness statement and, again, no doubt Dr Benson will
 15 be able to assist us tomorrow with the position in
 16 terms of hepatology care, at least in general terms
 17 from 2008 onwards.
 18 So that's the summary of the material relating
 19 to testing and providing information about diagnosis
 20 to patients in relation to hepatitis C, sir.
 21 If I can then pick up on a slightly different
 22 theme, which is that of record-keeping, we've said in
 23 our presentation note that a number of patients report
 24 difficulty in obtaining their medical records or not
 25 having complete medical records, and that's absolutely

1 right. But we've suggested in our note that the
2 general processes in relation to record-keeping are
3 presently unknown. In fact, we do have some
4 information about record-keeping which I should have
5 referred to.

6 First of all, Dr Anderson in her statement,
7 perhaps -- I think you have this, Soumik. It's
8 WITN4027001. If we go to page 60 -- it's a very long
9 statement. I should say Dr Anderson joined Belfast
10 centre in November 2000 and we'll see -- sorry, it's
11 page 16, not 60. My apologies.

12 We'll see her description of the state of
13 medical records at 6.8.23 of her statement. She says:

14 "Medical records were handwritten and kept
15 meticulously. There was excellent administrative and
16 secretarial support and it followed that the filing
17 was good with the medical records kept within dividers
18 in the case notes and any written results filed in
19 separate sections."

20 She says in the last sentence of that
21 paragraph:

22 "These case records were of a superior quality
23 to those I had seen at many other institutions I'd
24 worked at previously."

25 Then she describes in the next paragraph the

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1 going to go through the detail of what are, I think,
2 a number of exhibits but I just draw your attention to
3 the fact that there's said to be or there is
4 a retention and disposal schedule. It's said to be
5 based upon the principles contained within
6 a Department of Health guidance -- that's
7 paragraph 5.2 -- and she refers to policy being
8 adopted by the Trust. Then she says at 5.3:

9 "Prior to this, records were retained and/or
10 disposed of in accordance with the Trust and legacy
11 organisations' retention and destruction policy that
12 was in place at the relevant time."

13 Then there are a range of Northern Irish
14 circulars that are referred to relevant to the
15 question of document retention and document
16 destruction.

17 Then we look in paragraph 5.4, so if we just go
18 further down the page, we see reference to
19 a suspension of the destruction of any records in
20 August 2015. That was in response to the Historical
21 Institutional Abuse Inquiry and we are told that
22 suspension of destruction or records continues to
23 remain in place. Now, there's a lot more detail there
24 that will need to be unpicked at an appropriate stage
25 but, having said in the written note that the general

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1 medical records being kept within the day ward records
2 department in a separate section to other records
3 belonging to other haematology patients, and then
4 describes the transfer because the centre relocated.
5 So she describes the transfer of records, which she
6 says she personally oversaw at the time of the
7 centre's relocation, and then, bottom of the page, she
8 described introducing a typed record of all patients
9 attending for day case assessment. Of course, that
10 would have only been from November 2000 or whatever
11 date she introduced it onwards and wouldn't relate to
12 the quality of the notes at an earlier stage. That's
13 Dr Anderson describing the notes as she found them.

14 Then we do have the more general statement
15 about record-keeping within the Trust. Soumik, this
16 is the document you should have received today. It's
17 WITN3449007. This is a statement of Caroline Leonard
18 for the Belfast Health and Social Care Trust, and if
19 we go to -- if we go perhaps just to the last page,
20 there's a description of what archives the Trust hold
21 and a history given of the Trust's archiving system.

22 Then we see an account -- I'm sorry, can we go
23 to the page prior to that. Thank you. We see
24 a description there of retention and destruction
25 policies and processes from 1948 to date. I'm not

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1 processes in relation to record-keeping are presently
2 unknown, that wasn't a fair characterisation of the
3 fact that we have also got this material.

4 How any of this then explains individual
5 missing records is an exercise that we'll have to
6 undertake to the extent that we are able to do so and
7 it may be is that Dr Benson may be able to assist us
8 again tomorrow with what at least the position's been
9 since he has been director of the service.

10 Then in terms of the provision of information
11 more generally to third parties -- oh, I note the
12 time. I've still got a handful of matters I need to
13 dealt with; so it would be more than a few minutes, so
14 perhaps we could take a break at this point.

15 **SIR BRIAN LANGSTAFF:** Yes, certainly. Roughly how long do
16 you think you have left?

17 **MS RICHARDS:** Half an hour.

18 **SIR BRIAN LANGSTAFF:** Yes. Well, we will take a break now
19 until 3.45.

