1 Wednesday, 30 September 2020
2 **(10.00 am)**
3 **SIR BRIAN LANGSTAFF:** Yes, Ms Richards.
4 **MS RICHARDS:** Sir, I'm going to pick matters up in
5 relation to Cardiff and Professor Bloom in early 1983,
6 which is where I left off last week. Before I do so,
7 I should just mention that I identified last week
8 a number of statements that the Inquiry had received
9 from nursing or social work staff at Cardiff.
10 I should add we've also since received and been able
11 to disclose to core participants a statement from
12 Dr Giddings, who was the scientist working at Cardiff,
13 and a statement from Dr Liddell, who was a registrar
14 working under Professor Bloom at Cardiff. Those
15 documents have been shared with recognised legal
16 representatives and core participants.
17 Sir, picking things up in 1983, it was obviously
18 a hugely significant year in terms of the response of
19 Haemophilia Centre Directors to AIDS, led by
20 Professor Bloom as chair of UKHCDO.
21 If we could have on screen please, Henry,
22 PRSE0001991. This is a report prepared for
23 a January 1983 meeting of Scottish Health Service
24 Haemophilia Centre and Transfusion Service Directors.
25 The relevance of it for present purposes will become



1 apparent if we go to page 7. If we look halfway down
2 the page, under the heading "Miscellaneous", we'll see
3 under the heading "AIDS" it says:
4 "The attention of the Haemophilia Directors is
5 drawn to this problem (Appendix VI). It is noted that
6 in the US the National Haemophilia Foundation and CDC
7 are already conducting a survey and intend to
8 establish a permanent surveillance programme. The
9 information contained in Appendix VI has been sent to
10 Professor ... Bloom, Chairman of the UK Haemophilia
11 Centre Directors' meeting."
12 So we can see there appendix 6 is being drawn to
13 the attention of Scottish Haemophilia Centre Directors
14 but also we're told it's sent to Professor Bloom.
15 If we go on please, Henry, to -- it should be
16 page 14, we will see what appendix 6 comprised.
17 So this is -- we can see, the bottom right-hand
18 side of the page, the words at right angles to the
19 text say "Appendix VI", and this is the MMWR from
20 December of 1982. We can see that it contains the
21 update, and we'll just look at the text so we can see
22 what was being drawn to Professor Bloom's attention.
23 If we go back, please, to the top of the page,
24 Henry, left-hand side, first paragraph under the
25 heading "Update on Acquired Immune Deficiency



1 Syndrome", we see reference there to the specific
2 haemophilia patients identified in July 1982 and then
3 it's said, fourth line:
4 "All three have since died. In the intervening
5 4 months, four additional heterosexual haemophilia A
6 patients have developed one or more opportunistic
7 infections."
8 Then it says:
9 "... these four AIDS cases and one highly
10 suspect case are presented below."
11 It's set out there that:
12 "... inquiries about the patients ... provide no
13 suggestion that disease could have been acquired
14 through ..."
15 Other means such as contact or illicit drug use.
16 "All of these patients have received Factor VIII
17 concentrates, and all but one have also received other
18 blood components."
19 If we go back to the full page, please, Henry,
20 there are then details set out of the four cases.
21 Then the bottom right-hand side we have details of the
22 suspect case, which is a seven-year old severe
23 haemophiliac from Los Angeles.
24 Then if we could go over the page, please, we
25 can see in the editorial note it's said:



1 "These additional cases of AIDS among
2 haemophilia A patients share several features with the
3 three previously reported cases. All but one are
4 severe haemophiliacs requiring large amounts of
5 Factor VIII concentrate; none had experienced prior
6 opportunistic infections."
7 Reference is made to two of the five having
8 died.
9 Then in the right-hand side of the page, about
10 four paragraphs down, there is reference to these
11 additional cases providing important perspectives
12 on AIDS:
13 "Two of the patients described are ten years of
14 age or less and children with haemophilia must now be
15 considered at risk for the disease. In addition, the
16 number of cases continues to increase and the illness
17 may pose a significant risk for patients with
18 haemophilia."
19 Then if we go back to that full page, please,
20 Henry, we then see an extract from the further
21 report -- this is the bottom right-hand part of the
22 page, under the heading "Possible
23 transfusion-associated Acquired Immune Deficiency
24 Syndrome (AIDS)", reference there to the 20-month old
25 infant from San Francisco who had been transfused.

1 So that is material that we know from this
2 document was sent to Professor Bloom in January of
3 1983 and, as we can see, also shared with the Scottish
4 Haemophilia Centre Directors.
5 If we then have up on screen, please, Henry,
6 HCDO0000558, we can see on 19 January Professor Bloom
7 attended a meeting of the Hepatitis Working Party of
8 the UK Haemophilia Centre Directors. We'll see from
9 the list of attendees it also involved, from Oxford,
10 Dr Rizza, Dr Trow, Ms Spooner and other reference
11 centre directors there referred to, including
12 Dr Ludlum, Dr Kernoff, Dr Preston, and then we see
13 that Dr Craske welcomed Professor Bloom to the
14 meeting.
15 If we go to the bottom half of that page,
16 "Matters arising from the minutes", reference there to
17 the "prospective study of Factor VIII and IX
18 associated hepatitis", and that's a reference back to
19 the materials we looked at from autumn and December of
20 1982 about the evaluation of hepatitis-reduced
21 concentrate. We looked last week at Dr Lane's note of
22 the meeting that's there referred to, so I won't go
23 back to that.
24 If we go over the page, please, to the second
25 page of this document, we can see it says that



1 Professor Bloom said that as a result of the meeting,
2 that's the meeting that took place in December of '82:
3 "As a result of the meeting he and Dr Rizza had
4 attended, they had written to each Haemophilia Centre
5 Director requesting them not to take part in trials of
6 hepatitis-reduced products on a named patient basis
7 without taking advantage of an evaluation where the
8 powers of the Medicines Committee could be exercised
9 in the interests of the patient."
10 Then there's reference to two specific products.
11 "Dr Lane said that it was unlikely that
12 chimpanzee safety tests would be possible after the
13 first batch of hepatitis-reduced concentrate was
14 produced and that the results of clinical trials in
15 susceptible patients must be available to evaluate
16 these products."
17 Pausing there, you will recall that we looked
18 last week at a letter dated January 1982. That's the
19 perhaps now infamous letter sent by Professor Bloom
20 and Dr Rizza in which they discussed this issue. This
21 is an additional reason why it may well be that the
22 letter is misdated and should have been dated
23 January 1983, because it fits with the chronology of
24 events in late 1982 and early 1983, and it would
25 appear that what is being referred to here is that



1 letter. But that is a matter, sir, that you will need
2 to consider further in due course.
3 If we go down towards the bottom of this page
4 please, Henry, we can see there it says:
5 "It was agreed that the working party would
6 attempt to obtain the collaboration of all Haemophilia
7 Centre Directors in the organisation of trials under
8 alternative 2."
9 Alternative 2 was trials with an exemption from
10 clinical trial certificates.
11 Then it's said this:
12 "Questions which should be asked were (1) the
13 risk of non-A, non-B hepatitis when given to
14 susceptible patients. In view of the results of the
15 Oxford prospective study, these should be patients
16 with no prior exposure to Factor VIII or IX
17 concentrate."
18 So, to use the acronym that we've seen used
19 elsewhere, PUPS.
20 "It was probable that there would not be enough
21 susceptible patients for the inclusion of control
22 groups in the study of each product."
23 And then further detail set out about the
24 proposal.
25 Then if we could go on to the next page, please,



1 there's then further discussion about the potential
2 protocol for these trials of hepatitis-reduced
3 products. Then if we go down to the heading "Acquired
4 Immune Deficiency Syndrome", we'll see there's then
5 a detailed discussion of the current position in
6 relation to AIDS. We're told that:
7 "Dr Craske reviewed the developments in the
8 field since the last meeting of the Working Party. At
9 Dr Kernoff's suggestion he had written to
10 Dr Dale Lawrence at the Communicable Disease Centre
11 Atlanta, who was the coordinator of the surveillance
12 of AIDS cases and haemophilia A patients in the USA.
13 "So far ten cases of AIDS had occurred in
14 haemophilia A patients. They had none of the
15 predisposing causes such as heroin addiction,
16 promiscuous homosexuality or treatment with
17 immunosuppressive drugs, and it occurred in areas of
18 the USA where cases had not been found before. All
19 except one patient were patients with severe
20 coagulation defects on regular Factor VIII therapy.
21 The youngest was aged seven years. Both pneumocystis,
22 carinii and Kaposi's sarcoma had been found in this
23 group, of whom five had since died. It seemed
24 possible that Factor VIII or other blood products
25 administered to these patients might be implicated."

1 Pausing there, sir, a clear awareness amongst
2 those who attended this meeting of the up-to-date
3 position from the States as set out in the
4 communications we've already looked at.
5 **SIR BRIAN LANGSTAFF:** So at this time it's ten cases.
6 **MS RICHARDS:** Yes.
7 **SIR BRIAN LANGSTAFF:** So it's increasing?
8 **MS RICHARDS:** Yes, and it would appear that Dr Craske has
9 been able to receive up-to-date information
10 potentially from the States in relation to that.
11 **SIR BRIAN LANGSTAFF:** On 10 December it's seven or eight.
12 By this time, less -- or around about a month later,
13 it's up to ten?
14 **MS RICHARDS:** Yes.
15 Then we see it's there set out that the CDC AIDS
16 Task Force were working on the hypothesis that an
17 infective agent was involved, possibly a virus
18 specific for human T cells.
19 "Further support for this hypothesis has come
20 from the report of three cases associated with whole
21 blood or platelet transfusions. Two were in adults
22 who developed AIDS 14 and 18 months respectively after
23 transfusion to cover operations."
24 Then, skipping over a couple of lines:
25 "The third case was that of a 20-month old boy



1 from California who had been transfused with blood
2 platelets at birth for RH haemolytic disease of the
3 newborn."
4 That's the San Francisco baby case. So explicit
5 discussion of that case and its significance.
6 Then if we go over the page please, Henry, the
7 first main paragraph, I won't read out the discussion
8 there, but we'll just look at the last sentence of
9 that first main paragraph:
10 "Two recent papers in the New England Journal of
11 Medicine suggested that the transfusions of
12 freeze-dried Factor VIII concentrate may be a factor."
13 Again, sir, we've looked already at those
14 publications in the New England Journal of Medicine at
15 the beginning of 1983.
16 **SIR BRIAN LANGSTAFF:** That was the editorial by Janet
17 Desforges saying that we should now move to
18 cryoprecipitate.
19 **MS RICHARDS:** Yes, precisely, and clear awareness of that
20 amongst at least these haemophilia centre directors
21 and clinicians.
22 Then we see it goes on to say that:
23 "The Americans were keen for the UK Haemophilia
24 Centre Directors to collaborate in the reporting of
25 cases of AIDS possibly associated with transfusions of



1 US commercial Factor VIII."
2 It's set out that no cases have so far been
3 found in haemophilia B patients.
4 Then there is a discussion that's there recorded
5 about the kind of survey that could be undertaken.
6 There's reference to specific American forms for
7 reporting symptoms. Again, a reference to the two
8 recent papers in the New England Journal of Medicine
9 and so on, and the outcome is that:
10 "Dr Craske will draw up a form for the reporting
11 of AIDS cases and consider what further information
12 will be needed in a retrospective study."
13 So that's the Hepatitis Working Party of the
14 Haemophilia Centre Directors Organisation,
15 19th January 1983.
16 That same day if we have, Henry, please,
17 BPLL0001351_071, please.
18 That same day, 19 January 1983, Mr Watters of
19 The Haemophilia Society wrote to Professor Bloom in
20 these terms:
21 "Dear Professor Bloom,
22 "The Reverend Alan Tanner has asked that I write
23 to you enclosing this article from the Observer of
24 Sunday, 16th January ..."
25 Pausing there, I won't put the Observer article



1 up but it is referred to in the Knowledge of Risk
2 chronology, and I think it may have been one of the
3 documents I displayed last week.
4 "We are writing to you in your capacity as
5 chairman of the Centre Directors Meeting and our own
6 Medical Advisory Panel to seek some clarification on
7 current thinking in the UK on this matter, which has
8 naturally raised some anxiety, with calls coming from
9 as far away as The Hague. It would be most helpful to
10 us if you could offer guidance at this stage with
11 a possibility of an early date article for The
12 Bulletin, so we can keep our members in touch with the
13 situation."
14 Sir, pausing there, we will see from various
15 communications and publications throughout the course
16 of 1983 that The Haemophilia Society turned,
17 unsurprisingly, to Professor Bloom for advice on the
18 specific issue of AIDS with a view to working out what
19 it should be telling its members.
20 Professor Bloom's response is dated the
21 following day. So it's at HCDO0000003_066.
22 So, 20 January. Professor Bloom will have
23 attended the meeting on the 19th that we've just
24 looked at and we will see what he says to Mr Watters
25 of The Haemophilia Society:

1 "Thank you very much for your letter and for the
2 cutting from the Observer. This cutting does seem to
3 have caused some concern amongst the patients, and
4 indeed some medical administrators and physicians.
5 There may be a modicum of justification for this
6 concern. You are no doubt aware of the background
7 that a rather serious new disease began to be
8 recognised towards the end of 1981, particularly among
9 homosexuals in the USA."
10 Then he summarises the emerging knowledge in
11 that respect. Then a few lines down, picking it up,
12 he says this:
13 "However, later, as detailed in the Observer
14 article, several groups of people who were clearly not
15 homosexuals, including various immigrant groups in the
16 USA as well as the ten haemophiliacs, were identified
17 as suffering from the disease. Clearly at the present
18 time the cause is quite unknown and neither has it
19 been proven that it is transmitted through
20 contaminated blood products. The incidence of the
21 condition in America is not known but seems to be
22 about 1 per thousand of the severely affected treated
23 patients. On this basis, if the disease exists in the
24 UK, we could reasonably expect two or three cases
25 among British haemophiliacs. So far none have been



1 reported."
2 Pausing there, sir, of course at some point you
3 will no doubt wish to consider whether there is
4 a fallacy of reasoning in this advice given what was
5 known about the potential lapse of time between
6 infection and symptoms being displayed and whether
7 there was a conflation of incidence and risk.
8 Continuing with the letter, he says this:
9 "The Haemophilia Centre Directors Organisation
10 is closely monitoring the possibility of this
11 condition in the UK."
12 Then he refers to the Hepatitis Working Party,
13 which was the previous day, and the retrospective and
14 prospective surveys that are proposed, and then he
15 says:
16 "As the full-blown condition has not yet been
17 reported amongst British haemophiliacs, it is not
18 possible to state if the coagulation concentrations
19 produced in this country are safer in this respect
20 than the concentrates produced in the USA. Indeed,
21 there is no evidence yet in fact to implicate the
22 latter, however the Directors of several individual
23 Centres are investigating possible markers of the
24 condition in patients who receive various types of
25 blood products."



1 So, as at January of 1983, Professor Bloom is
2 there explaining that there are some directors who are
3 already investigating possible signs of the condition.
4 **SIR BRIAN LANGSTAFF:** I am just puzzled by the first full
5 sentence on that page:
6 "Indeed, there is no evidence yet in fact to
7 implicate the latter ..."
8 That is, to implicate the concentrates produced
9 in the USA.
10 I can understand his saying the cause is
11 unknown, I can understand him saying there is no
12 proof, if proof is what it is necessary to look for --
13 that is proof of effect, a cause and effect, but "no
14 evidence" seems to be a surprising claim.
15 **MS RICHARDS:** Yes.
16 **SIR BRIAN LANGSTAFF:** Yes.
17 **MS RICHARDS:** Then he says this, and this is effectively
18 the message that he is sending The Haemophilia
19 Society:
20 "In the meanwhile, there is certainly no need
21 for the haemophiliac community to be unduly concerned
22 about this new syndrome. They can rest assured that
23 every effort is being made to monitor the situation in
24 this country and to collaborate with the Center for
25 Disease Control in the USA. Although no cases have



1 been reported in the USA as far as I know in
2 haemophilia B, we are monitoring the situation in all
3 these related conditions. As you and your colleagues
4 in the Society know, coagulation factor therapy is so
5 essential for the safety and well-being of patients
6 that there is no doubt whatsoever that their
7 advantages far outweigh this disadvantage which, at
8 the moment, seems to be potential rather than real in
9 the UK, at any rate.
10 Further developments will depend upon
11 identifying the responsible agent or constituent of
12 concentrates if it exists and, no doubt, then steps
13 can be taken to eliminate them in much the same way as
14 steps are being taken to reduce the risk of
15 hepatitis."
16 We'll see shortly the publication that results
17 a little later on in that year authored
18 by Professor Bloom and published by The Haemophilia
19 Society, but in the meantime, staying with January of
20 1983 --
21 **SIR BRIAN LANGSTAFF:** Just as a matter of interest, did,
22 in the event, Dr Craske write an article for The
23 Haemophilia Society?
24 **MS RICHARDS:** I don't think so, sir. I'll need to check
25 and may be able to give a more positive answer to that

1 having done so. My recollection is, the first
2 bulletin of 1983 contains that question and answer
3 session with Dr Kernoff about AIDS, which we looked at
4 last week, in which he suggested that an epidemic of
5 AIDS was a ludicrous suggestion. I don't recollect
6 there being an article by Dr Craske in that bulletin.
7 I'll check the numbers of bulletins, but I think the
8 next bulletin in 1983 contains -- or there is
9 a message from Professor Bloom in one of the next
10 publications, but we'll check, sir. Certainly,
11 Dr Craske authors a lot of material in the course of
12 1983, but for the most part it seems to be shared with
13 the Haemophilia Centre reference directors and working
14 parties.
15 **SIR BRIAN LANGSTAFF:** Yes. It may be that he took
16 a slightly different approach to the risks than did
17 Bloom.
18 **MS RICHARDS:** We certainly see, I think, in a report from
19 November 1982 which we looked at last week that the
20 three possibilities being set out in terms of causal
21 agent by Dr Craske and an inference. Perhaps the most
22 reasonable inference to draw is that he thought the
23 most likely of those possibilities.
24 **SIR BRIAN LANGSTAFF:** He discounts two of them.
25 **MS RICHARDS:** He does.



1 **SIR BRIAN LANGSTAFF:** That leaves only infectious agent.
2 **MS RICHARDS:** Yes. Sir, I'll check because it is possible
3 that there might have been an article in The Bulletin
4 that I'm not aware of.
5 We then come a few days after this letter to
6 that meeting on 24 January 1983 at a London airport
7 hotel. We looked at the minutes of this meeting last
8 week, focusing on what it said about AIDS. I want to
9 go back to the minutes and look again at what is said
10 about AIDS but also what's said about hepatitis.
11 You'll recall, sir, that there are two records
12 of that meeting. The first is a record prepared, we
13 think, by Dr Boulton, and that's PRSE0002647. So we
14 see notes of meeting with Immuno at London Airport,
15 24 January. The topic is hepatitis-reduced
16 Factor VIII and Factor IX concentrates for haemophilia
17 therapy. If we go to the last page, please, first of
18 all, Henry, we can see there the list of those
19 present. It includes, relevant for the purposes of
20 this week's presentations, Dr Rizza and Dr Bloom, but
21 it includes a number of leading Haemophilia Centre
22 Directors, as well as Professor Zuckerman who was
23 a leading expert in hepatitis. Then we'll see it says
24 the Immuno team led by Dr Eibl. So there were
25 representatives of Immuno at the meeting and, indeed,



1 it was a meeting convened to take place with Immuno.
2 If we then go to the second page, please, of
3 this note, under the heading "Clinical trials design".
4 So this is in relation to the so-called
5 hepatitis-reduced products:
6 "There was some considerable discussion over the
7 nature of the design. Dr Craske, in preliminary
8 comments, pointed out that in work with Dr Rizza,
9 rather to their surprise, over 18 months, 30 patients
10 with no previous history of exposure or only slight
11 exposure had been recruited to a study of the
12 incidence of non-A, non-B after Factor VIII
13 concentrate. These patients included patients with
14 von Willebrand disease and mild haemophilia and
15 incidentally indicated that completely unexposed
16 patients had 100 per cent incidence of hepatitis with
17 BPL Factor VIII, and that patients who had previously
18 received 4 to 5 batches of material had a 50 per cent
19 chance of developing non-A, non-B hepatitis."
20 So that's a report of a study that had been
21 undertaken at Oxford by Dr Craske and Dr Rizza.
22 Then -- there is then discussion of the new
23 trial that is proposed. Picking it up at the bottom
24 of that page. It would appear that the issue of using
25 children in the trial had been raised because it's



1 then recorded that:
2 "Dr Hill and Professor Hardisty -- so that's
3 Birmingham and Great Ormond Street, respectively --
4 pointed out to the ethical difficulties of using newly
5 diagnosed children as first candidates in the trial.
6 This is because children may be safer on
7 cryoprecipitate because of the possible toxic effects
8 of the added chemicals, and also because of the need
9 for considerable follow up venepunctures which, in the
10 context of general ethical difficulties with working
11 on children as experiments, must be a severely
12 limiting factor. After some discussion, it was agreed
13 that trials should initially take place in adults, and
14 particularly those who require large doses of
15 Factor VIII frequently. Such patients could be used
16 for assessing data on recovery, half life and
17 toxicity. When such patients reveal satisfactory
18 data, the next stage is going to adults who have only
19 occasional requirements. However, these adults would
20 have to have a good reason for not receiving the
21 cryoprecipitate or DDAVP, such as major surgery.
22 After an initial period of satisfaction in such
23 patients, one could then go to children."
24 So that's the discussion about the proposed
25 trials in relation to the hepatitis product --

**SIR BRIAN LANGSTAFF:** Just pausing there, this paragraph is suggesting trialling on adults who require large doses of Factor VIII frequently. The letter we looked at of 11 January '82, or maybe '83, was talking about previously untreated patients as the only way you could work out whether heat treatment worked.

**MS RICHARDS:** Yes.

**SIR BRIAN LANGSTAFF:** This is looking to see if heat treatment works by treating those who have been not only previously exposed but heavily exposed.

**MS RICHARDS:** Yes.

**SIR BRIAN LANGSTAFF:** Because it must be the case, haemophilia being a life-long condition, that if they are serious as adults and require large doses of Factor VIII frequently, they would have done so for a long time.

**MS RICHARDS:** Yes. We do have the protocol in relation to this trial. I think it post-dates this meeting rather than pre-dates it, but I'll check, which I'm going to deal with when we deal with Oxford. So we can perhaps revisit that question at that point.

