

Thursday, 8 October 2020

(10.00 am)

Presentation by MS RICHARDS, continued

SIR BRIAN LANGSTAFF: Cardiff, part 2?

MS RICHARDS: Yes, sir. Or might even be part 3. Yes, the first part of today is to conclude the presentation on Cardiff and Professor Bloom.

I had last week gone through all the documents that I wanted to present in open session. There were two areas I wanted to deal with this morning. The first is just to point to some of the issues and questions that emerge from looking at the evidence from some individuals in relation to Professor Bloom's practices, and then to look at his litigation report. Not all of it -- it's very lengthy -- but just a handful of aspects and to raise some questions in relation to that.

Before I do so, one of the themes that emerged from the documents that we looked at in relation to Cardiff and Professor Bloom last week was the interrelationship between Professor Bloom and various pharmaceutical companies and representatives of pharmaceutical companies, and one of the observations or questions I posed was the extent to which Professor Bloom's views may have impacted upon what

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disclosed, that many people have heard. There are, of course, a number of other witness statements relevant to treatment in Cardiff which the Inquiry has -- which you, sir, have read and are considering but which aren't yet public and haven't gone through the necessary process or redaction or anonymisation. So I won't be referring to those, but I didn't want anyone in the position of having provided a statement to the Inquiry to think that they are of any less importance. They are not.

One of the first witnesses you heard from in Cardiff last year was Mr Gerald Stone, and there were a handful of core points emerging from his evidence which you may wish to consider when you look at the evidence relating to Professor Bloom and practices at Cardiff more widely. Mr Stone's evidence told us that he was on a home treatment programme from the beginning of 1976 onwards, in relation to his haemophilia B, and that for most of that time he was treated with British Factor IX. There then came a period in 1985 onwards when he received for a few months a commercial heat-treated product Profilnine. His evidence was that, although he had some awareness of hepatitis B, he was not told by Professor Bloom or anyone else involved in his care at Cardiff of any

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was being thought or said or done by pharmaceutical companies, and that might have had wider ramifications.

It's been observed to me by a Core Participant that, of course, it could also have been the other way around and information being provided, or views being expressed by pharmaceutical companies could have influenced Professor Bloom's views and his articulation of those views then more widely to Government and others which, of course, is entirely possible because we have only the correspondence that records usually a visit has taken place, rather than having the detail of what was discussed and what views were shared during those visits. It was a useful observation from a Core Participant that I wanted to pass on to you, sir.

So turning then to some of the thematic issues that emerged from evidence received from patients who were treated by Professor Bloom, or the relatives of patients who were treated by Professor Bloom. I'm only going to refer to a handful of statements, and the statements I refer to are -- and the evidence I refer to is all from those who gave oral evidence last year. The reason for that is because that is material that's in the public domain, it's been

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risks relating to the receipt of factor concentrates.

He had a recollection of there being a group meeting at Cardiff, to which all patients were invited in the lecture theatre in which Professor Bloom addressed the patients about what was known about AIDS. His evidence in relation to his own diagnosis of hepatitis C was that records showed he was tested without being told for hepatitis C in 1990, again in 1991, that in 1992 his general practitioner was told of the positive hepatitis C result that Mr Stone, the patient, was not. There are records that document, again, in September 1992 the hepatitis C positive result, but his evidence was that he was not told until July 1993. So there are a number of thematic issues there which then impact more widely, sir, upon your creation of policies and practices at the Cardiff Haemophilia Centre under Professor Bloom.

Similar themes emerged from the evidence of Susan Sparkes who told us about her late husband Les, also a haemophilia B sufferer, also mostly treated with British Factor IX, although on one occasion Profilnine. Her evidence, too, was that they were not told about any risks arising from this treatment. Her evidence was that they were asked by Professor Bloom in September of 1985 -- which may strike you, sir, as

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1 being relatively late -- to come to a meeting at which
2 Les was told that he had tested for the antibodies to
3 HIV or HTLV-III. There were entries in the medical
4 records relating to Les from April of 1983 which
5 referred to some form of screening for AIDS and being
6 seen for an AIDS study.

7 Sir, you will no doubt wish to consider
8 more broadly what that might indicate about
9 Professor Bloom's knowledge at that time, and also
10 whether consideration was being given to patient
11 symptomatology without patients being given any
12 information.

13 Her evidence was that it was in February 1985,
14 or that the records suggested it was in February 1985
15 that a test for HTLV-III was undertaken. There
16 appears to be some evidence of a test again in
17 July 1985, but there was some delay in the diagnosis
18 being communicated to them.

19 You heard, sir, from Mr AE, a haemophilia A
20 sufferer. His evidence, too, was that he was not
21 given information or advice or warnings about the
22 risks of infection from the factor concentrate
23 treatment that he was receiving at Cardiff and --
24 again, this is a theme that you heard about more
25 widely, sir -- when he was told that he was HIV

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1 The evidence further was that in September of
2 1985 -- so, again, that date appears to have some
3 significance in terms of testing -- Professor Bloom
4 told the family GP of Paul's diagnosis but didn't tell
5 him, as patient, and he was not aware that he was
6 being tested for HTLV-III. The evidence you will
7 recall, sir, was that he was never given that
8 information by Professor Bloom or the Cardiff
9 Haemophilia Centre but discovered it when he was seen
10 by a doctor in Plymouth where he was then studying.

11 You heard evidence from Mr AF who spoke about
12 himself and his late brother, both infected with HIV.
13 Mr AF described being treated with cryoprecipitate for
14 a number of years before the treatment changed to
15 Factor VIII concentrates. No warning or advice given.
16 His evidence was that if he had been told of the risks
17 of serious illness or disease, he would have chosen to
18 stay on cryoprecipitate. His records show he received
19 a range of different commercial Factor VIII products.
20 His records record in May 1983 -- again, April/May
21 seem to be significant in relation to Cardiff in that
22 respect -- bloods taken for AIDS. He was not told
23 that.

24 When he was given his diagnosis, he was not
25 aware that he had been tested.

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1 positive, he had not been aware that he was being
2 tested.

3 You may recall, too, sir, the evidence you heard
4 in relation to Paul Summers from his father and his
5 widow, Michael and Monica. Their evidence was that he
6 received no advice or information about any risks.
7 The evidence was that he was on some form of
8 prophylactic therapy from 1979 and you may recall,
9 too, sir, there were some periods of gaps when he
10 wasn't treated and then was treated again for the
11 first time in some 20 months or so with Factor VIII.

12 There was, sir, the particular entry in his
13 medical records from April 1983 -- and the
14 significance of that date will not escape anyone
15 because of the timing of the first patient, the
16 Cardiff patient under Professor Bloom's care believed
17 to have AIDS. In April of 1983, Paul's records
18 contained an entry: "Patient has had the same batch
19 number as [name redacted]", but for various reasons
20 which I won't go into in terms of various records that
21 the Inquiry has had access to in terms of individual
22 patient records, the redacted name is likely to be the
23 Cardiff patient. So some form of recognition in
24 April 1983 that those who had received that particular
25 batch may need particular consideration.

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1 You heard evidence from Gaynor Lewis, widow of
2 the late Haydn Lewis. He had been treated with
3 cryoprecipitate and fresh frozen plasma before moving
4 in the early 1970s on to treatment with factor
5 concentrates. He went on to a home treatment
6 programme in or around the late 1970s, and in the '70s
7 and 1980s received a range of different Factor VIII
8 products, including a range of different commercial
9 products over the years. The evidence there, too, was
10 that he had not been given any information or advice
11 or warnings about any risks of viral infection as a
12 result of the treatment. He had not been privy to any
13 discussion with Professor Bloom about the different
14 treatments or why treatments were being changed. When
15 in 1985 he was told he was HIV positive, he did not
16 know he had been tested.

17 The records in relation to hepatitis C suggested
18 that he may have been tested in 1991, but it may not
19 have been discussed with him until 1993. He had had,
20 as reported by his wife to you, sir, some recollection
21 of being told in the '70s that he might get jaundice,
22 but the evidence suggested that the risk in relation
23 to that had been underplayed.

24 You also heard from Haydn and Gareth's sister
25 about Gareth Lewis. She related how Factor VIII had

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1 been effectively described to them as a wonder drug,
2 and her evidence or her understanding was that Gareth
3 had not been given advice or warnings or information
4 about risks.

5 The last patient I wanted to talk about in terms
6 of the oral evidence that you heard, sir, is
7 Colin Smith, and you heard evidence from his parents,
8 Janet and Colin.

9 Just to remind you, because the dates here, you
10 may think, sir, are really very telling indeed, Colin
11 was born in 1982. He was seen by Professor Bloom on
12 21 July 1983, and the notes record he was a known
13 haemophiliac, not treated, never given 8 concentrate
14 or cryo.

15 The next day, 22 July, Colin was given
16 Factor VIII concentrate for the first time. That was
17 Lister Factor VIII -- so NHS product. You may recall,
18 sir, there was a letter in Colin's records from
19 Professor Bloom to the general practitioner which
20 said:

21 "All these materials carry the risk of
22 hepatitis, particularly non-A, non-B, but this is
23 something haemophiliacs have to accept."

24 You may wish to reflect, sir, on that
25 phraseology when you consider not just Cardiff but

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1 Dr Frank Boulton -- of that meeting, we know that in
2 the afternoon session of that meeting, at which
3 a number of haemophilia clinicians attended with
4 representatives of Immuno and others, including
5 Professor Bloom who chaired the meeting, there was
6 a detailed discussion of the current position, in
7 terms of cases of AIDS, reference to the New England
8 Journal report from January 1983, discussion of the
9 numbers being reported from the United States. So as
10 at 24 January 1983, all those attending that meeting,
11 including Professor Bloom, had that information.

12 We then move on in the course of 1983 -- and
13 whole host of relevant materials -- but move on
14 perhaps to the Galbraith letter of 9 May 1983.

15 Henry, I gave you the reference before we
16 started and I haven't written it down. It's the CBLA
17 reference I think you wrote down.

18 Although we looked at it yesterday with
19 Dr Colvin, we didn't look at it during the Cardiff
20 presentation, and that's why I'm going to put it up on
21 screen again because there may be those who were
22 watching the Cardiff presentation previously who did
23 not -- who have not seen this letter.

24 So here we are, 9 May 1983. This is two and
25 a half months before Colin was treated by

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1 haemophilia clinicians' decisions and actions more
2 widely.

3 Colin's parents' evidence was that they were not
4 told of the risk of non-A, non-B hepatitis, nor were
5 they told of any risk of AIDS. That is why the timing
6 of Colin's treatment is perhaps particularly
7 significant. I should add that not long after that
8 first treatment, which was with Lister Factor VIII, he
9 was treated with commercial products: Kryobulin in
10 August of 1983. He then received Elstree product
11 again. He was then treated with an Armour product,
12 Elstree again. He also at some stage received
13 cryoprecipitate.

14 The timing of that perhaps assumes particular
15 significance when we look at what was known or should
16 have been known about the risk of AIDS in the first
17 half of 1983. I'm not going to put back on screen a
18 whole host of documents, but just to remind those who
19 may not have heard all of the evidence thus far of
20 four key documents from the first half of 1983. The
21 first which I won't put up which we looked at
22 yesterday with Dr Colvin but which he did not remember
23 is the meeting at the Excelsior Hotel, Heathrow
24 Airport, on 24 January 1983. Thanks to the note taken
25 by Dr Frank Boulton -- at least we think it's by

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1 Professor Bloom for the first time. It's the letter
2 from Dr Spence Galbraith to the Department of Health
3 setting out the following very clearly:

4 "Last week whilst you were away in Geneva a case
5 of ... [AIDS] in a haemophiliac in Cardiff ..."

6 So a patient under Professor Bloom's care:

7 "... who had received USA factor VIII

8 concentrate was reported. The case fits the
9 recognised criteria for the diagnosis of AIDS. In the
10 Lancet of 30th April three cases in haemophiliacs in
11 Spain are reported; I have confirmed that they
12 received USA factor VIII concentrate. In the same
13 issue of the Lancet the tally of 11 reported cases in
14 haemophiliacs in the USA is recorded and a paper
15 describes a case in a multiply-transfused child in the
16 USA."

17 Now this was not a letter addressed to
18 Professor Bloom. I cannot, without checking, recall
19 whether we have evidence as to whether he saw it and,
20 if so, when, but the information that's reported there
21 is all information that would have been known to
22 Professor Bloom. Obviously, the position of his own
23 patient in Cardiff would have been known to him by
24 this time, and you may think it's fair to infer that
25 he would have been aware of what was being reported in

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1 The Lancet.
 2 If we then go to the second page, please, Henry.
 3 Again this is for the benefit of any who were
 4 not at the Inquiry hearing yesterday when we went
 5 through this. This is what is being said by
 6 Dr Spence Galbraith in early April 1983:
 7 "The AIDS epidemic is probably due to
 8 a transmissible agent.
 9 "The agent is probably transmitted by blood and
 10 blood products."
 11 If we go further down we can see there's express
 12 reference to Professor Bloom's case in Cardiff fitting
 13 the accepted criteria of AIDS and having received USA
 14 Factor VIII concentrate.
 15 We see him saying in point 3:
 16 "Although [the] number of cases ... is very
 17 small ... this may NOT indicate that the risk is
 18 small ..." and he goes on to explain why.
 19 If we go over the page please, Henry, we see
 20 at 4 he says:
 21 "Factor VIII concentrate (and pooled products)
 22 would appear to have a high risk of being contaminated
 23 with AIDS agent ..." and he explains why.
 24 He explains at paragraph 5 that there's no known
 25 means of ensuring that blood or blood products are

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1 referring to a case of AIDS as such, and it seems
 2 inconceivable, or it may be said to be
 3 inconceivable -- I will listen to any submissions the
 4 other way -- that Bloom didn't know about it.
 5 Precisely so, sir, and of course we have other
 6 material that refers to the Cardiff case, which is
 7 earlier than 9 May.
 8 **SIR BRIAN LANGSTAFF:** Part of the significance of that
 9 might be that a later meeting of the UKHCDO -- you
 10 showed me earlier that there was some concern about
 11 the fact that a case in Bristol had gone unnoticed
 12 because it hadn't been reported and it was emphasised
 13 how important it was to report cases.
 14 **MS RICHARDS:** To Dr Galbraith, yes.
 15 **SIR BRIAN LANGSTAFF:** So Cardiff was ahead of the game in
 16 reporting.
 17 **MS RICHARDS:** Yes.
 18 So that was 9 May, sir. Could we then go back
 19 to a document that we did look at last week in the
 20 Cardiff presentation but, again, just to see the
 21 timing.
 22 WITN4029002, please. WITN4029002. I may have
 23 written that down incorrectly. That's it.
 24 Again, sir, you will see the date. This is one
 25 of two sets of Cardiff guidelines provided to the

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1 free of the AIDS agent at that point in time.
 2 Then at 6:
 3 "The mortality rate of AIDS exceeds 60 per cent
 4 one year after diagnosis and is expected to reach
 5 70 per cent."
 6 **SIR BRIAN LANGSTAFF:** As I understood Dr Colvin's evidence
 7 yesterday, even though he was not a reference centre
 8 director himself at the time, he accepted that all
 9 those points corresponded with his then knowledge.
 10 **MS RICHARDS:** Yes, absolutely, and that the points being
 11 made by Dr Spence Galbraith here were effectively
 12 agreed.
 13 Again, sir, it will ultimately be a matter for
 14 your judgment, but if a doctor such as Dr Colvin, not
 15 then a reference centre director, is able to confirm
 16 his knowledge of these matters, it would seem
 17 inconceivable that Professor Bloom, as chair of UKHCDO
 18 and a leading reference centre director and privy to
 19 information that others did not have, would not have
 20 equally been aware of these points.
 21 **SIR BRIAN LANGSTAFF:** The inference is available to me
 22 that someone reported the case from Cardiff to the
 23 Centre, that that report must have been made before
 24 9 May, one would expect two or three days beforehand,
 25 it was plainly a report which was understood as

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1 Inquiry by Professor Collins, who is the current
 2 director at Cardiff. This is from May of 1983, and so
 3 it's internal, as far as we understand this document,
 4 to Cardiff. You'll see what's set out there in
 5 relation to children with severe haemophilia:
 6 "Use cryo, or NHS factor VIII as in 1(b) above."
 7 So the first port of call in terms of treatment
 8 for a child with severe haemophilia under Cardiff's
 9 own May '83 guidelines was cryoprecipitate. If that
 10 couldn't be used for some reason, then NHS
 11 Factor VIII.
 12 We then move from May 1983 to the following
 13 month, 24 June, and we'll just go back to a letter
 14 we've looked at on a number of occasions, sir,
 15 HCDO0000270_004.
 16 This is, of course, the letter co-authored by
 17 Professor Bloom of 24 June 1983. It follows the
 18 Haemophilia Reference Centre Directors' special
 19 meeting in May. Again, we can see the advice in
 20 relation to children set out at 2:
 21 "For treatment of children and mildly affected
 22 patients or patients unexposed to imported
 23 concentrates [and of course Colin was both a child and
 24 a patient unexposed to imported concentrates] many
 25 Directors already reserve supplies of NHS concentrates

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1 (cryoprecipitate or freeze-dried) and it would be
 2 circumspect to continue this policy."
 3 That is the advice being given more broadly, and
 4 we know from the Cardiff document we've just looked
 5 at, that was -- Cardiff's own policy was
 6 cryoprecipitate first and then NHS Factor VIII.
 7 So that is 24 June. That is just under
 8 four weeks before Colin was treated by Professor Bloom
 9 with factor concentrates, initially NHS and then
 10 commercial.
 11 The final document I wanted to look at again
 12 just to juxtapose what's known more broadly with
 13 what's being done in relation to treatment within
 14 Cardiff itself, is a document we've also looked at
 15 before.
 16 NHBT0020668, please. Have I given you the wrong
 17 reference, Henry? That's it, thank you.
 18 So this is the month of July. It's before the
 19 date when Colin was seen. It's 6 July 1983. This is
 20 the National Blood Transfusion Service letter. But if
 21 we go to the second page and go down towards the
 22 bottom of the page, we can see the question:
 23 "Can AIDS be transmitted by transfusion of blood
 24 and blood products?"
 25 And the answer:

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1 we looked at last week.
 2 **SIR BRIAN LANGSTAFF:** Well, what I have to resolve is, is
 3 it, whether there was a mismatch between what he was
 4 doing and what he should have known, or, by inference,
 5 must have known, and what he was saying, both publicly
 6 to the Haemophilia Society and others, and less
 7 publicly, as minuted in the October, for instance,
 8 minutes of the HCDO, when he appears to be saying to
 9 fellow directors there's absolutely no proof that
 10 blood transmits AIDS.
 11 **MS RICHARDS:** Yes, I think "absolutely", sir, is your own
 12 addition of an adverb, but certainly the minutes
 13 record him saying "no proof" in October 1983 in
 14 response to the point being expressly raised about
 15 reversion to cryoprecipitate by Dr Chisholm, as you
 16 will recall.
 17 **SIR BRIAN LANGSTAFF:** Yes.
 18 **MS RICHARDS:** Sir, there are then just a handful of
 19 matters I wanted to draw attention to. They mostly
 20 relate to the lengthy litigation report that
 21 Professor Bloom prepared.
 22 Before we look at that, there's just one matter
 23 I wanted to raise which I made some reference to last
 24 week when we were looking at the Cardiff and Bloom
 25 documents.