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

21 (3.18 pm)

(A short break)

22 (3.46 pm)

23 **MS RICHARDS:** Sir, I'm just then going to refer on the
24 topic of data and records to examples of information
25

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1 being provided to third parties, most commonly Oxford
2 and the Oxford returns.

3 We've already looked at some examples of the
4 annual returns in relation to Belfast which are not
5 just the generic annual returns but also contain
6 detailed patient data with named patients, information
7 about dates of birth and so on, the nature of their
8 bleeding disorder and the treatment they've received.

9 If we then look at BHCT0000850, this is
10 a letter from the Oxford Haemophilia Centre from
11 Ms Spooner dated 21 October 1992 to Dr Mayne,
12 Professor Bridges and Dr Dempsey and it says:

13 "On reviewing the cases of AIDS or AIDS Related
14 illness reported to us on FORM AIDS/3, CDSC's FORM
15 AIDS 1 or the Paediatric Surveillance Forms, we find
16 it is several months since we last had news of some of
17 the patients. I should be most grateful if you could
18 complete and return to me as soon as possible the
19 enclosed form(s) for your patient(s) to give
20 up-to-date information. The information will be
21 treated in strictest confidence; the completed forms
22 will not be passed to anyone outside Oxford
23 Haemophilia Centre."

24 Then if we go over the page we can see an
25 example of a completed form from Dr Mayne. So again

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1 these are by way of example -- we can see here we've
2 moved forward to May of 1984, and it's Dr Mayne
3 sending Ms Spooner information about the treatment
4 received by identified named patients.

5 Then if we go to BHCT0000861_003, we can see
6 a request here coming from Dr Rizza to Dr Mayne,
7 Dr Bridges and Dr Dempsey in December of 1986. It
8 refers to a recent survey of anti-HIV in haemophiliacs
9 and says:

10 "... the patient(s) listed below attending your
11 Centre have reported as being anti-HIV positive in the
12 1986 survey, having been anti-HIV negative in the 1985
13 survey. In order to find out how this seroconversion
14 relates to use of heated or unheated factor
15 concentrate I should be grateful if you could let us
16 have some more details ..."

17 We can see the reason is for the monitoring of
18 safety of heated blood products. So the requests may
19 be entirely understandable requests; the issue that
20 they give rise to, as we've seen with a number of
21 other centres and clinicians, is the extent to which
22 patients were aware of or asked to consent to or did
23 consent to the dissemination of information about
24 them. And if we look down the bottom of the page, we
25 see again this is a request relating to a specific

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1 we have redacted the details of the individual patient
2 but it's headed:

3 "Confidential
4 "UK Haemophilia Centre Directors' Survey of
5 Patients with AIDS or AIDS-related illness"

6 And then we can see information, if we go
7 further down the page, about the patient's clinical
8 condition and about their treatment being provided.

9 And then further down the page we can see under
10 the heading "Additional comments", a number of matters
11 set out about the individual patient.

12 As I say, although we've redacted the patient's
13 name, the name and date of birth are there in the
14 material that's sent to Oxford. That's one example
15 where information relating to HIV or AIDS diagnosis is
16 being communicated.

17 If we go back a number of years and look at an
18 example of another kind of data, HCDO0000054_005, we
19 can see here in a letter from Ms Spooner to Dr Mayne
20 dated April 1977 an expectation that Oxford will be
21 sent a form giving names and details of patients.

22 That was by reference to a particular cohort: five
23 von Willebrand's disease patients treated in Belfast
24 during the year 1978.

25 Then if we look at HCDO0000153_008 -- again

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1 named patient.

2 If we then go to BHCT0000831_001, again we can
3 see Dr Rizza asking for information, this is now
4 January 1989, about a particular patient, trying to
5 locate a death certificate, and information is
6 requested. If we go to the bottom of the page, to the
7 handwritten note it says:

8 "I am surveying all death certificates of
9 anti-HIV positive haemophiliacs to see how many ..."

10 I'm not sure --

11 **SIR BRIAN LANGSTAFF:** "... might have died ..."

12 **MS RICHARDS:** "... might have died of HIV-related illness
13 but not certified as AIDS."

14 So, again, an understandable reason, and this
15 is in relation to a deceased patient, but raises the
16 question of what patients or their families
17 understood.

18 If we go to BHCT0000831_003, I think we've only
19 got the first page of this letter but we can see it's
20 a fairly detailed response from Dr Mayne to Dr Rizza
21 giving information about the patient and their
22 circumstances.

23 Then if we look at what Dr Mayne has to say
24 about the provision of information --

25 **SIR BRIAN LANGSTAFF:** Just -- what's the date of that?