**SIR BRIAN LANGSTAFF:** There is probably an explanation that is escaping me at the moment which is scientific as to how the effectiveness or otherwise might be gauged.



**MS RICHARDS:** Yes. I don't know, sir. We must recall these are the notes taken by Dr Boulton, of course, and won't necessarily reflect a complete account of the meeting.

We then have, under the heading of "Acquired Immunodeficiency Syndrome" -- this was discussed in the after lunch period. I won't go through the detail of this because we looked at it during the knowledge of risk presentation last week, but there is a detailed discussion including data that:

"Up to 10 December 1982, 800 people had been reported as suffering from AIDS with a 45 per cent mortality."

Then details are given of the ten cases in the US. If we just go to the last page please, Henry, fourth paragraph down, it says:

"The attention of the meeting was then drawn to the two articles on the editorial in the New England Journal of Medicine on 13 January which, in summary, indicates that the T48 ratios among haemophiliacs receiving Factor VIII is greater among those who have been exposed to concentrates than those exposed to cryoprecipitate only. However, cryoprecipitate in the US comes from volunteer, unpaid donors and therefore are presumably well-motivated people."



So we've seen how, at the smaller meeting on 19 January, the New England Journal of Medicine article is discussed. Here, at a meeting involving a larger cohort of clinicians from Haemophilia Centre Directors, the attention of those present is being drawn to that article again.

**SIR BRIAN LANGSTAFF:** The letter, so far as you have drawn it to my attention, makes the points that it may well be an infectious agent, but the incubation period is a long period -- that's the top of the second page, I think -- and that the mortality rate is getting on for half at that stage, of those who have been already diagnosed.

**MS RICHARDS:** Yes. Then we'll just look at Immuno's own note of the meeting. Henry, this is at DHSC0001800. We see from the covering letter that the note is being sent on 18 March, some weeks later, to Professor Bloom:

"I have much pleasure in enclosing the summary of discussions of the meeting held at the Excelsior Hotel, Heathrow Airport, on Monday 24 January 1983."

If we go to the next page, please, we'll see under the heading that Professor Bloom chaired the meeting. This sets out in more detail than Dr Boulton's note what was being explained by the



representatives from Immuno. Then if we go to the next page, please, Henry, second paragraph, we see that a doctor from Immuno is then recorded as saying that:

"Guidance was required from the meeting as to the correct procedure as far as future use of these products were concerned."

The following points were made:

"1. Young children could not be used for trials as neither they nor their parents could give consent.

2. Adult haemophiliacs with an established immunity to non-A, non-B hepatitis would not benefit from a trial, but it was thought that they would be sufficiently public spirited to agree to these materials being used on them to show haemostatic effect and absence of toxicity due to remnants of additives.

3. All batches of NHS and US commercial concentrates have been shown to be capable of transmitting non-A, non-B hepatitis. It's believed that a one in 50 chance of transmission from cryoprecipitate occurs.

4. Because of 3, many thought it would be difficult to justify carrying out a prospective controlled trial. However, it was generally agreed

1 that sufficient susceptible adult patients needing
2 high level treatment, e.g. for surgery, could be
3 identified to warrant uncontrolled prospective trials
4 of this and other virus inactivated products. It was
5 agreed that such trials should be instituted."
6 Then I can skip over 5.
7 "6. It was not practical to test every batch in
8 animals. In fact, it is hoped that the requirement to
9 test batches of HB vaccine in chimpanzees will soon be
10 discontinued. However, it is intended that three
11 consecutive batches will be tested in animals.
12 7. Maximum effort so far had been to show
13 clearance of non-A, non-B hepatitis which is regarded
14 as the main problem. Later on, tests will be made on
15 the effect of both methods on hepatitis B and possibly
16 other viruses."
17 Then over the page, we can see a summary. Sir,
18 I've already noted, I think, in the knowledge of risk
19 presentation last week, at paragraph 13, there's just
20 a passing reference to AIDS in this note from Immuno.
21 Then we see Professor Bloom summarising the meeting as
22 follows:
23 "(a) Clarification should be sought from DHSS as
24 to whether the treatment of the final product could be
25 covered by a product licence variation or if



1 a clinical trial exemption certificate was necessary.
2 It was agreed that the best procedure would be to seek
3 a product licence, if necessary, via clinical trials
4 in preference to use on a named patient basis.
5 (b) Haemostatic activity in terms of in vivo
6 recovery and half life and absence of toxicity should
7 be ascertained in adult haemophiliacs.
8 (c) The material should then be assessed in the
9 treatment of adult haemophiliacs susceptible to non-A,
10 non-B hepatitis by a properly conducted trial in
11 susceptible patients in appropriate need of treatment.
12 It was agreed that it should be possible to identify
13 sufficient UK patients for such trials.
14 (d) The material could then be used on newly
15 diagnosed children.
16 (e) Trials could be arranged by the committee of
17 the Haemophilia Directors and it will be best to use
18 five separate batches, with two patients receiving
19 each batch."
20 That's the second account that we have --
21 **SIR BRIAN LANGSTAFF:** Could we just go back to the
22 opening -- the cover letter, please?
23 **MS RICHARDS:** Yes. That's the first page, please, Henry.
24 It's the first page of this document. DHSC0001800.
25 I think the system has frozen temporarily, sir. Thank



1 you, Henry. That's the covering letter, sir.
2 **SIR BRIAN LANGSTAFF:** Yes, it's not, therefore, minutes as
3 such.
4 **MS RICHARDS:** No.
5 **SIR BRIAN LANGSTAFF:** So the reason I ask is that the
6 normal protocol would be, I think, that the Chairman
7 at least reviews the minutes before they are released.
8 The chairman here was Professor Bloom. So this is not
9 necessarily minutes with which Professor Bloom is at
10 all responsible.
11 **MS RICHARDS:** No. No and, indeed, we don't have anything
12 that would be regarded as minutes. We have two notes
13 giving the author's separate accounts, one from
14 Professor Boulton, one from -- I think it is Mr Berry
15 of Immuno. So we don't have any formal minutes. It
16 doesn't appear that the meeting was in fact minuted.
17 One matter you may want to consider in due course,
18 sir, when you look at, respectively, the litigation
19 reports produced by Professor Bloom and Dr Rizza for
20 the purposes of the HIV litigation, they record
21 a number of meetings, but there is not, as far as
22 I can recall, any discussion of this meeting. I'll
23 double-check that because I'm going to look at both of
24 those litigation reports at some point either today or
25 next week. But that certainly is my recollection.



1 If we just then, please, Henry, have on screen
2 WITN0047004. If we go to the next page. We can see
3 here -- and this is a communication from Dr Liddell, a
4 registrar, and to Dr Bloom of 28 January 1983 to,
5 I think, probably a GP. We can see that awareness of
6 AIDS -- some awareness of AIDS and the risk of AIDS is
7 reflected in this letter. We can pick it up in the
8 second paragraph:
9 "Being a well-read man he -- that's the
10 patient -- is somewhat concerned about the possibility
11 of acquiring the acquired immunodeficiency syndrome,
12 although, of course, there is no grounds for
13 suspecting the diagnosis in him."
14 It's interesting, perhaps, to see the way in
15 which that's put, sir. I think you may have commented
16 on this when we heard from the patient's widow last
17 year. It's not suggested that the possibility of
18 acquiring AIDS is an absurd or unfounded suggestion.
19 What's being said there, there's no grounds for
20 thinking that this particular patient at this point in
21 time has it. So, clearly, awareness amongst those
22 working with Professor Bloom of the potential
23 connection with AIDS for haemophiliacs at that time.
24 If we then move to February of 1983, could we
25 please have, Henry, HCDO0000411. If we go to the next

1 page, please. We can see here these are the minutes
2 or draft minutes of the 16th meeting of Haemophilia
3 Reference Centre Directors held at the Royal Free
4 Hospital on Monday 14 February 1983. So this is the
5 next Reference Centre Directors' meeting. We can see
6 the attendees. Professor Bloom is in the chair. We
7 can see that Dr Rizza is there, Dr Ludlum, Dr Matthews
8 also from Oxford is there. Dr Savidge, Dr Tuddenham,
9 et cetera. Then if we go, please, Henry, to page 4,
10 we see, bottom half of the page, there is a report
11 from Dr Craske from the Hepatitis Working Party, and
12 reference there to there being an amended protocol for
13 the prospective study that we've seen being discussed
14 in the various documents we've already looked at, and
15 Dr Craske asks for feedback from Haemophilia Centre
16 Directors.
17 Then if we go to the next page, we have under
18 the heading "AIDS syndrome", we have an update from
19 Professor Bloom:
20 "Professor Bloom said that the syndrome would be
21 discussed at the Stockholm meeting of the World
22 Federation of Haemophilia."
23 I can't remember off the top of my head the
24 exact date. I'll check. But we know that, in due
25 course, that was attended by Professor Bloom:



1 "Reports from the US indicated that the
2 incidence of AIDS was higher than at first thought,
3 and there was some concern that the haemophiliac
4 population of the UK who had received American
5 concentrates might be at risk."
6 Then we see Dr Craske again summarising the
7 latest information from the US. Reference to the ten
8 cases, approximately ten cases, thought to have
9 occurred in non-haemophiliacs there in the UK and then
10 reference to the form that was being drawn up and
11 a lengthy discussion about the report form and which
12 of the various documents which Dr Craske had obtained
13 from the US should be circulated to the Haemophilia
14 Centre Directors.
15 Sir, at the moment, we've not been able to work
16 out precisely what documents are being referred to
17 there, other than the various forms that were proposed
18 on which directors were going to be asked to report
19 possible AIDS cases to Dr Craske.
20 Then you will see it was agreed there should be
21 a new form drawn up, and that would be circulated with
22 appropriate notes regarding the criteria on which the
23 diagnosis should be based, and a suggestion that an
24 immunologist be invited to join the Hepatitis Working
25 Party.



1 If we then go, please, still in February of
2 1983, to CVHB0000002_003, please, Henry.
3 CVHB0000002_003. I'll read out the letter, and
4 perhaps we can rectify showing it on screen later.
5 It's a letter dated 18 February 1983. It's "Dear
6 blank". It appears to be a *pro forma* letter that was
7 going to be sent to patients. Whether it was sent or
8 not and if so to which patients, we don't yet know.
9 It's from Professor Bloom and Dr Moffatt and it says:
10 "Dear [blank],
11 "You may already be aware of recent reports in
12 both medical and general press of unusual infectious
13 illnesses occurring in patients with haemophilia."
14 We have it. Thank you.
15 "There is no cause for alarm, and we stress that
16 the occurrence of these illnesses has been extremely
17 uncommon and has been confined to the United States.
18 On the other hand, it's important to identify any
19 predisposing factors to this type of illness in
20 patients suffering from blood coagulation disorders.
21 To this end, we request your co-operation in a limited
22 survey of patients registered with the Haemophilia
23 Centre in Cardiff. You would be asked to attend this
24 hospital for a straightforward blood test and also
25 a simple skin prick test on the forearm. This is too



1 trivial to require cover by concentrate treatment and
2 will only take a few minutes. If you are willing to
3 have these tests performed, please complete and return
4 the attached form. We will then contact you directly
5 to arrange a suitable weekday morning when the tests
6 can be performed."
7 As I say, we haven't yet married up this letter
8 with any of the particular sets of patient records
9 that we've looked at so far to know how extensively it
10 was circulated or, indeed, whether it was sent, but
11 this appears in documentation provided to us by the
12 relevant heath board in Cardiff.
13 **SIR BRIAN LANGSTAFF:** In terms of the drafting of the
14 first two sentences:
15 "The occurrence of these illnesses has been
16 extremely uncommon and has been confined to the
17 United States."
18 That, of course, doesn't fit with what Dr Craske
19 was saying about the fact that AIDS had been seen in
20 non-haemophilia patients in the UK.
21 **MS RICHARDS:** Yes, it's accurate only --
22 **SIR BRIAN LANGSTAFF:** So the reconciliation must be that
23 he's talking about just patients with haemophilia.
24 **MS RICHARDS:** Yes. Although that's not what it says in
25 terms, but, yes, that is one possibility.

1 **SIR BRIAN LANGSTAFF:** That's a possibility. Although, at
2 this stage, it was known that the World Federation of
3 Haemophiliacs meeting in Stockholm was going to
4 discuss the problem.
5 **MS RICHARDS:** Yes, I think that's right.
6 **SIR BRIAN LANGSTAFF:** Yes, I see.
7 **MS RICHARDS:** Of course, there was a lot more information
8 available to Dr Bloom and his colleagues, not least
9 from the transfusion and the San Francisco baby case
10 and others from the various medical reports that we
11 know he was aware of.
12 **SIR BRIAN LANGSTAFF:** Yes.
13 **MS RICHARDS:** We know that by March of this year
14 Professor Bloom was making enquiries in the States
15 directly himself. We can see that from
16 BPLL0001351_021. This is a letter from
17 Dr Bruce Evatt, the director of the Division of Host
18 Factors at the Center for Infectious Diseases in the
19 States. It's a letter dated 7 March 1983 to
20 Professor Bloom:
21 "Dear Arthur. Thank you for your recent enquiry
22 concerning the AIDS syndrome."
23 So it would appear Professor Bloom has been in
24 contact with Dr Evatt. Then he says this:
25 "I will be happy to present an update on the



1 current status of AIDS in North America during the
2 Stockholm meeting. As you can imagine, AIDS is having
3 a major impact on the treatment of haemophiliacs here
4 presently. The evolution of the epidemic is occurring
5 with a frightening pace. We now know of over 1,150
6 total cases in United States. To give you an example
7 of rapidity of development, approximately 80 patients
8 with AIDS reported to us during the month of December;
9 in January, 120; and in February, the number is
10 approaching 20 per cent above that level. In fact,
11 about 40 per cent of the cases have been reported to
12 us in the last three to four months.
13 We presently have 13 confirmed haemophiliac
14 patients with AIDS in the United States. One of the
15 patients is Factor IX deficiency; one is bisexual. In
16 addition, five more highly suspect cases are under
17 investigation. The incidence rate has been increasing
18 in haemophiliacs, and the epidemic curve paralays that
19 of the total epidemic curve. The first case appeared
20 in a haemophiliac in January 1982. A total of nine
21 were reported by December. Of those, eight died in
22 1982. From preliminary data obtained from
23 a nationwide surveillance, the AIDS syndrome was the
24 second cause of death among haemophiliacs in 1982 in
25 the US. Haemorrhage was the largest cause of death.



1 AIDS has developed in both mild and severe
2 haemophiliacs. Ages have been 7 to 62 years. The
3 clinical course has been rapid after the onset of
4 opportunistic infection. Most have had PCP. None
5 have had Kaposi sarcoma. All have received Factor
6 VIII concentrates, and all but one have received other
7 blood products such as plasma or blood transfusions.
8 Common lots among the concentrates have been rare.
9 We've accumulated a large amount of clinical data on
10 these patients, and it's very similar to that seen in
11 other cases of AIDS."
12 Then he goes on to talk about studies being
13 undertaken in the States by CDC. Then over the page
14 he says this:
15 "Transfusions as a source of AIDS infection is
16 another cause for concern here. Approximately 12
17 patients have developed AIDS following blood
18 transfusions. These cases are under intensive
19 investigation by us. Of these patients, half are
20 male, and half are female. They appear to be located
21 in the high instance areas of AIDS, i.e. New York,
22 San Francisco and Los Angeles, locations where we
23 would expect the majority of donors with AIDS to be.
24 I hope this information is useful to you. I suspect
25 it is a matter of time before you begin to see cases



1 in the United Kingdom."
2 **SIR BRIAN LANGSTAFF:** Could you just go back to the end of
3 the previous page.
4 **MS RICHARDS:** Certainly, sir.
5 **SIR BRIAN LANGSTAFF:** No, the second page. Is this the
6 previous page?
7 **MS RICHARDS:** This is the first page, yes.
8 **SIR BRIAN LANGSTAFF:** I beg your pardon. It's the bit at
9 the bottom which caught my eye. "Preliminary data
10 suggests."
11 **MS RICHARDS:** Sir, you are right. I should have read
12 that. It's important:
13 "Preliminary data suggests that one half of the
14 haemophiliac population has T cell abnormalities and,
15 in fact, 13 per cent are markedly abnormal in the
16 range that we see with the AIDS patients."
17 **SIR BRIAN LANGSTAFF:** Yes. Thank you.
18 **MS RICHARDS:** So, again, you will no doubt wish to
19 consider in due course, sir, the terms in which that
20 letter was written and the information that would have
21 been available to it from Professor Bloom.
22 We can see also that Professor Bloom was
23 receiving communications from pharmaceutical companies
24 on the issue of AIDS. So if we have, please, Henry,
25 CBLA0000060_067. This is a letter dated 16 March 1983

1 from Alpha Therapeutic Limited to Professor Bloom:
2 "Dear Prof Bloom. Acquired Immunodeficiency
3 Syndrome. Following the recent upsurge and interest
4 in media publicity regarding this problem, I've
5 obtained from our parent company in the USA, Alpha
6 Therapeutic Corporation of Los Angeles, more details
7 of the precautionary steps that have been introduced
8 to minimise the risk of this disease being transmitted
9 via our pool of donors to the haemophilia population.
10 They are as follows ..."
11 Then he sets out the steps which it is said
12 Alpha will be taking, in terms of donor screening and
13 provision of information to donors. He then says:
14 "I also attach a transcript of a press release
15 issued by the corporation in January 1983. I hope
16 this adequately demonstrates the company's rapid
17 response to the concern expressed by the medical
18 community, and that we appear to be leading the way as
19 far, as major plasma fractionaters are concerned, to
20 make our final products as safe as possible."
21 If we could go over the page to the press
22 release, please. This is an Alpha press release from
23 the States, 7 January 1983, being provided to
24 Professor Bloom in March of 1983. If we go down to
25 the second half of the page, please, having referred



1 to the new Alpha policy which the letter describes,
2 we're told:
3 "It was initiated the response to a request from
4 the National Haemophilia Foundation which recommended
5 late last year that individuals belonging to these
6 high-risk groups be excluded from donor pools. The
7 foundation issued its request after a half dozen AIDS
8 cases were discovered among haemophilia patients."
9 Then the next paragraph this -- and this is from
10 a pharmaceutical company in January of 83:
11 "The evidence suggests, although it does not
12 absolutely prove, that a virus or other disease agent
13 was transmitted to them in the Factor VIII
14 concentrate, derived from pooled human plasma which
15 they rely on for life and for sustaining a relatively
16 normal lifestyle."
17 So an acceptance there of the likely cause of
18 transmission to haemophiliacs. That's being drawn to
19 Professor Bloom's attention in March of 1983.
20 We can see, if we look at a document from that
21 same month, what was being done by the Haemophilia
22 Centre Directors organisation. HCDO0000517_001,
23 please. This is a letter from Dr Craske to Dr Rizza
24 and Professor Bloom to Haemophilia Centre Directors.
25 We assume it is to all directors and not just to



1 reference directors. I think that's a fair
2 assumption. It's 22 March 1983:
3 "Dear Director. Re acquired immune deficiency
4 syndrome. Recent discussions in both the Hepatitis
5 Working Party and a recent meeting of the Reference
6 Centre Directors have prompted us to circulate the
7 enclosed papers so that a system for the reporting of
8 possible cases of AIDS can be quickly set up to
9 examine the problem as quickly as possible. This was
10 initially prompted by a request from the US public
11 Health Service to the UK Haemophilia Centre
12 Directors."
13 We can then see there are papers referred to
14 which set out the criteria for reporting cases:
15 A paper "/AIDS 2" and "AIDS 3". Then we see in the
16 penultimate paragraph:
17 "We do strongly urge you to collaborate in
18 reporting cases of this syndrome as it is most
19 important that the extent of the problem is quickly
20 identified so that preventative measures can be
21 instituted as soon as possible to minimise numbers of
22 cases occurring in the UK."
23 So you will see, sir, the response at this stage
24 of the Haemophilia Centre Directors Organisation is to
25 set up a reporting system but not to change or



1 recommend changes to clinical practices in any
2 respect. The question of the provision of information
3 to patients is not addressed at all.
4 You, sir, may want to consider in due course
5 whether what is set out in that penultimate paragraph
6 is a case of shutting the stable door after the horse
7 has bolted or not.
8 There are then attached to this the various
9 forms referred to. I just want to go to one of them.
10 I think it's page 7, Henry. HCDO0000517_002.
11 So it is this document, but it should be the
12 seventh page of this document.
13 Whilst Henry tries to get that up -- sorry,
14 we're having problems with the speed of the system
15 this morning -- I'll describe what it is. It is
16 AIDS/1, so it's one of the documents being circulated
17 to Haemophilia Centre Directors, and it's a narrative
18 account of understanding of the current position in
19 relation to AIDS.
20 It is in fact in very similar form to -- Henry,
21 I might have given you an inaccurate reference.
22 I have, sorry.
23 HCDO0000517_002. It wasn't a seventh page
24 of 001. Sorry, Henry.
25 So this is in very similar form to that report

that we looked at from Dr Craske at about November of 1982. We can see, if we go halfway down this page, reference there to the extent of opportunistic infections. Then in the last paragraph:

"A considerable delay was noted between the occurrence of initial symptoms and diagnosis. This meant that there was an average three to six-month delay between the onset of symptoms and diagnosis. The signs and symptoms were in most cases insidious and non-specific in nature."

Then over the page he sets them out.

If we go to the third page of this document, please, Henry, we see under the heading "Aetiology":

"Several theories have been advanced. It seems likely this is a new syndrome."

Then we have the three theories that we saw in that earlier paper, sir, set out. If we go over the page to the fourth page, we can see there that the third incorporates the reference to possibly the transfusion of commercial blood concentrates.

Then Dr Craske goes on to say:

"If 3 is the most likely cause, then it's possible that such an agent might be present in the plasma pools used to prepare commercial Factor VIII and IX concentrate manufactured from donor plasma collected in the USA."



Then he adds:

"Three patients have acquired the disease where the most likely mode of transmission was blood or platelet transfusions."

It provides further detail of those patients, first though 5 having so far died.

Then it refers to the possibility of sexual transmission. Then the next page, towards the bottom of the first paragraph:

"All" --

**SIR BRIAN LANGSTAFF:** I think if you start at the top actually.

**MS RICHARDS:** Certainly, sir:

"It is also possible that the initial phase of the disease, characterised by enlarged lymph nodes, which is associated with a proliferation of lymphoreticular cells, the onset of autoimmune disease ..."

And he gives examples:

"... loss of weight and malaise, may not always progress to the final syndrome where marked depletion of the lymphoid cells is the most obvious appearance on histology of lymph nodes. It is therefore evident that the disease is not universally fatal and some patients may recover. All the epidemiological evidence is consistent with the existence of a transmissible agent whose mode of spread is remarkably similar to that of hepatitis B."