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1 "Almost certainly yes."
 2 That is the information that the Transfusion
 3 Service proposed to provide to donors. The evidence
 4 of Colin and Janet Smith was that they, as the parent
 5 of a child, a baby about to be treated, were not told
 6 anything about the risk of AIDS.
 7 That is from the short summary I've given, as
 8 I say, which is just a snapshot of some of the
 9 evidence from Cardiff, which in turn is a snapshot of
 10 the much wider evidence, sir, you have heard and read
 11 from haemophilia centre patients across the country,
 12 the evidence of not being told of the risk of AIDS is
 13 a very common feature of that evidence. The timing is
 14 obviously particularly telling in the particular case
 15 we've been looking at because this is a child about to
 16 be treated for the very first time.
 17 Lastly, in relation to that case, the evidence
 18 was that they were told Colin's diagnosis -- he was by
 19 then two and a half -- in a corridor, and that they
 20 had not known he was being tested for HTLV-III.
 21 Sir, that, as I say, is just a summary by way of
 22 snapshot of some of the evidence relating to
 23 Professor Bloom's treatment of patients, which you
 24 will no doubt wish then to fit into the broader
 25 picture as revealed by the documentation some of which

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1 You will recall the early May Haemophilia
 2 Society statement, the one sheet, I think dated 4 May,
 3 where -- we know sent to all Haemophilia Society
 4 members -- where Professor Bloom had provided
 5 information and advice.
 6 You may recall, sir, the issue of what was known
 7 or may have been known about cases emerging in Germany
 8 as an issue which arises from that document.
 9 We know from other material, material prepared
 10 for a Council of Europe meeting in May, that by the
 11 end of April it was known, certainly to those
 12 preparing the Council of Europe committee's report,
 13 that two cases had occurred in Germany. We don't
 14 know, and currently our investigations have not
 15 provided any further information about this -- we
 16 don't know whether that was material he would have
 17 known or been sent in advance of the early May 1983
 18 Haemophilia Society statement.
 19 We do know that the following month, in June,
 20 Dr Gunson reported to the CBLA an update on AIDS in
 21 which his report referred to the two suspected cases
 22 in Germany, and it seems likely from all the
 23 documentation we've seen that that is something that
 24 would, by then, late June, have come to
 25 Professor Bloom's attention at least by that route,

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the route of Dr Gunson's report, if not by then, through a range of possible other routes.

You will recall, sir, from the presentation last week that in July The Haemophilia Society invited Professor Bloom to consider whether he wanted to update his statement. He didn't take that opportunity. So whilst, therefore, his original May statement may have correctly recorded his then state of knowledge, no cases in Germany, an inference that may be open to you to draw from the documentation, sir, is that he failed to correct that when given the opportunity to do so in July of 1983, by which time it seems likely he would have had that information.

Sir, then Professor Bloom's litigation report. As can be seen, this is just the report and not the appendices, it was a lengthy document.

Can we just have it on screen, please, Henry. It's DHSC0001297.

You can see there the date of it, sir, June 1990. It was prepared for the then ongoing litigation. You will want to consider it, no doubt, sir, in some considerable detail. I'm just going to alight upon a handful of points by way of illustration and drawing attention to some matters that you are likely to want to consider further.

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recognised the risk of hepatitis in haemophiliacs after treatment with concentrates ..."

Again, you will wish to consider whether you accept that as a date or whether you consider there's an earlier date by which that was recognised or should have been recognised.

"The general recommendation however was that bleeding was still the main cause of morbidity and mortality and that treatment with concentrates should continue ..."

Then he says this:

"... except perhaps that treatment with cryoprecipitate may have been more circumspect in general in young children and that DDAVP should be used, within its constraints, in mildly affected patients with haemophilia A ..."

So there appears to be a recognition there from Professor Bloom that, by 1980, cryoprecipitate should perhaps have been being considered for young children, and DDAVP for mild haemophiliacs, rather than concentrates. Again, you will wish to consider both whether you accept that, whether you think it is something that should have been or could have been done earlier, and whether there is any mismatch between what's said here to be a general

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If we could go please, Henry, to -- it's the numbered page 45 but it might be page 48 on the version you have, Henry. Yes.

You will see here, sir, under the heading "Non A Non B Hepatitis", if we go down the page this is what Professor Bloom says in his expert report:

"The risk that [non-A, non-B] hepatitis progresses to chronic hepatitis was known in 1977 but the full significance of the information in ..."

We can look at the sub-paragraphs if necessary, but it's about the progression and seriousness of the condition:

"... above was not fully appreciated during the 1970s and developed mainly during the 1980s."

You will no doubt wish to consider whether that is an assertion that you accept or whether, in light of some of the material that we've been exploring over the last few weeks, you ultimately reach the conclusion that there should have been, in the second half of the 70s, that knowledge.

If we go on, please, to page 56 -- so it is probably 59, Henry, in the document you have -- we see Professor Bloom continues, at the top of the page, by saying this:

"... by 1980 most haemophilia specialists

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recommendation and what was actually being done in haemophilia centres.

If we turn to page 71 internal pagination -- so page 74, Henry, for you -- you'll see here a section headed "General availability of information to patients", and it said this, and of course this was a commentary, a report provided for the purposes of defending litigation:

"Individual plaintiffs may take up the question of information given to them concerning the possibility that blood and blood products may transmit hepatitis or other viruses. Here I comment briefly on general information with regard to hepatitis."

You will see that he refers to manufacturers' inserts and, at some stage, sir, during hearings over the coming months, we will try and set out and show what we have by way of manufacturers' inserts and what it says over the years.

"Representatives of The Haemophilia Society were regularly present at HCD meetings at which hepatitis was always discussed. Reference to hepatitis was included in the book 'Living With Haemophilia' by Dr Peter Jones, a book intended for patients and relatives and published in 1974."

So it may be said that here is Professor Bloom

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saying, well, patients could find out about the risk of hepatitis from other sources. It doesn't address here the question of what could or should have been provided by doctors to their patients and you may think, sir, that that would be expected to be the first port of call for any patient receiving treatment, would be to be given information by their doctor. You'll no doubt look, as I say, in due course, sir, at what the inserts say and whether the reference to representatives of The Haemophilia Society being present at Haemophilia Centre Director meetings is effectively suggesting, to some extent, that the responsibility for passing on information was somehow devolved to The Haemophilia Society.

We will look, at an appropriate stage, at what was actually said in Dr Jones's book on the subject of hepatitis, but you only need to look at the date, sir, 1974, to know that after 1974, or very soon after 1974, knowledge of non-A, non-B hepatitis and its potential consequences was being considered and published in the documents and journals that we've looked at -- '74/'75/'76. So that which is set out in a book in 1974 may not be the most reliable guide to what was known by 1976/1977 or 1978, for example, when Professor Preston's study was published in The Lancet.

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Professor Bloom about developing knowledge in relation to AIDS, and he refers there in September 1982 to a publication, the publication from the Centers for Disease Control, the MMWR. What he then says by way of comment is:

"Until September, most of the information on AIDS in haemophilia had been published in MMWR, a periodical not read by or available to haematologists or haemophilia doctors in UK."

Now, the question of what was read by individual clinicians is perhaps a question that can only be answered by individual clinicians, and you have I think thus far been told by Dr Winter that he did read them and by Dr Colvin that he didn't. The suggestion that the MMWR was not available to haematologists is a broader question which you'll no doubt wish to consider when you've heard further evidence.

SIR BRIAN LANGSTAFF: Well, Dr Winter got hold of it from somewhere.

MS RICHARDS: Yes. Of course, we know from documents we looked at last week that, certainly, the December 1982 MMWR report -- that's of the San Francisco baby case -- had, by January 1983, been sent to Professor Bloom. We know that because we saw

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SIR BRIAN LANGSTAFF: 1974 is only a year after concentrates became licensed for general distribution in the UK if they were imported, is it not?

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: So there would have been, at most, a year's experience of commercial concentrates and at that stage, although I think the precise figures are yet to be given to me, it may well be that NHS concentrate was made from much smaller pools than later was the case.

MS RICHARDS: Yes, and obviously the question of pool sizes at particular points in time and how they changed is a very important question for you to consider.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: But, in any event, that's what's said by Professor Bloom to be potential other sources of information but doesn't address what information would have been given as standard or good practice to patients by clinicians.

If we then just turn on to page 87 -- probably your page 90, Henry. You will see here this is -- as I say, sir, I am just alighting on certain passages. The report, obviously, needs to be read and considered in full. But this is part of a chronology provided by

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a reference to that happening in another document which I showed you last week.

If we go two pages further on, please, Henry, to internal pagination page 89, and we go to the bottom half of the page, you will see January 1983, he refers to the editorial by Dr Jane Desforjes in the New England Journal of Medicine which we've looked at on a number of occasions. We know, again from other material, that it had to have come to Professor Bloom's attention because it is referred to in that 24 January 1983 meeting at The London Airport hotel. He refers to this, and then says, by way of comment:

"This was a remarkably astute editorial, but it did not have a great impact ..."

Pausing there, it was described I think by Dr Winter as effectively something of a watershed moment, or words to that effect. I might not have the precise words used by Dr Winter accurately, but that was one of the -- the thrust of his evidence. But here is Professor Bloom saying it didn't have a great impact. A question for you, sir, may be: should it have done?

What he goes on to then say is -- give a number of reasons for that. Partly he says because AIDS in

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1 haemophilia was so uncommon and that again raises the
2 question of whether there was a proper understanding
3 of the difference between incidence and risk:

4 "Partly because the evidence in the two
5 accompanying papers was weak ..."

6 Again, sir, you may wish to consider whether
7 that is an assertion that you accept:

8 "Partly because of the cause of AIDS was quite
9 unknown ..."

10 And then he says this:

11 "... and partly but mainly [so this is the
12 reason he is giving as to why it didn't have a great
13 impact] because widespread conversion to
14 cryoprecipitate therapy would have completely upset
15 Factor VIII production and blood transfusion practice
16 in UK and elsewhere. Thus, diversion of plasma to
17 production of cryoprecipitate locally would have
18 stopped the flow of plasma to the fractionators, e.g.
19 at Elstree. In any case, provision of cryoprecipitate
20 locally would have meant recruitment of staff,
21 provision of facilities, et cetera, locally which were
22 not justified from the evidence available. It would
23 also have resulted in curtailment of home treatment
24 and reduction of hospital treatment, for which
25 eventuality neither doctors nor patients were ready."

29

1 evidence, and that is a core question that you will
2 need to consider, sir.

3 If we then come on to page 95 -- 98 for you,
4 Henry -- we can see in July of 1983, he says:

5 "CDSC reports on AIDS commenced."

6 That's the Communicable Disease Surveillance
7 Centre. That's not strictly accurate from what we've
8 seen, sir, because there is of course the May 1983
9 CDSC report which -- I think it was Mr Stone who
10 referred to that, first of all, in his evidence last
11 year in Cardiff which we looked at a couple of weeks
12 ago which was from early May and which reported the
13 Cardiff patient, Professor Bloom's own patient.

14 If we go on then to page 98 of the internal
15 pagination, we can see at the top of the page
16 November 1983. He says:

17 "The first AIDS case in the UK was reported in
18 the literature."

19 That is, I think, a reference to Dr Helena
20 Davies' report of the Bristol case. But, of course,
21 we know, whatever was or wasn't reported in the
22 medical literature, what had been reported widely by
23 then in material available to haemophilia clinicians
24 was the Cardiff case much earlier in the year.

25 Then if we go over the page, please, to

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1 Just dealing with that last observation, the
2 question of what patients were ready for may turn in
3 part upon what patients knew or had been told by their
4 doctors. But you will no doubt wish to consider that
5 explanation with some care. If I may paraphrase it,
6 it appears to be a desire not to upset the apple cart.
7 He doesn't suggest that any of the steps which would
8 have been needed in order for there to be widespread
9 conversion to cryoprecipitate -- he doesn't suggest
10 those steps would have been impossible or even highly
11 problematic. He just says, well, it would have been
12 a complete upset to what was then being done and would
13 have required arrangements to be made locally and
14 would have had an impact upon fractionation centres.

15 **SIR BRIAN LANGSTAFF:** Well, it's perfectly arguable, isn't
16 it, that that would have been problematic, to use your
17 word. So I am not sure it wouldn't have been
18 problematic.

19 **MS RICHARDS:** No, sir. He doesn't suggest it would have
20 been impossible. He suggests that there may have been
21 various steps that, as a matter of practicality, would
22 have to have been taken --

23 **SIR BRIAN LANGSTAFF:** Several logistical problems.

24 **MS RICHARDS:** Logistical issues, exactly. His view is
25 that those weren't justified from the available

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1 Professor Bloom's comment, you will see he says this:

2 "By the end of 1983, there was much
3 epidemiological and circumstantial evidence to suggest
4 that AIDS was transmitted by a hitherto unknown virus,
5 but proof of this was lacking."

6 So, again, that use of the word "proof":

7 "As far as severe haemophilia was concerned,
8 most authorities recommended that they should continue
9 to use Factor VIII concentrates. In the UK, this
10 meant both imported and domestic. For children,
11 cryoprecipitate was recommended when this was
12 practical. For mildly affected patients,
13 cryoprecipitate or DDAVP was recommended where
14 appropriate, but there would obviously be exceptions
15 for serious injury, head injury, home treatment,
16 et cetera."

17 So it would appear to be his understanding there
18 that there were mildly affected patients on home
19 treatment with concentrates.

20 Then if we go over to page 103, please, you'll
21 see there in the middle of the page his reference to
22 his own survey of AIDS in treated European
23 haemophiliacs, which was published in 1984 or produced
24 by him in 1984. Again, we just see some of the
25 terminology being used:

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"Although it was stated that the most likely culprit was imported Factor VIII concentrate, it was noted that no haemophiliac patient with AIDS definitely related to transfusion of blood products was from Germany."

Again, that is a potentially slightly puzzling reference, given reports from 1983 of two cases in Germany, and you will wish to consider the extent to which issues such as proof or looking for something to be definitely related, whether that was shaping Professor Bloom's response and reaction, and whether that was the appropriate way in which to view the risk.

If we then turn to page -- I think it is 144, Henry -- yes, page 143, so 147 for you. If we go to the previous page, this is a section of Professor Bloom's report which charts the response of Haemophilia Centre Directors. So it essentially records what was said, what meetings took place. This section of his report does not include a reference to the London Airport meeting with Immuno. It is right to note that that is referred to but not in any great detail in a section of his report which talks about interactions with pharmaceutical companies. But its significance or potential significance and the content

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society seems to have been made on an *ad hoc* basis. I corresponded with society officers at various times, but much advice was obtained, I suspect, through Dr Peter Jones of Newcastle."

We will look at a later stage at what advice Dr Jones may or may not have been giving to The Haemophilia Society, but you have seen the particularly prominent role played by Dr Bloom, Professor Bloom, in terms of his communications with The Haemophilia Society, in particular in his critical years, as far as AIDS is concerned, of 1983 and 1984.

If we just turn on to page 177 you will see here, for the entry 8 October '83, Professor Bloom's account of The Haemophilia Society meeting he attended on 8 October 1983. We've seen the correspondence between Professor Bloom and Mr Watters after that meeting. I showed you that last week, I won't go back to it. This is how Professor Bloom is recounting it. He says that:

"He was now more circumspect than previously with regard to the role of blood products in AIDS and suggested that until their role became more clear it would be wise to revise dosages and for haemophiliacs to modify their lifestyle to prevent bleeding."

So two issues there, two practical suggestions

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of the detailed discussion on AIDS is not described in the report.

Again, we can see how, for example, if we look at the following page, Henry, when Professor Bloom refers 7 March 1983 through to the letter he received from Dr Bruce Evatt at CDC -- I won't go back to that letter, sir -- we looked at it last week -- but you will recall the terms in which it was expressed, whether the urgency that seems to emerge from that letter is something that was fully recognised by Professor Bloom is going to be a matter that you will no doubt consider in due course.

If we just turn on then to page 173, you will see here that there's a section in the report headed "Liaison with The Haemophilia Society". You may wish to consider the terms in which the second paragraph is put:

"The Haemophilia Society has a medical advisory panel presently consisting [so that's as at 1990] of Drs Rizza, Tuddenham, Kernoff, Colvin, Mayne, Jones and me (as far as I can recall)."

He says it met infrequently until the last year -- and that is consistent with the documents that we've seen, sir -- and then he says this:

"Until then, most direct medical advice to the

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he says he made at that meeting: (1), presumably a reduction in dosages and, secondly, lifestyle modification to avoid the need for treatment, both of which were explored with Dr Colvin yesterday. Whether we see that advice recorded in any of the materials produced by UKHCDO will be a matter you will wish to consider. Whether we see that replicated in terms of the individual patient experience under Professor Bloom is a matter you will wish to consider, but here are two measures being suggested.

Then what's said by Professor Bloom is:

"This was met with a very poor reception by the audience. Several patients or parents spoke from the floor and the gist of the response was that they did not wish to, nor did they intend to, reduce demands for therapy using current products."

Again, you may wish to compare that with how the meeting was described by Mr Watters in his correspondence.

Sir, I am not going to refer to any further particular extracts from the litigation report. As I say, both for the issues which you need to consider and, of course, as a matter of fairness to the late Professor Bloom, the report needs to be read in full.

But, by way of a handful of concluding

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observations in relation to Cardiff and the position of Professor Bloom, it would appear to be clear from all the material that we've looked at so far that Professor Bloom was a central and perhaps the most important figure in shaping the response of haemophilia clinicians to the risk of AIDS. By the time of its emergence, in terms of haemophiliacs being affected, in 1982, he had been chair of UKHCDO for three years and was already clearly a significant and influential figure.

His role as chair and his role on the various committees and working groups that we looked at last week would, appear to show that he received more information than other clinicians working in the field of haemophilia may have done.

SIR BRIAN LANGSTAFF: Do we actually have a count of the number of committees concerned with the risks of AIDS and hepatitis upon which Professor Bloom sat during the years 1982 to 1984?

MS RICHARDS: I listed a number of them at the beginning of the Cardiff presentation. We know he was on -- although this appears to be a meeting in the 70s rather than the 80s -- the Expert Group on the Treatment of Haemophilia and Allied Conditions, which was a group advising the DHSS in the 1970s. He was on

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committees in which he had some role or other. The AIDS Medical Advisory Committee to the World Haemophilia AIDS Centre we've seen some reference to in papers. The British Society for Haematologists Working Party on AIDS, the National Blood Transfusion Service Advisory Committee Working Group on AIDS, and its Technical and Scientific Working Group on Viral Contamination of Blood, although that might have been later in the 1980s.

So we know he was one of a very -- a small number of experts who were asked to give their advice to the subcommittee of the Committee on Safety of Medicines in that critical July 1983 meeting, and the subcommittee's advice was then accepted by the committee.

We know that he was regularly -- or relatively frequently, in any event, in contact with the Department of Health, not least through Dr Walford, Dr Diana Walford. There are a number of communications and correspondence with him.

He was in communication with BPL and others within the National Blood Transfusion Service over the relevant period.

So that's not necessarily exhaustive but I hope is at least a partial answer to your question, sir.

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The Haemophilia Society Medical Advisory Panel from 1979 until his death in 1992. He was chair of UKHCDO from 1979 to 1985. So they had a three-year term of office and he served two terms of office in what you may think is perhaps the most critical period in terms of responding to risk.

He was, as a reference centre director, attending the reference centre director meetings both before and after his chairmanship, and therefore would have received routinely the various working party reports, including Dr Craske's various reports for the Hepatitis Working Party.

He was on the UKHCDO's AIDS group, but that didn't start until January 1985 and, of course, that's one of the issues you will want to consider, whether that was too late.

