Thursday, 24 September 2020

(10.00 am)

SIR BRIAN LANGSTAFF: Yes, Ms Richards.

MS RICHARDS: Sir, I should explain for the benefit of those who weren't here yesterday or who are watching remotely, I am still part way through the presentation on the knowledge of risk and we've reached April 1983.

That will probably take most of the rest of the morning and then I will turn to the presentation in relation to Professor Bloom and the Cardiff Haemophilia Centre.

There won't be any shortening of what is going to be presented in relation to Professor Bloom and Cardiff. We won't finish it today but it will then continue on next Wednesday.

So I just wanted to add that reassurance, I understand that there are people watching from Cardiff or from Wales who would obviously want to know those timings.

SIR BRIAN LANGSTAFF: So we will start again after today at 10.00 on Wednesday.

MS RICHARDS: With Professor Bloom, resuming with --

SIR BRIAN LANGSTAFF: With the balance of the presentation?

MS RICHARDS: Yes, and then we'll finish that on

Wednesday, and we probably should also finish the material relating to Oxford. If for any reason we don't we will simply carry that over to the following week, when there is next a presentation. We won't be cutting into any of the witnesses.

SIR BRIAN LANGSTAFF: It is important, particularly for those who had their treatment at those centres, that we don't cut it any shorter than you had originally planned.

Presentation by MS RICHARDS, continued

MS RICHARDS: Absolutely, and we won't.

Sir, so when we finished yesterday we had broadcast an extract from a BBC documentary called "Killer in the Village" which looked at the developing knowledge in relation to AIDS and the awareness of it affecting haemophiliacs. That was followed by a series of journal and newspaper articles in the United Kingdom.

Henry, could we have, please, PRSE0000317.

This is one of a series of articles published in The Lancet. I think the date is 30 April 1983. We can see it's called:

"Acquired immunodeficiency in an infant, possible transmission by means of blood products."

It refers to the case of an infant receiving

multiple transfusions and then becoming ill with recurrent infections, in the summary.

If we could go, please, Henry, to page 3, just a little bit further down -- thank you.

The concluding paragraph of the article reads this:

"Although AIDS as a consequence of a transmissible infectious agent cannot be definitely proven in this patient, the evidence strongly suggests such a possibility. Future prospective studies should attempt to determine the incidence of AIDS in transfused patients, especially newborn and premature infants, immuno-suppressed in-patients and patients receiving multiple blood products. As no diagnostic test is available for AIDS, serious consideration should be given to avoiding the use of blood products obtained from individuals with the potential to transmit AIDS. A disturbing observation in this report is that the platelet donor was healthy and did not become ill with AIDS until seven months after donation."

SIR BRIAN LANGSTAFF: Now this is the San Francisco baby?

MS RICHARDS: Yes, in all likelihood.

SIR BRIAN LANGSTAFF: But this is the English or Lancet report of what was reported four months earlier in the

States?

MS RICHARDS: Precisely. So whether or not it had been picked up by clinicians based in this country looking at American journals we may not know, but this is The Lancet, obviously one of the leading medical publications in this country, reporting this case in April 1983, only a few days after the BBC have aired a documentary which touched on the topic.

SIR BRIAN LANGSTAFF: The importance of this is the comment to which you have drawn our attention?

MS RICHARDS: Yes.

Then we see the issue being picked up in the mainstream media.

Henry, could we have PRSE0000199, please.

This is the Mail on Sunday on 1 May 1983, "Hospitals using killer blood":

"Blood imported by the NHS from America could be threatening the lives of thousands of British people. A sexually transmitted killer disease which has struck more than 1,300 Americans is present in contaminated blood used in transfusions and operations. Experts revealed exclusively to the Mail on Sunday that two men in hospital in London and Cardiff are suspected to be suffering from the disease after routine transfusions for haemophilia."

Then if we go down it a little further, please, Henry, we see a quote from a Dr Tony Pinching, an immunologist at St Mary's Hospital, London:

"It seems madness that our blood supplies are coming from a country suffering from an epidemic of an incurable killer disease that nobody can even test for. The Swiss Red Cross, chief producer in Switzerland of the anti-clotting factor needed by haemophiliacs, said this weekend they would welcome requests from Britain for clean plasma."

So we've gone from the BBC through to The Lancet through, now, to the Mail on Sunday, and the same date, 1 May, if we just look at one further example -- there are a number of articles that weekend -- MDIA0000015 please, Henry.

This is the Observer, the same day, "The epidemic spreads", and if we could pick it up at the bottom of the left-hand column first of all:

"However, incidents of the disease over the past 18 months among 200 drug abusers and 11 haemophiliacs has strengthened suspicions that AIDS could also be passed on through blood, either via ..."

If we go to the top of the next column:

"... infected needles or through blood products such as those used by haemophiliacs to prevent

bleeding, which may contain blood pooled from up to 1,000 donors."

Then if we scroll down a little further, please, Henry:

"The blood theory gained credibility a few months ago when a San Franciscan baby boy who received massive blood transfusions shortly after birth began to show early signs of AIDS four months later."

Then there is further reference to the case of the San Francisco baby.

So again, mainstream media in the United Kingdom picking up the story. There are other articles in The Guardian as well, which I won't go to.

That was 1 May. We're then going to look at some Department of Health documents on 3 May.

Henry, could we have DHSC0001651, please.

So we can see from this it's a minute dated 3 May 1983. It's headed "Acquired Immune Deficiency Syndrome (AIDS)":

"You will recall we were asked to providing briefing for Prime Minister's Questions on the stories which appeared over the weekend about AIDS."

We've just looked at a couple of those stories.

"I attach a copy of the line to take, which went to Number 10, together with a background note written

in supplementary question and answer form, both of which I'm circulating more widely within the office. Officials are in touch with representatives of directors of haemophilia centres and the Blood Transfusion Service as well as the Haemophilia Society. The Haemophilia Society indicate they would welcome an opportunity to discuss AIDS with ministers by the end of the week.