Which of course had been known for decades was transmissible through blood and blood products.

"Precautions against cross-infection should therefore be based on those taken for hepatitis B. It is thought likely that batches of Factor VIII concentrate which might contain the AIDS virus came into use since January 1, 1980 in the USA."

Then he goes on to refer to the CDC reporting request.

**SIR BRIAN LANGSTAFF:** Just looking at that for a moment in terms of timescale, there are two periods then, are there, contemplated by this information sheet? One is the period between first symptoms arising and diagnosis, which is three to six months in itself, but before the symptoms ever arise this would suggest there is a period of -- well, a long-ish period before they do?

**MS RICHARDS:** Yes, absolutely.

This is dated 1 March 1983, and we know, from the reference in the "Dear Director" letter that we looked at, this is material that is being sent, it would seem, to all Haemophilia Centre Directors in the United Kingdom.



If we then please, Henry, have CBLA0001693_002, we can see that also in March of 1983 -- this is headed "Draft Letter". There's no reason to think it wasn't sent but I should point that out.

It's a letter from Dr Craske, Dr Rizza and Professor Bloom. Again "Dear Director" -- so again one assumes to the Haemophilia Centre Directors of the UK -- and it's on this issue of "Trials of 'hepatitis reduced' Factor VIII":

"The Hepatitis Working Party has drawn up the enclosed protocol, as a result of discussions at the Haemophilia Reference Centre Directors meeting, for use in the trials of this product to assess the efficacy of the different methods used for the removal of hepatitis viruses. You will see that the class of patients to be given these products are those who have had no previous treatment with Factor VIII concentrate."

So previously untreated patients are now the class of patients identified in the protocol.

The protocol itself is at CBLA0001693_003. This particular document is a draft that was sent to members of the Hepatitis Working Party for comment.

1 We don't know for sure at the moment one way or
2 another whether it was the final version, but we can
3 see there under the heading "Trials of 'hepatitis
4 reduced' Factor VIII concentrate in the NHS -
5 assessment of residual infectivity". Details are set
6 out of the trials that are going to be undertaken.
7 I won't go through the detail of it now, but if we go
8 to the bottom of the page -- sorry, no, under the
9 heading "Methods":
10 "The decision to include any patient in these
11 trials will be made by the Director of the local
12 Haemophilia Centre responsible for the care of any
13 patient based on the following criteria:
14 "Subjects will be selected from infrequently
15 treated patient groups who have not previously been
16 treated with Factor VIII concentrate. They should not
17 have received any blood products in the 6 months prior
18 to entry into the trial, and preferably have received
19 less than 50 donor units of cryoprecipitate (or
20 3,500 Factor VIII units) in the past."
21 They need to be hepatitis B negative, et cetera.
22 They should have had no previous hepatitis.
23 Then I should point out it's said at the bottom
24 of the page that the object of the study will be
25 explained to them and their consent and that of their



1 parents obtained if under 16 years of age.
2 Then over the page, we see what's proposed is
3 there will be:
4 "... a full clinical examination, with special
5 reference to liver disease ... a full blood count and
6 liver function tests [will be taken]."
7 Then:
8 "Patients will be followed up for 52 weeks
9 following their treatment episode in the absence of
10 any transfusion hepatitis."
11 Again, we see reference there to the various
12 liver function tests and blood collections in the
13 course of the trial. We see the "Definition of
14 hepatitis" then set out.
15 "A patient will be considered to be suffering
16 from acute hepatitis if he develops clinical symptoms
17 and signs as described in form C1, or shows an
18 increase of at least two and a half times the upper
19 limit of normal serum aminotransferase levels, having
20 had normal values previously."
21 Then under the heading "Follow-up", at the
22 bottom of the page:
23 "Patients whose liver function tests remain
24 elevated for one year after the acute attack of non-A,
25 non-B hepatitis or become carriers of hepatitis B



1 virus will be referred to the local liver clinic for
2 investigation of chronic liver disease. Liver biopsy
3 will not be carried out unless clinically indicated."
4 Then the next page we see there will be various
5 assessments at intervals of the incidence of acute
6 hepatitis, both B and non-A, non-B.
7 So that's the protocol for the study and you
8 will see there the category of patients and the clear
9 recognition there of the possibility of liver disease.
10 Still in March, I'm afraid -- oh, I note the
11 time, sir. Shall we take a break now?
12 **SIR BRIAN LANGSTAFF:** Yes.
13 As last week, for those of you who were here,
14 and for those of you who weren't, we're taking
15 45 minutes for a break. The reason it's as long as
16 that is to make sure that you have a chance to go and
17 have refreshments brought to you at your designated
18 seats and have time to get there socially distanced,
19 keeping safe as you do. We do try our best to keep
20 everyone as safe and secure as we can in these
21 difficult times. So I look forward to seeing you
22 back -- that will make it, what, 11.50 -- ten to
23 twelve. Shall we make it 40 minutes, because there
24 are perhaps less of you this week than there were
25 last.



1 **(11.11 am)**
2 **(A short break)**
3 **(11.55 am)**
4 **MS RICHARDS:** Sir, I have reached March 1983.
5 I should just say in terms of timing for today,
6 obviously this is material that needs to be looked at
7 carefully and I'm not proposing to rush through any of
8 it. There are fewer documents to look at once we get
9 beyond 1984, for obvious reasons. But whether we get
10 on to the Oxford presentation today or not I'm not at
11 the present confident one way or another. We'll see
12 how matters go.
13 A lot of the documents being referred to today
14 are documents in common with the Oxford material,
15 because obviously Dr Bloom and Dr Rizza were working
16 very closely together at this time. But I just
17 thought I'd provide that update for those who are
18 listening both here and remotely.
19 **SIR BRIAN LANGSTAFF:** Thank you very much.
20 **MS RICHARDS:** Sir, 23 March 1983 Professor Bloom attended
21 a meeting of the CBLA, the Central Blood Laboratory
22 Authority. I'm not going to go to the minutes of that
23 meeting because they say very little of relevance in
24 relation to Professor Bloom, other than he suggested
25 that the CBLA should discuss AIDS at a future meeting.

1 But we do get an insight into the meeting from a note
2 prepared by Dr Lane of BPL.
3 Henry, could we have CBLA0001691, please.
4 This is an internal note from Dr Lane dated
5 24 March 1983, and we see he says:
6 "Professor Bloom drew to the attention of the
7 CBLA at their meeting on Wednesday, 23 March, the
8 problems that are becoming associated with blood
9 transfusion and blood product administration with the
10 increasing incidence of reported AIDS cases which
11 continues to gain momentum in the United States on
12 a monthly basis. The high mortality in reported cases
13 is a cause for concern and is a primary factor behind
14 what is described as the American over-reaction to the
15 problem. The aetiological factor or factors remain
16 unknown."
17 Pausing there, sir, this reads as though Dr Lane
18 is recounting what Professor Bloom had told the
19 meeting. So the description of an American
20 overreaction, and of course Professor Bloom had
21 received the letter from Bruce Evatt by this time,
22 seems likely to have been Professor Bloom's but we
23 can't be entirely confident. The minutes themselves
24 contain no reference to this issue. The note
25 continues:



1 "Professor Bloom will continue to keep the
2 Authority informed. Dr Gunson will be attending
3 a Council of Europe meeting in April where the
4 implications of AIDS on the plasma collection and
5 fractionation programme will be dealt with. The panel
6 of experts will determine what advice should be given
7 to blood transfusionists and special user groups in
8 Europe. This advice will be reported back to the
9 Authority.
10 "Meanwhile, patients potentially at risk in the
11 United Kingdom (notably haemophiliacs) are evidently
12 concerned and resistance against the use of imported
13 American coagulation factor concentrate is becoming
14 apparent. Equally, there is a likelihood that
15 a return to cryoprecipitate as a desirable formof
16 treatment may become irresistible, whether logical or
17 not."
18 Whether that is Dr Lane's own view or he is
19 recounting Professor Bloom's is unclear. The next
20 paragraph, however, seems fairly clearly to be
21 Dr Lane's proposal:
22 "It is necessary for this laboratory [i.e. BPL]
23 to develop a policy, which may only be implemented on
24 a short-term basis which will allow for the
25 presentation of a large proportion of NHS Factor VIII



1 as cryoprecipitate. Staff will be aware that many
2 Regional Transfusion Centres have not made wet
3 cryoprecipitate for some time and would now be both
4 out of practice and in some cases without the
5 facilities to recommence large-scale production. The
6 implications for BPL source material are very real."
7 Then there's a suggestion of setting up
8 a meeting to discuss this issue.
9 Moving to April of 1983, and of course by this
10 time the FDA in the States, on 24 March, has issued
11 its directive about ceasing to collect and fractionate
12 plasma from donors in high-risk groups. We then in
13 April see further contact from pharmaceutical
14 companies with Professor Bloom.
15 Henry, could we have BAYP0000028_076, please.
16 We can see this is a letter from -- it's from a cutter
17 sales representative:
18 "Dear Professor Bloom,
19 "Further to our discussion on 30 March [we don't
20 have any further details of that discussion], I am
21 writing to confirm our position with regard to AIDS.
22 "Cutter has instituted new screening procedures
23 for the selection of plasma donors ..."
24 And details of that are there set out. Then he
25 says further down the letter:



1 "You can be assured that Cutter has intensively
2 involved its people and resources in following all
3 AIDS developments, and we are in virtually constant
4 communication with responsible Health Authorities."
5 Then there's an offer of responding to any
6 further queries Professor Bloom may have.
7 We then, still in April 1983, see that
8 Professor Bloom gave a talk to The Haemophilia
9 Society's AGM, and we have details of that in
10 PRSE0000411.
11 This is a copy of The Haemophilia's Society's
12 Bulletin, the second of 1983. The precise date of
13 publication is unclear but either the middle or second
14 half of 1983 seems likely. But it reproduces the text
15 of Professor Bloom's talk.
16 So if we go please, Henry, to the second page --
17 and if we could just zoom in a little more, please,
18 thank you.
19 So we can see:
20 "Talk given at the [AGM] 23 April 1983
21 Professor AL Bloom."
22 The title of the talk is "Home Therapy - Myth or
23 Reality", and we can see he deals both with practices
24 in relation to home therapy and with the issue of
25 AIDS.

1 Picking it up in the first paragraph, a few
2 lines down, he says:
3 "... one of my tasks this afternoon is therefore
4 to explain why home therapy appears to be real.
5 I shall outline some of the logistic and medical
6 problems which may impart a mythical connotation to
7 what is otherwise real."
8 He then explains about how he started to treat
9 patients in the early 1960s, mostly with fresh frozen
10 plasma. Then refers to the late Dr Judith Pool's
11 development of cryoprecipitate and how that was
12 enthusiastically adopted:
13 "For the first time treatment of haemophilia A
14 at any rate was readily amenable to straight
15 intravenous injection therapy and on demand treatment
16 at haemophilia centres expanded rapidly. Although
17 storage of cryoprecipitate requires deep freeze
18 facilities and it is relatively inconvenient to use,
19 it was successfully adopted for home therapy
20 programmes, for example, by the late
21 Dr Katherine Dormandy at the Royal Free Hospital and
22 at several other Centres."
23 Then he goes on to talk about the advent of
24 freeze-dried preparations.
25 Under the heading a bit further down the page,



1 please, Henry, "Home Therapy in the UK", we'll pick it
2 up towards the bottom of that column:
3 "The reality of the situation with regard to
4 home treatment is in fact that just under half the
5 patients with haemophilia A or B are now established
6 on home treatment programmes and the number of
7 patients treated has now levelled out."
8 He then goes on to describe the sort of
9 treatment that's available for home treatment and says
10 this:
11 "... we see that cryoprecipitate accounts for
12 only a small proportion of material used for treatment
13 and about half of the freeze dried Factor VIII
14 concentrates are used at home for about half of the
15 patients."
16 He then goes on to discuss home treatment for
17 von Willebrand's. Then if we go to the top of the
18 right-hand column, Henry, please, under the heading
19 "Drawbacks":
20 "Does the introduction into the circulation of
21 all these blood derivatives have drawbacks? Whilst
22 there is no doubt of the immediate benefit of
23 treatment in terms of daily quality of life and the
24 maintenance of joint function, what about the less
25 beneficial effects?



1 "We are all familiar with the possibility of
2 immediate reactions but these do not pose major
3 problems."
4 Then skipping over a sentence, he says:
5 "However, the problems of hepatitis Factor VIII
6 inhibitor and the newly described Acquired Immuno
7 Deficiency Syndrome pose special risks although not
8 specifically related to home treatment."
9 Towards the bottom of that paragraph he refers
10 to the number of patients with overt acute hepatitis
11 remaining remarkably constant at about 2 to
12 3 per cent:
13 "... but there is increasing evidence that more
14 insidious signs of chronic inflammation of the liver
15 are much more common."
16 Then there's a reference to a survey of that
17 problem underway by the Hepatitis Working Party.
18 Then if we can go further down please, Henry,
19 under the heading "Acquired Immune Deficiency
20 Syndrome", he says this:
21 "I cannot end without a comment on one new
22 problem which may turn out to be the greatest myth or
23 the most significant reality of all. I refer to the
24 recently described and publicised Acquired Immuno
25 Deficiency Syndrome or AIDS."



1 He then refers to how it was first recognised.
2 If we could go to the next page please, Henry,
3 if we pick it up in the left-hand column, bottom half
4 of the page, he refers to in 1982 the condition being
5 reported in a few haemophiliac patients in the USA:
6 "By February 1983 thirteen cases have been
7 reported amongst American haemophiliacs only one of
8 whom was an admitted homosexual. Eight of these
9 patients have since died. I am unaware of any
10 definite cases in British haemophiliacs ..."
11 Sir, I just ask you to note that and bear in
12 mind the date, this is 23 April 1983, and we'll look
13 in a little while at what we know of the first
14 reported case in the UK which was a Cardiff case under
15 Professor Bloom.
16 But he says here:
17 "I am unaware of any definite cases in British
18 haemophiliacs ..."
19 And the use of "definite" may be deliberate:
20 "... although cases are occurring in British
21 homosexuals and it is rumoured that one of these has
22 haemophilia."
23 Then he refers to a survey being conducted by
24 the Haemophilia Centre Directors Organisation.
25 He refers at the bottom of the page to

physicians turning their attention to the "healthy" haemophiliac population. Then, at the very bottom of that, he says:

"... it is probable that like most newly described disorders less severe or early forms ..."

If you could go to the top of the next column, Henry:

"... will be detected and many research products are under way in attempts to elucidate the extent of these changes."

Then he says this:

"What is the cause of the disorder? This is still quite unknown. It could simply be a reaction on the part of our immunity mechanisms to the long-term infusions of other people's plasma proteins. Perhaps there is some unknown constituent of blood products which is responsible, but the occurrence of the condition in homosexuals, drug addicts, immigrants from tropical climes and in recipients of blood products makes the transmission of an infective agent the most likely cause."

Then he poses the question:

"How should we react to this development?"

And says this:

"... it is worth reflecting that thirteen cases amongst 20,000 haemophiliacs in the USA means only one expected case amongst 2,000 haemophiliacs in the UK."

Pausing there, sir, you may wish to consider in due course whether that is an error of reasoning.

**SIR BRIAN LANGSTAFF:** Well, it's comparing actual cases with expected cases.

**MS RICHARDS:** Yes.

**SIR BRIAN LANGSTAFF:** Which is not a proper comparison, is it?

**MS RICHARDS:** Well, sir, that is matter for your judgment but that is a reasonable inference you may wish to draw.

**SIR BRIAN LANGSTAFF:** In due course if I am wrong on that I can be persuaded otherwise.

**MS RICHARDS:** He then makes the point that:

"... evidence from the incidence of hepatitis does not lead one to believe that concentrates prepared from British blood are necessarily safer, in this latter respect at least. Although it's prudent to keep an open mind, the use of factor concentrates has revolutionised the lives of many sufferers from haemophilia A and B and it does not seem reasonable to curtail treatment at the present time."

There's then a question and answer session, which we see beginning in the right-hand column under the heading "Annual General Meeting - 1983 Question and answer time", involving Professor Bloom, Dr Forbes, Sister Fountain and the Reverend Alan Tanner.

I am not going to go through the details of it but there's a discussion about home treatment, there's discussion about prophylaxis.

If we could then go please to the next page Henry -- sorry, that can go to the following page. My apologies. One after that.

Picking it up halfway down the left-hand column there's a member of the audience who refers to a BBC Horizon programme on AIDS, and Professor Bloom says this:

"It is unfortunate that haemophilia has been linked with AIDS. Apart from that we must not overlook the AIDS problems. One of my patients may have a mild form of it."

That's a reference to what I'll refer to, for present purposes, as "the Cardiff case", without obviously identifying any patients by name:

"Some patients show laboratory changes. Laboratory changes do not mean that it is a serious disease. I do not know of any haemophiliac with AIDS in the UK, France or Germany. I do not think we need to get over-concerned about this. At the present time it would be absolutely wrong to curtail treatment."

Sir, just pausing there, the position in relation to Germany may require a little further explanation. There were cases reported by this time in Germany but it's not clear that Professor Bloom would have known that in April. He would have known it probably within a matter of weeks but he wouldn't necessarily have known it at this time and we don't know one way or another.

Then if we go to the top of the next column, please, where Professor Bloom says this:

"The concern has been that transmission has been from blood or blood products. The relevance is whether the transmission of this disease is by blood and associated blood products. That is what it is concerned with. If it is a transfusible agent it is strange that it has not happened in Western Europe. They are only assuming that it is transfusible by blood. Not everybody who gets blood will get the disease."

It may be thought there a degree of reassurance being given, but whether it's a correct reassurance will be a matter for you to consider, to those in the audience who are listening.

1 Then I just note further down that column
2 there's a reference then, below the picture, to
3 hepatitis, where Professor Bloom says there's no such
4 thing as a hepatitis-free concentrate, the
5 concentrates must be handled with care.
6 Whilst we're still looking at this document,
7 sir, I just ask you to note, if we go on to -- I think
8 it is probably page 11, Henry.
9 There's an article on AIDS by Dr Pinching, who
10 is an immunologist at St Mary's Medical School. It
11 continues on to the next page. But his view is that
12 whilst there are many other suggested causes, that
13 AIDS is "due to an infectious agent, transmitted by
14 intimate contact or blood product inoculation ...
15 seems the most likely", and he goes on to discuss that
16 in his article.
17 **SIR BRIAN LANGSTAFF:** What does he say at the bottom of
18 the page there?
19 **MS RICHARDS:** Dr Pinching?
20 **SIR BRIAN LANGSTAFF:** "A particular problem is", the last
21 sentence. How does that follow on?
22 **MS RICHARDS:** He says:
23 "A particular problem is that there appears to
24 be quite a long period, months or years, between
25 exposure to the causative agent and the person



1 becoming ill during the time he/she may be
2 infectious."
3 **SIR BRIAN LANGSTAFF:** Thank you.
4 **MS RICHARDS:** He goes on to discuss the disease carrying
5 with it a high mortality rate.
6 There's a further CBLA meeting in late
7 April 1983. The discussion there is relatively broad
8 in nature. It's said that Regional Transfusion
9 Directors had considered all the American literature.
10 In fact, we will go to it because there is a comment
11 from Professor Bloom that's worth noting. Sorry,
12 Henry, it's CBLA0001702. We can see the date Central
13 Blood Laboratories Authority minutes, 27 April 1983.
14 We can see that Professor Bloom is there. If we go,
15 please, to the fourth page, top of the page:
16 "Professor Bloom reported that he'd given a talk
17 on AIDS to the AGM of The Haemophilia Society. His
18 impression was that haemophiliacs were not greatly
19 concerned about AIDS."
20 Whether that, of course, is a result of the
21 advice or impression he was giving them may be
22 a matter for you to consider and, indeed, whether it's
23 consistent with what's said elsewhere will be a matter
24 for you to consider.
25 We know then that on 1 May 1983 there were



1 various newspaper articles published -- we've already
2 looked at a number of them in an earlier
3 presentation -- which referred to two men in hospital
4 in London and Cardiff suspected to be suffering from
5 AIDS after routine transfusions for haemophilia. That
6 triggers contact between The Haemophilia Society and
7 Professor Bloom. If we have, please, CBLA0000060_158.
8 It's a letter from Professor Bloom to the Reverend
9 Alan Tanner, the chair of The Haemophilia Society. It
10 says:
11 "Dear Alan. In response to David's telephone
12 call over the weekend, I've drafted out a letter which
13 is enclosed. I hope this is what you are looking for.
14 I'm not too sure if David meant it would be circulated
15 to members above both our signatures or just above
16 yours, but either procedure would be acceptable to me.
17 Please feel free to modify it as you wish. I am sorry
18 about the inaccurate reports, particularly in the
19 Mail, and was shocked to learn of the lengths to which
20 this reported -- it says; perhaps reporter -- had gone
21 with the Society. I hope you make headway with the
22 Press Council."
23 We know there was, indeed, a complaint to the
24 Press Council about the May 1983 article in the Mail
25 on Sunday, although my recollection is that was



1 a complaint made by Dr Peter Jones, rather than The
2 Haemophilia Society.
3 There's then, over the page, a draft text from
4 Professor Bloom, but rather than look at that, we'll
5 look at the published version of the text which is at
6 DHSC0001228. This is an important document, so I am
7 going to essentially read out what we have here. It's
8 a publication by The Haemophilia Society on 4 May of
9 1983, and it says this:
10 "In view of the unduly alarmist reports on AIDS
11 which appeared in the press over the weekend, we are
12 writing to reassure members of the society about the
13 true position. We have been in touch with Professor
14 Arthur Bloom -- it sets out who he is -- who has
15 kindly written to us all as follows."
16 Then this is the text from Professor Bloom:
17 "Reports from America of the acquired immune
18 deficiency syndrome in persons with haemophilia are
19 causing anxiety to members of this society and to
20 their relatives."
21 Pausing there, sir. The note we looked at
22 previously suggested that Professor Bloom's impression
23 was that haemophiliacs were not greatly concerned. In
24 any event, he identifies their anxiety and says this:
25 "Haemophiliacs, their parents and doctors have

always balanced the quality of life and the dangers from bleeding against the risks of treatment. We are no strangers to infective diseases, such as hepatitis, which can be transmitted by factor concentrates. Recent evidence suggests that, in this respect at any rate, concentrates prepared from British blood are not necessarily safer than those prepared in the United States. Even so, we welcome the fact that the Government is investing over GBP 20 million in the Blood Products Laboratory at Elstree so that this country shall become self-sufficient in blood products. Bearing this in mind, it is important to consider the facts concerning AIDS and haemophilia. The cause of AIDS is quite unknown, and it has not been proven to result from transmission of a specific infective agent in blood products."