He was a member of the CBLA, Central Blood Laboratories Authority, from '82 to '84 or '85.

He was on the MRC's working party on AIDS between 1983 and 1987.

He was a member of EAGA, the *Expert Advisory Group on AIDS* set up by the Department of Health, but you will recall that was not set up or didn't meet until 1985.

There are then various other groups or

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SIR BRIAN LANGSTAFF: Yes, thank you.

MS RICHARDS: What we appear to see from the material we've looked at so far, sir, is that within UKHCDO he took the lead as chair, perhaps unsurprisingly. You have already observed, sir, in relation to the October 1983 meeting, it's Professor Bloom who responded to Dr Chisholm's suggestion. So there is a sense from the minutes of Professor Bloom shaping the debate.

Outside of UKHCDO, he was often, in these groups or in these discussions with the department and others, the only one or one of very few haemophilia clinicians who were being consulted, and there were a number of groups upon which we will also see the presence of Dr Rizza, and we'll look at that tomorrow.

Of course, the relationship he had with The Haemophilia Society and the communications, whether it's the May 1983 letter or advice, his decision not to revise that in July 1983, his address in October 1983, the question and answer session we looked at as reported in The Haemophilia Society Bulletin, his advice and views would no doubt have been heard in terms of what patients were hearing, not only by his own patients but by the wider patient community through Haemophilia Society communications.

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So it's for those reasons essentially, sir, that his role is critical part of the analysis that you will need to undertake, both in terms of considering the position of the patients that were treated at the Cardiff under his care but also considering how his wider influence shaped the response of haemophilia clinicians and others more generally.

SIR BRIAN LANGSTAFF: Thank you.

MS RICHARDS: Sir, that's what I wanted to say about Cardiff and I think that leads neatly, in terms of timing, to the break.

SIR BRIAN LANGSTAFF: Yes. We'll take a break until, shall we say, 20 to 12. 20 to 12.

(11.07 am)

(A short break)

(11.42 am)

MS RICHARDS: Sir, I turn to St Thomas' haemophilia centre. As with all the presentations on haemophilia centres, these are intended as an introduction or an overview. They are not an exhaustive account of every piece of material, nor are they intended to be the last word in any sense.

In relation to St Thomas' there is substantially less documentary material of relevance than there is in relation to both Cardiff and Oxford, perhaps

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Dr Katharine Dormandy of the Royal Free) and then Dr Ingram representing St Thomas' Hospital. If we look under the heading "Introduction", we will see: "A meeting with the directors of three London haemophilia centres was preceded by an office meeting at which the situation in London was discussed with particular reference to the Royal Free."

The office meeting (so not including the Haemophilia Centre Directors) was an internal Department of Health discussion about the extent to which there should be reorganisation of the haemophilia centres within London. It was identified in paragraph 1 that the department's policy should be aimed at a reduction in the number of centres in London; there were then 13. Great Ormond Street would remain on any view because it dealt with children. The Lewisham was also going to remain. It was thought there was a need for a major treatment centre in London. Then there were discussions about the rival facilities of the Royal Free and St Thomas'.

If we go over the page to paragraph 6, we can see then Dr Ingram -- later Professor Ingram -- talks here about St Thomas'. So it gives us a snapshot as at 1970. He says:

"Work at his centre at St Thomas' Hospital was

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unsurprisingly because of the particular roles occupied by Professor Bloom at Cardiff and Dr Rizza at Oxford. I'm going to be looking at the material thematically, rather than in a strictly chronological order.

You will see when we get to it that we do have the evidence of Professor Savidge to the Archer Inquiry, both written and oral evidence, which you may find quite illuminating when we turn to the detail of it.

St Thomas' Haemophilia Centre is one of the major haemophilia centres in England. It was led by Professor G Ingram, who was usually known as Professor Illsley Ingram, from 1956 until 1979 and, as at 1970, it had around 157 registered patients.

If we can have up on screen, please, Henry, DHSC0100026_084 please. We can see a little of the history of St Thomas' here. This is a meeting, or two meetings, to discuss London haemophilia centres, 11 February 1970, at the Department of Health. We can see that those present include Dr Yellowlees, the Chief Medical Officer, and Dr Maycock and then, in terms of haemophilia centre clinicians, we have Professor Hardisty who was director of the haemophilia centre at Great Ormond Street, Dr Dormandy (that's

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increasing steadily. This was partly due to the fact that haemophiliacs could now be given more and better treatment, with the result that patients were attending more frequently, but also because it was becoming more widely known that St Thomas' was particularly active in haemophiliac work. Dr Ingram said he needed an additional technician to help carry the current workload. And a Deputy Director and a further technician was desirable to enable monitoring of cryoprecipitate material to be undertaken."

Then there's a reference to space:

"Cases requiring major surgery were referred to Oxford because of the shortage of anti-haemophiliac material. If therapeutic treatment was to continue to expand as currently indicated, there would be a need for further anti-haemophiliac material."

But Dr Ingram then says he requires more staff.

Then:

"In reply to a question from Dr Maycock, Dr Ingram said that out of the 157 registered cases at his centre, some 20 needed to attend frequently, and another 20 came fairly often."

If we go to the next page, there's a discussion in paragraph 11 of the physical facilities at both St Thomas' and at the Royal Free. In relation to

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1 St Thomas', it's reported that there will be space for
2 a haemophilia department in the rebuilding scheme, but
3 that may not be available for another seven years.

4 Then if we go to the next paragraph, we'll see
5 then issues about supply of treatment materials are
6 discussed, and it's recorded that Dr Ingram stressed
7 the need for additional material, likely to be
8 cryoprecipitate given the time:

9 "If therapeutic treatment of haemophiliacs was
10 to continue and to expand, Dr Maycock outlined the
11 measures which had been taken to increase production
12 of this material. It was expected that in three to
13 four years, good supplies of cryoprecipitate,
14 et cetera, would be available."

15 Then if we go further down towards the last
16 paragraph on the page, please, Henry, we can see the
17 conclusions were, or the agreement was that:

18 "It seemed likely that St Thomas' and the
19 Royal Free would naturally evolve as the main
20 haemophilia centres in London."

21 If we could then go, Henry, to DHSC0100005_061.
22 Go to the next page. This is a document dated
23 November 1973. It's prepared by Dr Sheila Waiter in
24 the Department of Health, addressed to Dr Reid who,
25 I think from recollection, was the Deputy Chief

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1 reviewed."

2 The next paragraph then refers to the
3 February 1970 meeting that we've already looked at,
4 and then it's recorded that:

5 "A survey of the activities of the 13
6 haemophilia centres in London revealed the majority of
7 cases were registered at Great Ormond Street,
8 St Thomas', the Royal Free, the London, and Lewisham
9 Hospital."

10 If we go further down:

11 "The first three of the centres listed above [so
12 that includes St Thomas'] were evolving as major
13 treatment and reference centres. In addition, they
14 were working with each other to offer a co-ordinated
15 service as far as they were able at that time."

16 Then it's recorded that:

17 "Professor Hardisty, Professor Ingram,
18 Dr Dormandy [so representing there Great Ormond
19 Street, St Thomas' and Royal Free] submitted to the
20 department a scheme outlining the requirements for
21 providing a full service to haemophiliacs in the
22 London area and its large catchment area."

23 If we go on this page, Henry, to the second
24 paragraph, please, we can see there's a reference
25 there to a further meeting in October 1970 where:

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1 Medical Officer. It's headed "Haemophilia centres in
2 London", and it gives a degree of insight into the way
3 in which haemophilia centres were recognised as
4 leading or reference centres. So we see in the second
5 paragraph:

6 "Haemophilia centres, where the condition could
7 be diagnosed, the patient registered, and treatment at
8 short notice made available were originally designated
9 by the Medical Research Council and HM (68)8 [that's
10 a department publication] formally announced takeover
11 of responsibility for designation by the Department of
12 Health."

13 If we go to the next paragraph:

14 "Three centres, Oxford, Manchester and
15 Sheffield, were designated as major centres. In
16 addition to providing facilities for diagnosis of
17 haemophilia and related disorders and the monitoring
18 of treatment, these centres were expected to act as
19 reference centres [so we see here the development of
20 the concept of reference centres which assumes much
21 greater importance in the following years] and also to
22 provide facilities for undertaking major surgery.
23 None of the 13 haemophilia centres in London was
24 designated a major centre at that time, although it
25 was noted that the situation might have to be

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1 "If major surgery or complex management was
2 required, directors would refer their patients to one
3 of the larger London centres (probably the Royal Free
4 or St Thomas'), or to the special treatment centre at
5 Oxford."

6 Then there's a discussion of whether to use the
7 title "regional" or "reference centre" as
8 a designation. But, effectively, this is when
9 St Thomas' emerges as what's recognised as a reference
10 centre.

11 If we go over to the next page, we see the role
12 of these reference centres referred to here as
13 regional or major administrative centres. So the
14 proposal, which we know is accepted, is that:

15 "The haemophilia centres at the Royal Free and
16 St Thomas' should be designated regional or major
17 administrative centres for the treatment of
18 haemophilia, and the major centres at Oxford,
19 Manchester and Sheffield should be renamed."

20 Then if we go further down, we can see it's
21 said:

22 "The roles of the major centres would be those
23 of administrative centres primarily but centres to
24 whom reference could be made in the event of
25 encountering difficulties in the management of a case,

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or in obtaining therapeutic agents or services. In practice, most centres already refer, when necessary, to the Royal Free, St Thomas' and Oxford centres, and a clear statement of their designated role would be a confirmation of the situation which exists now."

Sir, I've drawn attention to that not simply because it shows that this is the point in time at which St Thomas' becomes a reference centre, but because there have been some enquiries made by Core Participants, through their legal representatives, of quite how these centres came to be so important -- and that's something we'll no doubt be looking at over the course of the coming hearings again, but this helps provide an explanation as to what the particular role of the reference centres was. Then we see how that then feeds into there being the regular meetings of Reference Centre Directors, including therefore a representative of St Thomas' over the coming years which leads the response of haemophilia clinicians to both hepatitis and HIV and AIDS.

We know that Professor Ingram, as well as being the key consultant and director at St Thomas' at this time, was a member of the Medical Research Council's Cryoprecipitate Working Party. We can see that from OXUH0000831_001. This is not document we have looked

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purposes, on the detail. There's discussion of two trials relating to Factor IX products, but if we go to page 6, this is not specific to St Thomas', but there's just something I wanted to draw attention to in light of evidence we heard from Dr Colvin yesterday. Sorry, next page, please, Henry.

Again, in the context of a very long and detailed record of a discussion about a particular trial, if we look at the last sentence of the first main paragraph, you'll see here there's a discussion about hepatitis and about non-A, non-B types of hepatitis and what's being looked for. Then it says this:

"Dr Wyke thought Professor Zuckerman would think it an advantage to have stored samples in case the possibility of tests for non-A, non-B hepatitis virus became available in the future."

We don't know with any confidence what the position was in terms of stored samples at St Thomas', but I have drawn attention to this because, obviously, the issue of stored samples at The London Hospital and any possible interest that Professor Zuckerman might have in those stored samples came up in the course of Dr Colvin's evidence yesterday.

Professor Ingram was also a member of the Expert

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at before. You can see it's headed "Medical Research Council" and it says:

"MRC Cryoprecipitate Working Party. Minutes of special meeting held at Oxford on Tuesday 1 October 1968."

It appears to be, in part, out of this that what we now know as UKHCDO later evolves and we see, amongst those present, is members of the Working Party on Cryoprecipitate are Dr Biggs from Oxford, Dr Ingram representing St Thomas', Dr Maycock and Dr Rizza, and then a number of other directors and others invited.

If we just go to the bottom of the page, we'll see that amongst other matters being considered by this committee, on which Professor Ingram sat, was a survey of the incidence of jaundice in haemophilia.

Professor Ingram was also on a Factor IX working party. If we just look briefly at that, OXUH0000967_004, we can see here this is headed "Working Party on Factor IX concentrate". This is its seventh meeting -- it's really intended as an example -- and it's a meeting in January of 1978. We can see it's chaired by Dr Rizza, and then we have present a number of people. The second name is Professor Illsley Ingram.

I don't need to spend time, for present

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Group on the Treatment of Haemophilia and we can see that at DHSC0100007_010. I hope I have the requisite number of zeros there. First page of it. That was the second page. So it was the first page we needed.

So we're going to look tomorrow during the Oxford presentation a little more at some of the background to the committee -- to this group, but we can see it's headed "The expert group on the treatment of haemophilia". We're told it first convened in March 1973 to advise the department on the likely trends in haemophilia treatment and related matters, and its terms of reference are there set out. A particular function it had was advising the department on issues relevant to self-sufficiency -- so likely demand for product -- and we can see it was decided to reconvene it in 1976. We have Professor Ingram identified as attending that in paragraph 3.

Professor Ingram was also, as a Reference Centre Director, an attendee at the Reference Centre Director meetings of UKHCDO and co-Chair of UKHCDO for a shortish period, 1978 to 1979. He was succeeded at St Thomas' by Professor Savidge in 1979, and Professor Savidge remained director of the centre then until 2006.

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We have very few annual returns currently that we have been able to track down from the centre, but we have one from 1983 which gives us a snapshot of the patient profile then.

It is HCDO0000166_003. So we can see here, it's the 1983 annual return for St Thomas' completed by Dr Savidge. The total number of haemophilia A patients during 1983 and '90. There are no carriers of haemophilia A treated in that year. Then we have 13 with von Willebrand's disease treated during the year.

Then we can see the material that was being used in the course of 1983. So NHS human factor concentrate used -- the volume there for hospital treatment is 133,763 units, and for home treatment 109,900 units. You'll see, sir, there's no cryoprecipitate identified as being used. Then we see really very significant quantities of different commercial products being used. So we have Alpha Factor VIII (Profilate), 185,223 units for hospital treatment, and for home treatment 38,982. The Armour Factor VIII (Factorate), 890,650 units for hospital treatment, 924,257 for home treatment. Then Hyland (Hemofil), 1,129,775 units, and 779,000-odd for home treatment.

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Hospital of NHS Factor IX concentrate being used to treat the haemophilia B patients and we know from other material that there wasn't the same problem in terms of supply of NHS Factor IX as there was with NHS Factor VIII.

If we could then go, please, Henry, to IPSN0000584_003, please.

This is a document we looked at in part yesterday with Dr Colvin. So it's a report. It may well have -- well, I'm not sure who it was prepared by. I was about to say it was prepared for UKHCDO but I don't think one can necessarily draw that inference. It may have been a Speywood document.

It's "The use of concentrates in the treatment of inhibitor patients in the UK 1981-83". We'll look in a minute at what it says about Professor Savidge and St Thomas' but it may be relevant just to observe the first main paragraph, again in light of some of the evidence we heard yesterday from Dr Colvin:

"As can be seen ..."

So this gives national statistics about the treatment of inhibitor patients, and then it says this:

"As can be seen, only about 50 per cent of the registered inhibitor patients received treatment in

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So we can see there, in contrast to, for example, what Dr Colvin was describing at The London Hospital for around this time, very significant quantities of commercial product, much more than the NHS product, and commercial product very clearly featuring large in the home treatment. There's a modest amount of DDAVP recorded.

Then we see for von Willebrand's disease, there cryoprecipitate has had a role to play. There's no home treatment for von Willebrand's, it's cryoprecipitate and then Profilate, Factorate and Hemofil and a modest amount of DDAVP.

Then if we go, please, Henry, to HCDO0000166_005, we can see the annual return in relation to haemophilia B. 23 haemophilia B patients treated during the calendar year 1983 at St Thomas', no carriers treated. We can see there the predominant treatment is with the NHS Factor IX, both for hospital and for home treatment. There is then a specific entry for the use of Factor VIII, and we can see from what is written at the bottom that appears to have been for a particular patient who had both severe Factor IX deficiency and mild haemophilia A.

But the picture there, in any event, is one, at this time, similar to what we saw at The London

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any given year. This may be explained by the inhibitor patients leading more cautious lives because of their condition and thus bleeding less frequently or by the fact that patients who live a considerable distance from their centre may prefer to try to resolve the bleed by bed-rest than to risk a painful journey and a stay in hospital."

Then it goes on to say that:

"... many of the older patients were educated to believe that minor bleeds in inhibitor patients are better untreated and thus only present with serious bleeds."

But you will see there the reference to this cohort of patients, patients with inhibitors, perhaps not being treated as regularly as other patients because of lifestyle and management, if I can put it that way.

If we just go down the page to the next paragraph, Henry, please, we can see, in terms of the overall picture, that:

"... human [Factor] VIII is the most commonly used form of treatment for inhibitor patients."

And it's said that:

"Despite AIDS the usage has remained steady over the 3 year period."

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'81, '82, '83.
If then, specifically in relation to St Thomas',
we could go to page 4, please.

We can see, picking it up at the bottom of that
page, first of all, we can see how Professor Savidge
treated inhibitor patients. It says:

"St Thomas' have 18 inhibitor patients of whom
14 are treated with human [Factor] VIII, for most
bleeds. The remaining 4 are very high responders ...
and these have been treated with FIX or Autoplex for
minor bleeds and human Factor VIII or Autoplex for
major bleeds."

Then if we go to the next page we're told:

"Dr Savidge has been reluctant to use porcine
[Factor] VIII in the past, but claims to have been
reassured by recent publications and by the approval
of our UK Product Licence."

I think that does tell us that this is
a Speywood document, sir.

Then we just get an insight into what is said to
be the overall approach of St Thomas':

"St Thomas' have a very aggressive approach
towards surgery in haemophilia and carry out a large
number of joint-replacement operations. Porcine FVIII
is an obvious choice for surgery in inhibitor patients

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and none in 1983.

Oh, thank you, Henry. So the line for
St Thomas' is ten lines or so down.

If we then go, please, Henry, to CGRA0000605,
please, this is a document, we'll see, from
December 1985. It's an internal Cutter document
described as "UK Situation Report - November, 1985",
and it's setting out at that point in time who's
buying what in terms of Koate HT product.

If we go to the last page, please, Henry, last
paragraph, we have a snapshot from the pharmaceutical
representatives of St Thomas'. It says that they
visited Geoffrey Savidge:

"The UK haemophilia organisation was described
in depth by him ..."

If that's a reference to UKHCDO, it seems likely
we will come on and hear what his views were about the
organisation as relayed to the Archer Inquiry.

"... followed by a description of the St Thomas'
set-up. He has 250 to 300 patients attending the
Centre ... they use 5-6 million IU a year. St Thomas'
distributes to most of the Haemophilia Centres in the
South East Thames region ..."

You will have heard Dr Winter, sir, describe
some of the supply issues that he said beset the south

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and Dr Savidge intends to use it if the need arises.
He is obtaining some equipment from Sweden to enable
him to carry out extracorporeal adsorption of antibody
to [immobilised] Protein A ... and hopes to have the
system operating by mid 1985. This will enable him to
carry out surgery on the high-titre inhibitor patients
in which case he will use porcine [Factor] VIII as one
of the forms of replacement therapy.

"Dr Savidge considers that the most important
restriction on wider usage of porcine [Factor] VIII is
cost - particularly relative to human [Factor] VIII."

So we can see there clear information about
Dr Savidge's approach to treating this particular
cohort of patients with inhibitors, but more broadly
we are told that he or the hospital have an aggressive
approach towards surgery in haemophilia.

We can just see if we go to page 12 of this
document, please, Henry. I will just read it out
because it's a figure. Sorry, the system is slowing
down today, sir.