"Whilst one of the main purposes of the background briefing is to put the problem of AIDS into proper perspective, a view shared by The Society, we think it would be helpful if Mr Finsberg were to offer to meet representatives of The Society. Meanwhile there appears to be little to be gained from ministers issuing statements about a matter which has been sensationalised and, in some cases, distorted by the media, and on which, with the present state of knowledge, there is no immediate action which ministers could be advised to take. We should, however, review this line after official discussions are complete."

Then there's a reference to whether to have a meeting with The Haemophilia Society.

Could we go to the next page, please. This was "The Line to Take" that was drafted for Number 10:

"I was very concerned to read this weekend's press reports and can well understand the anxiety which some sensational reports may have caused. It is important to put this in perspective: there is as yet no conclusive proof that AIDS has been transmitted from American blood products. The risk that these products may transmit the disease must be balanced against the obvious risks to haemophiliacs of withdrawing a major source of supplies. Already in this country there is a special surveillance system established by the Communicable Disease Surveillance Centre to monitor the occurrence of AIDS, in collaboration with the Centers for Disease Control in the USA. Every opportunity is being taken for this country to learn from the experience of this disease in the USA."

Sir, you will see there the formulation that is then repeated on a number of occasions over the course of the year from the department: No conclusive proof that AIDS has been transmitted from American blood products.

Of course, one question which you will no doubt wish to consider in due course is whether that was the right question to be asking.

We will just look at the briefing note that is

also referred to in this minute.

Henry, could we have DHSC0001654, please.

We can see here the reference to what is AIDS, a reference to the symptoms, and then under the heading "Who is at risk from AIDS?":

"The disease occurred predominantly in homosexual males but other groups such as mainline drug abusers, Haitian immigrants and haemophiliacs requiring treatment with antihaemophilic factor concentrates have also been identified as being at increased risk.

"Is it caused by a virus?

"The cause is unknown. Although medical opinion is tending to favour a virus as the agent responsible, there is no proof that this is the case. There is no means of testing for the presence of AIDS in patients or in blood or blood products such as Factor VIII."

Then there is a reference to laboratory tests for AIDS.

Then if we go down to "Mortality":

"The mortality from the established disease is high. At least 40 per cent of cases die after a variable period of months or years after contracting the disease."

Then if we just go on to the question:

"Is it transmitted in blood or blood products?

"As yet there is no conclusive proof that AIDS is transmitted by blood as well as by homosexual contact, but the evidence is suggestive that this is likely to be the case. The evidence relates to some 11 haemophiliacs in the USA and 3 in Spain, in whom the most likely explanation for the development of AIDS was their exposure to American Factor VIII concentrates. There is also some evidence that AIDS has been transmitted to babies in blood transfusions.

"Are there any cases of AIDS in UK haemophiliacs?

"As far as can be established, there are no proven cases of AIDS in UK haemophiliacs. There is a suspect case in Cardiff of whom we have details ..."

Of course that will be of particular significance when you come to consider the decisions and actions of Professor Bloom.

"... but the reported in the Sunday Mail case has not yet been traced. The case in Cardiff has not received any American Factor VIII concentrate since 1980."

Pausing there, sir, that would suggest there had been some form of communication between the Department of Health and Professor Bloom or Cardiff in order for

them to have that information.

"This would not exonerate American Factor VIII because of the long incubation period which there may be between exposure to the agent and the manifestation of the disease. On the other hand, the patient, who is a severe haemophiliac, has received since 1980 a great deal of British-made Factor VIII concentrate, and it is not possible to know whether British concentrate may contain the AIDS agent.

"Should a ban be placed on imports of US Factor VIII concentrate?

"At present, haemophilia experts in this country take the view that to ban the imports of US Factor VIII would be to place haemophiliacs at greater risk from bleeding than they would be from acquiring AIDS.

"Should we switch to European countries' concentrates?

"AIDS has been reported in some European countries so that European plasma may not be free of the agent. Moreover, there is evidence that some European manufacturers may use plasma which comes not from Europe but from Latin America.

"What action are we taking?"

Then there's a reference to discussions from the

Blood Transfusion directors. Then:

"All Haemophilia Centre directors have received instructions to report any suspect case of AIDS both to a monitoring centre for AIDS at the Oxford Haemophilia Centre and to the Communicable Disease Surveillance Centre, Colindale."

There's reference to the Blood Transfusion Research Committee of the Central Blood Laboratories Authority considering the problems. Then there's a:

"What are the controls on importing blood products?"

Reference to the Medicines Act.

Then this is again further questions and answers:

"Is it true that if the Government had put more money into the blood products laboratory at an earlier stage, this problem would not now be with us?

"No. The agent of AIDS is already present in this country, since a number of cases of AIDS have been diagnosed in homosexuals who have not received any blood or blood products.

"When will this country be self-sufficient in blood products?

"The Central Blood Laboratories Authority is about to embark on a £21 million scheme to build a new

blood products laboratory at Elstree. This should be completed in three to four years ... will be of a size capable of making this country self-sufficient in blood products."

Henry, is there anything further on that page? I don't think there is, no. Thank you.

Again, sir, one of the questions you will no doubt wish to be considering in due course is whether what is said there about the causal connection with blood products was sufficiently reflected in the public statements that were being made by the department or in the approach being taken by Haemophilia Centre Directors, such as Professor Bloom.

Sir, I ask you to note that the following day, 4 May 1983, The Haemophilia Society published to its members a document containing Professor Bloom's advice on AIDS. I am going to come on to that this afternoon when looking at Professor Bloom's actions and decisions in more focus. But that's where it fits into the chronology. It is 4 May 1983.

If we could then, please, have on screen, Henry, DHS0002227_020, please.

This is a document you may recall seeing last year during the evidence of one of the witnesses who gave evidence in Cardiff. It's a communicable disease

report in relation to the week ending 6 May 1983, and you will see the heading, "Acquired Immune Deficiency Syndrome, Cardiff":

"Acquired Immune Deficiency Syndrome has been reported in a 20-year old man with haemophilia in Cardiff."