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1 **MS RICHARDS:** The date of the letter? If you go to the
 2 top of the page, it's February 1989.
 3 **SIR BRIAN LANGSTAFF:** Yes. And the cause of death there
 4 was liver failure related to a non-A, non-B hepatitis.
 5 **MS RICHARDS:** Yes.
 6 **SIR BRIAN LANGSTAFF:** Yes.
 7 **MS RICHARDS:** And of course that may cast into an
 8 interesting light some of what we've seen Dr Mayne
 9 saying in her statement about her understanding --
 10 and, indeed, in her correspondence in the 1990s --
 11 about the nature of hepatitis C.
 12 If we go to Dr Mayne's statement at
 13 WITN0736009, and we go to page 51, please, Soumik,
 14 Dr Mayne is asked a series of questions about
 15 involvement of patients in research studies. She says
 16 they weren't involved in research studies without
 17 their express consent. Then she's asked at
 18 paragraph 76 about patient data:
 19 "Was [that] used for the purpose of research or
 20 ... any other purpose without ... express consent?"
 21 She answers "no".
 22 Then in relation to the sharing of patient data
 23 (anonymised or otherwise) with third parties such as
 24 UKHCDO or the Oxford Haemophilia Centre, she says
 25 this:

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1 **SIR BRIAN LANGSTAFF:** What I think it appears to be saying
 2 is that no-one was actually asked to agree that this
 3 is how the information should be shared.
 4 **MS RICHARDS:** Yes.
 5 **SIR BRIAN LANGSTAFF:** Or shouldn't be shared.
 6 **MS RICHARDS:** Then I just want to pick up next on the
 7 issue of what was or was not recorded on death
 8 certificates. If we go to WITN0736001 and we go to
 9 page 10, bottom of the page, Dr Mayne says this:
 10 "... it is important to point out that the
 11 universal practice throughout the United Kingdom was
 12 to omit HIV on any death certificate; however, it was
 13 important and prudent on all doctors concerned to
 14 inform the undertakers in question so that appropriate
 15 precautions could be taken."
 16 If we look at Dr McNulty's witness statement,
 17 so WITN0921001, and we go to page 8, what she says in
 18 paragraph 3.19, so bottom half of the page, is this.
 19 "When dealing with the issue of death
 20 certificates it must be noted that Northern Ireland is
 21 a small place and it's difficult to go somewhere
 22 without meeting someone you know. This is
 23 particularly true in rural areas and the privacy and
 24 discretion which was paramount in the Centre did not
 25 always filter down to those places. It must also be

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1 "All patients attending the Centre were aware
 2 of the existence of UKHCDO."
 3 Top of the next page:
 4 "They were aware that the secretariat collected
 5 and compiled stats on an annual basis relating to
 6 their treatment and they realised the procedures were
 7 necessary in order to estimate changes in treatment
 8 product availability year by year. In those
 9 circumstances it was a matter of implied, rather than
 10 express, consent."
 11 Now, it may be right that patients had
 12 knowledge of UKHCDO. It may be right, I know not one
 13 way or another, that patients were aware of UKHCDO's
 14 secretariat collecting and compiling statistics.
 15 It doesn't, I think, follow as a matter of
 16 logic or inference that patients must be taken to have
 17 been aware that named data, in particular sensitive
 18 data about matters such as HIV status or the
 19 progression of medical conditions, was also being
 20 provided to UKHCDO.
 21 Again, we've seen this is not an issue unique
 22 to Belfast. It's an issue that's arisen in relation
 23 to many centres, probably all of them, and one which
 24 UKHCDO itself was attempting to wrestle with at some
 25 stage.

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1 noted that 25 years ago there was a lot of ignorance
 2 and fear associated with HIV and hepatitis and it was
 3 felt to be an act of humanity not to use those terms
 4 on the death certificate in order to protect the
 5 deceased and their relatives. Very often ..."
 6 She doesn't say "always", but:
 7 "Very often this was at the specific request of
 8 the patient or their family and was not done in any
 9 underhand way."
 10 So that's the evidence from those two
 11 clinicians about the approach taken to the completion
 12 of death certificates.
 13 Can I then turn relatively briefly to evidence
 14 relating to Dr Mayne's involvement in research. She
 15 describes in her evidence having undertaken some
 16 full-time research in the course of the 1960s and
 17 early '70s but she says in her statement once she
 18 returned to Northern Ireland and took up her post in
 19 the Haemophilia Centre she had little, if any, time or
 20 opportunity to carry out meaningful research.
 21 There are examples of Dr Mayne participating in
 22 some studies, trials or pieces of research. There are
 23 the two papers we've looked at in the Ulster Medical
 24 Journal in relation to hepatitis B and patients with
 25 HIV. There's some work and publications in relation

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1 to porcine products. Dr Mayne and I think Dr McNulty
2 had some involvement in a study in relation to the
3 purity of NHS Scottish concentrates or at least some
4 anticipated involvement in that issue.