There's a table which has records of the sales
of Hyate:C, that's the porcine Factor VIII product,
and we can see that the usage at St Thomas' is really
relatively low given the number of patients it had.
In 1981 the sales were 45,300 units, 30,000 in 1982,

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Thames region.

"... and he does not use any NHS material at
all, neither Factor VIII nor Factor IX."

So we're told here that, by the end of 1985,
Professor Savidge is solely using commercial rather
than NHS products, including for the treatment of
haemophilia B.

SIR BRIAN LANGSTAFF: Now might that be because the
commercial product was heat-treated?

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: And it wasn't until, I think,
October '85 that the NHS heat-treated product was on
general release.

MS RICHARDS: We'll see later Professor Savidge's support
for heat-treated products, and we've heard from
Dr Winter, at an earlier stage than many others.

That is no doubt absolutely right, sir, that the
reason, and we'll see it quite clearly, that he was
using by certainly 1984/1985 commercial products so
extensively was because of his view of the relative
safety of heat treatment. There may have been other
issues including cost but certainly that's part and
parcel of what seems to have been his reasoning.

SIR BRIAN LANGSTAFF: Well, the cost might be surprising,
given that NHS was supposedly free in terms of the

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1 cost of delivery to the unit, the individual hospital.
 2 **MS RICHARDS:** Yes, cost may have influenced his choice as
 3 between products rather than commercial versus NHS.
 4 But we see there, again, a sense of the size of
 5 the unit. It may just be instructive to look at
 6 pages 2 and 3 of this document, not insofar as they
 7 specifically relate to St Thomas' but just an insight
 8 as to the role of pharmaceutical companies and their
 9 visits to haemophilia clinicians more generally.
 10 We can see, if we go to the second page of the
 11 document, please, Henry, bottom half, thank you.
 12 So there's a reference there under the heading
 13 "NHS Supplies" to the expectation that supplies of 8Y
 14 will increase to all centres and then there's
 15 a recognition, in the next paragraph, of what they
 16 think the commercial share will increase to in 1986,
 17 their target sales. We can see there set out targets
 18 for the salesmen to achieve or surpass to give
 19 a market share of 18 per cent, and there's
 20 a particular target we see, towards the bottom, for
 21 St Thomas' of half a million.
 22 If we go to the next page, there's an assumption
 23 built into these targets:
 24 "1. The NHS will not exceed 25 million IU
 25 in 1986.

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1 "We have to be alert to the fact ..."
 2 So the commercial expectation was that product
 3 which had lost market share because it had too many
 4 extraneous proteins, it was less pure in that sense,
 5 might flood the UK market.
 6 **MS RICHARDS:** Yes, at low prices.
 7 **SIR BRIAN LANGSTAFF:** Yes.
 8 **MS RICHARDS:** It's recorded there that:
 9 "Alpha [has] increased their price in the South
 10 West region ... the Mersey/Liverpool region. They
 11 plan to increase their price to other Centres in
 12 January or April."
 13 One just notes, at the very bottom of the page
 14 under the heading "Hyland":
 15 "The material sold to Newcastle may possibly
 16 have been diverted to St Thomas'."
 17 We don't, I think, know why that has happened.
 18 But we can see certainly from the annual return
 19 in 1983 really through to what we see here in 1985
 20 that, in contrast to the picture at some other
 21 centres, Professor Savidge is very much a clinician
 22 who has been wedded, for reasons we will explore, to
 23 commercial products for much of the relevant period.
 24 If we go then, please, Henry, to
 25 DHSC0002293_019.

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1 "2. We can stop the infiltration of Alpha into
 2 Cutter accounts by positive direct selling against
 3 Alpha.
 4 "We do expect Alpha to continue to take virgin
 5 haemophiliacs at the rate of 5 per cent per annum
 6 until Koate HS is available to the UK customer."
 7 Then it's set out what the commercial Factor
 8 VIII market for 1986 is in terms of profits.
 9 I just draw attention to that because we've
 10 heard some evidence from Dr Winter and Dr Colvin of
 11 regular visits from pharmaceutical companies and we'll
 12 see some of that, no doubt, in relation to other
 13 clinicians, including Professor Savidge.
 14 We see here clearly, perhaps unsurprisingly,
 15 what the purpose of those visits may have been from
 16 the perspective of the pharmaceutical representative:
 17 It is to increase sales.
 18 Then if we go, please, to DHSC --
 19 **SIR BRIAN LANGSTAFF:** Just before you do that, I'm just
 20 intrigued by the first sentence of the paragraph at
 21 the very bottom of the page.
 22 **MS RICHARDS:** Yes, under "Hyland"?
 23 **SIR BRIAN LANGSTAFF:** Under "Alpha".
 24 **MS RICHARDS:** Oh, under "Alpha"? Yes?
 25 **SIR BRIAN LANGSTAFF:** The second paragraph:

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1 I will wait until we get there. This happens to
 2 be a meeting of the Royal College of Physicians in
 3 January 1986. It's a joint working party on
 4 supraregional services and haemophilia reference
 5 centres.
 6 If we go, please, to page 6, just to show the
 7 development of St Thomas' and the services it offers,
 8 under the heading "St Thomas' Centre" it's said:
 9 "The Working Party had no further information
 10 tabled from Dr Savidge but the problems were well
 11 known to the Working Party. St Thomas's was offering
 12 a tertiary care service across London and right down
 13 to the coast. Many centres were referring patients
 14 there and their orthopaedic surgery was particularly
 15 good. Dr Kernoff mentioned that Dr Savidge has
 16 produced convincing evidence that there were major
 17 advantages financially speaking in the service being
 18 organised from large centres, with good evidence that
 19 orthopaedic surgery is cost effective."
 20 We can see from the next paragraph that
 21 agreement is reached that St Thomas' will be
 22 recommended for supraregional designation. So it
 23 effectively then has a role in relation to a number of
 24 the other smaller centres in the south east region.
 25 Then if we could have, please, BPLL0001988_003.

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1 This is now 1989. Again, this is just an
2 overview of the facilities and services at St Thomas'.
3 We can see in 1989, so perhaps rather more than the
4 seven years that Professor Ingram had hoped, there is
5 a new haemophilia centre at St Thomas' about to be
6 opened or move into. Somewhat optimistically,
7 Professor Savidge was writing to PFL, and there's
8 another letter I don't need to refer you to, to BPL
9 asking for a financial contribution because of
10 financial constraints within the NHS. But in any
11 event, 1989, new facilities being opened.

12 Just turn to Professor Savidge in a little more
13 detail. His background he described to the
14 Archer Inquiry as being as a physician and as
15 a medical scientist, not as a conventional
16 haematologist.

17 If we could have on screen, please, Henry,
18 ARCH0000011 -- this is a transcript of a day's
19 evidence to the Archer Inquiry -- and if we could go,
20 please, to page 113, using the numbers at the bottom,
21 but I think it will be page 114 of your document,
22 Henry, we can see he says in the top half of the page:

23 "I am or was, rather, Professor of Medicine at
24 St Thomas' Hospital ... Most of my training is as
25 a physician and as a medical scientist, not as

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1 home treatment at St Thomas'. If we could have,
2 please, Henry, DHSC0100026_091, please.
3 So this is, as we see from the title, the note
4 of a meeting with representatives of The Haemophilia
5 Society, November 1970, at the Department of Health.
6 Dr Ingram was there as a representative of The
7 Haemophilia Society, and we can see the purpose of the
8 meeting is described as being "to discuss certain
9 matters relating to [the] treatment of haemophiliacs".

10 There is then a discussion under the heading
11 "Supply of concentrates", halfway down the page, to
12 the supply of cryoprecipitate, and it's recorded by
13 Dr Obank, who is there for the Department of Health:

14 "... that the supply of cryoprecipitate had
15 risen significantly over the last 3 to 4 years
16 production was continually increasing. The need for
17 further expansion had been stressed by Directors of
18 the London Haemophilia Centres at a recent meeting ...
19 the Department had the matter under constant review."

20 Then there's a discussion about the production
21 of Factor IX.

22 Then we can see if we go two pages further on,
23 please, to page 3, Henry.

24 We'll see from this that Dr Ingram was an early
25 advocate of home treatment and introduced it early at

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1 a conventional haematologist, which may explain why
2 there are divergent opinions perhaps in the text."

3 I think the text is a reference to his written
4 statement which he produced to the Archer Inquiry
5 about 2.00 in the morning on the day he gave evidence:

6 "I graduated from the University of Cambridge.
7 I have specialist accreditation in medicine and
8 chemistry, and I have, for my sins, spent a lot of
9 time abroad training, and while I was abroad I worked
10 in Stockholm, which is probably one of the most
11 prestigious places in the field of blood clotting and
12 coagulation, and I have my higher degrees from there."

13 We have details of his CV. He worked from 1968
14 pretty much consistently through to 1979 in Stockholm
15 in various capacities, and then in 1979 he transferred
16 from the Department of Blood Coagulation in Stockholm
17 to St Thomas' and took up the director's post upon
18 what I assume was the retirement of Professor Ingram.
19 Professor Savidge was then in charge of St Thomas'
20 from September 1979 until September 2006, when he
21 retired. He died I think five years later in 2011.

22 So that's an overview, sir, of the centre and,
23 in a very broad sense, some of its activities during
24 the relevant decades.

25 Just going to turn now to the theme of

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1 the centre at St Thomas'.

2 So it's the paragraph headed "Home treatment",
3 paragraph 8:

4 "Dr Obank said that the reference in the
5 Society's paper to certain patients having been
6 trained to administer their own infusions of
7 concentrate of fresh frozen plasma ..."

8 I don't know whether that should be "or" or
9 "of":

10 "... was the first that the Department had heard
11 of this form of treatment. Dr Ingram confirmed that
12 at present there were only few such cases but he
13 thought the number was likely to increase. Dr Ingram
14 explained that the material was kept in deep freeze
15 for use when the patient had an acute bleed. Dr Obank
16 said that if such a system was developed it could mean
17 that sizeable quantities of material would be held in
18 individual reserves; this was not likely to be
19 regarded with favour unless supplies were plentiful.
20 This method of treatment would have to be evaluated
21 before any consideration could be given to the
22 Department funding the provision of home deep
23 freezers."

24 So you will see there, sir, as at 1970,
25 Professor Ingram and The Haemophilia Society raising

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home treatment with the department. It would appear that part of the aim of the meeting was to obtain funding for the department to enable the purchase of freezers for people's homes so that people could have home treatment using cryoprecipitate at home.

If we go, please, to CBLA0006658. This is a letter from Professor Ingram to Dr Maycock at BPL, October 1972, and it's discussing home treatment.

And he explains that there are:

"... two haemophiliacs, both severely affected, aged 15 and 19 ... who require frequent treatments for early 'spontaneous' bleeds, sometimes several times a week ... Both are losing considerable time from work coming here for their treatments. Both have been taught to set up their own drips and give themselves their treatments and both have given themselves cryoprecipitate and EHF ..."

That's Elstree haemophilic factor, is what that stood for in the correspondence.

"...at home as well as here."

So home treatment had been instituted by Professor Ingram in this very early part of the 70s using cryoprecipitate, and then the request here, for convenience, is whether there could be made available a regular supply of the Elstree factor concentrate.

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It's again from Professor Ingram to Dr Maycock, "Home treatment in Haemophilia Study", it's a study ongoing:

"We are now well in our stride with the Home Treatment Study, and have taken in as many patients as the supplies of factor VIII concentrate allow. You are kindly letting us have 100 bottles a month; I do not wish to seem greedy but I wonder whether the supply of plasma from the Regions would allow you to increase our allocation so we could take in more patients?"

Then you will see from the last sentence of the letter that it's a study involving two centres. We can see that from later publications. St Thomas' is using Elstree concentrate in its study, Oxford using material produced by Dr Bidwell for their part of the study.

We can see, if we go to DHSC0002191_019, you can see a little more about that study:

"Home treatment in haemophilia: clinical, social and economic advantages."

So it's co-authored by a number of clinicians and others, including Professor Ingram, for St Thomas', and Dr Rizza, Ms Spooner and Dr Biggs for Oxford. We can, I think, just look at the summary

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If we go to the bottom of the page, we can see he says:

"We are pressing on with training as many severe haemophiliacs as possible to give themselves their own treatment. In fact, for those who do not have very frequent bleeds it is not so urgent to set them up actually to treat themselves at home, but those who need to attend here more than ... twice a month would save considerable time if they could avoid the journey. In some instances it has been possible for patients to obtain a domestic deep freeze and thus to be able to treat themselves with Cryoprecipitate ..."

But then he looks forward to the day when there will be sufficient concentrate for the patients to keep a stock at home. So, again, further indication of the early use of home treatment using cryoprecipitate at St Thomas', but also a description of an aspiration that concentrate would be more widely available.

If we move on to BPLL0003662, we can see now the further developments in home treatment in St Thomas'. So, again, this is earlier than a number of other centres that had home treatment programmes. By now we're in April 1976, and home treatment seems to be fully established at St Thomas'.

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probably:

"Twenty-eight severely affected haemophiliacs were observed for 3 months under treatment as hospital out-patients and for the subsequent 9 months while treating themselves at home. Delay in receiving treatment and financial costs were both clearly reduced by home treatment, the patients recovered from individual bleeds more quickly and reported a greater sense of personal freedom and independence. The amount of treatment required did not materially change and no untoward effects were noted ..."

We'll see from the very bottom of the page it involved 12 severe haemophiliacs at Oxford and 16 attending the centre at St Thomas'.

It's clear from the detail of the study that the home treatment by this time for the purposes of the study is with concentrate, but it's with NHS concentrate.

Professor Savidge continued with the home treatment programme. If we look at HCDO000 o406, we can see here a meeting of Reference Centre Directors in September of 1980. Professor Bloom is present, Dr Rizza, and we can see Dr Savidge is there present, representing St Thomas' as the reference centre director there.

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1 If we go please to page 11 there's a discussion
2 about freeze-dried cryoprecipitate. Halfway way down
3 the paragraph we then see Dr Savidge posing
4 a question:

5 "Dr Savidge asked what the policy was of the
6 Haemophilia Reference Centre Directors regarding the
7 use of cryoprecipitate for the treatment of
8 haemophilic patients and for home therapy ..."

9 So this is as at 1980 Dr Savidge raising the
10 possibility of using cryoprecipitate rather than
11 concentrates exclusively for home treatment. And
12 Professor Bloom's response: it was a matter for the
13 individual directors to decide.

14 Sir, you will see, and we've looked at it before
15 in other days of the hearing, the minutes then record
16 Professor Bloom referring to a discussion in 1978 --
17 that's before Dr Savidge had become Reference Centre
18 Director at St Thomas' -- where there had been
19 a discussion about the merits of cryoprecipitate
20 versus concentrate for home therapy, and there the
21 Reference Centre Directors had agreed that Factor VIII
22 concentrates were preferred for home therapy and,
23 I think I've already mentioned previously, perhaps
24 something of a tension between Professor Bloom saying,
25 "Well, it's a matter for the individual director", but

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1 **SIR BRIAN LANGSTAFF:** Ordinary cryoprecipitate.

2 **MS RICHARDS:** Yes, versus concentrate more generally.

3 In terms of interactions with pharmaceutical
4 companies we can see, for example, similar
5 communications between Dr Savidge and Speywood as
6 we've seen with Professor Bloom. So if we, by way of
7 example, look at IPSN0000323_007, this is in example
8 of letters between Mr Williams, representing Speywood,
9 and Dr Savidge. This is in October 1979, and we can
10 see there's obviously been a meeting:

11 "It was a great pleasure to meet you on
12 Wednesday ... I much appreciated your interest in our
13 work."

14 There's then a discussion about Speywood's
15 porcine product and then we can see there is an offer
16 in the last paragraph that Speywood will supply Koate,
17 Human Factor VIII. I don't need to go into the
18 details although we might come on to it tomorrow with
19 Oxford, sir.

20 Speywood was not the manufacturer of Koate but
21 it was at this time the distributor of it, or
22 a distributor of it in the UK.

23 There is then some subsequent correspondence
24 between Professor Savidge and Mr Williams. I don't
25 think I need to go into it but, again, it just

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1 then saying, "But actually we all agree concentrates
2 are better than cryoprecipitate."

3 Whether Professor Savidge did in fact use
4 cryoprecipitate for home therapy we can't elicit from
5 the documents we've seen. Certainly by 1983 the
6 annual return would suggest he wasn't. But whether he
7 did so in any point between 1979 and 1982 we don't
8 know.

9 **SIR BRIAN LANGSTAFF:** It does say in the sentence towards
10 the top of the page it was agreed that the material,
11 that is, I think -- freeze -- which material was that?

12 **MS RICHARDS:** That was a particular form of freeze-dried
13 cryoprecipitate.

14 **SIR BRIAN LANGSTAFF:** So freeze-dried cryoprecipitate,
15 not --

16 **MS RICHARDS:** Yes, so that a different -- not the
17 conventional cryoprecipitate that we are generally
18 discussing and it's that which, as I understand it,
19 was agreed was not really a suitable product to use
20 for home therapy.

21 **SIR BRIAN LANGSTAFF:** I follow.

22 **MS RICHARDS:** Then certainly my reading of the minutes --
23 but it will be a matter for you, sir -- is that the
24 discussion then goes on to talk about the merits of
25 conventional cryo.

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1 exemplifies the kind of communications that we have
2 seen in relation to other centres.

3 Professor Savidge returned to this in a little
4 more -- or dealt with this issue in some detail in his
5 evidence to the Archer Inquiry.

6 So if we could go back please, Henry, to
7 ARCH0000011, and if we could go to page number 106,
8 probably 107 for you.

9 He talked, first of all, about the role of
10 Haemophilia Centre Directors in relation to purchasing
11 blood products, and we can pick it up at the bottom of
12 the page 106, where Professor Savidge says:

13 "I started in 79 and I inherited, shall we say,
14 a rather low funding level.

15 "THE CHAIRMAN: From where?

16 "A. It was done through the usual mechanism,
17 the Department of Health down to the Regional Health
18 Authority."

19 Then if we pick it up halfway down the page, he
20 says:

21 "... in terms of the product, of which
22 85 per cent of haemophilia costs rest with, one had
23 product availability through two other sources: one
24 was from the Blood Transfusion Organisation that
25 supplied either fresh frozen plasma or

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1 cryoprecipitate, which is a sort of semi-enriched form
2 of plasma, or the Blood Products Laboratory, which at
3 that time was at Elstree and a little bit at Oxford
4 and a little bit here and a little bit there, and what
5 they did, they had an arrangement with the Blood
6 Transfusion Service whereby the Blood Transfusion
7 Service supplied them free of charge -- notionally
8 free of charge rather -- with plasma and
9 cryoprecipitate, this semi-prepared thing, which in
10 return was fractionated into a more purified form of
11 Factor 8 and Factor 9 and albumen, and then returned
12 back, notionally free, to the Blood Transfusion
13 Service for distribution out to the individual
14 district hospitals. So that was the bulk product
15 which was notionally free."

16 So that's Professor Savidge's description of
17 what was available in terms of NHS product, either
18 from the regional transfusion centre or from the
19 fractionation centres. Then he says this:

20 "... because there was always a shortfall and
21 that shortfall went down to perhaps much as
22 60 per cent -- so you only had 40 per cent back on
23 what was sent in, which, in effect, was not enough
24 anyway -- there had to be a source of money to
25 purchase blood products, usually from the

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1 with Elstree, not with RHL, not with Blood
2 Transfusion. So if you had an adventurous pharmacist
3 who wished to negotiate with his charming Americans,
4 that was fine."