Then there's a reference to the infections that he had had for three months:

"... a low T helper/suppressor ratio, 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, again, a key fact in the chronology in the course of 1983.

That is also immediately notified to the Department of Health, although the documents we've already looked at suggest that the Department of Health or some within the Department of Health were already aware of it.

If we have please, Henry, DHSC0002227_021, please.

This is an internal DHSS minute dated 6 May 1983. "AIDS, American Factor VIII" is the heading:

"Dr Spence Galbraith telephoned from CDSC this

morning with the following information:

"The male patient aged 23 years in Cardiff who is a known haemophiliac now appears to have the right symptoms and signs for a diagnosis of AIDS."

And reference there to opportunistic infection and so on.

"He has been ill for a month ... he has been treated with American Factor VIII ... no further news of the haemophiliac patient in London.

"Dr Galbraith last night received information from Spain that three haemophiliac patients there are thought to have AIDS and have also been treated with American Factor VIII. Dr Galbraith asks that the Department should consider the matter as a priority and asks that any top level meeting should include CDSC who are collecting all data on AIDS cases for us. I assured him we would liaise with CDSC and also told him that we had already met Dr Gunson, CA in blood transfusion, and he was in touch with regional transfusion directors and that alternative supplies of Factor VIII are being considered but are not going to be easy to come by. The matter is under active consideration. Swiss supplies are considered doubtful. Is Germany a possibility?"

So, again, direct communication to the

Department of Health of not only the Cardiff case but also the cases in Spain.

If we then go, please, to CBLA0000043_040, please, Henry.

This is a letter from Dr Spence Galbraith, who we've just seen referred to in the communication with the DHSS. It's dated 9 May, so three days later, and it's addressed to Dr Field at the Department of Health and Social Security:

"Dear Ian,

"Last week while you were away in Geneva a case of AIDS in a haemophiliac in Cardiff who had received USA Factor VIII concentrate was reported. The case fits the recognised criteria for the diagnosis of AIDS.

"In The Lancet of 30 April three cases in haemophiliacs in Spain are reported; I have confirmed that they received USA Factor VIII concentrates.

"In the same issue of The Lancet, the tally of 11 reported cases in haemophiliacs in the USA is recorded and a paper describes a case in a multiply transfused child in the USA."

Then he says this:

"I have reviewed the literature and come to the conclusion that all blood products made from blood

donated in the USA in 1978 should be withdrawn from use until the risk of AIDS transmission by these products has been clarified. Attached is a paper in which I set out my reasons for making this proposal. Perhaps the subject could be discussed at an early meeting with haematologists, virologists and others concerns so that a decision may be made as soon as possible."

We can see if we go over the page, we see his paper setting out his reasons. So reasons for withdrawal of USA blood products:

"1. The AIDS epidemic in the USA is probably due to a transmissible agent.

"2. The agent is probably transmitted by blood and blood products."

Then he sets out his reasons for reaching that conclusion and just picking it up towards the bottom of that paragraph:

"One of these cases, Professor Bloom's case in Cardiff, fits the accepted criteria of AIDS.

"3. Although this number of cases of AIDS associated with the administration of Factor VIII concentrate is very small in relation to the number of individuals receiving the product, this may not indicate that the risk is small because (a) the

earliest cases of AIDS reported in the USA developed symptoms in 1978 and, therefore, USA blood products manufactured from donations before 1978 are very unlikely to have been contaminated. Indeed, the earliest reported date of onset of AIDS in a haemophiliac is October 1980. (b) Most of the reported cases of AIDS had been diagnosed in 1981 and 1982", and he sets out various numbers:

"(c) The incubation period is long, between several months and two years, maybe as long as four years, and therefore one would not expect to see many cases due to USA blood products until a year or more after 1981/82 donated blood products had been given."

Pausing there, sir, you will have seen in a number of documents and indeed will see it in some further documents today reference made to the incidence, to the number of cases and the number of cases being small, and that effectively being conflated with the risk. Here Dr Galbraith is not falling into that error of conflating the two concepts.

SIR BRIAN LANGSTAFF: He might to this extent. If you go back to the previous page, he says the earliest cases of AIDS reported developed symptoms in 1978. Therefore, USA blood products manufactured from

donations before 1978 are very unlikely to have been contaminated. But he then goes on to say there's an incubation period of seven months or so, if one allows a year or so, he ought to have been saying '76 or '77, oughtn't he?

MS RICHARDS: Yes, that last part of that sentence may not follow from what he sets out elsewhere in the paragraph.

SIR BRIAN LANGSTAFF: He is being cautious but he may not be cautious enough.

MS RICHARDS: Yes, but he is certainly identifying the currently known number of cases may not be an accurate reflection of the true extent of risk.

SIR BRIAN LANGSTAFF: It is what is coming out of the tap, not what is in the pipeline.

MS RICHARDS: Then he goes on to say:

"4. Factor VIII concentrate of pooled products would appear to have a high risk of being contaminated with AIDS agent because homosexuals and drug abusers are known to be frequent blood donors and each plasma pool from which it is manufactured is collected from as many as 1,000 donors."

He refers to the possibility that the AIDS agent being present in the blood of healthy persons for several months before the onset of symptoms.

"5. There is apparently no known means of ensuring that blood or blood products are free of the AIDS agent."

Again, he refers to the San Francisco baby case.

"6. The mortality rate of AIDS exceeds 60 per cent one year after diagnosis and is expected to reach 70 per cent."

So those are his reasons for suggesting that action should be taken now to prevent the further use of American imported Factor VIII concentrate which of course we know did not as a matter of fact happen.

We go from Dr Galbraith to a pharmaceutical company communication to the Department. PRSE0004496. This is a letter of the same date, 9 May 1983, from Travenol to the DHSS:

"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 there's a reference to the March 24 directive from the FDA in the States and in the second paragraph Hyland having become aware that one of its

plasma donors had been identified as a possible victim of AIDS and it sets out a number of steps that Hyland was proposing and drawing to the attention of the DHSS. For present purposes, sir, in terms of looking at knowledge of risk it's really what is said in the first paragraph that I draw to your attention.