You will note there, again, sir, the use of the word "proven":

"The number of cases reported in American haemophiliacs is small, and in spite of inaccurate statements in the press, we are unaware of any proven case in our own haemophiliac population."

Pausing there, sir. Of course, there was a case. The use of the word "proven" may again be significant, but there was a case of a patient under



Professor Bloom's own care in Cardiff at this time.

"Neither have any cases been reported from Germany, where massive amounts of American concentrates have been used for many years."

As I indicated earlier, that's not correct, but Professor Bloom may not at this time have known about those cases.

"Nevertheless, the situation is being closely monitored by the Haemophilia Centre Directors and in a more general way by the Communicable Disease Surveillance Centre in London. In addition, the importation of licensed blood products has always been strictly monitored and controlled. Thus, whilst it would be wrong to be complacent, it would equally be counter-productive to alter our treatment programmes radically. We should avoid precipitate action and give those experts who are responsible a chance continually to assess the situation."

Then the publication continues, and this is the Reverend Tanner again:

"We're most grateful to Professor Bloom for this statement. If you have any further questions about AIDS and your own treatment programme then, of course, your centre director will be able to help you."

So that is the public message authored by



Professor Bloom, sent out by The Haemophilia Society on 4 May. If we look, please, Henry, at PRSE0000353 and if we could zoom in on that please, Henry. I know you've seen this document before, sir, as will others, but its date and content is significant. So it's the Communicable Disease Report. If we go down the page, we can see the date. It's the week ending 6 May 1983, so it's essentially around the same time as the publication from The Haemophilia Society we've just looked at. Then this:

"Acquired immune deficiency syndrome: Cardiff. Acquired immune deficiency syndrome has been reported in a 20-year-old man with haemophilia in Cardiff. For three months, he has had oropharyngeal and oesophageal candida infection and has recently been treated in hospital for epididymo-orchitis. He has lymphopenia and a low T-helper suppressor ratio. There is no known underlying cause of immunosuppression. This is the first report of AIDS in a patient with haemophilia in the United Kingdom known to CDSC."

So there doesn't appear to be any uncertainty in the minds of CDSC that this is a case of AIDS. Presumably, but it is only an assumption, that is information that's been reported to it by Cardiff and Professor Bloom.



Sir, just picking up on the point about cases in Germany, we know that on 28 April 1983 the Council of Europe's Committee of Experts on Blood Transfusion and Immunohaematology had published a report on AIDS in which it recorded two cases in haemophiliacs had occurred in January. I'm not going to put that up, but the reference is DHSC0000717.

We then see further communications from pharmaceutical companies to Professor Bloom. This is at DHSC0001291. This is 9 May 1983. It's a letter to Professor Bloom from the managing director of Travenol Laboratories in the UK:

"Dear Professor Bloom. I want to advise you of important developments and actions being taken by Hyland Therapeutics and Travenol Laboratories in connection with the risks of AIDS. While the causative agent of this disease remains to be identified, some evidence suggests it is caused by a virus that can be transmitted by blood and certain blood products."

Then it goes on in the next paragraph to identify that Hyland Therapeutics recently became aware that one of its plasma donors had been identified as a possible victim of AIDS, although it says no therapeutic products fractionated from plasma

1 pools containing that donor's plasma had been shipped
2 to Europe.
3 Then the letter continues about the steps that
4 were going to be taken or were being taken by Hyland
5 and Travenol.
6 We then see further communications between The
7 Haemophilia Society and Professor Bloom. We can pick
8 that up at CBLA0000060_044. If we go to the second
9 page, first of all, please, Henry, we can see a letter
10 from Mr Watters to all members of the medical advisory
11 panel, and Professor Bloom was one of the members of
12 The Haemophilia Society's medical advisory panel, as
13 I think was Dr Rizza. I'll double-check that.
14 It sets out how there's going to be a meeting in
15 connection with current AIDS publicity and that
16 various matters were going to be raised including:
17 "(b) An assurance that there will be no
18 immediate ban on the importation of US blood
19 products."
20 **SIR BRIAN LANGSTAFF:** Geoffrey Finsberg, he was the junior
21 minister, was he?
22 **MS RICHARDS:** I'm afraid I don't know, off the top of my
23 head.
24 **SIR BRIAN LANGSTAFF:** I think you may find that he
25 probably was at the DHSS.



1 **MS RICHARDS:** Yes. There are certainly references in
2 later communications with them meeting with ministers,
3 so that may be right. I'll check, sir.
4 Then we see that Mr Watters is saying:
5 "The Chairman's asked that -- I think there's
6 a "we" missing -- we obtain any view that you may hold
7 on those matters and also any other subjects which you
8 feel we should raise at this time which relate
9 specifically to AIDS."
10 Then we have the response on the first page of
11 this document from Professor Bloom:
12 "Thank you for your letter about AIDS. I'm glad
13 to see you'll be meeting Geoffrey Finsberg
14 on May 20th. I am sure the present Government has
15 made a definite commitment to UK self-sufficiency in
16 blood products, but I'm equally sure your strong
17 representations about the other three points would be
18 very appropriate."
19 So you will see there effectively
20 Professor Bloom endorsing The Haemophilia Society's
21 view that the Government should be asked to give an
22 assurance that there be no immediate ban on the
23 importation of US blood products.
24 There's then a reference to drawing the
25 attention of the MRC, Medical Research Council, to



1 AIDS and the desirability for funding for AIDS-related
2 projects.
3 Then there's a request to emphasise the
4 essential need for increased regional funding for
5 blood transfusion centres. He says this:
6 "This will be even more necessary if there's any
7 substantial demand for cryoprecipitate on the part of
8 haemophiliacs. Such a demand could reduce the supply
9 of available plasma at present funding levels, and
10 a considerable expansion of regional facilities will
11 be needed in any case."
12 So in terms of any opportunity to raise any
13 other matter with the minister, these are the matters
14 that Professor Bloom suggests are raised, and not
15 anything else.
16 If we then have, please, HSOC0029476_024,
17 please. This is a meeting of The Haemophilia
18 Society's executive committee on 12 May 1983. If we
19 go to the second page, please, Henry. Go down towards
20 the second half of the page under the heading "(b)
21 AIDS":
22 "The Chairman introduced the subject of the
23 present AIDS scare in the UK and referred to the
24 dossier of press cuttings ... it was agreed that the
25 co-ordinator should take appropriate steps in



1 connection with the Mail on Sunday. It was noted that
2 one centre director had already lodged a formal
3 complaint ... the Chairman outlined his action in
4 mailing his letter of 4 May 1983 to the entire
5 membership of the society ..."
6 So that's the document we looked at with the
7 statement from Professor Bloom.
8 "... and it was agreed unanimously that, until
9 there is evidence to prove otherwise, the Society's
10 policy would be to encourage members to continue with
11 their present treatment programmes, subject to the
12 advice of their centre directors, and that full
13 support would be given to self-sufficiency in blood
14 products at the earliest possible date."
15 Then if we see the next couple of lines, please,
16 Henry. So you are right about Mr Finsberg.
17 "A meeting with the minister, Mr Finsberg, had
18 been arranged, et cetera, et cetera."
19 So we can see there that the advice from
20 Professor Bloom has been shared with all members of
21 the Society and maybe a reasonable inference to see it
22 has an influence on the Society's response to the AIDS
23 crisis.
24 If we then go, please, to DHSC0001177, we see
25 that on 13 May of 1983 there was a special meeting of

1 Haemophilia Reference Centre Directors at St Thomas'
2 hospital. We can see who was present: Bloom, Craske
3 Hamilton, Kernoff, Ludlam, Savidge, Preston, Delamore,
4 Rizza and Dr Walford from the Department of Health and
5 Social Security.
6 This is the first specially convened meeting
7 that the Haemophilia Centre Directors held in order to
8 consider the issue of AIDS. Although, as we have
9 seen, it had been discussed at a number of earlier
10 routine meetings.
11 If we could go to the second page, please. The
12 first page contains Professor Bloom's update of the
13 position and then, on the second page, we see what the
14 Reference Centre Directors decide. So in the second
15 main paragraph beginning, "The steps to be taken," we
16 see what is suggested is that if a patient develops
17 the features of the full-blown condition, there was
18 insufficient information available to warrant changing
19 the type of concentrate.
20 Then in the next paragraph, with regard to
21 general policy to be followed in the use of
22 Factor VIII concentrates:
23 "It was noted that many directors have, up until
24 now ..."
25 And then "restricted their use of" is crossed



1 out and replaced with "reserved or", and I'm not quite
2 sure what the next word is.
3 "Reserved National Health Service concentrates
4 for children and mildly affected haemophiliacs, and it
5 was considered it would be circumspect to continue
6 with that policy. It was also agreed that there was,
7 as yet, insufficient evidence to warrant restriction
8 of the use of imported concentrates in other patients
9 in view of the immense benefits of therapy. The
10 situation shall be kept under constant review."
11 So that's the recommendation. In terms of
12 general policy, it's a we'll continue with what many
13 directors already do, it said, in relation to children
14 and mildly affected haemophiliacs.
15 **SIR BRIAN LANGSTAFF:** Can I just come back to the
16 underlying text for a moment?
17 **MS RICHARDS:** Yes.
18 **SIR BRIAN LANGSTAFF:** It's the last sentence of the
19 paragraph at the top:
20 "Moreover, once the condition is fully
21 developed, it seems to be irreversible, so there would
22 seem to be no clinical benefit to be gained by
23 changing to another type of Factor VIII."
24 Would it be for me to consider whether that
25 corresponds with what I heard from those who had been



1 infected as to what they were told about the likely
2 cause of their condition?
3 **MS RICHARDS:** Absolutely.
4 **SIR BRIAN LANGSTAFF:** Thank you.
5 **MS RICHARDS:** We'll see shortly that meeting resulted in
6 the sending out, in the following month, of a letter
7 to Haemophilia Centre Directors. But in the meantime,
8 we can see at DHSC0001206 on 16 May, Dr Walford wrote
9 to Professor Bloom referring to a telephone
10 conversation they had had. The issue that she then
11 refers to in this letter is about the possible need to
12 institute new labelling requirements for Factor VIII
13 concentrates derived from plasma taken before the new
14 FDA regulations came into force. The extent to which
15 the conversation itself may have roamed more widely is
16 not known, but there is in here another means of
17 direct communication, or another form of direct
18 communication, between Professor Bloom and those
19 within the Department instrumental in shaping
20 Government policy.
21 We have a letter then from Dr Bloom to
22 Dr Walford, Professor Bloom to Dr Walford, at
23 HCDO0000003_122. It's a letter of 17 May, and if we
24 look about -- we'll pick it up in the second sentence:
25 "This refers to the possibility that some of the



1 American Factor VIII manufacturers may consider it
2 advantageous to export products which were made from
3 plasma collected before March 24, rather than retain
4 it for domestic use. You are no doubt aware that on
5 that date the American Food and Drug Administration
6 circulated all American establishments collecting
7 source plasma, giving revised guidelines for
8 collecting plasma with regard to AIDS. I have some
9 misgivings concerning the possibility that stocks held
10 by the manufacturers and source plasma collected
11 before that date will be preferentially exported."
12 In other words, the potential dumping of
13 products that wouldn't be used for American
14 haemophiliacs on foreign markets.
15 "Whilst I do not wish to overstate the risk from
16 imported American Factor VIII concentrates,
17 nevertheless, I think that Haemophilia Centre
18 Directors would wish to be reassured that Factor VIII
19 concentrates imported are at least up to the standards
20 recommended for use in the USA."
21 We then, sir, go to an internal Cardiff document
22 which many may not have seen before. It's
23 WITN4029002. This is a document that's been provided
24 to the Inquiry by Professor Peter Collins who, as you
25 know, sir, is the current Haemophilia Centre director

1 in Cardiff and only joined Cardiff a number of years
2 after the events with which we're currently concerned.
3 But he refers to a protocol apparently written
4 in May 1983, and that is this document, so it's
5 understood to be a Cardiff-generated document. It's
6 called "Haemophilia treatment policy guidelines,
7 May 1983", and we'll see what it sets out here. So
8 for mild haemophiliacs and von Willebrand's:
9 "Use DDAVP for minor lesions expected to need
10 only one to two days' treatment.
11 (b) Use cryoprecipitate or NHS factor
12 concentration for other lesions."
13 And then examples given.
14 "NHS factor concentrate for out-patient mild
15 haemophiliacs."
16 So for that first category, mild haemophiliacs
17 and von Willebrand's, DDAVP, cryoprecipitate, or NHS
18 Factor VIII.
19 "Children with severe haemophilia -- is the
20 second category -- use cryo or NHS Factor VIII, as in
21 1 (b) above.
22 (3) Adults with severe haemophilia use
23 cryoprecipitate for in-patient treatment where
24 feasible. Those who have never received imported
25 concentrate should, where possible, only receive NHS



1 concentrate when concentrate therapy is needed. Other
2 patients should continue to receive imported
3 concentrate as previously described. Patients with
4 haemophilia B should receive NHS Factor IX concentrate
5 as needed."
6 Then there's a reference to FEIBA. Then under
7 the heading "General points":
8 "Try to maintain patients on same material and
9 same batch if possible to reduce donor exposure.
10 Remember that even NHS Factor VIII will transmit
11 non-A, non-B hepatitis. Use DDAVP or cryo where
12 possible for mild hepatitis-susceptible individuals."
13 Over the page --
14 **SIR BRIAN LANGSTAFF:** Should there be a stroke, do you
15 think, between mild and susceptible? Is it two
16 categories, susceptible patients and mild
17 haemophiliacs, or are the two running together?
18 **MS RICHARDS:** It could be either, sir. It would perhaps
19 make more sense for it to be two separate categories,
20 but the document itself doesn't seem to make that
21 distinction.
22 Then over the page:
23 "Try to avoid introducing a dose of commercial
24 concentrate during a treatment episode which has
25 already commenced on NHS material unless there is good



1 reason for changing."
2 Then the date that is given is May 18, 1983.
3 Now, you will no doubt, sir, wish to consider
4 whether these guidelines mirror what was actually done
5 in relation to patients at the Cardiff Haemophilia
6 Centre. In particular, in relation to the position of
7 children, mild haemophiliacs, and those who had not
8 previously received imported concentrates, whether
9 these guidelines were adhered to. There is no name on
10 these guidelines, but it would seem inconceivable that
11 they could have been produced in May 1983 for Cardiff
12 usage without Professor Bloom's knowledge.
13 **SIR BRIAN LANGSTAFF:** Would it be for me to consider
14 whether the item at (c) for adults with severe
15 haemophilia, where the guidelines say that
16 cryoprecipitate should be used for in-patient
17 treatment where feasible, whether that corresponds to
18 what was being said nationally, which was: continue
19 with whatever treatment you have been having?
20 **MS RICHARDS:** Yes, absolutely. There are two ways in
21 which you may wish to -- a number of ways in which you
22 may wish to utilise this document, sir: one is the
23 inferences you may draw from it, as to what
24 Professor Bloom may have thought was the true extent
25 of the risk; secondly, a comparison between this and



1 what was actually being done, and you will be able to
2 draw information from that from the many witness
3 statements that you have seen; and the third will be
4 to compare this with what was then said nationally,
5 and we'll look in a few minutes at the document that
6 was sent to Haemophilia Centre Directors, which is
7 much less detailed and much less prescriptive than
8 this.
9 Before we do that, we see a document PRSE0003701
10 which is a letter dated 23 May 1983 from
11 Professor Bloom to Dr Boulton. I should have said,
12 for any who don't know because I referred to him by
13 name already, he was the Deputy Director of the
14 regional blood transfusion service in Edinburgh, and
15 we see it's a response to a letter, and
16 Professor Bloom says -- refers to the special meeting
17 of Haemophilia Reference Centre Directors:
18 "Most of the recommendations which you suggest
19 have, in fact, been incorporated by the Haemophilia
20 Reference Centre Directors. We have not laid down
21 hard and fast regulations, since the details of
22 treatment will depend upon local circumstances. I do
23 not think that anyone is complacent about the
24 situation, but I think that we all agree that it would
25 be counter-productive to ban the importation of blood

1 products at this moment. We are, however, taking
2 steps to recommend that imported products from the USA
3 at least meet with the new FDA regulations. Your
4 comments about the use of cryoprecipitate and NHS
5 Factor VIII concentrate have been incorporated into
6 our advice. Although, at the moment, we are not
7 rigidly differentiating between cryoprecipitate and
8 NHS concentrate, as far as severely affected patients
9 are concerned, at any rate."
10 Sir, pausing there. You will have seen that, in
11 fact, from the document that we just looked at. There
12 appears to be an assumption that there may be no great
13 difference between cryoprecipitate and NHS
14 concentrate, in terms of risk of AIDS, which will be
15 a matter that you will no doubt wish to consider.
16 Then:
17 "With regard to" -- and then I'm not quite sure
18 what the verb there is, it might be "deferral" -- "of
19 home treatment for new patients, this is a matter for
20 further discussion. The Haemophilia Society have
21 expressed concern we're not expanding the home
22 treatment programme with sufficient vigour."
23 Then we don't, I think, need to look at it, but
24 there's an internal minute from Dr Boulton in which he
25 says he thinks that Arthur's -- that's



1 Professor Bloom's -- letter is not unreasonable, and
2 that's dated 30 May 1983.
3 **SIR BRIAN LANGSTAFF:** The second from last sentence:
4 "The Haemophilia Society have expressed concern
5 that we are not expanding the home treatment ..."
6 What is the word written --
7 **MS RICHARDS:** "Project" has been crossed out, and I think
8 that might be "programme" in its place, but I'm not
9 sure.
10 **SIR BRIAN LANGSTAFF:** Yes, I think it looks like that,
11 with sufficient vigour. So The Haemophilia Society
12 were wishing, in effect, factor concentrate to be more
13 used, that is freeze-dried factor concentrate.
14 **MS RICHARDS:** Certainly based upon this letter suggesting
15 that there should be more home treatment. It's also
16 right that the majority of home treatment by this time
17 was with concentrates.
18 **SIR BRIAN LANGSTAFF:** Very little would be
19 cryoprecipitate.
20 **MS RICHARDS:** Very little cryoprecipitate by this time,
21 but of course cryoprecipitate had been successfully
22 used for home treatment in the 1970s, not least by
23 Dr Dormandy at the Royal Free Hospital.
24 **SIR BRIAN LANGSTAFF:** Yes.
25 **MS RICHARDS:** So whether The Haemophilia Society expressly



1 had in mind concentrates or whether they --
2 **SIR BRIAN LANGSTAFF:** It may have that implication.
3 **MS RICHARDS:** Yes, it may.
4 Then we know that Professor Bloom wrote to
5 Armour on 23 May 1983, again raising the concern about
6 the possibility of what he called "preferential
7 exportation" of non-FDA-compliant material to the UK.
8 There is then, if we look at BAYP0000002_183,
9 this is a communication from Cutter to Dr Fowler at
10 the Department of Health. It's instructive for
11 present purposes because we see how the effect of
12 Professor Bloom's statements to The Haemophilia
13 Society are having wider effect. So the author of
14 this letter it says, first of all, on the first page
15 to Dr Fowler picking it up in the third paragraph last
16 sentence -- sorry, penultimate sentence refers to
17 recent examples in the Mail, and that's what's called
18 sensationalistic and erroneous reporting:
19 "... as a result, false conclusions are arrived
20 at and patient treatment as well as product supply are
21 endangered."
22 He says the facts about AIDS are very limited.
23 At 2:
24 "The aetiological agent is unknown ..."
25 It is not known whether it is a virus.