5 So just pausing there. Professor Savidge
6 suggesting there was a role in the procurement of
7 commercial products for the hospital pharmacist. Then
8 he says:

9 "If you had, on the other hand an
10 entrepreneurial doctor -- God forbid -- you would find
11 that he might do it, and they had to hand the numbers
12 to make sure there was some form of
13 cost-effectiveness. So one didn't buy in bulk enough
14 for 10 years and realise that, after 6 months, it had
15 all gone out of date."

16 So appearing to recognise there that, however,
17 doctors could effectively have their own direct
18 communications with the pharmaceutical companies for
19 the purchase of products, as we have seen from some of
20 the correspondence.

21 Then he says:

22 "... the local blood transfusion directors
23 within the districts, sometimes would take
24 responsibility for the purchase of it and store it
25 within the hospitals. So it was very much something

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1 United States. So that was where the money came on,
2 through the Regional Health Authority, divided down to
3 districts, and any money that was loosely at
4 a district level went into purchasing that, should it
5 be necessary.

6 "And of course it never was enough because
7 patients always wanted more and there was a general
8 move at that time in the mid-70s to the 80s to
9 actually increase the usage of patients' factor ..."

10 Then if we pick it up over the next page,
11 Professor Savidge was asked some questions about how
12 the material was procured. The question halfway down
13 the page is:

14 "Was that done ..."

15 That is the purchase of commercial products.

16 "... by a direct contract between the centre and
17 the suppliers, or was there bulk purchase, or how was
18 it done?"

19 Professor Savidge's answer was:

20 "It well depended who felt they could possibly
21 get the best deal out of the commercial companies. So
22 you would perhaps have a rather cavalier pharmacist
23 who would negotiate on behalf of the district hospital
24 because it was district money.

25 "The direct contract was with the district, not

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1 which was hit and miss, but invariably, the people who
2 actually did the negotiation were those who notionally
3 took responsibility for the budget ..."

4 If we go to the bottom of the page, he says:

5 "... that was the way the funding at that stage
6 was organised in 1979. There was a central purchasing
7 facility, which I don't know very much about ..."

8 Then he talks halfway down the following page
9 about how he would always estimate twice as much as
10 was needed. Then the Chair asks a question about the
11 use of a central purchasing facility, and he says:

12 "I don't know ... I never needed to use it,
13 because by the time I arrived there, it had been
14 abandoned because it was a bit of a catastrophe. So
15 it was really left up to the individual districts to
16 negotiate with their money, with the individual
17 commercial companies for the amount of product they
18 considered was necessary at a certain price."

19 It's not perhaps an entirely clear picture which
20 emerges from Professor Savidge about the purchasing
21 arrangements, but those are his own words in 2007.

22 We'll come back in a little more detail to what
23 he says further about visits from pharmaceutical
24 companies.

25 The next theme I wanted to make some reference

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to was issues of supply, in particular supply of NHS product, both to St Thomas' directly and in terms of broader concerns about national self-sufficiency.

We can see or we have seen from documents from the 1970s that Professor Ingram repeatedly raised concerns about insufficient supplies of NHS product, and there was reference to that, for example, in that meeting from 1970.

If we look at CBLA0000210, please. This is June 1974. This is a concern about lack of sufficient funds to purchase concentrate being expressed. It's a letter from the Regional Medical Officer to Professor Ingram recording discussions with the Department of Health:

"I have talked to the [department] about your request for further funds to be made available for the purchase of AHG Concentrate for haemophilic surgery. You are right in your statement that the DHSS is unable to grant additional money for 1974/75 onwards, and it is left to the Regional Health Authority to decide whether the development should be underwritten.

"I appreciate your views about the inadequacy of supplies of AHG Concentrate ..."

And the suggestion is that he approaches the area medical officer.

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calculate what is likely to be the total but on the high side. It is still a large some per annum, and we are actively seeking ways to find more money for the central labs, including co-operation of regions. The equation is more complex than at first sight, as you will appreciate."

Then this:

"One real problem is to know the real target for the self-sufficiency the NHS is striving for. Our working target is 50 million units of Factor VIII per annum for England and Wales but, for example, Dr Lane claims this will be much higher. To make realistic and lasting plans, we must have a target. I would value your views on this."

So we can see Professor Ingram's raising essentially two issues: one is funding to enable, if necessary, the purchase of commercial concentrate and consideration there to some form of central funding, and the second is the issue of supply and self-sufficiency.

There's a number of documents which show it; I won't go to most of them. But that was a concern of Professor Ingram's we can see, for example, from a letter he wrote to The Lancet. Henry, could we have HSOC0022702. The first part of this is a bulletin

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We can see it remains a concern, so when we look at DHSC0002191_016, we can see here now a broader concern about funding and availability of concentrate. This is December 1978. It's Dr Waiter at the DHSS to Professor Ingram, and it's clearly in response to a letter from Professor Ingram. It says:

"By coincidence, on the same day as I received copies of your correspondence with Sir Henry Yellowlees [that's the Chief Medical Officer], Dr Buxton passed to me your letter dated 11 December on the subject of NHS production of factor VIII. The point you make about increasing expenditure on NHS manufacture is one which a number of people have made to the department, but as yet no mechanism exists for diverting money which would be spent by health authorities from allocated funds to a central fund for expenditure on the central processing laboratories of the National Blood Transfusion Service. We, in fact, know the total sum spent on Factor VIII from commercial sources as we have in confidence from those firms which sell the material to haemophilia centres or their agents returns giving the information, in terms of units of Factor VIII supplied. Of course, we do not know the negotiated price of the material, but based on the quoted manufacturers' prices, we can

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from The Haemophilia Society in August of 1974 where they say:

"During the past few weeks, there's been a good deal of correspondence in The Lancet which has highlighted how the financial troubles of the NHS were affecting the supplies of materials used for the treatment of haemophilia."

And then reference is made to a letter from Dr Biggs stating that:

"Because of the shortage of material, 90 per cent of haemophilic patients are receiving less than the optimum treatment. Essential but non-urgent operations are being postponed. Delay is arising in putting patients on to home treatment."

Then it said other doctors had written giving their views. We can see that if you go, first of all, to page 5. There's a long letter there from Dr Biggs. We're going to look at that tomorrow in the Oxford presentation, so I won't go into the detail of it now. But if we go over the page, we see the letter of support from Professor Ingram. It's the top left-hand entry, please, Henry:

"Blood fractions for treatment of haemophilia. I write to support Dr Biggs' plea for a realistic supply of blood fractions for treating haemophilia.

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For 20 years, we have been able to make a precise diagnosis. For 10 years, the preparation of appropriate blood fractions has been possible. We know that treatment material is being provided within the Health Service in increasing amounts, but it is still far short of what we need. Until the NHS provision is adequate, it is cruel not to make good the shortfall from large supplies of good commercial material which, as Dr Biggs says, are now available."

Then if we go to the last sentence of the letter:

"Money must be found so that sufficient may be purchased until NHS resources are adequate ..."

So, again, it's a twofold plea from 1974. One is for increased production of NHS material, so self-sufficiency, but the other is for more money to enable haemophilia centres, through whatever precise contractual route, to purchase commercial concentrate --

SIR BRIAN LANGSTAFF: That takes me back to the previous document we looked at, DHSC0002191_016. Can you just go back to that for a moment?

MS RICHARDS: Do you need it again, Henry? DHSC0002191_016.

SIR BRIAN LANGSTAFF: You pointed out there were two

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is a twofold plea. One is in support of self-sufficiency. The other is: until you have self-sufficiency, you need to give us the money so that we can buy commercial concentrates to make up the shortfall. That's 1974. And there are a number of other letters in which, in the course of the '70s, Professor Ingram corresponds with, amongst others, Dr Maycock about specific lack of funding for St Thomas'.

You are right, sir, that this letter in December 1978 is looking at different aspects of funding. In other words, the funding that would need to be made available to build up the infrastructure for increased NHS production, albeit Dr Waiter is suggesting that there might be some form of equation to be done by looking at the funding that is currently spent on commercial concentrates.

SIR BRIAN LANGSTAFF: So the first one, the '74, is: you're not giving us enough. We've got to go and buy it elsewhere. Give us the money. The second is -- to buy it -- the second: is we're not getting enough. Give us more money so that we can make it.

MS RICHARDS: Yes. We've set out in the written presentation -- as I say, I won't go through all the documents -- some of the communications and pleas for

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different matters addressed. One was money for expenditure; the other was self-sufficiency. Might it be that the letter, in fact, was drawing those two together because if one looks at the first few lines, the point you make about increasing expenditure on NHS manufacture is one a number of people have made, but that's talking about manufacture.

"As yet, no mechanism exists for diverting money which would be spent by health authorities for allocated funds to a central fund ..."

Now, that's not for purchase; it's for expenditure on the central processing laboratories of the NBTS.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: So it's talking about funding not for buying but for creating the infrastructure to produce.

MS RICHARDS: It is.

SIR BRIAN LANGSTAFF: That, I think, might be a little different from the emphasis which you have just given from the letter of which Ingram wrote in support of Biggs.

MS RICHARDS: Yes, you are absolutely right, sir. Funding is being raised in slightly different ways in those two letters. So in the 1974 letter to The Lancet, it

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product that Professor Ingram makes to Dr Maycock on a number of occasions.

Turning to Professor Savidge, again perhaps the best source of insight into Professor Savidge's views on the issue of self-sufficiency and NHS production comes from -- in his own words, from his evidence to Archer. If we start with his written evidence. Henry, that is ARCH0002508_002. This was the written statement dated 17 September that Professor Savidge sent to the Archer Inquiry. If we turn to the top of page 3 -- in fact, we can pick it up from the bottom of page 2 because it ties in with the observation that you were making, sir, about that 1978 letter. Picking it up in the last six lines:

"The funding of such projected increased expenditure on product would require central support. That was only forthcoming through the RHAs funding for the allocation to all DGHs [so that's Regional Health Authorities and then District General Hospitals, I think] to disperse to each and every discipline to fund ongoing service and proposed development. Consequently little money, if any, reached hospitals treating haemophilia patients with the proposed requirement for additional replacement therapy."

Then he says this:

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"... and further reliance of any increased product supply was demanded of an inert Blood Transfusion Service and a terminally failing BPL fractionation facility. Thus extra money when found was spent on the purchase of commercial imported Factor VIII concentrate, usually from the US, in preference to the safer cryoprecipitate that was the recommend treatment [probably that's meant to be "recommended" treatment] of children and mild haemophilia patients (assuming failure with DDAVP) generally available (in some regions in excess)."

So we see there (and we'll see it in Professor Savidge's oral evidence) he's fairly scathing about BPL and he's identifying there that the money that is provided ultimately from Central Government was being spent on the commercial concentrates, rather than building up BPL.

Sir, you may be interested in his observation about cryoprecipitate, both that it was safer and that it was the recommended treatment for children and mild haemophilia patients. Of course, we can't tell from that particularly what point in time he's referring to.

If we go on in this same document to the last page, we can see again Professor Savidge doesn't mince

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for the experts in the field felt assured that a potential public health catastrophe was beginning to unfold."

Sir, as Professor Savidge's oral evidence to the Archer Inquiry made clear, he finished this in the middle of the night and he did recognise there were a number of typographical errors in it.

There's obviously an awful lot to unpick thematically in his evidence there: he is critical of the Blood Transfusion Service; he is critical of BPL; he is critical of assumptions about the safety of BPL products; he is critical of the failure to support intensive research into viral inactivation by heat treatment, and to what he says were omissions/failures on the part of the Blood Transfusion Service to do more in relation to safety, for example, by way of donor selection. So there's a whole range of issues that ultimately you'll need to consider, but we see there the kernel of Professor Savidge's views.

SIR BRIAN LANGSTAFF: He puts it in the context of two dates.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: So he is saying that it was quite evident by 1978, one could read this as saying, that he was calling for there to be greater research into

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his words:

"From the events prior to 1979 and between the years 1979 to 1986, decisions regarding blood products for the management of haemophilia were, in my view, prioritised by the financial and political considerations of the Blood Transfusion Services and by the BPL plasma fractionation facility. In terms of factors of relevance to the failure of the Blood Transfusion Services and BPL in effecting self-sufficiency and eliminating plasma product contamination, one must attribute the failures to poor leadership, relying on the assumed safety of BPL's products, and reluctance to endorse intensive research into treat inactivated products ..."

SIR BRIAN LANGSTAFF: That must be "heat".

MS RICHARDS: Heat inactivated products, yes:

"... and inferior reactive management to restructure the Blood Transfusion Service to introduce greater safety aspects with donor selection and improved productivity and efficiency to achieve self-sufficiency. Central financial considerations determined by general healthcare political motives, in my view, led to the eventual lack of political will to spearhead these essential changes that were quite evident by 1978 for hepatitis and 1982 for HIV, which

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heat inactivation in 1978 onwards.

MS RICHARDS: Yes. There's a more detailed discussion of heat inactivation in his oral evidence which I will look at a little later.

There's just one further document where we see Professor Savidge's views on self-sufficiency set out a little more contemporaneously than his Archer evidence. It's CBLA0002399. We can see there it's the minutes of a meeting headed "AIDS, HIV and Haemophilia" held in Manchester in January of 1988. It's said to be a meeting in Manchester of the UK Haemophilia Association. It's a record I think by Dr Lane of BPL. We can just pick it up halfway down the page. There's a range of issues relating to HIV that are discussed but his first observation here:

"Concluding comments made by Dr Savidge were in three areas. 1. The requirement for Factor VIII in UK patients would continue to rise and would always create demand which was ahead of NHS supply. NHS self-sufficiency was therefore a myth and it was important to decide which products should be selected by haemophilia directors for treatment of first-time users of coagulation products."

Now, it may be that what he's doing there is looking the position solely from the perspective of

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1 1988 and he's looking forward from that point in time,
2 because he then talks about his clear preference for
3 "wet pasteurised products for this purpose" and then
4 we see Professor Bloom's preference for NHS 8Y.

5 We can just note at the top of the next page
6 Dr Lane's observation:

7 "Haemophilia directors continue to demonstrate
8 their mixed attitudes towards self-sufficient NHS
9 provision of coagulation factors."

10 So that is, again, a snapshot from 1988 of what
11 was being considered and discussed in relation to
12 self-sufficiency by that time.

13 I note the time. There's quite a long passage
14 from Professor Savidge's oral evidence about heat
15 treatment that we need to look at, but we'll do that
16 after lunch, sir.

17 **SIR BRIAN LANGSTAFF:** Yes. So 2 o'clock.
18 (1.01 pm)

19 (Luncheon Adjournment)

20 (2.00 pm)

21 **MS RICHARDS:** Sir, as we heard from the evidence of
22 Dr Winter, Professor Savidge was instrumental in the
23 arrangement made by Dr Winter, Professor Savidge and
24 two others in 1984 to use heat-treated products on
25 a named patient basis in response to the AIDS crisis.

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1 And they made representations over here to a number of
2 my colleagues, I believe -- there was never really any
3 report that came back about this -- and I would assume
4 that they came here to explain their findings in
5 greater depth because this was available to people who
6 were attending conferences."

7 If we then go on, Henry, to page 129, please.
8 He says at the bottom of the page:

9 "I first started using heat-treated products in
10 '82."

11 So he is suggesting here that he's doing that
12 rather earlier than the initiative then in 1984 with
13 Dr Winter:

14 "I first started using heat-treated products in
15 '82 after going through lots of discussions with the
16 Americans in '81. That was for the first trial, and
17 the second trial was started about '84/'85. For trial
18 purposes, it cost absolutely as much as BPL's
19 product -- namely zero -- but because it was quite
20 clear that in some patients, and it was meant to treat
21 non-A, non-B hepatitis to prevent it. So you had to
22 use naive patients [by which he means either virgin
23 haemophiliacs or PUPs, either of those two unfortunate
24 terms] patients who had not been exposed before
25 because the majority of the data that came out, shall

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1 We can see from Professor Savidge's evidence to
2 the Archer Inquiry that he had a long-standing
3 interest, if I can put it that way, in attempts to
4 heat-treat products. We can pick it up in his oral
5 evidence to the Archer Inquiry. Henry, it's
6 ARCH0000011, please. If we go to page 116, please, in
7 your pagination, Henry.

8 We can pick it up at the bottom of that page
9 where Professor Savidge says this, referring to
10 suspicions about non-A, non-B hepatitis being conveyed
11 through the blood and through large pool products. He
12 says this:

13 "That is the simple reason why 99.9 per cent of
14 producers of commercial Factor VIII and Factor IX in
15 the world then started to invest money in their
16 research and development departments to clean up their
17 blood products. At the end of the '70s, in fact, the
18 first product that was produced to go into patients
19 was produced in Germany in 1978, and they treated
20 I think about 34 patients with it over two years
21 following all the parameters -- because the Germans
22 are quite strict about these things -- following every
23 known parameter, and they demonstrated quite clearly
24 that there was no biochemical evidence of transmission
25 of non-A, non-B hepatitis using a pasteurised product.

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1 we say, one year to one and a half years later, after
2 the trial started, was very encouraging, and it looked
3 as if that particular combination of 38 degrees
4 Celsius for 72 hours was enough.

5 "My view was very much, well, that must be
6 better, even if it costs something, than giving
7 a patient what I know for sure that it is loaded in
8 100 per cent of cases with non-A, non-B hepatitis;
9 namely, the BPL product. So although I never used any
10 BPL products, it all went to the 26 smaller centres in
11 the south-east because they had the first bite of it
12 from the Blood Transfusion Service. I was always left
13 with nothing at the end of the year, so I had to
14 survive on money initially from the district and,
15 subsequently, from top-slicing of the region.

16 "So I knew most of these companies, and it was
17 quite easy to get involved as the trial co-ordinator
18 over here to test out the first products which were
19 heat-treated and available for research. I couldn't
20 get any of the German stuff which I really wanted for
21 the simple reason that, after they came over here in
22 discussion with some doctors and some people in 1981,
23 they were scared away. They never decided to come
24 back. So it was a bit difficult to get any product.
25 I think they had such negative vibes here that they

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1 thought, well, let's stick to France, Belgium, Sweden
2 the US and the rest of the world."

3 Then he goes on to say that:

4 "There was a perception amongst quite a number
5 of haemophilia treaters that the BPL product was
6 safer, relatively safer -- I can't quantify it -- than
7 the American commercial product because there were
8 slightly fewer donors in the large donor pool."

9 He goes on to explain that difference of
10 perception.

11 Then if we go on, please, to page 142, Henry.
12 We pick it up second paragraph. This way -- he says
13 this in simple terms:

14 "Lots of people tried to explain it on other
15 bases, but the most logical thing is the fact that you
16 kill the virus; it is not there. So we felt perfectly
17 justified in going out and completely disobeying the
18 current ethical concepts and everything else, which
19 I was accused -- I was accused of being a charlatan at
20 one stage which I thought was quite nice."

21 Then he says that was definitely a compliment
22 coming from those people.

23 So that's an account in his own words of his
24 interest in heat-treated product really from the late
25 '70s onwards and his involvement in early trials, and

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1 phased out. I'm not prepared to wait and expose my
2 patients to the risk. It's a horrible issue and
3 a horrible dilemma."

4 Then it said -- the journalist said:

5 "Recent evidence suggested that NHS Factor VIII
6 which is not heat-treated might be contaminated.
7 Dr Savidge says, 'One cannot be sure, and from the
8 patients' point of view, it would be better not to use
9 it until one is damn sure it is okay.'"

10 It's not entirely clear how one reconciles that
11 with exactly what he told the Archer Inquiry because
12 this would appear to suggest at the time that he was
13 using commercial Factor VIII, non-heat-treated and
14 some NHS Factor VIII.