On 13 May there was a special meeting of the Haemophilia Reference Centre directors, the purpose of which was to discuss recent publicity about AIDS. I'm going to come back to that when we look at Professor Bloom later on because he was chair of the Haemophilia Centre Directors Organisation at the time and it fits neatly into the account of what he was doing, but that was happening at the same time as the correspondence that we're seeing.

Then if we could please have, Henry, NHBT0017430, please. This is a report by Dr Gunson on proceedings in Lisbon that had taken place between 16 and 19 May 1983 in the Committee of Experts on blood transfusion and immuno-haematology. You can see under the heading of "Acquired Immune Deficiency Syndrome", he says this:

"There is no doubt that this subject dominated the meeting and a report is to be submitted to a meeting of ministers in June, 1983."

In the next paragraph he sets out some of what has been observed and concludes the disease carries a high mortality rate. There is then a reference to reports by members of the incidence of AIDS:

"Within the European countries, with one exception, there were less than ten cases of AIDS reported from each country. The exception was Belgium where 15 had been found", and then this:

"The significance of AIDS to the committee was in relation to the effects with respect to the transfusion of blood and blood products, particularly with coagulation factor concentrates given to patients suffering from haemophilia. Absolute proof that AIDS is caused by a transmissible infectious agent is not yet available but the consensus in the Committee was that it should be regarded as such and that a recommendation should be made to the Council of Ministers at the meeting in June to take necessary steps to minimise the transmission of AIDS by the transfusion of blood products."

There, sir, we see what is being said at a European level. We don't yet have --

SIR BRIAN LANGSTAFF: What were the recommendations it went on to make?

MS RICHARDS: We'll come to that I think, sir -- yes,

we'll come to that. Recommendations were made on 23 June 1983 so I will get to that shortly.

Around this time we have Montagnier's report in the Journal of Science of a possible link between AIDS and the virus referred to by him as LAV. I don't have any particular documentation that I am proposing to show you in relation to that.

DHSC0003824_164, please, Henry. This is a letter dated 20 May 1983. It is from Dr Richard Tedder of the School of Pathology at the Middlesex Hospital Medical School to Dr Walford of the DHSS. You will see it is essentially a recommendation for there to be research but in the second paragraph he says this:

"This condition [i.e. AIDS] is likely to be caused by an infectious agent or agents. It's epidemiology bears a striking similarity to hepatitis B", which was of course known and had been known for decades to be transmissible by blood and blood products.

Henry, could we then have PRSE0000984. If we turn it round, thank you.

This is a document dated May 1983. I think we have established it's likely to be towards the end of May of 1983. It's headed, "AIDS and blood

transfusion, some background to the recent publicity". It's produced by Dr A Smith, I understand from the South East Scotland Blood Transfusion Service. He refers to, in the first paragraph:

"There has been a lot of publicity about AIDS in the media recently and we thought we should explain something about the disease for donors who are worried about it."

Then further down there's a question:

"Who can get the disease? AIDS has been occurring particularly in the USA in certain people who are apparently susceptible to the disease ..."

Then we have a number listed and the fifth is haemophiliacs, this is the top of the middle column:

"... who may be more susceptible or may become infected by their use of blood products which may have come from a blood donor with AIDS. Has AIDS occurred in the UK? The answer is yes. Does this mean the UK is relatively safe? We do not know. Can it be transmitted by blood transfusion? It appears it can. This might produce the disease in people who are not normally at risk. It may have infected clotting factors that cause AIDS in haemophiliac men in USA. We have not had any definite cases of AIDS in haemophiliacs in the UK."

Then this:

"The disease cannot be taken lightly. Those getting AIDS may die because they are more susceptible to serious infections and cancer due to their impaired immune system."

Could we then please, Henry, have DHSC0002231_051. We can see again this is part of an internal DHSS communication in relation to AIDS. There's reference to there having been a meeting on 3 June. The document itself or the minute itself is dated 6 June 1983.

If we look in paragraph 3 of that, it says:

"Dr Walford who is the author of this minute has written a paper for Dr Harris to accompany an agenda item for the CBLA, see attached sheet B."

If we could go please Henry to the third page of this document, we can see the paper authored by Dr Walford:

"Possible implications of AIDS for plasma supply and manufacture at BPL. There are increasing indications that the acquired immune deficiency syndrome may be transmitted by blood and blood products. Because of the number of donations to which they are exposed haemophiliacs receiving large pool Factor VIII concentrate such as that manufactured at

BPL might be at greater risk than those receiving single donor cryoprecipitate or small pool products."

Reference is made there to the Council of Europe meeting.

Henry, if we then have please PRSE0002741. Sorry, I think I may have given you the wrong reference. Don't worry I may come back to that. That's another version of Dr Gunson's report. It's an updated version of Dr Gunson's report.

If we have please -- no, I think I might in fact have given you the right one, sorry, PRSE0002741. Thank you, it was the right one. This is the CBLA meeting, 21 June 1983. We can see attendees include Dr Gunson, Professor Bloom, Dr Rizza and representative Dr Bell from the Scottish Home and Health Department, Dr Gibson from the Medical Research Council, Dr Walford from the DHSS.

If we just go to the bottom of that page, please, under the heading "AIDS":

"The Chairman outlined the problems caused by AIDS. Since it appeared to be transmitted through blood and blood products, then it should be considered by the committee."

SIR BRIAN LANGSTAFF: I think we may not be in the same part of the page, not on the screen. Can we just --

Henry, can we check that we are in the right place please.

MS RICHARDS: I think we are. It was the very bottom of the first page, the very last line of the first page.

SIR BRIAN LANGSTAFF: Thank you.