1 3:
2 "Hence it can only be an assumption that AIDS
3 can be transmitted by certain blood products. This
4 has not been shown. Also, it is unclear whether the
5 syndrome contracted by haemophiliacs really is the
6 same as the AIDS syndrome contracted by other high
7 risk groups."
8 So that's the lobbying of Cutter to the
9 Department of Health.
10 But if we go over the page -- sorry, I should
11 just pick it up at the beginning of the first page.
12 My apologies:
13 "As medicine and the plasma suppliers,
14 commercial and NHS, struggle to find the correct
15 actions to take to exclude the elusive AIDS donor, it
16 is imperative that the supply of products in
17 particular Factor VIII not be reduced to levels where
18 patients cannot be treated."
19 Then he says this:
20 "The statement by Professor Bloom in the
21 attached communication from The Haemophilia Society is
22 particularly pertinent."
23 So the wider ripples or effect there of
24 Professor Bloom's pronouncement. We see that also in
25 further internal Cutter communications, where

1 reference to Professor Bloom's statement is repeated.
2 There's a further meeting of the CBLA attended
3 by Professor Bloom and Dr Rizza on 21 June 1983.
4 We'll just look at it briefly. PRSE0002741. We'll
5 see from the list of attendees there that they include
6 Professor Bloom and Dr Rizza, Dr Walford from the
7 DHSS, and others. Under the heading "AIDS", at the
8 bottom of the page, we're told:
9 "The Chairman outlined the problems caused by
10 AIDS. Since it appeared to be transmitted through
11 blood and blood products, then it should be considered
12 by the committee."
13 So a statement there from Dr Gunson, as chair of
14 the CBLA, that AIDS appeared to be transmitted through
15 blood and blood products. This is June 1983 now.
16 Then there is a discussion about the possibility of
17 a circular from the Transfusion Service and the
18 question of research to be undertaken.
19 Sir, if we then move to what was sent out to
20 Haemophilia Centre Directors by way of guidelines
21 following that special meeting in May,
22 HCDO0000270_004. This is 24 June 1983:
23 "Dear [blank]."
24 But we know that it was sent to Haemophilia
25 Centre Directors. It's authored by Professor Bloom as



1 chair of the Haemophilia Centre Directors
2 Organisation, and Dr Rizza as secretary of that
3 organisation. It refers to the special meeting on
4 13 May. It says this:
5 "So far one possible case has been reported to
6 our organisation."
7 Again, sir, you may wish to consider in due
8 course whether that's a correct characterisation, with
9 by this time of the Cardiff case as being a possible
10 case. The sentence continues:
11 "This patient ... conforms to the definition
12 published by the CDC in Atlanta, Georgia but cannot be
13 considered as a definite case. We are not aware of
14 any other definable patients amongst the UK
15 haemophiliac population."
16 Then it sets out recommendations:
17 "1. For mildly affected patients with
18 haemophilia A or von Willebrand's disease and minor
19 lesions, treatment with DDAVP should be considered.
20 Because of the increased risk of transmitting
21 hepatitis by means of large pool concentrates in such
22 patients, this is in any case the usual practice of
23 many Directors.
24 "2. For treatment of children and mildly
25 affected patients or patients unexposed to importation



1 concentrates many Directors already reserve supplies
2 of NHS concentrates (cryoprecipitate or freeze-dried)
3 and it would be circumspect to continue this policy."
4 So, pausing there, sir, you'll see the way in
5 which it's there characterised is: Consider DDAVP in
6 the circumstances set out in paragraph 1, for children
7 mild haemophiliacs or previously untreated patients,
8 circumspect --
9 **SIR BRIAN LANGSTAFF:** Not previously untreated, previously
10 untreated with imported concentrate.
11 **MS RICHARDS:** With imported concentrate. Sorry, sir, yes,
12 you are right.
13 So it falls short of being an instruction. It's
14 a suggestion that it would be circumspect to continue
15 with an existing policy.
16 Then it continues:
17 "It was agreed that there is as yet insufficient
18 evidence to warrant restriction of the use of imported
19 concentrates in other patients in view of the immense
20 benefits of therapy but the situation will be
21 constantly reviewed."
22 Then reference is made to two additional points
23 that have been drawn to their attention since the
24 meeting of 13 May. The first was treatment of
25 patients with haemophilia B, and it's said there:



1 "... logical to continue to use our normal
2 supplies of NHS concentrate."
3 Then the second concerns the proposed trials of
4 hepatitis reduced Factor VIII concentrates.
5 So that's the guidance issued in those terms to
6 Haemophilia Centre Directors in mid-1983.
7 The next key event involving Professor Bloom is
8 again on the national level. It's his attendance at
9 the meeting of the Subcommittee on Biological Products
10 of the Committee on the Safety of Medicines,
11 13 July 1983. We can pick that up at ARSH0001710.
12 Sir, we looked, I think in the course of the
13 Knowledge of Risk presentation, at the agenda, and
14 some preliminary material for this meeting. These are
15 the minutes of the meeting itself.
16 We can see it's chaired by Dr J Smith, various
17 other attendees then set out, and then
18 Professor Bloom, Dr Craske, Dr Galbraith, Dr Gunson,
19 Dr Mortimer attend the morning session. Picking it up
20 under the heating "Confidentiality and Announcements":
21 "The Chairman welcomed Professor Bloom
22 [et cetera, et cetera, the others] and the DHSS
23 officials, who were attending the meeting for item 5
24 on the agenda only. He said that this item would be
25 considered first. The Chairman reminded members, and

1 guests, that the material they received was
2 confidential and should not be disclosed outside the
3 meeting."
4 Then if we go over the page, please, to the
5 second page, Henry, "Acquired Immune Deficiency
6 Syndrome", it's said:
7 "The Sub-Committee's consideration of the
8 question of AIDS and licensed blood products was
9 augmented by the following expert advisers."
10 Professor Bloom is the first there listed. It's
11 then said:
12 "Consideration was given to the current
13 information available on instance and epidemiology,
14 aetiology and related factors. Strategies for
15 limiting or eliminating risks from blood products were
16 examined, together with possible practical measures."
17 Then we see the conclusions of the committee
18 there set out. I won't go through all of them. It's
19 clearly a key event and a key document that you'll no
20 doubt look at many times, but the main points:
21 "5.1. The cause of AIDS is unknown, but an
22 infectious aetiology seems likely.
23 "5.2. Patients who repeatedly receive blood
24 clotting-factor concentrates appear to be at risk, but
25 the evidence so far available suggests that this risk



1 is small. The risk appears to be greatest in the case
2 of products derived from the blood of homosexuals and
3 IV drug abusers resident in areas of high incidence
4 ... and in those who repeatedly receive concentrates
5 in high dosage. Balanced against the risks of AIDS
6 (and of other infections transmitted by blood
7 products) are the benefits of their use; in the case
8 of haemophilia they are life-saving."
9 Then consideration is given in 5.3 to the
10 possibility of withdrawing clotted factor concentrates
11 and replacing it with cryoprecipitate.
12 The conclusion there set out, and no doubt you
13 will want to explore this in due course, sir, as to
14 what the basis of this was:
15 "It was concluded that this is not feasible in
16 the UK on grounds of supply."
17 Then:
18 "The possibility was considered of withdrawing
19 US preparations from the UK."
20 That's rejected as "not at present feasible on
21 grounds of supply". It's also said that:
22 "... the perceived level of risk does not at
23 present justify serious consideration of such
24 a solution."
25 At the top of the next page we see that the



1 subcommittee was informed that the UK Haemophilia
2 Centre Directors had adopted a policy for use of US
3 Factor VIII in order to minimise risks as far as
4 possible.
5 Now, that information must be information
6 provided to the subcommittee by Professor Bloom. That
7 seems reasonable at least; he is the only haemophilia
8 clinician who addresses them as an expert adviser.
9 You will no doubt wish to consider, sir, whether the
10 document we just looked at, the guidelines, does
11 constitute a policy for the use of Factor VIII that
12 minimises risks as far as possible.
13 There's then discussion about the issue about
14 plasma collected pre the FDA regulations of
15 23 March 1983; a viral inactivation as a future
16 prospect is discussed in 5.6.; and then
17 hepatitis-reduced or so-called hepatitis-reduced
18 products and issues relating to the hepatitis B
19 vaccine were then considered.
20 Sir, that's the decision of the Subcommittee on
21 Biological Products and Committee on the Safety of
22 Medicines, and you will no doubt wish to consider the
23 role that Professor Bloom may have played in shaping
24 that decision.
25 If we could then just have, please, DHSC0001207,



1 please, Henry. We can see this is a letter written on
2 27 July by the chair of the committee to
3 Professor Bloom:
4 "Dear Arthur,
5 "The Committee on Safety of Medicine considered
6 the AIDS question last Thursday and Friday and
7 endorsed the recommendations that came from the
8 Subcommittee ... The Chairman of the committee,
9 Sir Abraham Goldberg, asked me to convey his thanks
10 and those of the committee to you for the help you
11 gave.
12 "I am afraid that it is necessary to ask that
13 the recommendations remain confidential, largely
14 because of the commercial implications."
15 **SIR BRIAN LANGSTAFF:** It may perhaps be of greater
16 significance but the Thursday and Friday were, on my
17 understanding of the calendar, the 21st and 22 July.
18 There was an intervening meeting before the congress
19 of the USA I think between the subcommittee and that
20 meeting.
21 **MS RICHARDS:** Yes. Yes, what additional material was
22 considered by the committee in addition to the
23 material from the subcommittee which we just looked
24 at, I don't think -- it's not clear from the materials
25 I currently have available. Again, we'll be exploring

1 that with Government decision-makers in due course.
2 We then see the position of The Haemophilia
3 Society in mid-July 1983, HSOC0029476_026. The date
4 of the meeting, 14 July, is apparent from the first
5 page. If we go to the second page again we can see
6 the influence of Professor Bloom.
7 So, under the heading "AIDS" we can see:
8 "The Chairman introduced this subject and
9 commented upon the WFH [that's the World Federation of
10 Haemophilia] Medical Board report presented at
11 Stockholm by Dr Shelby Dietrich. This report ...
12 carried the same essential message as that sent to our
13 members in early May of this year."
14 Then there's a discussion about a resolution
15 from the Southern Group of the Haemophilia Society.
16 Then we see this:
17 "The Executive Committee were unanimous in their
18 view that the position in the UK remains as it did on
19 4 May when the Chairman wrote to all Society members
20 along with a statement from Professor Bloom. It was
21 agreed that the Co-ordinator should write to
22 Professor Bloom giving him an opportunity to write
23 again amending any statements in that letter."
24 So we'll see that the invitation was made to
25 Professor Bloom: do you want to update or change



1 anything you said in your 4 May 1983 communication?
2 A letter was duly sent to Professor Bloom on
3 19 July of 1983 giving him the opportunity to issue
4 any amending statement. I won't put it up on screen,
5 sir, but the reference for your note is
6 BPLL0001351_084.
7 Then we will look at Professor Bloom's reply.
8 Henry, this is CBLA0000062_053. Zoom in please so we
9 can read that. 25 July 1983:
10 "Dear David [Professor Bloom writes] with regard
11 to the status of AIDS in the UK, I agree with you that
12 there hasn't been any major change."
13 Then he refers to the recommendations of the
14 World Federation of Haemophilia Medical Board:
15 "... seemed to me to be clearly benign, not very
16 conscientious. If anything, it errs in recommending
17 too little but I don't think we need to emphasise this
18 to the Society members. I'm not convinced that much
19 is to be gained by circulating them again at the
20 present time. For your information, I'm enclosing
21 a copy of a letter which Dr Rizza and I have
22 circulated to Haemophilia Centre Directors."
23 That's, no doubt, the June 1983 guidelines. So
24 offered the opportunity to update or amend his
25 statement in light of any subsequent developments,



1 that is Professor Bloom's response.
2 There's a further letter from the
3 Reverend Tanner on 26 July to Professor Bloom.
4 Perhaps look at this because, again, it shows the
5 extent of The Haemophilia Society's reliance upon
6 Professor Bloom's advice. DHSC0001246:
7 "Dear Arthur ..." et cetera, et cetera.
8 If we go to the second paragraph, he expresses:
9 "We were very grateful indeed for your preparing
10 a statement for us so quickly [that's the 4 May 1983
11 document] because that gave us a definite Society
12 policy regarding AIDS and helped to allay a good deal
13 of anxiety among our members."
14 So we see there the role of Professor Bloom's
15 statement in shaping The Haemophilia Society policy
16 and its wider impact upon members. Then if we scroll
17 down please, Henry, to the bottom half of the page, we
18 can see the penultimate paragraph:
19 "We've circulated to the groups the paper
20 presented by Dr Shelby Dietrich but I wonder whether
21 following any conversation you may have had in
22 Stockholm you would wish to add anything to the
23 statement which you prepared for us or whether you
24 think that this is still sufficient without any
25 amendments."



1 So he's asked again, this time by the
2 Reverend Tanner "Do you want to amend or add anything"
3 and his response is CBLA0000060_050.
4 We can see there Professor Bloom's answer on
5 2 August 1983 to the Reverend Tanner is effectively
6 no. He says:
7 "With regard to a further circular on AIDS,
8 I doubt if anything is needed at the present time
9 since there has been little development ..."
10 Again, you will no doubt wish to consider, sir,
11 whether that's a fair reflection of events between May
12 and August of 1983.
13 Sir, I note the time. I'm going to move to
14 September of 1983, so that might be a convenient point
15 at which to stop.
16 **SIR BRIAN LANGSTAFF:** Yes, very well. We'll take a break
17 then until 2 o'clock. So 2 o'clock, if you please.
18 **(1.03 pm)**
19 **(Luncheon Adjournment)**
20 **(2.00 pm)**
21 **MS RICHARDS:** Sir, September 1983 sees another meeting of
22 the Reference Centre Directors on 19 September 1983.
23 We'll look at it briefly. HCDO0000413.
24 There is, if we go to the third page, a further
25 debate about the current situation regarding AIDS, and

1 we learn from that that a patient in Bristol had died.
2 There's reference to follow-up and then concern
3 expressed at the use of commercial concentrates at
4 hospitals that weren't haemophilia centres and actions
5 agreed in relation to that.
6 There's no particular action that emerges from
7 this meeting in relation to any change to the guidance
8 given to Haemophilia Centre Directors. There is
9 a discussion about a proposal being considered by the
10 department as to whether to centralise the supply of
11 blood products via Regional Transfusion Centres, to
12 take it away, effectively, from Haemophilia Centre
13 Directors.
14 That, over the coming weeks and months, gives
15 rise to a lot of consternation on the part of
16 Haemophilia Centre Directors. We won't go into that
17 correspondence but you will wish to consider what
18 issues were troubling the directors and which weren't.
19 Then if we go over the page, please, Henry, we
20 can see in the first main paragraph, about six lines
21 down, issues about communication or problems with
22 communication raised. Dr Galbraith is the director of
23 the Communicable Disease Surveillance Centre,
24 concerned he hadn't heard about the Bristol case until
25 after the patient's death. There was a discussion



1 that reporting would be through Dr Craske.
2 But no further guidelines in relation to the
3 treatment of haemophiliacs in light of the risk of
4 AIDS. There is, if we go over two pages, please,
5 Henry, to what should be page 6, a further discussion
6 on hepatitis, and we can pick that up towards the top
7 of the page:
8 "Hepatitis-reduced commercial factor VIII
9 concentrates.
10 "Dr Craske had received unofficial reports
11 regarding patients who had been treated with these
12 products and it appeared that several patients had
13 developed hepatitis. In view of the concern about
14 AIDS it was felt that where possible the commercial
15 products non-heat-treated products should not be ..."
16 It's not very clear because of the amendments:
17 "... should not be given to previously
18 un-transfused patients."
19 I don't think it's clear whose handwriting that
20 is, sir, making those amendments.
21 **SIR BRIAN LANGSTAFF:** The meaning appears to be clear:
22 that non-heat-treated shouldn't be given to PUPs.
23 **MS RICHARDS:** Yes, where possible.
24 That's September of 1983. We know from
25 Haemophilia Society documents that on 8 October 1983



1 Professor Bloom attended a Haemophilia Society council
2 meeting to discuss AIDS, as did Dr Rizza and
3 Dr Aronstam of Treloars.
4 If we go to CBLA0000060_050, and go to the third
5 page please, Henry, we can see a letter of
6 10 October 1983 which is addressed to
7 Professor Bloom -- if we go to the text of the letter
8 please, Henry, thank you -- thanking him for his talk
9 on AIDS at the council meeting on 8 October. Then it
10 says this:
11 "As I am sure you have gathered, this was a most
12 useful session and did help us considerably to allay
13 unfounded fears held by a large number of our members.
14 I happen to know that people arrived at the meeting
15 quite prepared to take up cudgels and create war
16 within and against the Executive Committee!
17 Happily, in the event, this did not happen since
18 people had AIDS put into a helpful perspective ..."
19 It says "prospective", probably means
20 perspective:
21 "... which can only benefit relationships
22 between the Society, its Groups and its members.
23 "With our grateful thanks and best wishes."
24 It was from David Watters.
25 Now, we don't have a detailed text of the talk



1 on AIDS on 8 October but we can see the effect of it
2 appears to have been to provide reassurance and put
3 fears into perspective, whatever precisely that means.
4 We then, on 10 October, have Professor Bloom
5 attending the NRC working party on AIDS. That's
6 PRSE0000389. We see the list of attendees including
7 Professor Bloom.
8 We can see under the heading
9 "Chairman's Introduction" that:
10 "[The chair] outlined the background to the
11 setting up of the Working Party and indicated the need
12 to ensure that the best use be made of the special
13 combination of suitable patients for study and the
14 clinical, immunological, virological and other
15 expertise available in the United Kingdom."
16 Then if we go on to the next page, please,
17 Henry, we can see the heading "AIDS: The current
18 position". Under the heading "Clinical":
19 "It was noted that AIDS provided a good example
20 of a problem arising in clinical medicine which was
21 posing many new and unexpected questions of basic
22 science."
23 Then there's a reference to the overall clinical
24 picture of AIDS. Then, picking it up about halfway
25 down the paragraph:

1 "The special features arising in relation to
2 haemophilia were discussed and the possibility of
3 identifying the role of imported Factor VIII
4 concentrate used for UK patients was outlined."
5 Then this, sir:
6 "There followed discussion on the varying and
7 considerable period of incubation (1 to 4 years) and
8 the possible relationship between the size of inoculum
9 of the proposed agent and the length of latency. The
10 possibility that AIDS as currently defined was the tip
11 of an iceberg in terms of a range of clinical or
12 subclinical responses to infection with a putative
13 AIDS agent was mentioned; it was recognised that the
14 existence of milder forms would be hard to establish
15 without a marker for such an agent."
16 Then if we go --
17 **SIR BRIAN LANGSTAFF:** If we can just go back, Henry, for a
18 moment, the bit that we had highlighted, bottom of the
19 page. Thank you.
20 Where it says "relationship between the size of
21 inoculum of the proposed agent and the length of
22 latency", it doesn't I think, but you can tell me if
23 I've interpreted this right or wrongly, or may have
24 done, I don't think it's saying that you have to have
25 a particular amount of the proposed agent before you



1 get the disease. It might be but it seems more to be
2 saying that however long it takes to show itself may
3 depend on how much virus, assuming a virus, you get.
4 **MS RICHARDS:** Yes, that's my understanding of what's being
5 said.
6 **SIR BRIAN LANGSTAFF:** So this is not saying you won't have
7 it if there is an infectious agent, it just may depend
8 how much infections agent, whatever it is, you get.
9 **MS RICHARDS:** Yes.
10 **SIR BRIAN LANGSTAFF:** Thank you.
11 **MS RICHARDS:** If we turn to page 4 please, Henry, under
12 the heading, point 4, "Opportunities special to the
13 UK", the minutes say this:
14 "The Working Party sought to identify particular
15 opportunities for research unique or special to the
16 UK. The fact that the epidemic was lagging some three
17 years behind that in the USA was considered an
18 important factor in enabling the background against
19 which the AIDS develops to be delineated. This could
20 enhance our ability to detect the emergence of AIDS
21 and AIDS-related conditions in high risk groups."
22 Then if we go towards the bottom of the next
23 paragraph which is headed "Clinical" it says this:
24 "The UK system for haemophilia treatment and for
25 blood product organisation would allow detailed study



1 of haemophilia associated cases which has not been
2 possible in the USA due to their system of
3 record-keeping and organisation."
4 So identification there of an opportunity for
5 research and study in the United Kingdom.
6 We then move, please, to the next Haemophilia
7 Centre Directors meeting on 17 October 1983. This is
8 PRSE0004440. So we can see this is the meeting of all
9 Haemophilia Centre Directors, not just the limited
10 number of Reference Centre Directors.
11 Henry, could we go to page 10, please. Picking
12 it up under "Any Other Business", and I know you've
13 seen this before, sir, but it's an important debate
14 and worth, therefore, emphasising and looking in
15 particular at Professor Bloom's response:
16 "Dr Chisholm ..."
17 So that's Dr Morag Chisholm of the Southampton
18 Haemophilia Centre:
19 "... raised the problem of patients refusing to
20 take up commercial Factor VIII concentrate because of
21 the AIDS scare. She wondered, in view of the worry of
22 the patients whether the Directors could revert to
23 using cryoprecipitate for home therapy.
24 Professor Bloom replied that he felt that there was no
25 need for patients to stop using the commercial



1 concentrates because at present there was no proof
2 that the commercial concentrates were the cause of
3 AIDS."
4 Sir, how that sits with the May 1983 internal
5 Cardiff guidelines, amongst other matters, is no doubt
6 an issue that you'll explore in due course.
7 "Dr Chisholm pointed out there was a further
8 problem in her region because of problems in getting
9 large amounts of commercial concentrates whereas she
10 could get unlimited supplies of cryoprecipitate.
11 Other Directors reported that they had the same
12 problems. After discussion it was agreed that
13 patients should not be encouraged to go over to
14 cryoprecipitate for home therapy but should continue
15 to receive the NHS or commercial concentrates in the
16 same way."
17 **SIR BRIAN LANGSTAFF:** What is being spoken about there is
18 home therapy.
19 **MS RICHARDS:** Yes, it is. Then we see on the next page --
20 yes, and sorry, just pausing there, the response does
21 not appear to be cryoprecipitate is inherently
22 unsuitable for home therapy; Professor Bloom's view is
23 there's no need. We've seen elsewhere references to
24 supply problems but we have Dr Chisholm and at least
25 some of the directors suggesting that the supply

1 position in their local areas is in fact the reverse.
2 This is no doubt an issue that will be explored with
3 a number of clinicians over the coming weeks, sir.
4 **SIR BRIAN LANGSTAFF:** In due course, I might be assisted
5 by knowing really how easy or difficult it was to
6 create cryoprecipitate. It may be that it was
7 actually relatively simple as some of the documents
8 might suggest, for a regional transfusion centre to do
9 it, which would give rise to the comments such as
10 Dr Chisholm made.
11 **MS RICHARDS:** Yes, certainly it had historically been
12 produced in Regional Transfusion Centres and not in
13 specialist laboratory such as BPL, or not only in
14 specialist laboratories.
15 There is a discussion about the current
16 situation regarding AIDS, but again that's really just
17 looking at various matters relating to investigating
18 cases rather than any substantive changes in the
19 approach to the treatment.
20 Throughout this time Professor Bloom attends
21 various meetings, including meetings of the CBLA
22 committee and others. I'm not going to go through all
23 the details of the meetings. They are set out in full
24 in our written note. Which, I should say, as well as
25 having already been made available to the core



1 participants and legal representatives, will be
2 published on the website, the Inquiry website, so that
3 it's accessible by all.
4 The meeting that Professor Bloom attended,
5 however, on 7 November of the CBLA committee is worth
6 considering further, not for the minutes of the
7 meeting but for a comment recorded by an observer
8 about Professor Bloom's comments at the meeting.
9 It's PRSE0004444. There's a note by Dr Bell
10 dated 9 November 1983. He attended the meeting as an
11 SHHD so Scottish Home and Health Department observer.
12 I won't go through the detail of it but if we
13 could just go to the second page please, Paul, bottom
14 half of the page, we can just see two observations
15 from Professor Bloom. So if we zoom in on the last
16 three paragraphs:
17 "Professor Bloom welcomed the potential
18 availability of a British heat treated Factor VIII
19 which haemophilia directors would prefer to use on
20 virgin haemophiliacs rather than US products."
21 Then, next paragraph:
22 "Professor Bloom also mentioned the possibility
23 of doing pharmacokinetic studies on 'old'
24 haemophiliacs."
25 Sir, I'm very conscious of the fact that the



1 issue of research and studies, involvement in studies,
2 is a matter of some considerable importance to core
3 participants and patients, and that's the reason for
4 highlighting the observations that were made there.
5 If we then go, please, Henry, to PRSE0003439.
6 We're in December 1983, 5 December 1983, and this is
7 a letter from Professor Bloom to Haemophilia Centre
8 Directors:
9 "We're attempting to determine the prevalence of
10 AIDS in haemophiliacs, especially in relationship to
11 the use of blood products."
12 He asks for a simple questionnaire to be
13 completed and returned. He wants to:
14 "... analyse the data and present it ... at
15 a meeting of haemophilia experts which is being held
16 at the end of February. The meeting is a small one
17 and is being held because of the concern about the
18 risk of AIDS to sufferers from haemophilia."
19 It's not clear whether that's referring to the
20 next Reference Centre Directors meeting or to
21 a different meeting, but you will see in any event he
22 is conducting a survey.
23 **SIR BRIAN LANGSTAFF:** I wonder if you can help me with
24 what is a possible inference from this relative to
25 what was said earlier in the 4 May letter to The