15 **SIR BRIAN LANGSTAFF:** I think the date of this is most
16 probably 20 December.

17 **MS RICHARDS:** Yes, maybe.

18 **SIR BRIAN LANGSTAFF:** My reason for saying that is that it
19 was said to be, in some sources, a suggestion that the
20 Yorkshire Post was going to publish an article on
21 13 December, which led to Professor Ludlam in
22 Edinburgh holding a meeting on 19th because he feared
23 or maybe thought that he feared that the press were
24 going to release details the next day.

25 **MS RICHARDS:** Yes, that may well be right, sir.

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1 then his use of the heat-treated product following the
2 trials in 1984, along with Dr Winter and others.

3 There's a further document I should draw your
4 attention to, sir, at PRSE0004577. If we go to the
5 second page, please. This is a newspaper article. We
6 can't date it precisely, but it would seem -- or we
7 haven't currently dated it precisely, but it's
8 probably 1984. And if we look in the bottom -- sorry,
9 the left-hand column to start with, we can see the
10 journalist reporting what he had been told from
11 St Thomas'.

12 "At St Thomas' Hospital, London, which serves
13 haemophiliacs from south-east and south-west Thames
14 area, two patients who received exclusively NHS
15 Factor VIII from Elstree are also carrying the
16 suspected AIDS virus antibodies. The director of the
17 haemophilia centre there, Dr Geoffrey Savidge, said,
18 'It's going to be hell on earth when this comes out.
19 I am dumping all my commercial Factor VIII from the US
20 in favour of heat-treated material. The majority of
21 my patients will be getting it within the next three
22 days. It's more difficult, politically and
23 practically, to dump the NHS Factor VIII because if
24 I did that straight away, the switchover would
25 bankrupt hospitals in the area. It will have to be

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1 **SIR BRIAN LANGSTAFF:** I think that is probably the date.

2 **MS RICHARDS:** It probably is because it ties in with the
3 evidence that we looked at yesterday with Dr Colvin.
4 You will recall there were communications late
5 December/early January 1985, so after the Elstree
6 meeting on 10 December, in which there's an issue
7 about the extent to which there's going to be usage of
8 heat-treated product or usage of existing stock, and
9 reference is made to there being reports in the media.
10 So that date would fit in with all those matters, sir.

11 So that's Dr Savidge, as reported by
12 a journalist, at the end of 1984.

13 **SIR BRIAN LANGSTAFF:** In fact, we have a reference to the
14 Scottish batch which might have produced problems for
15 the NHS in the middle of the second column from the
16 left on the page which is on the screen.

17 **MS RICHARDS:** Yes.

18 **SIR BRIAN LANGSTAFF:** A comment made by Professor Bloom,
19 I think.

20 **MS RICHARDS:** Yes, and reference to the Yorkshire Post as
21 well.

22 **SIR BRIAN LANGSTAFF:** Interestingly, he's quoted as
23 saying:

24 "Regrettable though this is, it does not really
25 constitute a comparable situation with the USA, where

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1 I believe almost every batch of Factor VIII is
2 contaminated."

3 So whatever Professor Bloom's views may have
4 been, they are then reported in rather different terms
5 here.

6 **MS RICHARDS:** Yes.

7 In terms of use of heat-treated product, other
8 than what we have from Professor Savidge in his Archer
9 evidence and obviously what we understand through
10 Dr Winter's evidence, we don't have a huge amount of
11 contemporaneous material otherwise. We do have
12 a document at SHPL0000983_002. This is a January 1983
13 document. It's an internal Travenol Hyland document.
14 We can see the subject is "Hyland therapeutics meeting
15 to discuss regulatory issues 19 January 1983", and the
16 memo itself is dated 27 January 1983. If we go to the
17 bottom of the second page, please, Henry, we can see
18 here reference to a trial at St Thomas' hospital.

19 Under the heading "Hemofil T":

20 "The UK trial at St Thomas' Hospital was
21 discussed. Dr G Savidge is very keen to have product
22 immediately as he has had to treat three of his five
23 initial virgin haemophiliacs with non-treated product
24 [that presumably is non-heat-treated product] so now
25 has only two patients left in the trial. It's

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1 hepatitis. We don't know any more currently than is
2 set out in that document about that particular issue.

3 Sir, we do know that Professor Savidge had
4 a range of interactions with pharmaceutical companies
5 from trials such as this. There are a number of
6 references to him being either an investigator or
7 medical adviser in trials or in product licence
8 applications, and we have documents which demonstrate
9 involvement in relation to Hyate:C, that's the
10 Speywood porcine product, and Hemofil.

11 If we look at BAYP0000024_051, we can see
12 reference to him having had some discussions with
13 a pharmaceutical company rep in relation to Koate HT,
14 and that would perhaps fit in with what we then saw in
15 the document we just looked at. So this is a letter
16 to Dr Savidge thanking him for his hospitality and
17 confirming the prices for the Koate HT heat-treated
18 Factor VIII product and the Konyne heat-treated
19 product. We don't currently know, I think, whether he
20 used the Konyne, but it looks highly likely that he
21 may have used Koate HT at some point.

22 Again, looking at Dr Savidge's oral evidence,
23 Professor Savidge's oral evidence to the
24 Archer Inquiry, he talked in general terms about the
25 relationships between doctors and pharmaceutical

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1 therefore been decided to supply product on a
2 prescription release basis until full clinical trial
3 exemption approval has been received."

4 So we can see there some confirmation of
5 Professor Savidge's involvement in a trial of
6 heat-treated material, as at the beginning of 1983.

7 There is a document then from 1985.
8 BAYP0000007_113. This is rather later on, so this is
9 a memo dated 2 October 1985. It's a
10 Cutter Laboratories document. It's headed "Area
11 report, September 1985", and under the heading "Major
12 happenings, Derby", we can see it says:

13 "Results from a virgin haemophiliac using
14 Profilate HT demonstrate that the patient has raised
15 transaminases ... suggestive of non-A, non-B
16 hepatitis."

17 Reference there is made to Dr Mitchell who was
18 the Haemophilia Centre Director at Derby. Then we
19 just see in brackets:

20 "(It is worth noting that this patient is using
21 a different batch to the one that has caused non-A,
22 non-B hepatitis in three of Dr Savidge's patients.)"

23 So it would appear from that that by 1985,
24 Dr Savidge has been using Profilate HT in some of his
25 patients, three of whom have developed non-A, non-B

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1 companies and it is, I think, worth going to that.

2 Henry, it is again ARCH0000011, please.

3 If we go to -- it should be your page 146,
4 Henry. The question that Professor Savidge was asked
5 is at the top of the page:

6 "What funding did doctors receive from plasma
7 companies? Were any haematologists acting as paid
8 advisers to companies or received incentives with
9 regard to research funding or funding for lectures",
10 et cetera, et cetera.

11 He's asked if he has any comment. This is
12 Professor Savidge's response:

13 "Generally speaking, if one had dealings with
14 a commercial company -- and I have probably had more
15 dealings with commercial companies than most -- the
16 rules are very simple: they pay for everything to do
17 with the research that they expect you to do. That
18 includes patient travel, patient expenditure, how much
19 it costs to photocopy the notes, et cetera, et cetera,
20 what the lab costs cost, and they get a breakdown of
21 each and every cost before you even embark upon
22 signing anything. One is expected, as part and parcel
23 of being involved with a research product for
24 a commercial company, to actually present one's data.
25 You cannot expect 6,000 people to travel halfway

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1 across the world and cram them into St Thomas' dining
2 room. So you have to go where you are requested to go
3 and give a presentation.

4 "You may be offered an honorarium or you may
5 not, but that really covers the fact that you're up
6 until 2.30 doing a report or something similar and you
7 expect perhaps to have at least a few shekels to keep
8 your eyes open. So I think it depends very much upon
9 the individuals of what happens. In my case, I had
10 funds which existed within the hospital and within the
11 trustees, and money was paid directly from those
12 companies into those trust funds. So I actually never
13 saw the money, although I did have the luxury of
14 spending it, as I was the only signatory, but it had
15 to be spent on something which related to the project,
16 whether a staff member or the agents or anything else.

17 "I am aware that there were many colleagues at
18 that time particularly who were working as consultants
19 for commercial companies, and I suppose in a way there
20 were some which were working not necessarily on
21 a remunerative basis for companies such as BPL because
22 BPL required advice, it may well be that perhaps such
23 incentives could be recommendations for this or
24 recommendations for that. I have no idea because
25 I had no dealings with BPL.

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1 a Meeting of the Haemostasis Club will be held ..."

2 Not quite sure what that is, sir.

3 "... the topic being 'Blood Products'.

4 "Dr Zuckerman or Dr Williams, Consultant
5 Hepatologists from Kings will be invited, as will
6 Dr P Kernoff from the Royal Free to talk on Clinical
7 Trials. Eric Preston from Sheffield to talk on Liver
8 Disease, Charles Rizza from Oxford to talk on the
9 NHS 8Y experience and Dr Lane from The Blood Products
10 Laboratory at Elstree to talk on UK self-sufficiency.

11 "The Chairman will be Geoff Savidge from
12 St Thomas' who, together with Drs Kernoff and Preston,
13 are the leading advocates for the 'safer wet heat
14 treated' Alpha factor VIII (Profilate).

15 "I suspect that this could be a very cleverly
16 connived Meeting at the instigation of either these
17 three Clinicians or Alpha themselves to convert all
18 Directors to a product/s which can be shown to have
19 a better track record with regard to the elimination
20 of non-A, non-B hepatitis. It is also, obviously, an
21 attempt to expose the potential mid/long-term problems
22 associated with liver disease in haemophilia, as
23 initially advocated by Hay et al in articles in
24 The Lancet during 1985."

25 Then going to the last paragraph:

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1 "So the answer to your question is: probably
2 yes, depending upon the individual. How much? No
3 idea. Because that is directly proportional to greed
4 more than anything else, and really, you know, these
5 things happen all the time in all walks of life
6 without necessarily being related to medicine or HIV
7 or blood product."

8 So you will see there, sir, he talks about what
9 he says were the arrangements within St Thomas' for
10 money received from pharmaceutical companies. In
11 terms of the more general point he makes about
12 colleagues working as consultants for commercial
13 companies, unfortunately the question isn't asked of
14 him, "Who are you referring to?" And so we're not in
15 a position to know whether there are particular
16 individuals he had in mind, and if so, who they were.

17 There is some evidence to suggest a particularly
18 close relationship between Professor Savidge and
19 Armour. If we look at ARMO0000505_001, please, Henry.

20 This is again an internal memo. It's dated
21 6 March 1986. The subject is "UK Haemophilia Centre
22 Directors Meeting - St Thomas' Hospital ... 17 March",
23 and it said this:

24 "Following the above, at which it is anticipated
25 most, if not all, the UK Directors will be present,

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1 "... I know you will appreciate the vital
2 significance and importance of this meeting to
3 haemophiliacs, clinicians and the Factor VIII
4 producers alike and, in your absence, Robert has
5 agreed to accompany me. I also strongly urge, in most
6 forceful terms, that Bill Terry or Mike Hinda, or
7 somebody from the US, attends this Meeting to hear the
8 story 'from the horse's mouth' and particularly as it
9 relates to our market position in the UK."

10 Then this:

11 "Geoff Savidge has kindly agreed to put
12 questions on our behalf to the Panel and this will be
13 an ideal opportunity to obtain an authoritative
14 opinion from the leaders in the field on any subjects
15 which are of particular interest to us and I would
16 suggest that one or two very carefully constructed
17 questions be discussed between us and put to Geoff in
18 advance."

19 So a potentially revealing insight into
20 relationships between pharmaceutical companies and
21 clinicians and meetings which we don't currently have
22 formal records of, such as this meeting of what is
23 described as the "Haemostasis Club".

24 Sir, I turn to consider, thematically,
25 developing knowledge of risk of hepatitis, in

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particular non-A, non-B hepatitis, at St Thomas'.
 There are a number of references in
 communications from Professor Ingram in the 1970s to
 incidence of jaundice or hepatitis. It's not usually
 clear whether what is being considered is hepatitis B
 or non-A, non-B hepatitis. Often the term is just
 generically "hepatitis". There's some references to
 "post-transfusion hepatitis". Occasionally there's
 a clear reference to "Australia antigen".
 There are communications, by way of example, and
 we've included in our written notes a handful of
 examples, with Dr Maycock, Dr Mayne in Belfast, with
 Treloars, which raise issues either about particular
 batches or particular patients in the context of
 either jaundice or hepatitis or liver function tests.
 If we just look at one meeting from
 September 1975.
 It is OXUH0003735, please, Henry.
 This is a meeting from 18 September 1975. It's
 the meeting of Haemophilia Centre Directors.
 Dr Ingram at that time is the Haemophilia Centre
 Director for St Thomas'.
 If we go please, Henry, to page 4 we can see
 there, towards the top of the page, the heading
 "Progress of the Directors study of Jaundice and

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SIR BRIAN LANGSTAFF: -- four donations.
MS RICHARDS: Yes.
SIR BRIAN LANGSTAFF: So the scale that would indicate --
 and I appreciate that I'm yet to hear a small
 presentation on pool sizes -- that at this time the
 view of the speaker was that NHS concentrate had about
 500 to 750 donations whereas commercial plasma had
 somewhere upward of 8,000 to whatever it was.
MS RICHARDS: Yes, and it's obviously right to note that
 we see references to all sorts of different pool sizes
 in all sorts of different documents, in particular in
 the course of the 1970s, and clearly it will be
 important to achieve as much clarity as possible as to
 what in truth the relative pool sizes were.
 But certainly, here, Professor Ingram's
 understanding is that there is a difference, and it's
 a difference that he, at that time, regarded as
 relevant.
SIR BRIAN LANGSTAFF: It's a very substantial magnitude
 greater.
MS RICHARDS: Yes.
 Still sticking with Professor Ingram and the
 70s, he was a fairly loyal attender of the Centre
 Directors and Reference Centre Directors meetings, and
 so would have been privy to, for example, the reports

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Factor VIII Antibodies".
 There's reference to a paper presented by
 Dr Biggs, and then a full discussion about the
 incidence of hepatitis and the problem of anicteric
 cases.
 Then I just wanted to draw your attention, sir,
 towards the bottom of the page.
 I think I should, in fairness, point out there's
 a discussion about how difficult it can be to
 interpret liver function test results.
 Bottom of the page we see this:
 "The influence on the pool size of material used
 for fractionation was discussed. Prof Ingram said
 that NHS Factor VIII was derived from pools of 500-750
 donations whereas the commercial Factor VIII was often
 derived from pools of 2,000 to 6,000 litres of plasma
 and that the probability of including an infected
 donation was greater with commercial Factor VIII."
 So Professor Ingram there clearly alive to the
 differential pool sizes and its potential
 significance.
SIR BRIAN LANGSTAFF: A donation of plasma would generally
 be, what, half a pint, roughly, and a litre is roughly
 two pints. So a litre is about four times --
MS RICHARDS: Yes.

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that Dr Craske used to produce. We can see an example
 of that at PRSE0002268, please, Henry.
 This is a Haemophilia Centre Directors meeting
 in January of 1977. Professor Ingram is one of the
 listed attendees.
 If we go to page 6, I think it is, Henry. No?
 Page 10 then. That's it, internal pagination 6.
 Thank you.
 We can see at the bottom of the page -- this is
 just an example of a fairly typical occurrence at
 these meetings, under the heading "Study of Hepatitis
 in haemophilic Patients":
 "Dr Craske presented a written report to the
 meeting and outlined the findings ..."
 It refers to a follow-up of the 371 patients
 receiving Hemofil. It says this:
 "Only 1 death was possibly attributable to
 hepatitis B."
 Dr Craske is then suggesting a special study in
 relation to those with Factor VIII antibodies
 receiving large doses of concentrate. Then he says he
 would like to continue a study over the next
 two years, a follow-up of patients who had had
 Hemofil-associated hepatitis, to study the incidence
 of chronic sequelae and a comparison of jaundice

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1 associated with NHS Factor VIII and commercial
2 product. There's an ongoing discussion. Then the
3 question is raised about halfway down the page:

4 "Dr Mibashan asked Dr Craske got clarify how he
5 distinguished between hepatitis B and non-B types and
6 Dr Craske said he looked at each individual case."

7 So a clear awareness there of there being these
8 two, at these times, different forms of blood-borne
9 viral hepatitis, but perhaps not particularly
10 illuminating in terms of advancing the knowledge of
11 the nature of the non-A, non-B hepatitis.

12 Professor Savidge talks again in his evidence to
13 the Archer Inquiry about the developing state of
14 knowledge in relation to non-A, non-B hepatitis.

15 So could we go back to that, please, Henry.
16 Again, it's ARCH0000011, and if we could go, please,
17 to page 115, we can pick it up at the bottom of the
18 page -- sorry, we will pick it up halfway down the
19 page.

20 He's talking about a failure to implement
21 self-sufficiency, which he describes as a mixture of
22 safety and finance. Then he says at line 11:

23 "... it became pretty clear, towards the end of
24 the 70s, that non-A non-B hepatitis, as it was called
25 then, was not merely just a biochemical abnormality

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1 "... perhaps it was a little bit more than
2 inflammation of blood tests.

3 "So I think the majority of responsible
4 physicians and people treating these patients knew by
5 the end of the 70s -- in fact, pretty closely about 78
6 I think tipped it -- that large donor pool
7 concentrates, whether it be for Factor VIII or
8 Factor IX were the cause of non-A, non-B hepatitis.
9 Nobody knew what the agent was but they assumed it was
10 an infective disorder; it came from an infection. And
11 as time moved on, it became proven that that was the
12 case."

13 So there is Professor Savidge identifying
14 those -- what he describes two schools of thought.

15 He picks it up again -- if we go to page 120,
16 please, Henry -- he's asked a question about non-A,
17 non-B hepatitis and he says this at line 10:

18 "The definition of non-A, non-B hepatitis, which
19 was invented in fact by an Italian, to complicate it
20 even worse, was that you would follow certain liver
21 function tests on a regular basis, usually every two
22 weeks, and if those liver function tests exceeded
23 2.5 times the upper limit of normal, on two occasions,
24 with a minimum of six weeks apart, after being exposed
25 for the first time to a large donor pool product, by

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1 that a few chemistry departments picked up. It did
2 have clinical impact, but not in the short-term
3 necessarily, in the longer term, and that all
4 concentrates made from large donor pools had a similar
5 rate of infectivity."

6 There was the 100 per cent on first exposure
7 point, which obviously will need to be looked at in
8 more detail at a later stage. But he then goes on to
9 talk about non-A, non-B hepatitis in these terms:

10 "You had two schools of thought. One school of
11 thought was that this causes problems, and it was
12 backed up by a lot of tissue work biopsies, liver
13 biopsies, which showed progressive liver disease, and
14 then you had another group of individuals, who are
15 quite happy to say that, you know: we just measure it
16 with blood test, and the blood tests stay the same, so
17 we just think it's a little bit of inflammation of
18 blood tests from the liver. So-called transaminitis,
19 which has no clinical connotation and which is merely
20 a figment of a few people's imagination. So, by the
21 time the histology data started come through and by
22 the time children started developing cirrhosis of the
23 liver ..."

24 That may be a reference to that 1980 article
25 that we looked at a couple of weeks ago:

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1 definition you had non-A, non-B hepatitis if you were
2 negative to hepatitis B and hepatitis A and CNV, the
3 other things that can cause problems."