MS RICHARDS: "The Chairman outlined the problems caused by AIDS. Since it appeared [then we go to the next page] to be transmitted through blood and blood products, then it should be considered by the Committee", and then there are various discussions about research and consideration by the transfusion committee. But then you will see there, sir, the CBLA seemingly accepting the causal connection between blood and blood products and AIDS and certainly not advancing any alternative cause.

Then, Henry, if we could have PRSE0000372. This is the Council of Europe Committee of Ministers' recommendations, 23 June 1983.

If we go down to the third paragraph:

"Considering the growing importance of a new severe health hazard, AIDS, that may be caused by an infectious agent transmissible by blood and blood products", and then if we go to the next page, please, Henry:

"Recommends the Governments of Member States (1)

to take all necessary steps and measures with respect to AIDS and, in particular, to avoid wherever possible the use of coagulation factor products prepared from large plasma pools. This is especially important for those countries where self-sufficiency in the production of such products has not been achieved, to inform attending physicians and selected recipients such as haemophiliacs of the potential health hazards of haemotherapy and the possibilities of minimising these risks", and then, thirdly, "to provide all blood donors with information on AIDS so that those in risk groups will refrain from donating."

SIR BRIAN LANGSTAFF: Does it give a definition of what large plasma pools are?

MS RICHARDS: Certainly not in this document. I haven't put before you, sir, all the material relating to the Council of Europe meeting. There were reports from a number of different European countries. We do I think have much of the material so we can check what the position was there.

But you'll see there, sir, in relation to the first two recommendations the overall arching recommendation is take all necessary steps and measures but, in particular, the (2) is to avoid wherever possible the use of factor products prepared

from large plasma pools and to inform physicians and recipients, in other words, patients, of the potential health hazards and the possibilities of minimising the risks.

Again, one of the key questions for you, sir, will be in particular evaluating the evidence you have heard from individuals whether clinicians did provide information or warnings about the risk of AIDS to their patients and no doubt you will be assisted too by the evidence you will hear from clinicians on that issue in the coming months.

Without going to it, sir, 24 June 1983, there's a further MMWR publication from the Centers for Disease Control in Atlanta updating the increasing numbers of cases of AIDS, 1,641 now reported in the USA and its territories.

We then get to HCDO0000270_004. Again, this is a document we will no doubt come back to possibly in relation to Professor Bloom or in relation to Oxford and Dr Rizza. It is dated 24 June 1983. It says "Dear blank" but we know from other material it was sent to the haemophilia centre directors following the meeting of reference centre directors held on 13 May 1983. It says:

"So far one possible case has been reported to

our organisation [that is presumably the Cardiff case]. This patient conforms to the definition published by the CDC but cannot be considered as a definite case, not aware of any other definable patients amongst the UK haemophilic population."

Then it refers to the general recommendations agreed on 13 May:

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

"2. For treatment of children and mildly affected patients or patients unexposed to imported concentrates, many directors already reserve supplies of NHS concentrates (cryoprecipitate or freeze-dried) and it would be circumspect to continue this policy. It was agreed that there is as yet insufficient evidence to warrant restriction of the use of imported concentrates in other patients in view of the immense benefits of therapy but the situation will be constantly reviewed."

Then it goes on to deal with treatment of patients with haemophilia B where it's said:

"It seems logical to continue to use our normal supplies of NHS concentrate."

Then it looks at proposed trials in relation to hepatitis reduced Factor VIII concentrates. Again, sir, one of the many questions that you will need to consider in due course is whether this was an adequate and appropriate response to the developing knowledge of the risk of AIDS for haemophiliacs and, indeed, whether the advice that was set out here, in such terms as it is, was implemented by clinicians in centres across the country.

Could we then please have DHSC0001209, please, Henry. This is a document prepared for a key meeting on 13 July 1983 of a subcommittee of the Committee on the Safety of Medicines. This is a suggested agenda for the meeting. You'll see it's said at:

"(1) that the aim of the discussion is to help the subcommittee to formulate advice to the CSM and whether any action is needed and, if so, what action in respect of AIDS and blood products licensed under the Medicines Act."

We can see at (2) that there have been a number invited to attend the subcommittee, including Professor Bloom but also Dr Craske, Dr Galbraith Dr Gunson and Dr Mortimer. Then at (4) it says:

"This agenda suggests heading for the discussion", and a suggested first speaker is given.

"As a target for discussion, brief possible conclusions are indicated -- doubtless these will be changed radically."

It is a somewhat unusual document because under the heading "agenda" it sets out suggested conclusions.

If we go down the page we see under the heading, "Factor VIII and other clotting factors:

"Aetiology, current possibilities, conclusion and infectious cause seems likely and a single new agent could be responsible, repeated exposure to or reactivation of known viruses cannot be excluded. Although possible agents have been proposed their relationship to the disease remains very uncertain. The infectivity of the supposed agent appears to be low, requiring for transmission intimate contact or introduction into the body tissues."

Then epidemiology:

"Current position, assessment of risk from Factor VIII", if we go over the page.

"Conclusion. Recipients of clotting factor concentrates are at risk. The degree of risk cannot yet be quantified. The risk is likely to be greatest

from products derived from the blood of homosexuals and IV drug abusers resident in areas of high incidence, and in those who repeatedly receive concentrates in high dosage."

Then the next part goes on to look at possible approaches to avoiding or reducing the presence of viruses in clotting factor preparation, including screening of donors, screening of donor blood, and a number of other matters one of which is -- and this is on the third page, please, Henry:

"4. Consideration of the different operational possibilities for reducing the risks from clotting factor preparations. Withdraw Factor VIII and IX concentrates, i.e. use only cryoprecipitate for treatment", and it looks like it's suggesting Professor Bloom will be the one to address the committee on that.

"Conclusion. This step cannot at present be recommended: (a) it is probably impossible to satisfy UK needs in this way; (b) even if needs could be satisfied it would involve a major rethink of UK policy for preparing blood products; (c) the perceived level of risk at present does not justify serious consideration of this solution."

Then the next suggestion is:

"Withdraw US preparations from the UK market. Conclusion. Impracticable on grounds of supply."