5 If we have a look at MACK0001300_002, we can
6 see Dr Mayne being sent a copy of a protocol for a PUP
7 study in December 1988 and that appears to be from
8 other documents in relation to a further Scottish
9 product said to be purer than Z8. It's not clear what
10 happened in relation to that study, I should say.

11 Some other handful of examples of Dr Mayne's
12 involvement OXUH0000451, if we go to the second page
13 we can see this is a reference to UKHCDO's Factor VIII
14 inhibitor working party and there is a trial of
15 Factor VIII versus Autoplex and it says a meeting of
16 the participants in this trial was held in
17 February 1982 in London and then a number of
18 participants are listed including Dr Mayne.

19 If we look further down the page there's
20 reference to a discussion about a draft clinical
21 protocol and then the trial comprising a double-blind
22 random allocation assessment of Factor VIII versus
23 Autoplex. So that's again one example at least of
24 anticipated involvement in a trial.

25 If we then look at BHCT0000951, there's some

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1 whether it's -- I think it is made in life actually.
2 If we look further up the page, first paragraph on
3 that page, the last four lines, it says:
4 "... he had liver failure related to his
5 carrier status for Hepatitis B and Hepatitis C ..."

6 So again, that may be an indication which casts
7 some further light upon what Dr Mayne is elsewhere
8 saying about the serious or otherwise nature of
9 hepatitis C at this time.

10 There's a reference -- we can take that down,
11 thank you -- there's a reference again in one of the
12 documents to Dr Mayne receiving some modest funding,
13 £500, for a piece of work on the immune response for
14 patients with haemophilia. That's from The
15 Haemophilia Society. It's not known what that work
16 then entailed.

17 Then if we look at BPLL0005964, this is about
18 provision of clinical data and not participation in
19 any specific trial as far as I can tell, but it's an
20 internal memo, BPL memo, 19 April 1991, and it says:
21 "I attach up-to-date lists of users of products
22 formerly issued from PFL, mostly without charge on the
23 understanding that clinical data would be provided."
24 Again, we've seen I think an example of this in
25 relation to another clinician. There appears to have

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1 evidence of involvement in a clinical trial, so this
2 is the Concorde trial, and there's a request there by
3 the Medical Research Council for information relating
4 to the patient's death. That's a request in
5 September 1992. Dr Mayne's response, we should
6 perhaps go to this for what it may indicate more
7 generally about her knowledge, is at BHCT0000948.

8 If we go to the second page, we can see in the
9 first paragraph -- so it's a letter 30 November 1992.
10 She refers to or she says -- apologises for the delay
11 in responding to the letter regarding the patient
12 involved in the Concorde trial. She then gives
13 a detailed description of his admission to the
14 haematology unit.

15 If we go over the page or rather back a page,
16 these letters are in the wrong order, again she gives
17 further details leading up to the patient's death. If
18 we just look at the third paragraph it says this:

19 "In summary; severe haemophiliac who was
20 a carrier for Hepatitis B and Hepatitis C who
21 developed HIV illness ..."

22 And then gives details of that illness.

23 So again we can see in relation to this patient
24 at least a diagnosis of hepatitis C having apparently
25 formally been made by -- it's not clear I think

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1 been some arrangement whereby some products were
2 provided free of charge to clinicians in return for
3 the provision of clinical data.

4 Then if we go two pages further on, there's
5 a list of some 52 clinicians, but bottom of the page
6 we see there listed Dr Mayne as one of them.

7 I want to move next to a separate topic which
8 now postdates Dr Mayne's retirement which is in
9 relation to the vCJD notification exercises. There is
10 a very detailed account from Dr Anderson in her recent
11 witness statement which I'll come to in a moment and
12 it was just one contemporaneous document that I'm
13 going to invite you to look at now, sir.

14 It's at DHNI0000049_036, so this is a letter
15 dated 22 January 2001. It's from Dr Anderson to
16 a Dr Carson, Medical Director, Royal Group of
17 Hospitals, and this concerns the first notification
18 exercise with which Dr Anderson had any involvement,
19 so the 2001 notification. She provides a useful
20 summary in this letter:

21 "I am writing to update you on the current
22 situation at the Northern Ireland Comprehensive Care
23 Centre. I have now identified six patients who have
24 been affected with the implicated batch ... this
25 includes two adults and four children."