4 Then he says at the bottom of the page
5 essentially it's a diagnosis by exclusion, and says
6 this:

7 "It was pretty effective doing it by exclusion
8 because you got rid of CNV and usually the type of
9 patients we were talking about -- if you were treating
10 children in the way that was recommended with low
11 donor pools, they should not have problems -- at least
12 until they reached 50 bags of cryoprecipitate, they
13 should not have problems with non-A, non-B."

14 Then he goes on to talk about it being
15 a combination of biochemical diagnosis:

16 "If you were lucky but the patient was unlucky,
17 they developed symptoms as well, but those symptoms
18 were highly variable and there was a variable
19 incubation period. So you could have something, shall
20 we say, after two to four to six weeks, which
21 resembled influenza, or, after three months, you could
22 become very jaundiced and very sick, so very, very
23 variable."

24 **SIR BRIAN LANGSTAFF:** So summing that up, he's saying that
25 in some cases you get an acute infection, in other

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1 cases, the way you work out whether it's non-A, non-B
 2 is, first of all, positive material, which -- the
 3 raised liver enzymes, and secondly, the diagnosis of
 4 exclusion: it's not one of the other things.

5 **MS RICHARDS:** Yes.

6 **SIR BRIAN LANGSTAFF:** So what you are left with is: the
 7 only marker, clinically, is the raised liver enzymes.

8 **MS RICHARDS:** That is what he's saying, yes.

9 **SIR BRIAN LANGSTAFF:** Thank you.

10 **MS RICHARDS:** Professor Savidge had attended, once he took
 11 over from Professor Ingram, the meetings of UKHCDO on
 12 a regular basis. At his first meeting that he
 13 attended, which was 20 November 1979, Dr Craske there
 14 spoke on behalf of the Hepatitis Working Party and
 15 talked about non-A, non-B viruses and the possibility
 16 of a relationship with different methods of
 17 fractionation.

18 Again, I'm not going to go to all these
 19 documents, sir. We've seen most or all of them.

20 Professor Savidge attended a second meeting of
 21 Haemophilia Reference Centre Directors in
 22 September 1980, and as really with all the meetings at
 23 this time, non-A, non-B hepatitis was discussed, and
 24 there is information provided by Dr Craske.

25 We know both from documents that we've seen and

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1 There's express reference to the New England Journal
 2 of Medicine editorial from January 1983 and so on.

3 Professor Savidge having attended that meeting
 4 on 24 January 1983 then attends a UKHCDO meeting on
 5 14 February 1983. That's a Reference Centre Directors
 6 meeting.

7 Again, we've looked at that but there's an
 8 update from Professor Bloom who referred to what was
 9 going to be later in the year the Stockholm meeting of
 10 the World Federation of Haemophilia.

11 There's reference to reports from the US
 12 indicating the incidence of AIDS being higher than at
 13 first thought and concern that the haemophiliac
 14 population of the UK who had received American
 15 concentrates might be at risk.

16 Of course, we know from the annual return and
 17 everything else we've read from Professor Savidge that
 18 he was a firm user, even before he switched to
 19 heat treatment, of commercial products rather than
 20 exclusively NHS products.

21 So he's there at that February meeting.

22 Professor Savidge also attended the special
 23 meeting that was held of Reference Centre Directors on
 24 13 May 1983, and that, you will recall, sir, was the
 25 specifically called, not least in light of recent

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1 from the testimony of patients that liver function
 2 tests were being undertaken and presumably analysed in
 3 the way Professor Savidge describes during this
 4 period.

5 In terms of the knowledge, developing knowledge
 6 in relation to HIV, again we can trace
 7 Professor Savidge's attendance at key UKHCDO meetings
 8 through the documents.

9 I'll just refer to some of the key dates, sir,
 10 because these are all documents we've looked at very
 11 recently.

12 So he attended, for example, the Haemophilia
 13 Centre Directors meeting in Manchester on
 14 13 September 1982 in which Dr Craske, having been
 15 asked to look into the report from the States on AIDS,
 16 provides a brief update. That's the meeting where the
 17 records refer to a remote possibility that commercial
 18 blood products had been involved.

19 Professor Savidge also attended that meeting on
 20 24 January 1983 at the London Airport hotel with
 21 Immuno. We've now looked at it on a number of
 22 occasions and, sir, you will recall that there is, in
 23 one of the records of that meeting, what appears to be
 24 a detailed discussion about the "currently available
 25 information" about AIDS cases coming from the States.

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1 publicity in the press, radio and TV, to discuss what
 2 should be done in relation to AIDS. Again, we've
 3 looked at that on a number of occasions, and that's
 4 13 May.

5 We can see from a Haemophilia Society document,
 6 which is at HSOC0029476_024, that this was a meeting
 7 of The Haemophilia Society's executive committee on
 8 12 May -- so it's the day before 13 May special
 9 meeting -- and if we turn to the fourth page, under
 10 the heading "Research grants" -- there's a number of
 11 applications for research grants. This was a fairly
 12 common feature of these meetings at the time -- the
 13 second one refers to:

14 "Dr Savidge, St Thomas', London: This
 15 AIDS-related application had been outlined to the
 16 Council meeting and subsequently referred to the
 17 Medical Advisory Panel. While the application sought
 18 £8,235 for an MLSO and £3,000 for consumables, it was
 19 agreed that, subject to the agreement of groups who
 20 will be written to urgently, that a grant of £8,000 be
 21 made available to enable the MLSO to be employed as
 22 soon as possible and in advance of the next meeting of
 23 the Council."

24 So we don't know what that refers to precisely
 25 but it's clear that there has been, prior to this

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1 date, an application for a research grant submitted by
2 Professor Savidge to The Haemophilia Society which is
3 an AIDS-related application.

4 We know too from documents we've already looked
5 at that Professor Savidge would have been a recipient
6 of that 24 June 1983 communication from
7 Professor Bloom and Rizza, with the recommendations,
8 such they were, about the treatment of children and
9 mildly affected patients and a handful of others.

10 We can also see from the documents that
11 Professor Savidge then attended the Haemophilia Centre
12 Directors meeting on 17 October 1983, and you will
13 recall, sir, that's the meeting at which Dr Chisholm
14 raised the concern about, "Shall we go back to
15 cryoprecipitate?" And that's an idea that's squashed
16 by Professor Bloom it would seem.

17 We don't know from the record of the meeting
18 whether Professor Savidge was one of the directors who
19 was, as it were, in the Dr Chisholm camp, of having
20 ample supplies of cryoprecipitate, but his Archer
21 statement I referred to a while ago, his written
22 statement, suggests that he may possibly have been
23 within that camp, because he talks about
24 cryoprecipitate as being both safer and available.

25 But that's a matter of speculation, sir. The

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1 It may be that's a general comment rather than
2 one particular to his own circumstances because our
3 understanding is, given in particular the evidence we
4 have heard from Dr Winter, that by this time he is
5 treating his patients, and has for some months, with
6 an early heat-treated product.

7 If we go on to the next page, please, Henry,
8 bottom of the next page, we see that:

9 "Dr Savidge suggested that a task group be set
10 up to look specifically at the AIDS problem in
11 relation to haemophilia. The Chairman agreed that the
12 Reference Centre Directors would consider this."

13 That would appear to be the suggestion which led
14 to the establishment of UKHCDO's AIDS group, which
15 then met for the first time in January of 1985.

16 If we then go on, Henry, another -- to your
17 page 9, Henry, I think. We can see halfway down the
18 page:

19 "Dr Savidge raised the problem of treatment for
20 haemophiliacs who had only received NHS product.
21 Until NHS [heat-treated] material was available, the
22 alternatives were commercial [heat-treated] or
23 non-[heat-treated] NHS material."

24 So he's flagging up there a particular dilemma.

25 "Options varied as to whether non-[heat-treated]

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1 minutes don't identify which directors were recorded
2 as expressing a similar view to Dr Chisholm.

3 We know then, if we move forward to
4 December 1984, that Professor Savidge attended the
5 meeting at Elstree Reference Centre Directors. We
6 will look at that just to see his interventions in the
7 meeting.

8 So if we go to HCDO0000394_117.

9 We can see here the list of attendees which
10 include, down towards the bottom, Dr Savidge. Again,
11 sir, we've looked at this on a number of occasions,
12 but I'll just flag up, therefore, some of Dr Savidge's
13 particular interventions.

14 If we go to bottom of page 4, please, we can see
15 under the heading "Factor VIII Concentrates":

16 "It was agreed that HT [so heat-treated]
17 products should be given to all products, if freely
18 available, to include those found to be antibody
19 [positive]. In the case of antibody [negative]
20 patients, it was agreed that from now on, treatment
21 must be with HT material."

22 Then we see the observation from Dr Savidge at
23 the top of the next page:

24 "... this has and would continue to create
25 severe financial problems for treatment centres."

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1 NHS product would be used. The Chairman suggested
2 that it be left to individual treatment centres to
3 determine their policy."

4 Then if we go over to the next page we see the
5 final minuted intervention from Dr Savidge. It's
6 towards the bottom of the page above the heading
7 "Handling of HTLV-III positive samples".

8 "On the question of finance, Dr Savidge
9 suggested that a case be put to the DHSS for financial
10 support by representatives of the Haemophilia
11 Directors Organisation. Any recommendations for
12 treatment would need to be supported by
13 recommendations for financial support. The Chairman
14 advised that the case for more money had already been
15 put to the DHSS."

16 So that's the individual interventions of
17 Professor Savidge at that particular meeting.

18 You'll no doubt draw your own conclusions as to
19 what Professor Savidge did know or ought to have known
20 about the developing picture in relation to the risk
21 of HIV and AIDS.

22 We can look at what he said to the
23 Archer Inquiry in that respect, perhaps most usefully
24 in his written statement to the Archer Inquiry.
25 That's ARCH0002508_002.

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We can see -- if we go to page 6, please, Henry -- he gives here quite a detailed account at least of how it was being looked at by UKHCDO and what publications there were.

So he says:

"Under the leadership of Dr Craske who was in charge initially of the Hepatitis Working Party and subsequently the AIDS Working Party, initially a waiting brief was introduced ... throughout 1981 through to July 1982 AIDS related disorders were reported exclusively among homosexual men in the US."

Then he refers to the MMWR from 1982. He refers to the November 1982 US Haemophilia Foundation deliberations. He refers to various press reports in early 1983, and to recommendations that were emanating from the States, including the use of cryoprecipitate in all young -- 4 years, or under 4 years old children -- newly identified previously treated patients and clinically mild and infrequently treated patients, and recommendations for the expanded use of DDAVP.

He refers to recommendations about reassessing surgical procedures and delaying surgical procedures. Then it says this, as it were, by comparison with the States:

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to the benefit of the reactive UK haemophilia treaters, by comparing the apparent favourable AIDS incidence in patients receiving products made from domestic or US-imported products with the incidence when product made in 1983 was reportedly given."

Then he talks about key reports in May 1983, referring to a Lancet report of a child. Whether he's referring to a later report --

SIR BRIAN LANGSTAFF: That's the San Francisco baby?

MS RICHARDS: Yes, which was reported rather earlier than May 1983 --

SIR BRIAN LANGSTAFF: It was, I think, picked in The Lancet later in the year.

MS RICHARDS: Yes.

"This illustrates [he says] that AIDS is a transmissible agent in the transfused blood that was not another identifiable virus."

He refers to a report in Science journal, and so on. If we go further down the page, we see he's then referring to decisions taken in the United States. He says this at the bottom of the page:

"At this time and with increasing reports of AIDS antibody negativity associated with heat-treated product therapy, one can question why such extensive delays were incurring in the UK to licence these

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"No such recommendations were made by the UKHCDO until June 1983, although cryoprecipitate has been in surplus for some years ..."

That would suggest he may have been associating himself with the Dr Chisholm school of thought about the availability of cryo.

"... and BPL was showing it usual predictably low output of concentrate. US Health Officials recommended the introduction of surrogate testing in blood donors and exclusion of high risk groups (February 1983)."

That may be a reference to the FDA in March. Then he says this:

"It was quite clear by late 1982 that there was concern that high-risk donors were infecting the large plasma pools used to fractionate concentrates, and voluntary exclusion of donors was recommended."

He refers to various actions by commercial companies and then says that:

"During 1983 there was a plethora of reports in the literature on Haemophilia and various aspects of AIDS and immune suppression."

It says this -- it's not entirely clear what articles he referring to. He describes The Lancet as: "... confusing the issue considerably, clearly

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products. Would recommend abandonment of untreated sources of Factor VIII concentrate."

So although it's not -- the sentence isn't entirely clear, it seems to be a criticism of delays in bringing forward the availability of a heat-treated product.

SIR BRIAN LANGSTAFF: If you go back to the previous page.

MS RICHARDS: He refers to the FDA's licensing in the States.

SIR BRIAN LANGSTAFF: Yes, and it was the sentence before that:

"... that led in February in the US to conclude that heat-treated Factor VIII from homosexual-excluded donors would be available first in March/April '83."

And, in fact, that may deal with donor selection -- who could give plasma -- and:

"In fact, the FDA issued full licences to these heat-treated products in late '83/early '84."

So it's saying that, in the States, heat-treated product was available in late '83.

MS RICHARDS: He's drawing, I think it's fair to say, an unfavourable or unflattering comparison between the progress and speed of response in the States and that in United Kingdom.

We then see his criticisms continuing in the

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following paragraph. If we go to the next page, please, Henry, where he says:

"During the years 1983 to 1985, the UKHCDO received little, if any, information concerning haemophilia treatment from the representative Professor Bloom regarding information from other more influential committees but recommended in December 1984, [that's the document we've just looked at, or the minutes we've just looked at] some 14 months after the US recommendations on cryoprecipitate and three months after MASAC declared the overall use of heat-treated products for haemophilia, that heat-treated Factor VIII concentrate should be used, with the caveat that NHS untreated product would be the second choice if treated products were unavailable."

Then his criticism becomes very clear:

"This could hardly be termed expedient and to some extent preserved the political and financial future of BPL."

Then he goes on to observe that:

"Not until June 1985 that Professor Bloom, on behalf of UKHCDO and the BMJ, recommended the use of heat-treated Factor VIII."

So one can see there both what he says about the

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contemporaneous documents, very much information about how St Thomas' or Professor Savidge organised the care and treatment, either of those diagnosed with HIV, or, in the early 1990s, the care and treatment of those diagnosed with hepatitis C. So, sir, your best guide to that is likely to be to go back to the individual witness statements of those who were treated at St Thomas'. The themes that arise from those are the familiar themes that we have seen from evidence relating to the experience of patients in other centres, not being given advice or warnings of risks of non-A, non-B hepatitis, not being given advice or warnings of risks associated with HIV, being tested then for HIV without the patients' knowledge.

There were some or various examples of patients describing the way in which news of their HIV diagnosis was conveyed to them. There's a particularly vivid account by one patient of Professor Savidge putting his feet on the desk, lighting a cigarette and saying, "You're HIV positive," or words to that effect.

The same picture emerges, or a similar picture emerges, in relation to diagnosis of hepatitis C. Again, there are patient statements which describe patients not being told that they were being tested

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state of knowledge, and there's no suggestion from him that this is anything he personally was unaware of, and then his criticism of a delayed response in the United Kingdom, including on behalf of UKHCDO.

So that's the evidence that we have currently in relation to Professor Savidge's participation in and knowledge of decision-making in relation to HIV. I'll come back to summarise what we have gleaned from the patient evidence on these issues at the end.

Professor Savidge was obviously still in post during the growing sense of concern about vCJD in the 1990s. We detailed in our written note his attendance at a range of UKHCDO meetings which map out how this matter is being considered, the question of vCJD, and what the response should be in terms of the provision of information to patients. There is nothing in particular that suggests that Professor Savidge was particularly instrumental in shaping that response -- he's a faithful attendee at most of the meetings -- and the evidence suggests that the -- effectively, the standard form notifications to patients in relation to vCJD which we've seen from other haemophilia centres were probably the materials used at St Thomas' to notify patients of the position in relation to vCJD.

We don't have in the documents, the

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for hepatitis C, there are statements which are critical of the way in which then the positive diagnosis was communicated, and there are concerns expressed about delays in the communication of that diagnosis.

I'm not going to deal with any individual statements by name, not least because many of those are still in the process of needing to go through the stages of redaction and, in certain cases, anonymisation that would be needed before the material could be disclosed. But the picture that we see from St Thomas' is really remarkably similar to the picture that emerges from patients describing their experiences in other centres.

There is some evidence in a meeting of the UKHCDO's AIDS group of a recognition by Professor Savidge of a need for there to be counselling. There is also some evidence that the centre at St Thomas' employed a psychologist at some stage, but it's unclear from the materials we have seen whether that was a full-time post, whether it was a bespoke post for those with bleeding disorders or those who had been infected, and it's not been possible to determine at the moment exactly when that psychologist was appointed. It looks as though it

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might have been the late 1990s or the early 2000s, and it's not clear how long that post remained.

There are accounts from individuals, some who said that they did receive psychological support and assistance at St Thomas', and others who describe a very different experience.

I am going to come to consider Professor Savidge's involvement in research. It may be -- I'm fairly comfortably going to finish the presentation today, so it may be that's a convenient point at which to take a break now, perhaps for half an hour, and then pick it up at 3.30 and I can complete the presentation then.

SIR BRIAN LANGSTAFF: Let us do that then, 3.30, and we will conclude -- do you have a rough time so that people know what their plans might be?

MS RICHARDS: No, I would expect we would be finished by 4.15, sir.

SIR BRIAN LANGSTAFF: So no later than 4.30 probably.
(3.02 pm)

(A short break)

(3.30 pm)

MS RICHARDS: Sir, as we have seen from material already, Professor Savidge was closely involved in clinical trials and studies in various research products. By

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Dr Colvin yesterday, and Professor Savidge.

We can -- perhaps if we go to the next page, Henry, under the heading "Patients and method", we can see that:

"Five different lots of a heated Factor VIII concentrate -- Hemofil T -- were used in this study. Each lot was made from pooled plasma collected in 1982, 1983 and 1984 from approximately 5,000 North American plasmapheresis donors."

Then under the heading "Patients":

"Haemophilia centres in Milan, Heidelberg, London and Paris enrolled patients who needed treatment with Factor VIII concentrate. Only patients highly susceptible to post-transfusion hepatitis were considered, i.e. those who had never received blood or blood products [so previously untreated patients]."

Then there were various other criteria for inclusion. Then we're told that:

"21 patients with severe, moderate or mild haemophilia A met these criteria and gave their written informed consent."

We don't have the underlying documents relating to the trial, but that's the report that they gave written informed consent.

We can see under the heading "Results" that:

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way of further examples, there are two I'll mention and then a couple that we'll look at the documents.

There is a reference in a document authored by Dr Rizza which suggests that, in 1983, Professor Savidge was carrying out what's described as virological studies on patients treated with suspect batches of Factor VIII concentrate. Then, to illustrate the width of the work that Professor Savidge was undertaking, he appears to have been involved in encouraging colleagues and himself to enter patients into a trial on AZT later on in the course of the 1980s.

Obviously, a particular area of interest to him was the impact of the use of heat-treated concentrates, and there are two papers published in The Lancet in 1985 which show some of the work that he was undertaking in that respect. There's range of different references for them, so I'm not sure what version Henry has.

Henry, could we try PRSE0001848, please. Excellent. That's the one. That's The Lancet, July 1985, and we can see it's entitled "Transmission of non-A, non-B hepatitis by heat-treated Factor VIII concentrate". There are a number of authors, including Professor Mannucci, who was referred to by

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"21 patients were included. 13 were followed up regularly, 7 missed some critical visits, 1 was followed up and then defaulted."