Then the next suggestion is:

"Use US blood products as sparingly as possible. Note: this possibility is largely a matter for physicians treating haemophilia but it could in theory be decided to modify product licences, eg not for use in children with mild haemophilia."

Again, it looks like that is going to be a matter on which Professor Bloom is going to be asked to advise the committee.

"Conclusion. The uncertain balance of risk/benefit considerations in various categories of patient are too finely balanced to justify action via licensing. The matter should be left to clinical judgment."

So that's the agenda with suggested conclusions.

We then -- before we get to the CSM meeting itself, this document I think is produced -- it's 28 June of 1983 for a meeting that was going to take place on 13 July. So dealing with matters in strict chronological order the next relevant event is on 29 June a meeting of the World Federation of Haemophilia General Assembly.

Henry, could we have PRSE0001351 please.

If we go to the third page, the recommendations here are set out there.

"The Medical Board reached agreement on two issues and wish to advise the Council and General Assembly accordingly. There is insufficient evidence to recommend at the present any change in treatment. Therefore, present treatment of haemophilia should continue with whatever blood products are available according to the judgment of the individual physician. (2) Longitudinal studies are urgently needed on the questions already mentioned ..."

So that was the recommendation being made by the Medical Board to the Council and General Assembly of the World Federation of Haemophilia at the end of June.

There is an interesting reflection on that meeting. If we go to ARCH0002544, please. This is a note from Dr Foster 15 July 1983 it might be helpful if I summarise the key points concerning AIDS from the World Federation for haemophilia and ISTH Stockholm meetings. Most of the information was presented by Dr Evatt. We can skip down the next few paragraphs.

We can see:

"(6) Haemophiliacs are in a group which develops opportunistic infections.

"(7) For haemophiliacs there are 16 confirmed cases in the USA, 8 now dead; 5 in Europe; 3 Spain; 1 Wales; 1 Canada."

I am not quite sure why it is thought Canada is in Europe.

"Other delegates seemed to think there were more cases than this outside the USA, eg Canada, Germany, Israel, Sweden. Of the 16 USA cases 1 is a mild haemophilia B case who also received two units of New York blood. Haemophilia A cases are mild, moderate and severe."

Go to the next page:

"AIDS is still located mainly in key urban areas in the USA ... however the haemophilia cases are generally located in non-AIDS areas. This is strong evidence for transmission by Factor VIII."

Paragraph 11:

"The AIDS haemophiliac in Cardiff has received products from Armour and Immuno as well as NHS. Other suspected European cases have received products from Hyland and Immuno."

Then this, this is Dr Foster's impression:

"My general impression was that there was a concentrated attempt from USA delegates to play down the situation. The risk to haemophiliacs was said

a number of times to be one in a million, though simple arithmetic suggests 1 in 1,000. It was stressed that the causes of death for USA haemophiliacs is bleeding 36 per cent, AIDS 11 per cent, cancer 11 per cent, heart disease 7 per cent, i.e. keep on taking concentrates."

Then if we just go a little further down:

"With the first haemophiliac case only 12 months ago and a possible incubation period from one to three years a number of delegates, mainly European, were clearly uneasy and felt that we may be still only seeing the tip of the iceberg."

So there is an insight perhaps into some of the discussions that informed the recommendation, sir, that we just looked at.

Then if we could have, please, PRSE0002301. This is a publication called Transfusion International. It's a newsletter from the League of Red Cross Societies and it's from July 1983. If we go to the second page we see under the heading "AIDS":

"New concern for blood transfusionists."

Go to the right-hand column:

"How does this concern blood transfusion services, blood bank directors, blood donor recruiters? There is relatively strong evidence

indicating that the disease may be transmitted by blood."

Then reference to the 11 cases so far in the US and the additional cases in Europe.

"There is a suspicion that commercial Factor VIII concentrate prepared from large pools of US plasma as being a source of infection. Although there's no absolute proof that blood really does transmit AIDS infection there is one case where the causal relationship is highly suggestive", and we come back to what I think is the San Francisco baby case.

So, there, warnings being given in relation to transfusion more generally and then if we could have, please, NHBT0020668, please. NHBT0020668.

So you will see this is from a Dr Wagstaff of the regional transfusion centre in Sheffield:

"Dear colleague, AIDS leaflet."

It is dated 6 July 1983:

"I am enclosing a copy of the final form of the leaflet which you will see has been altered from the original only in the manner of presentation ... the majority of RTDs [regional transfusion directors] still feel strongly that approach to donors should be at the lowest key possible and were correspondingly reluctant to either hand the leaflet to every donor at

a session or to send it out as part of the call-up material. However, one or two regions felt that there might be some benefit in a slightly more aggressive approach and these RTDs may be asked to develop a kind of trial in their regions by either posting or handing out the leaflets."

Then we look at the leaflet itself, and it's instructive to see what it says -- next page, please, Henry:

"Why is a leaflet on AIDS necessary?

"Recently there's been considerable publicity in the newspapers ..."

Et cetera, et cetera:

"What is AIDS? Who is at risk of AIDS?"

Then if we keep going down, please:

"Has AIDS occurred in the United Kingdom?

"Yes, a few cases have been reported."

Then this:

"Can AIDS be transmitted by transfusion of blood and blood products?

"Almost certainly yes. There is only the most remote chance of this happening with ordinary blood transfusions. However, in the USA about ten patients suffering from haemophilia have developed AIDS."

It refers to the use of Factor VIII:

"Should just one of the donors be suffering from AIDS then Factor VIII could transmit the disease."

But you have there, sir, the straightforward answer to a straightforward question: Can it be transmitted by blood and blood products?

"Almost certainly yes."

We will just see how that leaflet was being considered within the Department of Health briefly.

It is DHSC0001511.

We can see this is a meeting on 6 July 1983:

"Present: MSH ..."