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1 Then in the next paragraph she deals with the
2 issue of patient notification and says this:

3 "With regards to the action being taken to
4 inform or not inform patients, as you know there was
5 considerable controversy over whether or not patients
6 should be informed, and if they were to be informed in
7 what manner. As you are aware, a letter was sent from
8 the Haemophilia Society to its members and was
9 received in Northern Ireland on Friday, 19th January."

10 She encloses a copy of that, and then says:

11 "I have tried to gauge how different
12 haemophilia centres have approached the problem around
13 the [UK]. The Scottish Centres are minimally involved
14 as they do not use BPL products. The Welsh Centre in
15 Cardiff have informed all their patients (17 last
16 week) by phoning them and asking them to come up to
17 the haemophilia centre, and thereafter informing them
18 with appropriate counselling. In Sheffield,
19 a different approach was taken, following along the
20 lines of Dr Frank Hill, the Chairman of [UKHCDO].
21 A letter was sent from the Sheffield Children's
22 Hospital on Wednesday and it would appear that the
23 majority of parents want to know if their children
24 have received the implicated batch."

25 Over the page, again this is in relation to

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1 informed. The patient was counselled by myself and
2 took the information relatively quietly, with the
3 comment that this was probably inevitable for any
4 patient receiving plasma derived blood products."

5 Then there is discussion about the problem
6 about whether or not to inform patients with
7 antithrombin III who had received the antithrombin III
8 concentrate. And she describes how there are
9 relatively few centres where that arises, the only
10 other identified centre being the Royal Cornwall
11 Hospital.

12 If we go to the next page she refers to
13 anticipating Department of Health guidelines and says:

14 "Perhaps it would be appropriate to wait until
15 these guidelines are available prior to informing the
16 patients who have received the antithrombin III
17 concentrate. There are also implications from
18 informing other patients who have received
19 immunoglobulin G, albumin and plasma derived products
20 from this affected donor. This obviously involves
21 UK-wide population.

22 "I am concerned that I may be accused of
23 withholding information from one set of patients
24 whilst informing another set of patients. This is of
25 concern ..."

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1 Sheffield:

2 "On the other hand, in the adult population
3 only a minority wanted to know."

4 And there's reference there to information that
5 Dr Anderson had received from Dr Makris. She then
6 says:

7 "I do know that two hospitals in London, the
8 Oxford Haemophilia Centre and the Canterbury
9 Haemophilia Centre are directly informing their
10 patients.

11 "After several lengthy discussions with
12 Dr Dempsey, who has the majority of affected Factor IX
13 patients, it was felt appropriate to take the
14 situation forward in Belfast by directly writing to
15 affected patients, all of which now parents of
16 children involved, outlining the situation and asking
17 them to ring Dr Dempsey urgently. The mother will
18 also be informed by Dr Dempsey. It is hoped that this
19 counselling will take place later this week."

20 Then there's a reference to another adult
21 patient described as being a prominent member of The
22 Haemophilia Society, and then Dr Anderson says this:

23 "... it was felt both by myself and also by
24 Dr Mayne, with whom I discussed the situation on
25 Saturday morning, that it was essential he was

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1 And she raises concern about whether that is
2 professional misconduct, and then says:

3 "At the end of the day I think this is an
4 extremely complex situation. Dr Dempsey and I have
5 chosen to approach the situation by considering our
6 centre on a particularly individual basis."

7 So that's an account of Dr Anderson's thinking
8 in January 2001. There is, as I say, a very detailed
9 account from Dr Anderson in her witness statement and
10 it covers some 30 or so pages of her statement. I am
11 obviously not going to go through it all now but
12 I will just flag up, if I may, where the relevant
13 passages are and then just look at a couple of them.

14 So it's WITN4027001. Her evidence in relation
15 to vCJD starts on page 140 and she deals in
16 paragraph 83 of her statement, which runs through to
17 page 144, with the circumstances in which she became
18 aware of possible risks of transmission of vCJD. I'm
19 not going to read through that but that's where she
20 sets out her background knowledge and understanding.

21 If we then go to page 144, the bottom of the
22 page she's asked the question how and by whom were
23 decisions taken either nationally or locally or both
24 as to information that should be provided to patients
25 about vCJD and as to any steps which should be taken

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1 in relation to patients and their care and treatment.
 2 Then she deals with the position at both a national
 3 and a local level. Her statement also covers
 4 Edinburgh because she moved from Belfast elsewhere and
 5 then on to Edinburgh.