Then if we go to the next page under the heading "Discussion", we can see:

"The primary purpose of the study was to assess whether hepatitis could be transmitted by heat-treated Factor VIII concentrate. The enrolment of only patients previously untreated with blood or blood products is of critical importance for the accurate assessment of post-transfusion hepatitis. Our decision to select only first-exposure patients meant that only a small number of patients with haemophilia A could be recruited."

Then we can perhaps just go to the concluding paragraph on the right-hand column:

"Our finding that non-A, non-B hepatitis is transmitted by a heated concentrate [so that was the outcome] should not be taken as evidence that heat treatment is equally ineffective for other viral agents ..." and then reference made to AIDS.

So that's one example of one of the studies that Professor Savidge was involved with and, clearly, some patients under his care it would seem, previously untreated patients, were provided with this particular

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heat-treated concentrate for the purposes of the study.

We can then see at it should be RLIT0000186, Henry. This is a further study reported in The Lancet of September 1985 headed "Wet heating for safer Factor VIII concentrate". It's authored by Dr Kernoff, Dr Miller, Professor Savidge, Dr Machin, Dr Dewar and Professor Preston. We can see there this is said -- it's a letter to The Lancet on this occasion:

"After a first exposure to large donor pool unheated Factor VIII concentrates of either commercial or volunteer NHS origin, acute non-A, non-B hepatitis is a virtual certainty, implying the invariable contamination of these products. Although heat treatment probably eliminates the risk of HTLV-III transmission, the most commonly used heating process [we see there it's a form of dry heating] seems to have little or no effect in reducing the risk of non-A, non-B hepatitis. Such infections may have serious long-term consequences.

"Preliminary response results for a prospective multi-centre clinical study indicate that wet heating is more effective in reducing the risk of post-transfusion non-A, non-B hepatitis."

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4."

Details of that are given, and it says that they are examining the reasons. There's a suggestion, no more than that at that stage of the study, that the product carries a lesser overall risk of non-A, non-B transmission than either unheated or dry-heated concentrates.

So those are two the particular pieces of work that Professor Savidge was involved in, in terms of research, by 1985.

He published later in 1987 a further article in the British Journal of Haematology about the reduced risk of non-A, non-B hepatitis after first exposure to wet-heated Factor VIII concentrate. So a follow-up.

Obviously, we have seen references to some of the earlier research that he was involved in, in the earlier part of the '80s, in terms of the earlier heat-treated products.

We do see that -- when we get to the early 1990s, we see Professor Savidge raising concerns about patient consent and the use of patient data, and that emerges in a letter he wrote to the Oxford Haemophilia Centre. It's OXUH0002131_007. It's to the clinical nurse specialist at the Oxford Haemophilia Centre, and it's a response to correspondence concerning an 8Y

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We can see there that this is concerned with a different product:

"Profilate heat treated, prepared by Alpha, prepared from American commercial plasma pools (5,000 to 32,000 donors per batch)."

They refer to the study protocol:

"Patients admitted have never previously received Factor VIII concentrate, although they may have been treated with other blood products."

Then it describes the taking of serial blood samples:

"18 patients have been admitted to the study so far. They've been followed up for 42 weeks. All but one, an Italian, were treated in England."

We're told:

"11 had no prior exposure to any blood product. 7 had previously blood, plasma or cryoprecipitate, up to a maximum of 56 donor units. Nine different batches of Profilate have been used, only one patient having been exposed to more than one batch. Total dosage has varied considerably. None of the patients have shown serological evidence of acute infection with hepatitis A, B, cytomegalovirus, Epstein Barr virus. They're all seronegative for HTLV-III. However, acute non-A, non-B hepatitis has developed in

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study. He says this, as that 28 February 1990:

"I have some reservations concerning sending you samples for hepatitis C, particularly in view of possible litigation and the ethics of the clinical trial. I feel that before one can take such samples, one should secure a revised clinical trial protocol which should be cleared by the local ethical committee, and a patient consent form should be prepared. A further issue involves what we tell the patient/parents regarding the test and the interpretation of the results we receive. As you can see, this whole area raises a number of issues which have to be resolved now and if not could lead to embarrassment at a later stage."

He expresses the hope that Mrs Fletcher will be able to discuss these matters with Dr Rizza.

So, again, we haven't at the moment been able to track through further correspondence to get a full sense of what this issue went to, but it is here in 1990 an expression of concern about the importance of appropriate ethical committee approval for and patient consent. How it's resolved with, or if it was resolved, we're yet to ascertain.

The issue of consent in relation to either the holding or the sharing of patient data is something

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which became, in the years that followed, an area of some dispute between Professor Savidge and others within UKHCDO. I'll just give a couple of examples. There's a whole chain of correspondence and communications at meetings. But we can see if we look at HCDO0000266_046 that we're getting here to the early 2000s. So this is December 2002, and it's a letter from Professor Savidge to Dr Hay headed "Data protection issues and the UKHCDO". There's something of a back story to this when one looks at the UKHCDO minutes. But we can see in the second paragraph, he is essentially saying he hasn't agreed to submit data to UKHCDO, and he records his views on data protection issues being well known to most of the audience at the meeting -- that's to his fellow directors -- and little would have been, he says, gained by reiterating the obvious.

We get a sense of what the underlying issue was if we look at correspondence that Professor Savidge had with Professor Hill who was the then Chair of UKHCDO. Henry, it's HCDO0000266_126. And, again, for present purposes, I think I can just look at the third paragraph where he says this:

"As you know, I have for many years withheld sending data to the UKHCDO due to the fact that

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resolved, so we'll just look at that. HCDO0000002_032. This is a letter from St Thomas' -- Guy's and St Thomas' medical director and Caldicott guardian. It's copied to Professor Savidge. It's headed "Request for immediate submission of patient identifiable data to the National Haemophilia Database".

Pausing there, so we're not talking about de-identified data but identifiable data.

The second paragraph says:

"The Trust is eager to assist the [National Haemophilia Database] in its important work. However, you will understand our concern that we are being asked to disclose confidential patient data without either the permission of patients or a clear assurance that the relevant regulations are being complied with."

I won't go on to deal with the rest of the letter and, sir, it's not a legal issue that you will necessarily need to resolve but clearly, thematically, the question of patient consent is one which manifests itself over the years in a number of different ways and this is one such manifestation.

Dealing more broadly with Professor Savidge's involvement with UKHCDO, as I've already indicated he

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personal data has been used in manual systems. No patient consent has been obtained, and no mandate from the Department of Health to the UKHCDO to collect this data has been made available. To that end, in 1998 when the data protection act came into force, I informed my Chief Executive of the Trust in writing that, as data controller, I considered the legal risk to the Trust of supplying these data to the UKHCDO as unacceptably high."

Sir, you will have seen, and we looked at a couple of examples with Dr Colvin yesterday -- it was undoubtedly standard practice throughout the 1980s, and indeed earlier in the 1970s, for information about individual patients to be sent, first of all, to Oxford and then, when the National Haemophilia Database was established in Manchester, to Manchester. An issue which is a recurrent theme at a number of UKHCDO meetings is this issue that we see being ventilated here by Professor Savidge, whether that was a matter that required patient consent, and if so, whether that patient consent had been obtained.

I won't go through the detail of the backwards and forwards of the communications and correspondence and in meetings, but as at 2006, we can see that, at least from St Thomas' perspective, the issues are not

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was confirmed as a Reference Centre Director and attended in that capacity from October 1979, and he was certainly at most of the Reference Centre Director meetings throughout the 1980s. He held a number of positions within UKHCDO on committees or working groups.

Again, it is clear from the material that we've seen that he is, on a number of occasions, at odds with his fellow directors on a range of issues.

For your purposes, sir, what may be most useful to observe is his description of how UKHCDO operated in those critical early years of the 1980s. For that, we need to go back to his evidence to the Archer Inquiry.

Henry, that's ARCH0000011. If we go, please, to -- it's page 134, Henry. Earlier than that. Can we go to page 132.

So he says this:

"I talk about the UKHCDO in considerable depth ..."

That a reference to his written statement:

"... about its composition, its function.

Essentially, I compared it more or less with a club, rather than a formal organisation, because it really didn't have any affiliations with any of the learned

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societies, or with the Royal Colleges, it was not part of the NHS. It was not even funded by the NHS. It was there, really, as -- I tried to think of it as best I put in legal terms. So I came up with this concept of 'Unincorporated Association of Interested Haemophilia Physicians', that was about the closest I could get because its legal status was plus/minus zero.

"I think quite a lot of the information -- there was a lot of information that was fed back as and when required on an *ad hoc* basis on a number of instances."

Presumably, he is talking there about information sharing from Reference Centre Directors more widely, and then he goes on to talk about another issue. So if we turn over the page, Henry, to your page 134, we can pick it up at the bottom of the page. He's prompted:

"You were talking about UKHCDO."

And he says:

"Yes."

"As I say, there were really 10 main players ..."

Of course he was one such player, in the sense he was a Reference Centre Director from '79 onwards:

"... and those players were those centres that

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Then, if we go down towards the bottom of that page, he says -- and it's unclear here whether he's talking simply here about UKHCDO or more generally about the medical profession, he says:

"... I think that there should have been far more stringent and dominant leadership from the doctors' side than had currently existed. It was very much, 'Let us cobble together some sort of compromise so everybody is happy', which was fine if you are not playing around with a lethal disease."

Then Lord Archer puts to him a suggestion that patients were simply listening to doctors and he says this:

"... I ... think that it is asking a little bit too much to put the responsibility on to the patients' backs and say that they insisted, because they were advised, or they should have been advised."

Then he goes back to talking about UKHCDO at the bottom of the page:

"We have little feedback as a member of the UKHCDO from any other committees ..."

It may be he is talking there about committees such as the Committee on Safety of Medicines or other national committees.

"... particularly the more influential

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were considered to be the largest and the most influential. I am not necessarily talking about influential at a district level or even at a regional level, but mostly at a national level.

"It was not, shall we say, very much sort of the type of meeting where one could discuss things. It was really information exchange. They set up their own working parties, they presented -- in fact I headed up a few working parties and one did bits and pieces, but, really, at the end of the day, it didn't make much of a contribution because it was very difficult to get anything published that had UKHCDO on it, because invariably it was going to be statistical, it was not really going to influence any form of general medical people."

Then, skipping over a couple of lines, he says:

"It was very much sort of a DIY job; let us keep the smaller haemophilia centres, which are made up 80/90 per cent of the body, with information about what currently is being done nationally on a national basis."

"In terms of the type of things relating to blood product safety, some concerns about that with the general people, but normally they followed what came from the top."

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committees, because there was unofficially -- there was an arrangement of an unofficial delegation whereby the chairman ..."

And this here is Professor Bloom.

"... who sat on all these committees and was so busy changing hats throughout the course of the day from one committee to another, he was really informally delegated to be a representative to explain the feelings of the UKHCDO, or his interpretation of the feelings of the UKHCDO, which we never found out about because we never saw any meetings back, and we had very few reports back about what actually what he said, what they answered and what actions were taken. We had no idea."

"So in fact we were functioning more in a sort of information-fed vacuum. And for my purpose, I have a problem with that."

And then he goes on to talk about his own decision:

"That is why I decided to do -- go the heat-treated way much earlier -- about two or three years earlier than anybody else, because I was not prepared to wait around for somebody to tell me that it would be better to use a Crown immune, approved product that I knew was contaminated in preference to

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1 a product that I knew had gone through formal FDA-type
2 testing [et cetera, et cetera]. So we swung into that
3 much earlier, to the concern of lots of people."

4 So that's Professor Savidge's take on how UKHCDO
5 operated, and in particular the role of its Chairman
6 and his relationship with all these other committees
7 in what was obviously a key period.

8 Sir, Professor Savidge had some involvement with
9 The Haemophilia Society. His predecessor
10 Professor Ingram had been probably a more key player
11 within The Haemophilia Society from the records we've
12 seen.

13 Professor Savidge from time to time was awarded
14 research grants, we saw one example, from The
15 Haemophilia Society, and applied for and obtained
16 donations or assistance with funds from The
17 Haemophilia Society. He also spoke at Haemophilia
18 Society events, attended The Haemophilia Society
19 annual conference, but there doesn't appear to be
20 quite the same level of involvement in terms of
21 influencing Haemophilia Society publications or
22 positions as we've seen, at least so far, with
23 Professor Bloom, and we may see with other clinicians.

24 There is also some evidence in the documents of
25 Professor Savidge having patients who were attending

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1 There is a reference to litigation at the bottom
2 of the page, and I should say this is a meeting at
3 which members -- someone on behalf of Doctors Defence
4 Union attended, and it's Dr Savidge who, at the bottom
5 of the page:

6 "... [raises a] point that one member of the
7 AIDS Group was acting as an expert on behalf of the
8 Plaintiffs and wondered whether it was acceptable for
9 him to take part in the Group's discussions on
10 Litigation and the Defence of the main statement of
11 Claim."

12 That was a reference to Dr Aronstam.

13 There is thereafter a discussion about -- which
14 reveals that a number of different members of the
15 group are involved in one form or another in relation
16 to parts of the HIV litigation.

17 There is a reference, again if we go to the next
18 page, please, in the second paragraph this is said:

19 "With regard to Health Authorities' Defence to
20 the Re-amended Statement of Claim Dr Savidge said that
21 he had been using heat-treated Factor VIII as early as
22 1983."

23 We've seen it may even have been late 1982 in
24 terms of early trials.

25 "... and he was trying to get the Defence's

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1 Treloars school, and there is correspondence between
2 Professor Savidge and patients of his at Treloars.

3 Again, it's typical of some of the
4 communications that we've seen in relation to other
5 centres and of what -- I think it was Dr Colvin --
6 described as "shared care", so that there are --
7 a patient at Treloars who will be receiving care under
8 Dr Aronstam or Dr Wassef during term time and then
9 reverting back to the care of the haemophilia centre
10 in the school holidays.

11 In terms of participation in litigation,
12 Professor Savidge's evidence to the Archer Inquiry as
13 to the extent to which he had a role in any of the big
14 pieces of litigation, is -- his answers are unclear.
15 But we can see from one HCDO meeting some of the
16 issues that arose in relation to the HIV litigation
17 from his perspective.

18 It's HCDO0000271_014.

19 If we go to the next page, please, these are the
20 minutes of a meeting of the AIDS Group of Haemophilia
21 Centre Directors in February 1990. You will have seen
22 that it was Dr Savidge who suggested, or seemingly
23 suggested, that there should be an AIDS group of some
24 of kind in that December '84 meeting and he sat on the
25 AIDS group thereafter.

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1 Statement amended as it said heat-treated Factor VIII
2 was not used until the end of 1984."

3 We've not, sir, been able to unearth any more
4 detailed involvement on Professor Savidge's part in
5 the HIV litigation beyond what we see described in
6 this meeting. We don't have, for example, the
7 equivalent of the litigation report that we have from
8 Professor Bloom or the report that we have from
9 Dr Rizza, which we'll be looking at tomorrow during
10 the Oxford presentation.

11 **SIR BRIAN LANGSTAFF:** Dr -- Professor Bloom, I should say,
12 his involvement was as an expert witness.

13 **MS RICHARDS:** Yes.

14 **SIR BRIAN LANGSTAFF:** If what Dr Savidge wished to
15 contribute was that he had been using heat-treated
16 Factor VIII, that makes him, if anything, a factual
17 witness.

18 **MS RICHARDS:** Yes.

19 **SIR BRIAN LANGSTAFF:** There may be a difference in how the
20 two are supposed to relate. After all, experts are
21 not supposed to be on any side at all.

22 **MS RICHARDS:** Sir, that's obviously absolutely right. We
23 may see tomorrow with Dr Rizza that that distinction
24 wasn't always easy to maintain because there were
25 doctors, who were being asked to act as experts, who

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had obviously had direct decision-making roles in relation to the very decisions that were the subject of the litigation. Indeed, we can see that from the discussion here. It's said that Dr Aronstam was acting as an expert on behalf of the plaintiffs. Then there's reference to there being litigation in the Wessex region. Then there's reference to Dr Jones or one of the doctors acting for the plaintiffs in Scotland but, of course, there was litigation against the Newcastle health authority going on in England.

So the position in terms of roles in litigation for these doctors was, I think at best, a pretty muddled one.

SIR BRIAN LANGSTAFF: There may be -- I don't know enough to say definitively -- but there may be a conflict of interest somewhere.

MS RICHARDS: Yes, that's possible.

SIR BRIAN LANGSTAFF: What would matter then would be -- and it's entirely not for me -- was whether that was disclosed in the litigation.

MS RICHARDS: Yes. The matter that may be for you is the use you put or what you make of the reports that were produced by some doctors: so we have, for example, obviously Professor Bloom's report; there is a report from Dr Rizza that we'll look at tomorrow; there's

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very short clips from a 1985 documentary. It is the 1985 Bad Blood documentary (it's a World in Action documentary, I think) and we have three very short clips which are interviews with Professor Savidge during that documentary. So I will just play those and then make a couple of observations. Henry, could we have those three clips.

(Clips from Bad Blood documentary played)

Sir, those are the three short clips that we have of Professor Savidge talking on the documentary in 1985. Just two short observations from me in relation to the first and the third clip. In the first clip, you will see he clearly regarded the ability to treat with concentrates as important and you may wish to consider whether the question he was there contemplating was the stark question of treatment or no treatment, rather than the question of whether there could have been modified or different forms of treatment.

In relation to the third clip, you will see there his observations about the role for commercial material and essentially the issue of self-sufficiency and there being an insufficient supply of NHS material appears to be what he is alluding to in the third clip. That's all we have from that documentary from

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a detailed document that was prepared by Dr Peter Jones that we will look at some point during the course of this tranche of hearings, and you may wish to consider when you look at those materials the capacity in which the author was providing them.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: But we don't have very much more from Professor Savidge in terms of his involvement than what we've been able to piece together from this.

Those are the documents I wanted to show you in relation to Professor Savidge and St Thomas'. As I say, there's a lot that doesn't emerge from the documentation, in particular in terms of information provision to patients about risks; how and when the testing for both HIV and hepatitis C was undertaken; what information was given and how to patients about testing, about diagnosis, about treatment, and those are gaps that you will need to fill undoubtedly through looking at the individual witness statements from patients who were treated at St Thomas' and such information as you can glean from their narratives and from the medical records that they produce. It's an incomplete jigsaw, clearly, in terms of the picture that the contemporaneous documents show us.

The last thing, therefore, is just to play three

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Professor Savidge.

Sir, that's the material in relation to St Thomas'.

SIR BRIAN LANGSTAFF: Yes. Well, thank you very much.

That concludes the work today -- I said work, I mean the session today. The work continues for all of us. But what do we have tomorrow?

MS RICHARDS: Tomorrow, sir, we have the presentation on Oxford Haemophilia Centre.

SIR BRIAN LANGSTAFF: Do you have any sense when you might be likely to conclude that?

MS RICHARDS: My sense, sir, is that it's likely to take most of the day but ought to conclude by the end of the day.

SIR BRIAN LANGSTAFF: And by the end the day you mean ...?

MS RICHARDS: 4.15/4.30.

SIR BRIAN LANGSTAFF: So that is some indication for those of you who are planning to be here tomorrow when you might need to make if you travel from some distance, it is the start of what used to be the weekend before Covid, and just so that you know where we are likely to be. So tomorrow 10.00.

MS RICHARDS: Yes, sir.

(4.08 pm)

(Adjourned until 10.00 am the following day)

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