That's the Minister of State to Health, then Kenneth Clarke, and Lord Glenarthur, and then three others in the department:

"MSH [so the Minister] had two main concerns: to establish the necessity of a leaflet and to agree how the inevitable publicity surrounding it should be handled. Officials felt that ministers did not have the option of doing nothing. The main objective of the leaflet was to discourage those who were at most risk from AIDS from giving blood and thereby spreading the infection to patients who needed large amounts of blood, principally haemophiliacs."

Then it refers to similar guidance from the American Blood Transfusion Service and the

recommendation from the Council of Europe that we've looked at.

"Moreover, one of the regional transfusion directors had let slip to the press that a leaflet was in the offing and if nothing was now done, speculation would be rife."

Pausing there, sir, there doesn't appear to be any doubt expressed in this minute of the existence of the causal relationship. The question is only should a leaflet be issued, is that the appropriate course, rather than it being suggested that there's insufficient evidence that AIDS was transmitted through blood or blood products.

Then we see the minister's response at 3:

"MSH accepted the strength of these arguments, he thought the leaflet as drafted read well although he would like it to emphasise more strongly how few cases of AIDS there have been in the UK, perhaps by quoting numbers."

Then there's reference to Lord Glenarthur would be answering an oral Parliamentary question about AIDS from Baroness Dudley on 14 July. If she asked about the Blood Transfusion Service, Lord Glenarthur should emphasise that the risk to haemophiliacs was very small.

SIR BRIAN LANGSTAFF: I appreciate we're looking at risk at the moment but the subtext of this meeting seems to be that the leaflet itself was saying to people who were in particular risk groups that they shouldn't give blood.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: Can we go back to the leaflet?

MS RICHARDS: Yes, certainly. That is NHBT0020668.

SIR BRIAN LANGSTAFF: Does it actually say anywhere in the leaflet that people who are homosexual men who have had many different partners or drug addicts and sexual contacts of people suffering with AIDS should not give blood?

MS RICHARDS: The way it is put is -- under the question at the bottom of the page:

"How can risks be reduced?

"At present there is no screening test the Transfusion Service can use to detect people with AIDS, so until there is and until more is known about this disease, donors are requested not to give blood if they think they might either have the disease or be at risk from it."

SIR BRIAN LANGSTAFF: So it's not particularly specific, is it?

MS RICHARDS: No, although it is fair to say that the

categories of those who appear to be particularly susceptible is set out above under the heading, "Who is at risk of AIDS?" We see there:

"Gay men with many different partners, drug addicts using injections, sexual contact with people suffering from AIDS."

But yes, it is a request rather than an injunction.

SIR BRIAN LANGSTAFF: It obliges the person to say, "Oh, I'm at risk".

MS RICHARDS: To self-identify effectively, yes.

SIR BRIAN LANGSTAFF: Yes, thank you.

MS RICHARDS: Sir, I should say there is other evidence that suggests that the leaflet was published in early September 1983.

Then if we could have, please, DHSC0001208 -- and this is probably the last document before we break -- this is a report of the meeting that took place in the committee -- the subcommittee of the Committee on Safety of Medicines on 13 July 1983. We do also have the minutes. I am not going to put them up. If anyone wants them, they're at ARCH0001710, but actually the minutes, in terms of content, don't really say anything more than what we have here.

"Summary of main points from a consideration of

AIDS and licensed blood products by CSMB, 13 July 1983.

"The subcommittee was helped by the following expert advisers: Professor Bloom, Dr Craske, Dr Galbraith, Dr Gunson and Dr Mortimer.

"Consideration was given to the current information available on incidence and epidemiology, aetiology and related factors. Strategies for limiting or eliminating risks from blood products were examined together with possible practical measures.

"The following conclusions were reached:

"(1) The cause of AIDS is unknown but an infectious aetiology seems likely. A previously unrecognised or new agent may be responsible. Heightened susceptibility may be an important factor, eg immunological deficiencies induced by unusual sexual practices or exposure to blood products.

"(2) Patients who repeatedly receive blood clotting factor concentrates appear to be at risk, but the evidence so far available suggests that this risk is small. The risk appears to be greatest in the case of products derived from the blood of homosexuals and IV drug abusers resident in areas of high incidence, eg New York and California, and in those who repeatedly receive concentrates in high dosage.

Balanced against the risks of AIDS (and of other infections transmitted by blood products) are the benefits of their use: in the case of haemophilia they are life-saving.

"The possibility was considered of withdrawing clotting factor concentrates from the market and replacing them with cryoprecipitate. It was concluded that this is not feasible in the UK on grounds of supply."

Then the note goes through effectively the various other options that were considered at the meeting.

Sir, obviously this is a document you will return to, I have no doubt, on a number of occasions, so I won't go through it in detail at this stage.

But we'll see that the possibility was considered of withdrawing US preparations from the UK. This is point 4. It was concluded that wasn't feasible on grounds of supply and that:

"... the perceived level of risk didn't at present justify serious consideration of such a solution."

There was consideration of the position in relation to pre and post marked 23rd of 1983 supply in paragraph 5.

Viral inactivation is considered as a promising future development in point 6. Consideration is given to the hepatitis B vaccine and others and then, at 11, it concludes there's a need for research work on AIDS in the UK.

As I say, you will no doubt look at that, sir, with witnesses in due course.

In fact, sir, we have reached 11 o'clock or just gone 11.00, so before I move to another document, that may be a convenient point at which to finish.

SIR BRIAN LANGSTAFF: That would be a convenient moment.

We break off at the position in which the subcommittee is recommending that there be no ban on the importation?

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: Very well.

We will come back, as always, in three-quarters of an hour to make sure you have time to go, socially distanced, to pick up the coffee or to be served with coffee or whatever you have. I look forward to seeing you back here at 11.45.

(11.03 am)

(A short break)

(11.45 am)

MS RICHARDS: Sir, we move to August of 1983.

PRSE0004729, please, Henry.