6 So if we go over the page there is then
 7 a useful summary on this page and the next of the
 8 notification exercise, so we can see at the top of the
 9 page, paragraph 84.1.1 she refers to the first
 10 notification involving BPL products in January 2001,
 11 refers to the proposed approach from UKHCDO, and then
 12 the next paragraph she talks about there being
 13 a consensus view that patients had the right to be
 14 informed of receipt of an implicated batch of product.

15 If we go further down the page she refers then
 16 in paragraph 84.1.3 to The Haemophilia Society letter,
 17 and we saw that referenced in Dr Anderson's own letter
 18 a few minutes ago.

19 We see reference in 84.1.4 to a draft letter
 20 being circulated by UKHCDO and then if we go -- so
 21 that's the 2001 notification in a nutshell in terms of
 22 what was considered on a national level.

23 If we go over the page, she then refers to the
 24 second notification involving SNBTS products in
 25 November 2002 and gives details of what advice was

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1 Northern Ireland, it was felt appropriate to inform
 2 patients through a notification process in the same
 3 manner in both regions and at exactly the same time,
 4 with the same letter albeit with minor local
 5 modifications to reflect the prior notification
 6 exercise in Belfast."

7 Then she gives further information following
 8 that about the 2004 notification exercise and
 9 explains, if we go just a little further down, at
 10 paragraph 84.2.8, that she wasn't involved in final
 11 decisions about the exact nature of the notification
 12 exercise in 2004 as she left her post.

13 Then if we go on to page 150, there is then
 14 question 85:

15 "What was the process at ... Belfast" -- also
 16 at Edinburgh, but I needn't refer to that for present
 17 purposes -- "for informing patients about possible
 18 exposure to vCJD?"

19 And again she goes through the detail, if we
 20 follow over the page, of the procedure that was
 21 adopted to identify patients and ascertain what
 22 information to provide.

23 That is a detailed account which continues over
 24 the page, until page 153. If we just pick it up at
 25 paragraph 85.1.8.5, so the third paragraph down, she

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1 received at a national level in relation to that.

2 Then in paragraph 84.1.7 she refers to
 3 a further notification process in September 2004
 4 which, in fact, was completed after she'd left her
 5 position as the director of the centre and refers
 6 there to the national discussion in relation to that.

7 Then she goes on to talk about, if we go
 8 further down the page, discussions at a local level,
 9 and we've seen one example of that in the letter we
 10 looked at. So she gives an account in relation to the
 11 first notification exercise of local discussions in
 12 January 2001.

13 If we go over the page she gives information
 14 about an urgent meeting convened to discuss it. She
 15 then gives similar information in paragraph 84.2.2
 16 about the second notification exercise and, again, I'm
 17 not going to read through it but we can see that's
 18 where it's located within her witness statement and if
 19 we continue down the page she refers to there being
 20 ongoing discussions in relation to Scottish and
 21 Northern Ireland haemophilia doctors group and so on.

22 If we go over the page, we can see in
 23 paragraph 84.2.5 she says:

24 "As the second notification involved SNBTS
 25 product and affected patients in Scotland and

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1 refers to:

2 "... [recalling] very few telephone calls to
 3 the Centre, and I can recall that no patients
 4 requested counselling following the letter ...
 5 However, at clinic visits, patients did seek more
 6 information about the situation in general, and this
 7 enabled a general discussion to take place and any
 8 queries to be answered."

9 Then in the final paragraph she says:

10 "I found, in general, that the majority of my
 11 patients did not wish to be informed of an implicated
 12 batch in the future. We recorded the patient's wishes
 13 in the case notes."

14 Then there's the BPL antithrombin III
 15 discussion again we saw alluded to in the letter from
 16 Dr Anderson, and over the page we see details being
 17 set out of the procedure followed.

18 If we go to page 155, we can then pick up the
 19 picture in relation to the 2002 notification regarding
 20 SNBTS and again there's a detailed account from
 21 Dr Anderson about the procedure that was adopted and
 22 that continues for most of the following page,
 23 page 156. She gives such details as she is then able
 24 to on the following page about the notification
 25 regarding the third implicated batch.

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1 If we go on to page 158, there's then also
 2 a detailed account of how and when patients were
 3 provided with information and, as I say, that
 4 continues again over a number of pages, and I'm not
 5 going to go through the detail of that.

6 If we pick matters up on page 163 she then, in
 7 response to question 88, sets out what information was
 8 providing to patients about risks of vCJD at the
 9 Belfast Centre and she summarises that on page 163 and
 10 over the page on to page 164.