1 Haemophilia Society, because this would suggest that
2 he needed to have or there needed to be a survey sent
3 round in order to discover whether there were any
4 cases of AIDS amongst haemophilia patients, whereas it
5 had been stated as a fact in the letter of 4 May that
6 there weren't any proven cases.
7 **MS RICHARDS:** Yes.
8 **SIR BRIAN LANGSTAFF:** And how the two quite fit.
9 **MS RICHARDS:** Sir, an apt question to ask. It's also
10 unclear why this was being sent at this particular
11 time in circumstances where already there had been
12 multiple occasions where Haemophilia Centre Directors
13 had been asked to respond to or alert Dr Craske of any
14 possible cases.
15 We do have the forms on the following pages.
16 I should say we know -- I should have made this
17 clear -- this is not simply, however, for UK
18 Haemophilia Centre Directors. It was a European
19 survey that he was attempting to undertake. We can
20 see that from the next page:
21 "Prevalence of AIDS in European haemophiliacs."
22 This is in fact a UK response. This happens to
23 be Dr Ludlumam's response. But we know from later
24 material published by Professor Bloom that he was
25 attempting to get some figures about the number of

1 cases in haemophiliacs in other European countries.
2 **SIR BRIAN LANGSTAFF:** At the moment, I can understand
3 asking for the number of patients, but that may be
4 different from the number of patients suffering from
5 AIDS.
6 **MS RICHARDS:** Yes.
7 Sir, you mentioned the reference in the May
8 letter to the presence or absence of existing cases in
9 the UK. We discover more information about the
10 Cardiff case from CVHB0000157_580. This is a letter
11 about that first Cardiff patient:
12 "You may remember seeing him a couple of years
13 ago."
14 So it's a letter from Professor Bloom to another
15 doctor.
16 "He's the 20-year-old youth with severe
17 haemophilia."
18 Then it refers to:
19 "During the last nine months, he's had some
20 rather more serious troubles. He presented in March."
21 Then we see the various physical problems there
22 set out:
23 "He lost a stone in weight. It became clear his
24 cell mediated immunity was quite severely impaired.
25 He developed further opportunistic infections and more



1 recently an acute pneumonia, clinically typical of
2 PCP. This responded to treatment with Septrin. In
3 summary, therefore, he is a severe haemophiliac who
4 almost certainly has the Acquired Immuno Deficiency
5 Syndrome and has suffered from a number of opportunist
6 infections over the past nine months."
7 So we see there no longer expressed in terms of
8 possibility, if it ever correctly was, but we can also
9 get a sense of the timespan. This was someone who had
10 presented in March of 1983 to Professor Bloom.
11 We can look at one further document which is
12 CVHB0000157_421. This is from the patient's notes.
13 This is an entry 17 June 1983, and we can just see
14 halfway down the page there is:
15 "? AIDS. Also had T cell deficiency."
16 So that is recorded in this particular patient's
17 own medical records on 17 June 1983.
18 Last document 41983 is at BSHA0000023_081.
19 This is a report of the British Society for
20 Haematology AIDS Working Party. We can see its
21 members included Professor Bloom and Dr Rizza and
22 Dr Pinching, the immunologist whose article we looked
23 at earlier in the Haemophilia Society Bulletin. If we
24 can go further into the heading "introduction" -- this
25 is a report prepared by the Working Party, so



1 presumably contributed to by Professor Bloom and
2 Dr Rizza.
3 "The aetiology of AIDS is yet to be established,
4 but current knowledge points to it being caused by
5 a transmissible agent, possibly a virus, but
6 a non-infective cause is possible."
7 Then skipping over a couple of sentences:
8 "The pattern of transmission of the disease and
9 its mode of spread appears to resemble those of
10 hepatitis B virus. The incubation period of AIDS,
11 however, seems to be considerably longer than for
12 hepatitis B, and its mortality is much higher."
13 So it's unclear why, as at December 1983, given
14 everything else we've looked at, including material
15 emanating from Professor Bloom, that we see the cause
16 still being identified in terms of possibility.
17 The document goes on to set out a number of
18 recommendations about bio-hazard precautions that
19 should be taken by staff, in particular laboratory
20 staff.
21 We have now reached 1984, and the first document
22 I'm going to refer to is the Reference Centre
23 Directors meeting on 14 February 1984. That is at
24 HCDO0000415. If we can go to page 4, please, Henry,
25 we can see at the bottom of the page, we see the



1 heading "Current situation regarding AIDS". We again
2 see an update from Dr Craske who explains that there
3 had been, in the US, 21 cases of AIDS in haemophilic
4 cases, which included 2 cases in haemophilia B
5 patients. Then there's a review of a protocol for
6 a study. Then the next page, the discussion at the
7 top of the page is all about the study. There are no
8 further recommendations to the advice or guidance in
9 relation to treatment, or any reference to any
10 provision of information to patients. Under the
11 heading "Additional information" on this page, we see
12 the survey, so the letter that we looked at from the
13 end of the previous year. Here we have the result of
14 it:
15 "Professor Bloom gave a report about a survey
16 which he'd undertaken regarding the possible incidence
17 of AIDS cases in Europe. He'd sent out a
18 questionnaire, received 132 replies from all over
19 Europe which he estimated gave information on
20 65 per cent of haemophilia A patients. Eleven cases
21 of AIDS have been reported in the UK and in Europe,
22 although one or two cases did not fit the CDC
23 criteria."
24 Then he gives some further details, and then
25 says this:

"One-third of the centres [so this is across Europe] had changed their treatment regimes for patients, following the onset of the AIDS problem."

So that is recorded, but there is no further discussion as to whether, within the United Kingdom, centres should change their treatment regimes for patients.

**SIR BRIAN LANGSTAFF:** What is interesting about that -- go back up the page, please, Henry, to wherever -- it may be the previous page that we had the numbers which Dr Craske was reporting. 21, I think.

**MS RICHARDS:** Yes, it's the bottom of the previous page, Henry. 21 cases of AIDS in haemophilic patients in the US.

**SIR BRIAN LANGSTAFF:** In the United States. So that's the United States. 11 in Europe. I see.

**MS RICHARDS:** Then also in February 1984 and early March, there is an exchange of correspondence between Professor Bloom and Dr Cash about studies in relation to a possible SNBTS, so Scottish National Blood Transfusion Service, wet heat-treated Factor VIII product. We'll just look at those letters for what they tell us about the stance of the two who are having the debate. OXUH0000680. So on 17 February, Dr Cash wrote to Professor Bloom, confirming the



conversation the previous Friday:

"We hope to have sufficient wet heat-treated Factor VIII for limited clinical studies by September '84. We are particularly keen to see part of this product is put into 'virgin haemophiliacs' and would much appreciate the assistance of the UK Haemophilia Centre Directors working party on hepatitis."

If we then go to the response of Professor Bloom, NHBT0008622_009, 27 February 1984, from Professor Bloom:

"Dear John. Thank you very much for your letter. I will pass this on to Charlie Rizza and John Craske. On a personal basis, I would be very pleased to use Scottish material on any 'virgin haemophiliacs' who come my way."

We then see that response from Dr Cash, NHBT0008622_010, second paragraph:

"I'm delighted that on a personal basis you would be pleased to look at some of the SNBTS heat-treated VIII. However, I'm very much aware of Richard Lane's concerns [that's Dr Lane BPL] that we, SNBTS, don't interfere with his existing programme on small pool product, in terms of using up these precious 'virgin haemophiliacs'! I wonder whether you can suggest a solution to my dilemma. I'm very



anxious not to rock the boat, yet I would be delighted to press some of what I hope is very much in the national interest. Perhaps the matter may be resolved on the basis that the small pool project is concentrated in Charlie Rizza's group."

So that is an exchange on the issue of studies involving virgin haemophiliacs that I had been asked in particular to draw to your attention, sir, by some core participants.

We then can see further influence Professor Bloom has on Haemophilia Society decision-making. If we look first at BPLL0001351_092, we can see here this is a letter from Mr Watters to the Medical Advisory Panel, 17 February 1984, so that includes but is not limited to Professor Bloom:

"I enclose a discussion document on blood products. We will be glad to receive any comments you feel you wanted to make on the paper."

If we then go on to the next page, we see the discussion document. The next page might be blank, so if you go on to the one after. I'm sorry. It's a different reference. BPLL0001351_093.

This is a discussion document. It's authored by Mr Milne of the Blood Products Subcommittee of The Haemophilia Society. I'm not going to go through the



detail of it. Much of it is concerned with usage and supply of Factor VIII products. But if we could go, please, to page 4, Henry. Bottom of the page under the heading "AIDS", paragraph 13:

"No discussion of blood products can be complete at present without referring to AIDS. Unfortunately, facts are in very short supply. No infective agent has been identified for AIDS, and there is no reliable evidence that the disease is transmitted through blood products."

This is early 1984, sir:

"Although, this still seems the most popular theory."

Then it goes on to say:

"If that is the case, then the Mail on Sunday reasoning about American blood products may be an oversimplification, as AIDS could still be transmitted from the British donor population."

And it talks about passing from the frying pan into the fire.

If we then go to the top of the next page, please, we'll see Mr Milne -- I'm sorry. The page before that, Henry. My apologies. Under the heading "Conclusions":

"The AIDS scare has given us the opportunity

1 which we've not yet utilised to campaign strongly for
2 self-sufficiency in blood products. Given, however,
3 that the original factors in our policy no longer
4 apply or have reduced force, and that AIDS is still a
5 great unknown, I submit we should not undertake such
6 a campaign. Now is not the time to ask that all our
7 blood products eggs should be placed in one basket.
8 Indeed, without necessarily abandoning our long-term
9 objectives, we should take Mr Asquith's advice of
10 "wait and see". When more facts emerge about AIDS, we
11 would then be in a better position to press for
12 whatever action these facts seem to demand."
13 So that's the paper that's sent to the members
14 of the Medical Advisory Panel. We can see
15 Professor Bloom's response at BPLL0001351_094. It's
16 a letter dated 29 February 1984:
17 "Dear David. Thank you very much for letting me
18 see Ken Milne's discussion document on Factor VIII
19 concentrates. In general, I think this is an
20 admirable document, although, obviously, I do have one
21 or two comments."
22 Then he sets out some comments, but they're not
23 on the passages we just looked at about AIDS and the
24 connection with blood products. If we go over the
25 page, we see the second page of Professor Bloom's



1 letter. The detailed comments end with a comment on
2 paragraph 11. He does, however -- this is
3 Professor Bloom -- go on to say that he's not quite so
4 complacent about importing American blood products as
5 Mr Milne and presumably the subcommittee feel:
6 "We must bear in mind that we may not have had
7 the AIDS problem in the UK, had we been
8 self-sufficient in blood products. At least, we
9 certainly wouldn't have this niggling worry about the
10 importation of a hypothetical AIDS virus, or other
11 unknown viruses from the New World in the future.
12 Thus, although we must still use imported materials,
13 I would not be happy about accepting this situation
14 forever, and I think it would be nice if the Society
15 could continue to press for an increase in facilities
16 for producing all the necessary Factor VIII
17 concentrates within the UK."
18 So you will see, although there is that rider,
19 as it were, to the paper, Professor Bloom does not
20 take the opportunity to address the causal link
21 between blood products and AIDS, and characterises it
22 in a different way from the way in which Mr Milne's
23 paper had.
24 **SIR BRIAN LANGSTAFF:** But he doesn't go quite as far as
25 Mr Milne does when he says the right policy is to wait



1 and see.
2 **MS RICHARDS:** He doesn't.
3 **SIR BRIAN LANGSTAFF:** He's saying, no, I don't think
4 that's appropriate. I rather think you ought to do
5 something about increasing the supply of domestic
6 product.
7 **MS RICHARDS:** Yes. He is suggesting that the Society
8 should continue to press for increased domestic
9 production.
10 Sir, without going to the document, I just ask
11 you, sir, to note that in March of 1984, 12 March,
12 there's correspondence from Professor Bloom to Drs
13 Rizza and Craske about, again, this issue of assessing
14 hepatitis-reduced concentrates. The reference, for
15 your note, sir, is HCDO0000392_065. I mention it
16 because, again, it talks about the desirability of
17 maintaining an available pool of virgin cases for
18 assessment, and I know that's an issue, as I say, of
19 importance for some core participants.
20 We do then see a revised -- sorry, a memo on
21 this issue of hepatitis-reduced Factor VIII, and
22 that's at CBLA0001831. It's dated 29 March 1984.
23 It's authored by Professor Bloom, Dr Craske and
24 Dr Rizza, and it's to all UK Haemophilia Centre
25 Directors. The subject is "Trials of



1 hepatitis-reduced Factor VIII, an update". Picking it
2 up about four lines down, it says:
3 "There are at present eight different products
4 in preparation or available for trial. Clinical
5 trials have only been completed on one product, the
6 Hemofil HT Factor VIII, which is prepared using a dry
7 heat method. The results indicated that there was
8 still a 63 per cent attack rate of non-A, non-B
9 hepatitis on first exposure to this product in
10 patients who have not received Factor VIII concentrate
11 previously."
12 But then it sets out the products that are
13 currently available. Then, bottom of the page:
14 "All products, except those derived from NHS
15 Factor VIII, are made from plasma imported from the
16 USA and, therefore, they carry a putative risk of
17 transmission of AIDS."
18 This doesn't address the issue separately of
19 whether NHS Factor VIII would also carry a putative
20 risk of transmission of AIDS.
21 Sir, the European --
22 **SIR BRIAN LANGSTAFF:** It might be suggested that -- in
23 that paragraph, it's suggested that, in some way, NHS
24 Factor VIII is unlikely.
25 **MS RICHARDS:** Yes. Or was safe, yes. Again, the question

1 of putative risk of transmission of AIDS, whether
2 that's a sufficiently accurate characterisation of the
3 risk as known at that stage is another issue for
4 consideration.
5 The European survey that Professor Bloom
6 undertook resulted in a publication in The Lancet on
7 30 June 1984. That is at PRSE0003037. You can see
8 the heading, sir, "Acquired Immunodeficiency Syndrome
9 and other possible immunological disorders in European
10 haemophiliacs." He refers to the survey being sent to
11 directors of 201 European haemophilia centres and sets
12 out the data received in response. You have already
13 seen a summary of that in the earlier materials.
14 But if we go to the last page, please, Henry,
15 left-hand column, top half of the page, just picking
16 up the last ten lines or so of the article.
17 Professor Bloom says this:
18 "The role of American concentrates in the
19 causation of AIDS in European haemophiliacs must be
20 regarded as unproven."
21 This is June 1984, sir:
22 "23 of 135 haemophilia physicians in Europe have
23 reduced their prescribing of American blood products.
24 Only 7 had stopped using them altogether. In view of
25 the immense benefits that haemophiliacs have derived



1 from treatment, physicians are naturally reluctant to
2 abandon these agents with their hypothetical dangers
3 in the absence of alternative concentrates which have
4 been proven safer. This attitude may change as
5 information accrues, and haemophilia treatment needs
6 to be monitored worldwide."
7 Again, sir, the use of "hypothetical" as an
8 adjective to describe risk may raise some questions.
9 Then if we go to HSOC0002735 -- whilst we're
10 getting that, sir, in the summer of 1984, in late
11 August 1984, we know that Professor Bloom attended the
12 World Federation of Haemophilia Congress in
13 Rio de Janeiro. He reported on his survey during that
14 congress -- we know that from an internal Cutter
15 memorandum. I won't go to that now, but the
16 information that Professor Bloom had gathered was
17 being shared by him, it would appear, on some form of
18 international stage.
19 If we see this letter, this is from
20 February 1985, but it refers to the Rio de Janeiro
21 conference in August 1984 and to a document provided
22 by Professor Bloom in November 1984.
23 If we go over the page, we can see
24 Professor Bloom's document. We can see it's
25 a postscript because September 1984 from the top of



1 the page. It says:
2 "Since this article was written [that's
3 presumably the original article] there have been
4 several notable developments, especially with regard
5 to AIDS."
6 Then under the heading "Identification of the
7 cause", there's reference to the American and French
8 discoveries. Then, picking it up halfway down that
9 page, it said:
10 "Several lines of evidence suggest that the
11 virus is the cause of AIDS. The evidence is not
12 conclusive, but already a test for the antibodies has
13 been developed in the USA, France and the UK."
14 Then at the very bottom of that page, we see
15 a piece of data:
16 "70 per cent of treated American haemophiliacs
17 and 34 per cent of treated British haemophiliacs were
18 positive for the antibodies."
19 Then there is an expression of optimism, bottom
20 of the next page. There's reference to work being
21 undertaken to clone the Factor VIII gene and marker
22 tests for HTLV-III. Then the last sentence is this:
23 "On the whole, it seems likely that the problem
24 of AIDS would be conquered for haemophiliacs in the
25 not too distant future."



1 **SIR BRIAN LANGSTAFF:** So the inference from that is that
2 every haemophiliac in the United Kingdom would have
3 had a test?
4 **MS RICHARDS:** Yes.
5 **SIR BRIAN LANGSTAFF:** Every treated one because,
6 otherwise, they wouldn't have known what the
7 percentage was, would they?
8 **MS RICHARDS:** Yes.
9 **SIR BRIAN LANGSTAFF:** And the test must have been done
10 before September which is when this update was given.
11 **MS RICHARDS:** That is what it appears to suggest, although
12 you, sir, will recall of course the considerable range
13 of information of evidence you've heard about
14 individual patients themselves only being given their
15 diagnosis well into 1985 and in some cases later.
16 **SIR BRIAN LANGSTAFF:** Yes.
17 **MS RICHARDS:** And, of course, had been tested without
18 their knowledge.
19 **SIR BRIAN LANGSTAFF:** Yes.
20 **MS RICHARDS:** We then, in September 1984, pick up matters
21 with the next Reference Centre Directors meeting.
22 That's 10 September 1984 and the reference to that,
23 Henry, is HCDO0000416.
24 If we could go, please, Henry, to page 8, we can
25 see the update from Dr Craske under the heading

1 "Current situation regarding AIDS". This is now
2 September 1984. Dr Craske presents some graphs
3 analysing data he had received from Haemophilia Centre
4 patients who had received -- been treated with
5 suspected batches of concentrate. He referred to
6 a paper published in The Lancet on September on
7 HTLV-III:
8 "He said that he and colleagues were very
9 guarded about the significance of the positive
10 antibody results but proposed to continue the study.
11 A further 20 patients with AIDS-related symptoms have
12 been notified to him."
13 There's a suggestion of the problem with
14 reporting. Then he says:
15 "He felt that extensive testing of patients at
16 risk was now required."
17 So this would appear to suggest there hadn't
18 been extensive testing at that stage:
19 "Follow-ups at six-monthly intervals terminating
20 five years after the receipt of the suspect batch
21 should be undertaken. Data from CDC indicated the
22 first AIDS case was January '82, two years after the
23 material had been received by the patient. No two
24 AIDS cases in the USA had received the same batch of
25 Factor VIII concentrate. There were now 41 cases of



1 AIDS in the USA in haemophiliacs. Dr Craske offered
2 to arrange for HTLV3 testing on samples from
3 haemophilia centres if the Haemophilia Centre
4 Directors would like him to organise this for them."
5 So that's the update, but again no change in
6 terms of recommendations or advice being given as to
7 treatment of patients at that time.
8 There's a further meeting then of all Centre
9 Directors on 27 September 1984 in Cardiff.
10 Essentially, we see a repetition and summary of what
11 had been set out there by Dr Craske.
12 It's also relevant to note that in October of
13 1984 there was correspondence between Professor Bloom
14 and Dr Snape and Dr Smith regarding the recall of
15 a BPL batch due to the possible risk of AIDS
16 infection.
17 Then, picking matters up in November 1984, at
18 BPLL0010493, we see a reply to an invitation from
19 Dr Lane. This is Professor Bloom to Dr Lane:
20 "Dear Richard. Thank you very much for your
21 letter and especially for setting up the meeting for
22 December 10. I look forward to seeing you. Clearly,
23 the matter is of great importance and has certainly
24 come to a head with the Australian experience and with
25 the unfortunate death of the Newcastle patient. I am



1 only glad that we had decided in advance of these
2 events to take some action."
3 The reference to the meeting on 10 December of
4 1984 is to a meeting we'll look at in a moment at BPL
5 which resulted in the production of further guidelines
6 eventually, or at last for Haemophilia Centre
7 Directors.
8 It appears that this issue has come to a head
9 with what's described as the Australian experience --
10 not clear precisely what is meant by that -- and
11 a further death, which is the Newcastle patient which
12 we heard about in other evidence last year. Quite
13 what Professor Bloom had in mind, in terms of action
14 that he had taken in advance of these events, by the
15 last sentence remains unclear.
16 But we then come to -- no, in fact, before we
17 come to the 10 December meeting, we'll just pick up
18 a further communication in November 1984. This is
19 CBLA0000010_188.
20 This is a letter sent by Dr Craske to a number
21 of recipients, including Professor Bloom. It's
22 triggered by a particular batch, HL3186, the
23 particular batch of Factor VIII.
24 If you go to the next page, please, Henry, we
25 can see it refers to a donor contributing the plasma



1 pool used in the manufacture of a particular batch,
2 having been admitted to hospital with clinical
3 features consistent with AIDS which had now been
4 confirmed. Dr Craske was following up from the
5 epidemiological perspective recipients of that batch.
6 You will see in the next paragraph he refers to a
7 survey having been conducted of the blood products
8 transfused to AIDS case A1, the Cardiff case, and A4,
9 the Bristol case, earlier this year. That rather
10 suggests that there were two other cases in between
11 the Cardiff and Bristol cases.
12 So we can see from this that earlier in 1984
13 there had been attempts, it would appear, to consider
14 the position in relation to the particular blood
15 products received by those two patients.
16 Then if we go to page 5, Henry, Dr Craske sets
17 out various matters in relation to further
18 investigation.
19 Just the heading, "Should the patient be told?"
20 This is of investigations and tests being undertaken.
21 "Ideally I think he should, but this will depend
22 on many factors, including the amount of anxiety
23 concerning AIDS there is already present at the
24 Centre, and the degree to which the patient is capable
25 of understanding the situation. Every effort should

1 be made to encourage the patient to discuss the
2 problem with his spouse and help them to face the
3 problem together. The General Practitioner should
4 also be informed by letter."
5 That appears to be the expression of the view
6 that the general practitioner will be automatically
7 informed but the question of whether the patient is to
8 be informed will depend on factors including those set
9 out there and will presumably be a matter for the
10 judgement of the clinician.
11 It's fair to say that's not the last word from
12 Dr Craske on that issue and we dealt with that in more
13 detail in our note.
14 Still in November, DHSE0003211, this is
15 a hard-to-read letter from Professor Bloom,
16 21 November 1984, to Dr Smithies at the Department of
17 Health:
18 "I am sure you have been involved in all the
19 recent furore regarding AIDS. It looks very much that
20 we are going to be driven into using heat treated
21 concentrates. It could give unfavourable publicity if
22 these concentrates are freely available in the USA and
23 say Germany but are not licensed in this country
24 making prescription difficult. Could you advise if
25 ..."