11 Then if we turn to page 165 she's asked about
 12 counselling support and advice and says in
 13 paragraph 89.1.1 -- thank you, Soumik -- in relation
 14 to the 2001 and 2002 notification exercises she refers
 15 to help-lines, counselling being available through
 16 face-to-face sessions with herself and the associate
 17 specialist should patients wish it. Patients were
 18 also giving counselling and support and updates at
 19 review clinics and then she also refers to the
 20 availability in 2001 of face-to-face sessions of the
 21 paediatric centre if required.

22 Then finally, if we go to page 166, the
 23 question is asked at the bottom of the page about
 24 measures put in place regarding vCJD at the Belfast
 25 Centre from a public health perspective and she begins

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1 She then refers to further revised guidance in
 2 2003 regarding decontamination of surgical instruments
 3 and again refers to endoscopy being viewed as
 4 a high-risk procedure, so endoscopes were quarantined
 5 and reused for single patients. Then says in
 6 paragraph 91.1.6:

7 "With such practical difficulties for the
 8 multidisciplinary team in terms of knowing which
 9 patients had wished to be informed, and those who
 10 wished not to be informed, to the best of my
 11 recollection around 2003 I think we took a pragmatic
 12 approach at the Belfast Centre to apply the same
 13 infection control measures to all the patients. As
 14 this involved quarantine of only some surgical
 15 instruments this was relatively straightforward.
 16 Operating theatre staff would be informed of the need
 17 for disposable instruments, and it seemed that these
 18 were becoming more commonplace in use."

19 Then she refers to her recollection about the
 20 position in 2004 and then explains again that she
 21 wasn't involved in the execution of the 2004 vCJD
 22 notification exercise.

23 So there is then some further evidence in the
 24 pages that follow from Dr Anderson about some specific
 25 issues relating to the antithrombin III product

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1 to answer, the bottom of the page:
 2 "In January 2001, to the best of my
 3 recollection, there was no advice available regarding
 4 the public health measures required in relation to the
 5 care and treatment of patients who had received factor
 6 concentrate ..."

7 She explains she raised this issue with the
 8 Director of Public Health and in the next paragraph
 9 she explains it was problematic. She recalls an
 10 instance when the dental school at the Royal Hospital
 11 site was required to shut for decontamination of
 12 surgical instruments.

13 She refers then to all surgical instruments and
 14 ventilators being quarantined for patients who had
 15 received implicated batches of product, many of whom
 16 had not wished to be informed of their exposure:

17 "Patients were not able to undergo endoscopy
 18 and colonoscopy as the public health risk had not been
 19 clearly defined, leading to waiting lists for
 20 procedures and delays to diagnosis. From discussion
 21 with other Centre Directors at the time, this was
 22 a common situation around the UK and not unique to the
 23 Belfast Centre."

24 Again, that accords with the evidence the
 25 Inquiry has heard.

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1 notification exercise and various communications that
 2 Dr Anderson had at the time but, as I say, it's a very
 3 detailed 30-plus page account from her perspective of
 4 what happened in Belfast in relation to vCJD.

5 Sir, in our written note we have sought to
 6 summarise Dr Mayne's involvement with UKHCDO as chair
 7 in 1990 to 1993. We've referred to her membership of
 8 The Haemophilia Society's Medical Advisory Panel,
 9 which she seems to have been on from 1982 to 1994,
 10 although there's little documentation revealing the
 11 substantive content of her involvement, and we've
 12 referred to her appointment as trustee of the
 13 Macfarlane Trust between 1991 and 1996 and then her
 14 appointment to the Eileen Trust from 1993 to 1996.

15 I'm not proposing to deal with any of those
 16 matters now because the focus yesterday and today is
 17 upon Belfast rather than some of Dr Mayne's later and
 18 more national activities.

19 We've also in the written note highlighted some
 20 documents describing interactions that Dr Mayne had
 21 with pharmaceutical companies. We've looked yesterday
 22 at some of her exchanges with Speywood.

23 There are bits and pieces of correspondence,
 24 for example, Dr Mayne providing an account of a named
 25 patient requiring Hemofil to a pharmaceutical company,

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1 discussions about patients' adverse reaction to
 2 Hyate:C, again with Speywood.
 3 There is some evidence of sponsorship by
 4 pharmaceutical companies of attendances at
 5 conferences. So, for example, there is documentation
 6 to suggest that Speywood sponsored Dr Mayne to attend
 7 a conference to present a paper on porcine factor, and
 8 there is also some evidence of Dr Mayne having a role,
 9 perhaps in her capacity as chair of UKHCDO, with an
 10 inspection of the Octapharma plant in Vienna in 1992
 11 and attending with Dr Lee, Dr Jones, Professor Peake
 12 and Professor Preston to obtain detailed information
 13 about the fractionation procedures. That was at the
 14 time of an outbreak of hepatitis A.