1 And I'm not quite sure what the next word is:
2 "... steps are now taken to" --
3 **SIR BRIAN LANGSTAFF:** "... are being taken ..."
4 **MS RICHARDS:** "... are being taken to review the licensing
5 of heat treated Factor VIII consequent upon
6 applications from the manufacturers."
7 So, a slightly curiously worded letter from
8 Professor Bloom, "driven into using heat treated
9 concentrates", but saying it will be somehow wrong if
10 they were available in other parts of the world but
11 not available in the UK.
12 **SIR BRIAN LANGSTAFF:** If perhaps one thought of him as
13 advocating the need to get on and licence heat treated
14 products, this is perhaps a way of putting it across
15 to the DHSS whom he thinks may be reluctant to do it.
16 **MS RICHARDS:** Yes.
17 **SIR BRIAN LANGSTAFF:** So if one looks at it in that light,
18 the "driven" isn't his word so much as his way of
19 persuading them.
20 **MS RICHARDS:** That is entirely possible, sir.
21 One further document as well from November is at
22 SHPL0000068_070. This is an internal Immuno note,
23 November 24, 1984. For present purposes I just want
24 to look at the fourth page. Halfway down the page, it
25 says:



1 "As Mr Berry explained, it would be essential to
2 amend our public licence applications to introduce
3 inactivated products if we do not want to lose the
4 British market. Lane promised the products that have
5 not been virus-inactivated will not be used after
6 April 1985."
7 Then this:
8 "Bloom also stated that he will no longer use
9 any products that have not been inactivated after his
10 stock has run out."
11 It's those last two words that are relevant for
12 consideration of Professor Bloom's practices.
13 Then we finally come to the 10 December meeting.
14 There is an aide-memoire prepared by Professor Bloom,
15 although it's not particularly detailed but we should
16 perhaps look at it.
17 BPLL0006225_003.
18 BPLL0006225_003. No? Never mind.
19 It is, in any event, a list of points for
20 discussion. I refer to it really only because the
21 minutes of the meeting or the notes of the meeting
22 suggest that an aide-memoire had been prepared by
23 Professor Bloom in advance and this is the document
24 that appears to match up to it.
25 He lists as concentrate, type of concentrate to



1 be recommended, specific recommendations for certain
2 categories. Implications of testing: Should all
3 patients be tested? Should patients be informed of
4 results? Should spouses be tested? And then
5 reference to a number of other matters including the
6 issuing of advisory statements. So that was, as it
7 were, the agenda.
8 The note we then have of the meeting is at
9 PRSE0000890. We can see "Notes of the Haemophilia
10 Reference Centre Directors Meeting, [BPL], Elstree,
11 10 [December] 1984".
12 It's chaired by Professor Bloom, and a range of
13 individuals present not limited to Reference Centre
14 Directors, also representatives from BPL, DHSS, the
15 Public Health Laboratory Service and others. And
16 these are notes taken by Norman Pettet of BPL. We
17 don't have UKHCDO-originated minutes of this meeting.
18 If we look at item 1 on that first page, we see
19 what appears to trigger the meeting:
20 "The Chairman [that's Professor Bloom] outlined
21 that the resulting publicity surrounding the events in
22 Newcastle and Australia, and the continuing work on
23 HTLV III has precipitated today's meeting."
24 So the or a trigger for this meeting taking
25 place appears to be adverse publicity or publicity

about those events.
Then if we go, please, to the fourth page -- and, sir, I know you've looked at this document on a number of occasions so I'm not going to go through the detail of it but just alight upon contributions from Professor Bloom. We see there, second paragraph:
"In summary, the Chairman outlined that HTLV-III positive persons should be considered a risk but that one still could not assume that negative contacts are not infective. Haemophiliacs who are positive should therefore be considered a high risk until the situation becomes clearer."
Then, further down that page, under the heading "Advice to patients and donors", if we have the last paragraph of that section:
"A long discussion took place on whether persons found to be positive were to be informed."
I read that in the context of the fact that they had been said to pose a high risk to others.
"Several differing views were expressed. It was agreed that each clinician would decide for each case depending on the facts of the case but, in general, to provide information if asked for",
which may be thought to beg the question how do you know to ask for information if you don't know



you're being tested.
The next page, about the fourth paragraph down, we have:
"The Chairman summarised [so that's Bloom again] by saying that testing should be instituted as soon as possible, and that information on the test results should not be given automatically but if asked for."
Same point arises.
"HT [so heat-treated material] should be given preferentially in those cases where concentrate is required. The financial consideration must be considered secondarily to the primary aim of treatment."
Then if we could go on two pages, please, there's a discussion about heat and non-heat treated products. And then the fourth paragraph on that page:
"In summary, the Chairman said that one has to accept, for the present, that it is difficult to avoid the argument that non-[heat treated] constitutes a risk. There were problems in adopting a two tier system of treatment."
And then if we could go, please, Henry to -- I think it's three pages, that's it.
Second paragraph:
"The Chairman advised that he would issue



guidelines following the meeting. In summary, the first choice would be [heat treated] material followed by the judgment of the individual clinician. He also suggested that peripheral treatment centres return all non-[heat treated] commercial material to the Reference Centres for transfer back to the Company involved."
And then the meeting concludes by saying that recommendations would be issued on the day's proceedings and these would be widely circulated.
We are then told there's a private meeting of haemophilia directors but we don't have any minutes of that. So that is the meeting that finally takes place on 10 December 1984 that results in the issue of further guidelines to the Haemophilia Centre Directors. We can pick that up at HCDO0000270_007. We see some raw data on the first page. It's called "AIDS Advisory Document" and then we see:
"In the USA, there are over 6,000 cases of AIDS, including 52 haemophiliacs. In the UK there have been 102 cases with three reported haemophiliacs. No doubt other cases are developing in the haemophiliac population."
Then we're told that tests are available from Dr Mortimer or from Dr Tedder. If we go to the second



page, we now see at the bottom of the page, the last half of the page, the recommendations:
"Options in probable decreasing order of safety from AIDS to haemophilia A:
"(1) Heated UK concentrate. Note: still non-A, non-B hepatitis risk.
"(2) Single donor cryo or FFP (freeze frozen plasma).
"(3) Heated imported concentrate. Note: still non-A, non-B hepatitis risk.
"(4) Unheated UK concentrate.
"(5) Unheated importation concentrate [so that which has been used for a significant period of time until this point] almost certain to be contaminated. Note: heated concentrates may still transmit hepatitis.
"Some of the distinctions (e.g. between 3 and 4) are debatable ..." et cetera.
Then, recommendations:
"(1) Concentrate is still needed. Bleeding is the commonest cause of disability and death.
"(2) Use DDAVP in mild haemophilia A and von Willebrand's disease if possible.
"(3) For haemophilia A needing blood products (a) virgin patients, those not previously exposed to

1 concentrate and children, use cryo or heated NHS
2 Factor VIII if available. (b) severe and moderate
3 haemophiliacs previously treated with Factor VIII use
4 heat treated Factor VIII if available or heat treated
5 US commercial."
6 Then for haemophilia B the recommendation is:
7 "For mild Christmas disease, fresh frozen plasma
8 if possible, otherwise NHS Factor IX. For virgin
9 patients and those not previously exposed to
10 concentrate, use fresh frozen plasma or NHS factor
11 concentrate. Severe and moderate Christmas disease
12 previously exposed, continue to use NHS Factor IX."
13 Then:
14 "In individual patients, there may need to be
15 a choice. In general, heated concentrate appears to
16 be the recommendation of virologists consulted but
17 individual directors may wish to make up their own
18 minds. This is particularly true of unheated NHS
19 material."
20 Then it goes on to talk about evidence as to
21 whether heated US Factor VIII is safer than unheated
22 NHS being debatable.
23 Those are the guidelines issued, sir, or
24 prepared on 14 December 1984. There is some evidence
25 that they were distributed to Haemophilia Centre



1 Directors in early January 1985.
2 One further document brings me to the end of
3 1984 and after that we could break. That's an article
4 in The Lancet. PRSE0002758. Our understanding is
5 that this was prepared by Professor Bloom. It's
6 entitled:
7 "Blood Transfusion, Haemophilia and AIDS. There
8 are new anxieties concerning AIDS [I'm not quite sure
9 why they're described as 'new'] especially in its
10 relation to blood transfusion and the use of plasma
11 derivatives."
12 Then the right-hand column:
13 "What of the risk in haemophiliacs? 52
14 haemophilia associated cases of AIDS have been
15 reported in the USA, including two in haemophilia B
16 patients and two in patients with other clotting
17 disorders, and three in the UK."
18 Then there's a discussion of what is described
19 as "prevalence in American and European
20 haemophiliacs."
21 If we then go to page 3, please, it's
22 a document, sir, that merits being read in full but
23 I'll just pick it up in the top left-hand column:
24 "Ethical questions are raised by HTLV antibody
25 testing of blood donors and haemophiliacs. An



1 unenviable task will be the counselling of people with
2 positive results. Although the AIDS crisis is
3 worsening, silver linings can be discerned in the
4 clouds. The main causal virus seems to have been
5 identified and although there will be difficulties,
6 a vaccine will probably be developed. In addition,
7 several drugs active against [et cetera, et cetera you
8 see there set out] are under study. Meanwhile, we
9 must not forget that by far the commonest cause of
10 haemophilic death is bleeding."
11 That brings us, sir, to the end of 1984 -- it
12 feels very Orwellian saying that -- and I can pick up
13 after the break with 1985 and I hope complete the
14 information in relation to Cardiff documents before
15 the end of the day.
16 **SIR BRIAN LANGSTAFF:** So we will come back at the start of
17 1985, which is going to be in, let's say, just over
18 half hour's time -- 3:40.
19 **(3.07 pm)**
20 **(A short break)**
21 **(3.39 pm)**
22 **MS RICHARDS:** Sir, there are fewer documents to look at
23 for 1985 onwards but still some, and a handful of
24 events and issues I should make reference to.
25 Henry, could we have BPLL0001351_103, please.



1 No?
2 Whilst we see if there's an alternative
3 reference, this is quite an important document, it's
4 a letter from Professor Bloom, but I can read aloud
5 the relevant paragraphs because it contains an element
6 of reflection by Professor Bloom as at the beginning
7 of 1985, but the terms in which that reflection is
8 expressed may be instructive.
9 It's a letter from Professor Bloom to Mr Watters
10 at The Haemophilia Society, dated 2 January 1985.
11 Amongst other matters he says this:
12 "With regard to the general situation regarding
13 AIDS, the whole thing is worrying. We are in a catch
14 22 situation. In the past, my committee ..."
15 It may be by that he is referring to the
16 Haemophilia Centre Directors Organisation, it's not
17 clear.
18 **SIR BRIAN LANGSTAFF:** He was on quite a number of
19 committees.
20 **MS RICHARDS:** He was, but that would appear to be the one
21 he had the most intimate involvement with, but you are
22 right, sir:
23 "In the past, my committee has always been under
24 pressure from patients and from the Society to seek
25 increased funding for the purchase of commercial

1 Factor VIII."
2 So he is suggesting there the drive for
3 commercial Factor VIII products came from patients and
4 from The Haemophilia Society.
5 He continues:
6 "It is perhaps natural that the usage of Factor
7 VIII for patients in the UK was compared unfavourably
8 with the greater usage in some other countries. Some
9 more conservative UK haemophilia specialists felt
10 themselves under criticism, even from some of their
11 colleagues, in spite of a feeling that it would be
12 unwise to increase treatment levels *ad lib* with
13 potentially dangerous concentrates. These
14 considerations of course pre-dated the AIDS crisis."
15 He continues:
16 "We are now in a situation in which we are being
17 driven to administer large volumes of heat-treated
18 Factor VIII without adequate clinical trial."
19 And he sets out a concern about not knowing the
20 short or medium-term effects, let alone the long-term
21 effects of heat-treated product.
22 And invites Mr Watters to draw the attention of
23 his colleagues to these fears.
24 Then he says this:
25 "As a haemophilia clinician I feel somewhat



1 guilty that my therapeutic endeavours have resulted in
2 exposure of patients to this newly discovered HTLV
3 virus. I do not wish to see this type of process
4 repeated in the future albeit with a different hazard.
5 For this reason I wish to draw your attention to the
6 need for caution. I realise the desire of
7 haemophiliacs to lead a normal life but at the same
8 time one must realistically conclude that ideal
9 treatment is not available. If I were to act as
10 devil's advocate, I would suggest that it is
11 reasonable to steady out at levels of treatment
12 attained during the last five years, say at an average
13 of 25,000 units per patient per year. In light of
14 present knowledge, I am not convinced that it's wise
15 to push for steady increase to 100 million units per
16 year. Although we are right to ensure that the
17 necessary potential is available, expectations must be
18 balanced against informed reality. I leave it to you
19 and your colleagues to consider the best ways by which
20 this particular nettle may be grasped, always
21 accepting that there is in fact a nettle."
22 I did give the correct reference for that but we
23 don't have it currently on the system. But that was
24 his letter reflecting on the current situation.
25 In January 1985 it's also relevant to note, and



1 we don't need to look at any documents for this, that
2 the Haemophilia Centre Directors Organisation set up
3 for the first time a working group on AIDS, and its
4 first meeting took place on 11 January 1985 and it met
5 at various intervals in the course of 1985 and some of
6 the years that followed.
7 Documentation relating to Professor Bloom during
8 1985 is characterised by a couple of issues. The
9 first is debate about the availability and safety and
10 suitability of heat-treated products, in particular
11 BPL products, and when those would be fully available,
12 and also issues being raised by Professor Bloom about
13 funding. He raised those issues on a couple of
14 occasions at least with the Department of Health and
15 Social Security. It's also relevant to note that
16 January 1985 was the first meeting of an expert
17 advisory group set up by the Department of Health and
18 Social Security, EAGA, the Expert Advisory Group on
19 AIDS. So that met for the first time on
20 29 January 1985 and Professor Bloom was a member of
21 that particular group.
22 In February 1985, The Lancet published a letter
23 from Professor Bloom, and we'll just look at that. It
24 is at PRSE0001758. It's a letter from Professor Bloom
25 published in The Lancet on 9 February 1985, and it's



1 instructive to see the terms in which Professor Bloom
2 now expresses himself.
3 Bottom of the left-hand column he refers to
4 a letter from Dr Bird and his colleagues about
5 possible side effects of heated blood products, and
6 then says:
7 "... their arguments for the continued use of
8 non-heated Factor VIII concentrates are debatable."
9 He refers to contaminated batches of British
10 Factor VIII having been identified. Then, bottom of
11 that page:
12 "Although American concentrates pose the most
13 risk, untreated Factor VIII concentrates of any type
14 must be considered potentially to be infected with
15 HTLV-III."
16 And then the next column, please, right-hand
17 column, same page:
18 "Whilst attempts are often made to restrict
19 viral exposure by reserving batches for individual
20 patients, rapid turnover and lack of stocks of British
21 concentrates often makes this logistically
22 impracticable. Plans sometimes fail after hours when
23 treatments are administered by inexperienced staff."
24 He suggests that proposals made by Dr Bird and
25 others could lead to infection of previously

uninfected patients or family members.

We know that Professor Bloom continued as chair of UKHCDO until towards the end of 1985 when Dr Forbes took over. He chaired a meeting of Reference Centre Directors on 18 February 1985, and a particular issue that was discussed there, we don't need the document on screen, were difficulties in getting tests carried out on samples.

There's then an exchange of correspondence between Professor Bloom and the chair of the CBLA in February 1985 which we will look at.

I think this is right, Henry, DHSC0001214. That's right.

Slightly curious letter.

Professor Bloom, 21 February 1985, to Mr D Smart, Chairman, Central Blood Laboratories Authority:

"I am writing to you in my capacity as Chairman of the UK Haemophilia Centre Directors. At our 'Committee' meeting on February 18th, I was asked to write to you to seek clarification of our responsibilities as physicians when undertaking clinical trials of new products. Our immediate concern obviously relates to heat treated intermediate concentrate and the new 8Y materials. My colleagues



inform me that when undertaking initial trials of commercial products, individual companies will undertake to offer indemnity in the event of serious untoward reaction in recipients. We would be grateful to learn if such facilities are available also in the case of BPL products."

So a request for indemnity for physicians. Then he says:

"We all appreciate that the AIDS scare is causing Richard Lane and his colleagues some difficulties with regard to the time scale for introduction soft new or heat modified products. I may have added to his embarrassment in a letter which was recently published in the Lancet. Sometimes my roles as a Physician and Chairman of the Haemophilia Centre Directors and Medical Advisor to the Haemophilia Society may appear to conflict with immediate pragmatic issues at CBLA. Nevertheless, I hope that I can act in a reasonably objective manner."

It's not entirely clear what he means by that in the second paragraph of the letter.

There is further correspondence and communication between Professor Bloom and Dr Smith and Dr Lane, and it's instructive to note -- this is an



internal meno from Dr Lane, I'll just refer to it briefly -- Dr Lane describes Professor Bloom's criticism of BPL's product as "theoretical, non-specific and unsupported by scientific data, hardly a scientific approach from a leader in the British field of haemophilia care".

I just want to pick up then in relation to Professor Bloom's own dealings with patients. The document that's at WITN1275005. This is a letter from Professor Bloom to another clinician, possibly a GP. If we just pick it up in the second paragraph, second line:

"As with many of the haemophiliacs, he [that's the patient] has of course been exposed to the HTLV-III virus, the putative agent of AIDS. His tests for antibodies to this virus were positive. Although I think it is extremely unlikely he will develop the condition, there is a slight possibility that he is a symptomless carrier of the virus."

And then he refers to counselling him and his wife.

That, sir, begs the question of how and on what basis Professor Bloom could form the view that someone who has tested positive to HTLV-III is nonetheless extremely unlikely to develop AIDS and the reliability



of information being provided to patients in that regard.

Throughout 1985 Professor Bloom attends meetings of the expert advisory group on AIDS, meetings of the Haemophilia Centre Directors AIDS Group. The issues that emerge in the course of those meetings include issues about screening tests and HTLV-III testing. There's also reference to various trials of commercial heat-treated products and references to Professor Bloom agreeing to contribute patients to participate in trials, for example, of Koate HT."

If we then go to CBHB0000002_028, please, we get a glimpse into Professor Bloom's arrangements for and decision-making in relation to the purchase of concentrates.

CBHC0000002_028.

*(Pause)*

No? It's a letter from Professor Bloom 12 April 1985 to the acting chief pharmacist at the University Hospital of Wales. And the purpose of referring to it, sir, shows Professor Bloom's role in the decision-making in terms of which products to purchase. It's very clear from this letter that the decision as to which concentrates to use is a decision for him. He says:

"With regard to ordering Factor VIII concentrate, I am afraid I'm finding Cutter's Koate less than satisfactory at the moment. Instead of receiving extended batches as would be clinically desirable, they are only supplying the dregs of various batches that they can scrounge from the USA. In addition, the heat-treatment process is not as effective as that applied by Alpha to Profilate HT. I appreciate the latter is 2p a unit more expensive but even so, I think that clinical considerations must be the over-riding factor and I therefore think that we should restrict our Factor VIII orders to Profilate HT, until such time as one of the other manufacturers can compete. I hope that you will find this course of action acceptable."

There are various documents, sir, in 1985 onwards similar to some of the documents we have seen before, exchanges and interactions with various pharmaceutical companies in which it's very clear that the decisions as to which products to purchase for the Haemophilia Centre in Cardiff are decisions for Professor Bloom.

I will only gone to one further document to show that. It's BAYP0000024_214.

It's an internal Cutter memo. If we go to the



bottom of the page, we can just see what's said about Cardiff:

"Lack of stock and inability to reserve a batch have pushed Professor Bloom to go to Alpha for supplies. Alpha were able to reserve a large batch and have supplied at a 'competitive price'."

There's a reference to the price reduction:

"Professor Bloom is now looking at the safety of Profilate HT for non-A, non-B hepatitis."

And if we go to the next page:

"However, Professor Bloom has assured me that when this batch is finished and if Cutter is able to reserve a batch, he will start buying again from Cutter. This is estimated to be a three month period."

Then this:

"It must also be remembered that it is the policy of Professor Bloom to change suppliers once a year. This change was due last September and Cutter have held on very well to delay it until the end of March, 1985."

So that's the insight there into at Professor Bloom's approach to decisions as to what products to purchase. As well as EAGA and AIDS group meetings, Professor Bloom attended a meeting of the



MRC working party on AIDS in April of 1985. We don't need to go to it but one particular suggestion that Professor Bloom put forward as an area suitable for UK research at that meeting was the possible transmission of HTLV-III infection from haemophiliacs to their wives, and the minutes record this:

"The integrated system for the care of these patients would readily enable the study of large numbers of heterosexual couples in whom one partner was infected in order to establish the risk of heterosexual transmission in this setting."

Then, Henry, if we could have, please, DHSC0002269_069.

This is a letter from Professor Bloom to Dr Rizza at Oxford, 9 May 1985:

"... enclosing tables on the results of my recent questionnaire."

It's for consideration at the next meeting of the AIDS Group of the Haemophilia Centre Directors Organisation.

If we go to the second page, we can see there reference to centres using heated or unheated product.

Unheated commercial Factor VIII, one centre still using concentrate in that description.

Unheated domestic Factor VIII, it's recorded



that 32 centres are still using unheated domestic Factor VIII. And the asterisk tells us that that includes three centres using it on HTLV-III patients only.

Then we see, heated commercial concentrate, 16 centres not using it, and we are told that five Scottish centres are using heated domestic Factor VIII. Others include small centres using unheated domestic VIII or Cryo.

So there is evidence of unheated Factor VIII concentrate still being used, as at May 1985, in some centres.