15 Those are, in broad terms, the interactions
 16 that the documents reveal in relation to
 17 pharmaceutical companies.

18 If we go to Dr Mayne's own statement
 19 WITN0736009 and it's -- first of all, if we turn to
 20 page 13, paragraph 11.1, bottom half of the page she
 21 suggests that the relationship which existed between
 22 the centre and the pharmaceutical companies was
 23 business-like and professional.

24 Then if we turn -- if I can find the page
 25 reference -- to page 70 she says, bottom of the page,

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1 active member, in September 1994 the minutes of the
 2 UKHCDO meeting record Dr Mayne introducing a paper
 3 setting out a process for Haemophilia Centre Directors
 4 to make declarations of interest, which was agreed and
 5 it doesn't appear that there had been any such
 6 requirement prior to that in relation to UKHCDO rather
 7 than local Trusts.

8 So that's the documentary evidence and the
 9 thrust of the witness statement evidence received in
 10 relation to policies and practices at the Belfast
 11 Haemophilia Centre.

12 **SIR BRIAN LANGSTAFF:** Yes. Well, thank you very much. So
 13 tomorrow we have Dr Benson.

14 **MS RICHARDS:** Tomorrow Dr Benson at 10 am.

15 **SIR BRIAN LANGSTAFF:** Ten o'clock. Ten o'clock it is.

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

17 (4.28 pm)

18 (Adjourned until 10.00 am the following day)

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1 she's "never provided advice or consultancy services
 2 to [a] pharmaceutical company".

3 Top of the next page:

4 "... never received ... pecuniary gain ..."

5 Then if we look at paragraph 117:

6 "... never received any financial incentives
 7 from pharmaceutical companies to use certain blood
 8 products."

9 And then she says at 118.1:

10 "I believe it became known throughout the
 11 pharmaceutical industry that I was unreceptive to
 12 gifts. If a company product was in use or if
 13 a pharmaceutical company so desired, educational gifts
 14 at the centre or extra accessories for the patients
 15 were acceptable, i.e. slides, pamphlets and books."

16 She refers then to getting sponsorship for the
 17 meeting on hepatitis C (that's the hotel conference
 18 she describes elsewhere in her statement) in 1995 and
 19 she says funding was accepted for travel to scientific
 20 meetings, either to present a paper or take part in
 21 discussion groups.

22 So that is again an outline of the position in
 23 relation to involvement with pharmaceutical companies.
 24 It's perhaps relevant to note that, following her
 25 stepping down as chair of UKHCDO but whilst still an

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<p>MS RICHARDS: [68] 1/3 3/21 4/1 7/10 7/22 23/17 23/20 24/4 24/13 24/17 24/22 24/25 34/13 38/2 38/11 41/7 41/16 46/2 49/20 49/25 51/14 51/20 51/23 52/4 56/1 71/20 75/3 76/21 76/25 77/2 77/6 77/11 77/16 77/18 86/8 88/11 88/17 90/22 95/21 97/3 97/8 101/7 107/20 110/4 110/10 110/14 111/8 119/12 119/18 125/12 125/23 126/1 126/5 141/2 142/3 142/6 142/10 148/17 148/20 148/24 152/12 153/1 153/5 153/7 155/4 155/6 175/14 175/16</p> <p>SIR BRIAN LANGSTAFF: [66] 3/19 3/22 7/5 7/11 23/10 23/18 24/2 24/11 24/16 24/20 24/23 34/6 37/24 38/10 40/23 41/11 45/23 49/18 49/24 51/8 51/15 51/21 52/2 55/24 71/16 75/2 76/15 76/23 77/1 77/3 77/7 77/14 77/17 85/24 88/3 88/12 90/17 95/20 97/2 97/4 101/5 107/19 109/22 110/9 110/11 111/7 119/10 119/15 125/7 125/19 125/24 126/3 141/1 141/25 142/4 142/8 148/15 148/18 152/11 152/25 153/3 153/6 155/1 155/5 175/12 175/15</p> <p>'70s [2] 58/25 156/17 '83 [8] 62/24 67/22 67/23 67/23 67/24 67/24 67/24 67/25 '84 [9] 67/14 67/15 67/17 67/18 67/22 67/23 67/24 67/25 67/25 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