One other feature of the communications and documentation in the course of 1985 is Professor Bloom raising what he regarded as the need for there to be HTLV-III antibody screening of blood donors. And he communicated with Dr Harris, the chair of the Expert Advisory Group on AIDS, to express his views that that should be rapidly introduced.

Following up from the survey of haemophilia centres that we've just looked at and the use of unheated products, that resulted in a letter in the BMJ in June of 1985 referring to a substantial number of centres still using unheated UK Factor VIII concentrate. The observation that's then included in

1 the letter is that this may have represented clearing
2 of existing stock.
3 There are then various -- there's ongoing
4 communications about what Professor Bloom regards as
5 a delay in the Blood Transfusion Service introducing
6 antibody screening tests for blood donation. And
7 there are various intemperate exchanges between
8 Professor Bloom and Dr Cash. I don't propose to go
9 into the detail of those.
10 Professor Bloom raised again in July of 1985 at
11 a CBLA committee meeting concerns about the undue
12 delay in the introduction of screening tests, in terms
13 of blood donation. And we see him also in July of
14 1985 making representations on this occasion to
15 Baroness Trumpington, who was a minister within the
16 Department of Health and Social Security,
17 representations for additional funding for haemophilia
18 services because of the impact of AIDS.
19 Then, sir, picking matters up, September 1985,
20 I think we have one of the last meetings of Reference
21 Centre Directors, chaired by Professor Bloom, and that
22 is at PRSE0004271. We'll just go, if I may, to
23 page 6, please. It is 30 September 1985. If we go
24 about halfway down the page, please, there's
25 a discussion about the allocation of money to



1 reference centres for AIDS counselling, and then we
2 see Professor Bloom expressing concern about some of
3 the literature issued by The Haemophilia Society:
4 "Hemofact 9 was particularly worrying as it
5 advised haemophiliacs not to tell their GPs their
6 HTLV III results. Professor Bloom was concerned that
7 The Haemophilia Society did not consult their medical
8 advisory committee before sending out Hemofact sheets,
9 et cetera. During discussion, it became evident that
10 there were several different policies amongst
11 Reference Centre Directors regarding informing GPs of
12 patients' HTLV-III results. Some directors would not
13 give information to GPs about individual patients."
14 Then there is an issue about the position of
15 HTLV-III positive children and difficulties
16 experienced at school.
17 If we just go to the top of the next page,
18 please, Henry, we also see an update there -- sorry,
19 next page. My apologies. Update, in the first main
20 paragraph, about non-A, non-B hepatitis and profilate.
21 Dr Kernoff reporting a publication in The Lancet with
22 four cases of hepatitis all related to one batch of
23 heat-treated profilate.
24 We then, at WITN4029003, see an updated version
25 of Cardiff's internal policy treatment guidelines.



1 I'm not going to go through the details of it. We can
2 see it addresses -- it's dated October 1985. It gives
3 indications for the use of DDAVP, indications for the
4 use of fresh frozen plasma, and then further down,
5 indications for the use of cryoprecipitate. And then
6 perhaps worth just mentioning there, the main
7 indications are said to be von Willebrand's disease,
8 mild haemophilia A and exposure to non-A, non-B
9 hepatitis, and from 14 October 1985, HTLV-III is to be
10 avoided, and DDAVP is unsuitable. Then two virgin
11 haemophiliacs when exposure to non-A, non-B hepatitis
12 and HTLV-III is to be avoided and DDAVP is not
13 suitable.
14 So clear recommendations there for the use of
15 cryoprecipitate.
16 Over the page, we then see various
17 recommendations for different heat-treated products.
18 And then if we go to the third page, we see at
19 point 8:
20 "Factor IX BPL not heated. Not acceptable.
21 Risk of HTLV-III."
22 So those are the updated October 1985 Cardiff
23 internal policy guidance.
24 We can then, I think, move to 1986. Again,
25 Professor Bloom is attending EAGA meetings. He's



1 attending meetings with Reference Centre Directors,
2 although he's no longer, by this time, I think,
3 a chair.
4 We get a further insight into Professor Bloom's
5 relationship with pharmaceutical companies and how he
6 was viewed by them from a document that is at
7 BAYP0000008_084. So it's an internal Cutter document.
8 If we go to the next page, please. If you keep
9 going -- that page. So the heading "Cardiff", and the
10 author of this says:
11 "I spent a long time with Professor Bloom and
12 discussed the Kernoff paper and the product profiles.
13 He agreed that there are disadvantages with the
14 profilate, and the non-A, non-B results are by no
15 means conclusive. He said he could foresee that he
16 could use the new 8Y new haemophilia patients and for
17 those already seroconverted and that have had non-A,
18 non-B, he could use Koate HT instead of profilate.
19 **SIR BRIAN LANGSTAFF:** The new 8Y, that is the BPL product.
20 **MS RICHARDS:** That's right:
21 "He still has stock. I think he still needs
22 a little more time and another push."
23 Then she says she'll write to Professor Bloom,
24 emphasising the Koate HT features and disadvantages of
25 other product.

1 So, again, an insight into the ongoing dialogue
2 that Professor Bloom had with representatives of
3 pharmaceutical companies and how he was perceived by
4 them.
5 Then if we go, please, to CBHB0000002_036. This
6 then is a document signed by Professor Bloom, dated
7 17 February 1986. The subject is "HTLV-III negative
8 haemophiliacs", and this says:
9 "This note is just to remind you of the policy
10 of treating all seronegative haemophiliacs, A or B,
11 only with UK heat-treated Factor VIII or Factor IX
12 concentrate. On no account should commercial
13 concentrates be used for such patients unless such use
14 is endorsed by a consultant. In the event that
15 insufficient UK concentrate is available,
16 cryoprecipitate should be used for haemophilia A, and
17 fresh frozen plasma for haemophilia B."
18 Quite how that fits with what else we've seen
19 about his purchase of commercial products is unclear,
20 unless it's designed to ensure that such decisions are
21 taken only by him as a consultant or other consultants
22 and that no commercial concentrates are administered
23 by more junior colleagues. But it is a slightly
24 puzzling document when one tries to fit it against the
25 other material that we've seen.



1 **SIR BRIAN LANGSTAFF:** Albeit that couple of years have
2 passed, it's a complete turnaround from the views he
3 was expressing in 1983.
4 **MS RICHARDS:** Yes, absolutely. Not least in relation to
5 the position regarding cryoprecipitate and its use.
6 **SIR BRIAN LANGSTAFF:** Well, he was saying then you can't
7 get rid of using commercial factor concentrate,
8 although there's a theoretical risk, not a very big
9 risk, on supply grounds.
10 **MS RICHARDS:** Yes. It may be that this is concerned with
11 inpatient in-hospital treatment, as opposed to home
12 therapy, but the document says what it says.
13 One of the other issues that characterised
14 discussions in the various meetings and communications
15 Professor Bloom had in the course of 1986 is concern
16 about apparent seroconversions from heat-treated
17 materials, and that's discussed by the Expert Advisory
18 Group on AIDS, by Reference Centre Directors and the
19 like.
20 There is one other document in terms of internal
21 pharmaceutical company material that it's worth
22 looking at. It's ARMO0000525, please, Henry. This is
23 an internal Armour document and, again, it's just
24 about looking at how Professor Bloom was viewed more
25 widely. In the third paragraph -- well, the second



1 paragraph:
2 "I have been advised by Professor Bloom that the
3 treaters [so physicians] are likely to play safe and
4 go for the most severe heat treatment. In the UK,
5 there's currently a league table for heat treatment
6 effectively on HTLV-III, as well as non-A, non-B, and
7 unfortunately, ours appears in the relegation zone.
8 Professor Bloom and other opinion leaders accept our
9 HTLV III viral inactivation data, but I think we're
10 now talking about a psychological barrier, and
11 treaters do not wish to be confused with facts."
12 I draw attention to the fact that Professor
13 Bloom is there viewed by Armour as an opinion leader,
14 which is undoubtedly the case from all the material
15 that we've seen.
16 There's one further document to pick up in the
17 middle of 1986. Actually, I don't have the reference,
18 so I will read out the relevant bit. It's a report of
19 an International Congress in Sidney at which
20 Professor Bloom reported data relating to Cardiff
21 patients and said this:
22 "In Cardiff, 43 out of 153 patients had
23 seroconverted. Two had already died from AIDS. One
24 was dying, and seven were showing clinical symptoms of
25 the disease."



1 Then, sir, I should just mention that there are
2 communications between Cutter again and
3 Professor Bloom in 1986 about the trial of a new
4 product, Koate HS. That trial was eventually
5 abandoned, but it's instructive to note, and for your
6 reference, sir -- we don't need it on screen, Henry --
7 it's BAYP0000008_296. There's a memo from Cutter
8 recording a discussion with Professor Bloom in which
9 he said he didn't want to co-ordinate the trial but
10 might contribute if a virgin turns up. So, again, we
11 see the characterisation of the role of the previously
12 untreated patient or the virgin haemophiliac as
13 suitable subjects for trials. There's a further
14 exchange of correspondence with Cutter which we have
15 set out in full in the written note and I won't refer
16 to now.
17 It may just be useful to point out that, in
18 November 1986, the UK Haemophilia Centre Directors
19 Organisation arranged a course about counselling
20 patients exposed to HIV infection. We noted that
21 Professor Bloom chaired one of those sessions entitled
22 "Telling the patient experiences from two groups who
23 have used a team approach but different strategies".
24 And you, sir, will no doubt remember well the evidence
25 from Cardiff about the manner in which some patients

1 describe being informed of their diagnosis and the
2 presence or absence of counselling.
3 From 1987 onwards, many of the documents deal
4 with the threat or presence of the HIV litigation.
5 The Haemophilia Society wrote to Professor Bloom in
6 relation to that and asked for his comments on their
7 proposed publication in Hemofact 12, with their view
8 that very few people with haemophilia would appear to
9 have a legal case. Professor Bloom's response was to
10 say that that seems quite appropriate, and he didn't
11 think the Society's advice was unreasonable.
12 It is also, however, in fairness, right to note
13 that that same year it was agreed that a Reference
14 Centre director meeting -- so this is 1987 -- that
15 Professor Bloom would write to EAGA, the Expert
16 Advisory Group, to suggest that compensation for
17 haemophiliacs was a matter which might be discussed by
18 the group. The Reference Centre Directors said that
19 they supported The Haemophilia Society's attempts to
20 obtain some compensation for haemophiliacs infected
21 with HIV.
22 Perhaps, again, focusing upon the patient
23 experience for a moment, we could look in 1987 at
24 CBHB0000004_122. This is a letter about a particular
25 patient. Various symptoms identified. And it's then



1 said:
2 "His mother does not know of these findings."
3 And the question posed to Professor Bloom:
4 "In view of his antibody status, is there
5 anything you wish me to do?"
6 Professor Bloom's response is at
7 CBHB0000004_121. Just zoom in a little closer,
8 please. 24 August 1987:
9 "Thank you for your worrying letter, et cetera,
10 et cetera."
11 It refers to the potential for immunology
12 testing, and then says:
13 "At some time, his mother will need to know."
14 So again, sir, you may wish to review the
15 evidence you've heard directly from patients, in light
16 of that material.
17 Then just picking matters up in 1988, if we go
18 to BHSC0001024. This is letter from Professor Bloom
19 to Dr Smithies of the DHSS, but these are his notes of
20 a meeting that he attended in Atlanta. And if we go
21 to next page, we can see the heading "Factor VIII
22 concentrates. Viral safety. Résumé of Atlanta
23 meeting". And then it considered the general viral
24 safety of current factor concentrates. If we go,
25 please, to page 5, we see it goes through various



1 products. For example:
2 "(2) Dry heat Koate Cutter not been implicated
3 in seroconversion to HIV but probably transmits non-A,
4 non-B hepatitis.
5 (3) Dry heat BPL probably safe from HIV, but
6 hepatitis safety is still being assessed.
7 (5) Profilate and Kryobulin probably safe from
8 HIV, reduced infectivity for hepatitis."
9 And then he identifies what he regards as the
10 safest heat-treated products. Then this comment:
11 "Best buy. There isn't one. Maybe one needs
12 a safe product for HIV negatives and new, unexposed to
13 hepatitis patients, and a reasonably safe product for
14 other patients to avoid risk of frequent
15 superinfection."
16 In the course of 1988 we see Professor Bloom
17 expressing a preference for the NHS 8Y at a meeting of
18 Reference Centre Directors in BPL in early 1988.
19 In May of that year he attended a special
20 meeting of Reference Centre Directors to discuss HIV
21 litigation with a presentation from Dr Alsop of the
22 Medical Defence Union. There's a reference there --
23 and we can't tell whether this refers expressly to
24 Professor Bloom or it's a more general reference, but
25 there's a question about patients' notes. The



1 representative from the Medical Defence Union was
2 asked what the situation was regarding the private
3 notes about patients, which some directors kept
4 separate from official hospital notes and which
5 contain very confidential information disclosed by
6 patients when being counselled.
7 Then in 1989 there is continued communications
8 about possible involvement in clinical trials of
9 Cardiff patients and there's an observation from
10 Professor Bloom in February 1989 that he'd be unable
11 to enter any Cardiff haemophiliacs into a trial of
12 prophylaxis, partly because they had so few patients
13 with symptoms and partly because this small group of
14 patients is so heavily committed to one or other of
15 the HIV or Factor VIII trials; so, many Cardiff
16 patients involved in trials.
17 Then one are further Cardiff document that we
18 should look at, CBHB0000002_070. This is a further
19 memo from Professor Bloom, 14 August 1989 headed
20 "Factor Concentrates After Hours." He is essentially
21 saying that:
22 "... house officers and other staff members
23 unfamiliar with haemophilia management shouldn't have
24 access to the storage refrigerators in the haemophilia
25 centre. Administration of inappropriate concentrate

to individual patients could have very serious consequences. For this reason, only NHS Factor VIII or IX should be administered after hours and that should be dispensed only by the registrar or senior registrar on call. Other types or brands of VIII or IX concentrate should be dispensed only during normal hours by Haemophilia Centre staff."

It's not known whether there was any particular event or trigger for the issuing of that memorandum but it was obviously a matter of concern to Professor Bloom.

I think I can complete in relatively short time the documents. That won't entirely complete the presentation on Cardiff but I think we can finish looking at the contemporaneous material within 5 to 10 minutes or so if that's fine for you, sir, and for the others.

So there's a document then in February 1990 which may be, again, instructive to look at. PRSE0004635. These are the minutes of the 19th meeting of the AIDS Group of Haemophilia Centre Directors at the Royal Free, 12 February 1990. Dr Rizza is now in the chair but Dr Bloom is present as a reference centre director.

If we could just go please, Henry, to the fourth



page, this is on the issue of testing for hepatitis C. If we pick it up about six lines down:

"Dr Lowe thought there was a difference between testing LFTs [that's liver function tests] and testing for hepatitis C and he wondered whether the patient's consent to testing should be sought. Dr Mortimer said he thought that reliable hepatitis C tests would be available in about a year."

Skipping over the next sentence:

"Professor Bloom didn't see why permission needed to be asked for hepatitis C tests as this was just another LFT."

Then we see Dr Savidge's response, from St Thomas':

"... patients were now becoming more and more conscious of what tests were, so he would advise caution at present."

So that attitude may explain the evidence that you heard last year, sir, from patients that testing was undertaken that they were unaware of.

Then if we look at meeting of Haemophilia Centre Directors in September of 1990, HCDO0000015_021 I'm just trying to find the right page. It's the third page please, Henry.

Again, it's instructive to see how



Professor Bloom is accounting for the historic situation.

Second paragraph:

"Professor Bloom pointed out that in 1979 to '85, when he was Chairman, all the Haemophilia Centre Directors and The Haemophilia Society were pushing the Department of Health to purchase imported products. Everyone knew the result of that."

So presumably -- previously, sir, you will recall we saw a reference to him suggesting that it was patients and the Haemophilia Society who were pushing that. This appears to be a recognition that a push for imported products came from Haemophilia Centre Directors themselves.

**SIR BRIAN LANGSTAFF:** It's also a recognition that, at least in his view at this stage, imported products were the principal cause of the problems that followed.

**MS RICHARDS:** Yes. And that's consistent with what he then says -- or borne out by what he says in the following paragraph, which concludes with he was not convinced that there were good reasons to use imported concentrates rather than British products.

In the middle of 1990, June 1990, Professor Bloom prepared a lengthy report for the



purposes of the HIV litigation, and I'll come back to that, if I may.

Picking matters up in 1991, an issue is raised in the course of that year about inquests being held in relation to patients whose deaths were caused or contributed to by AIDS. In February of that year, Professor Bloom records at a meeting that he had a very good rapport with the local coroner who did not hold inquests but had been dismayed to get a phone call from another part of Wales from a patient's widow when an inquest was being held. Slightly puzzlingly, in the autumn of that year, September 1991, at a later meeting it's recorded that Professor Bloom there says the coroner in his region insisted on being told and on holding an inquest but there was no publicity. It may be that that is a matter that will require some further investigation by the Inquiry with the relevant coronial officers.

There's a continued reluctance to use American products expressed by Professor Bloom, for example, at a meeting in April 1991 within -- in Cardiff, and in a meeting of Reference Centre Directors in September of 1991.

That takes us then to 1992. There is, I think, only one document I need to refer to from 1992.

1 Before I do that, the documentation shows involvement
2 of Cardiff patients in trials, in a comparative study
3 of half-life and recovery of two Factor IX
4 concentrates in patients with haemophilia B, and
5 trials for HIV treatment in relation to the use of
6 AZT. There's also a reference to Professor Bloom
7 wanting to include patients in trials relating to
8 hepatitis C but facing funding difficulties.
9 The one final document I wanted to refer to on
10 the issue of hepatitis C is at WITN2362005.
11 Second page please, Henry.
12 This is a letter from Professor Bloom at
13 16 September 1992 to a patient who, as we can see, has
14 "been so ill". He says in the second paragraph:
15 "I do not know much about the treatment of this
16 other than Interferon and I am not sure why he [that's
17 Professor Thomas] offered you Ribavirin ... As far as
18 Interferon is concerned, I would certainly recommend
19 going on a course of treatment if that is offered to
20 you. It does have side effects, it makes people feel
21 fluey 3 times a week ..."
22 So there's that communication that we've heard
23 from other patients of the side effects of Interferon,
24 very different from the reality.
25 Then if we go further down the page, please, the



1 last few lines, he says this:
2 "I am sure that you know that almost all people
3 with haemophilia who have been exposed to various
4 blood products have picked up hepatitis C since the
5 hepatitis C antibody rate in treated haemophilia is
6 about 80 per cent. This is no consolation to you,
7 I know, but it does show yet another aspect of the
8 bad luck to which the haemophilia population has been
9 exposed."
10 In the course of 1992 Professor Bloom continued
11 to attend various meetings, in particular of the
12 Haemophilia Centre Directors Organisation, and in the
13 September 1992 meeting that year he said he would use
14 Interferon in patients with significant hepatitis. We
15 then know that Professor Bloom died on
16 12 November 1992.
17 Sir, that completes the review of the documents,
18 the key documents, not obviously all the documents,
19 relevant to Professor Bloom and his decision-making
20 and activities.
21 There are two further parts of the presentation
22 on Professor Bloom and Cardiff. One is to look at
23 some of the patient experiences and then marry that
24 into what you've learnt from the documents, what we've
25 all learnt from the documents, and the second is just



1 to look at some of the contents of Professor Bloom's
2 litigation report.
3 It's not practicable to do that now given the
4 time. It won't be very lengthy but it won't be less
5 than half an hour, and possibly longer. So sir, I'm
6 afraid, contrary to expectation, therefore, and hope,
7 I haven't completely finished the Cardiff
8 presentation, but as said, I think last week, I'm keen
9 not to rush any part of any of the presentations
10 because the material is too important to be
11 overlooked.
12 **SIR BRIAN LANGSTAFF:** In my last job, Ms Richards, it used
13 to be said that where counsel gives you an estimate of
14 time, you can at least double it.
15 **MS RICHARDS:** Yes.
16 **SIR BRIAN LANGSTAFF:** You've done it remarkably quickly
17 but effectively and you haven't missed anything, and
18 those are the important things I think. I'm sorry
19 that those who may have expected to hear the whole of
20 it haven't yet but they will.
21 **MS RICHARDS:** Yes.
22 Sir, there will be will probably be about
23 another hour on Cardiff to complete.
24 **SIR BRIAN LANGSTAFF:** We don't want to rush it. It's
25 important. It's particularly important to relate the



1 patient experiences to what's been said, and so we
2 will find time, however we do it, whenever we do it,
3 to do that.
4 **MS RICHARDS:** Yes. I hope we will be able to update the
5 timetable at the end of tomorrow. We have obviously
6 live evidence from Dr Winter tomorrow and Friday, and
7 then from Dr Colvin next Tuesday and Wednesday, and
8 those arrangements won't be altered. But we'll review
9 the timetable and then, hopefully, update at the end
10 of tomorrow when the last part of the Cardiff
11 presentation will be concluded, and then when we will
12 do the Oxford presentation and the St Thomas'
13 presentation, which are currently both scheduled for
14 next Thursday, but that won't be enough time to
15 complete all of that.
16 **SIR BRIAN LANGSTAFF:** Right.
17 **MS RICHARDS:** Essentially if those who are watching
18 remotely or who aren't here tomorrow look at the
19 Inquiry website and timetable either the end of
20 tomorrow or Friday morning, the position should be
21 made clear then.
22 **SIR BRIAN LANGSTAFF:** Thank you very much. So that leaves
23 us with tomorrow starting at 10 o'clock with
24 Dr Winter.
25 So those of you who are booked in tomorrow,

1 I look forward to seeing you then. Have a good
2 evening, stay safe.
3 **(4.32 pm)**
4 **(Adjourned until 10.00 am the following day)**
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**MS RICHARDS: [85]** 1/4 9/6 9/8 9/14 10/19 15/15 15/17 16/24 17/18 17/25 18/2 21/7 21/11 21/17 22/1 23/14 26/23 27/4 27/11 32/21 32/24 33/5 33/7 33/13 36/4 36/7 36/11 36/18 42/14 43/22 48/4 48/20 58/7 58/10 58/15 61/19 61/22 62/4 69/22 70/1 74/17 75/3 75/5 78/18 79/20 82/7 82/14 82/20 82/25 83/3 87/11 92/21 96/21 98/23 102/4 102/9 102/11 104/19 105/11 108/7 108/9 109/6 113/12 113/17 119/2 119/7 120/25 124/4 124/8 124/11 124/17 124/20 130/4 130/16 130/20 139/22 140/20 156/20 158/4 158/10 167/19 171/15 171/21 172/4 172/17
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**3**

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## 3

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