This is, again, an internal DHSS minute. It's dated 23 August and it's entitled "Use of blood from prisons". Picking it up at paragraph 2:

"It's difficult to advise any particular departmental policy on the collection of blood from borstals and prisons at the moment. It's for regional transfusion directors to determine how and from where donations are sought in the light of the targets they need to achieve and the number of donors on their panels.

"However, transfusion directors have been aware of the dangers of relying too heavily on prison as a source of donations for some time, i.e. prior to the advent of AIDS as a cause for concern, because of the risk of hepatitis in prisons, also connected with a higher incidence of homosexuality, which can be spread through blood transfusion. Nevertheless although most regions, especially those with no shortage of donors, may not need to use prisons, there is at least one which has to view them as a major source of donations in order to meet targets.

"AIDS has now, of course, called to the wisdom of continuing to view prisons as a source of blood even further into question and the directors are due

to discuss it at their next meeting in September. If the risks are now considered too great to justify continued collection from prisons, some measures will be needed to compensate for the loss of that source of donors. Perhaps, for example, a system whereby regions with no need to rely on prisons can take extra blood to be transferred to those regions for whom loss of prisons as a source of blood will cause difficulties.

"I shall of course advise you of any developments which occur. I gather this problem has been debated by transfusion directors in Scotland but no particular policy line emerged. We shall obviously need to liaise closely with Home Office also since they have in the past been very much in favour of blood donation by prisoners."

Sir, I draw attention to that because of course we looked in some detail at the sources of blood in America feeding into the pooled plasma and the concentrates used by those with bleeding disorders, but we see here, in August 1983, blood still being collected from prisons and borstals in the United Kingdom and no clear policy line emerging.

I'm afraid I don't have a note of what was then, if anything, discussed and concluded at the meeting in

September, but I can check that.

If we then, please, have DHSC0002231_036, please, Henry.

Yes, DHSC0002231_036. This is a letter of 26 August 1983, so around the same time as the memo. It's addressed to the general secretary, Clive Jenkins, of the Association of Scientific, Technical and Managerial Staffs, and it is from the Joint Parliamentary Under-Secretary of State, Lord Glenarthur. I draw attention only to the second paragraph:

"I think I should emphasise, firstly, that there is no conclusive evidence that AIDS is transmitted through blood products."

So as at the end of August 1983, that is still the Government's articulated public position. Then he goes on to say:

"Nevertheless, we are taking all practicable measures to reduce any possible risks to recipients of blood and blood products. Our scope for action in this is limited as there is no means of testing for the presence of AIDS in blood donors or in blood products."

Then there's a reference to various specific issues.

Again, sir, it will be an issue for you to consider in due course whether there is any mismatch between the suggestion here that the Department is taking all practicable measures to reduce any possible risks and the outcome of the meeting on 13 July of the Committee on Safety of Medicines.

Reported in the media -- I'm not going to go to it -- but at the beginning of September 1983 is a further case of a baby given a blood transfusion who died of AIDS. That was in Canada.

If we pick matters up towards the end of September of 1983 -- Henry, could we have DHSC0003824_060, please.

This is just to show what the next document is. So this is a handwritten note, September 22, 1983. It is for the CMO, so the chief medical officers meeting with the association of district medical officers, and it refers to attaching an updated information paper on AIDS for the district medical officers.

Then if we go, please, Henry, to same reference but 061 at the end, DHSC0003824_061.

So this is the document produced in September of 1983 for the chief medical officers' meeting.

We can go down to "AIDS in the USA", and we see the current figures. Some 2,008 cases of AIDS have

been reported to the Centers for Disease Control. There is thought to be considerable under-reporting. Then there's reference to 75 per cent occurring in male homosexuals. Then it says:

"Homosexuals, together with three other distinct groups of individuals, comprise the so-called '4-H List' of those particularly susceptible to the disease."

They are there set out, the last of which is haemophiliacs.

Then if we carry on down, we see it says just above the heading "Spread of the disease":

"A handful of cases have developed in recipients of ordinary blood transfusions, and these have provided valuable evidence to indicate that the incubation period for the disease may vary from several months up to four years.

"Spread of the disease.

"The pattern which emerges is of a disease which appears to be transmitted predominantly by male homosexual activity but also by heterosexual means. As a secondary method of spread, contaminated needles used by drug addicts and the transfusion of blood and plasma taken from donors carrying the AIDS agent account for the occurrence of AIDS in intravenous drug

abusers, haemophiliacs and recipients of blood transfusions.

"Haemophiliacs seem at greatest risk of acquiring AIDS in this way since the clotting factor which they need is prepared from the pooled plasma from many thousands of donations."

Then we go down to the heading, "Cause of AIDS":

"The cause of AIDS is unknown but the evidence is suggestive that it may be a virus."

Then if we go to the next page, please, under the heading haemophiliacs:

"It is thought that the greatest risk to haemophiliacs at present is from the use of Factor VIII concentrate prepared from American plasma. Although the BPL is to be redeveloped over the next three years at the cost of £21 million to achieve national self-sufficiency in blood products, until this time some 50 per cent of the Factor VIII concentrate needed to treat haemophilia will have to be imported mainly from the USA. In March of this year the FDA instituted new regulations governing the selection of plasma donors, which were aimed at excluding as far as possible donors from high-risk groups. The Department's medicines and supply divisions are endeavouring to ensure that there will

be no dumping of high-risk plasma products on the UK market and are seeking various assurances from the manufacturers in relation to the quality of their products. It should be noted that certain commercial manufacturers are proposing to introduce heat treated Factor VIII concentrate. There's no evidence whatsoever that such material reduces the risk of transmitting AIDS."

So you will see there, sir, in September 1983 identification of the risk to haemophiliacs in those fairly stark terms. That is only a month or so after the letter from Lord Glenarthur suggesting no conclusive evidence of AIDS being transmitted through blood products.

A few days after this document at PRSE0004533, we have the report in The Guardian of the first AIDS fatality in a British haemophiliac. If we then move two or three weeks after that to PRSE0004440, please. No, that's not it. Don't worry, I can read the relevant passage it may be that the references have changed.

This is on 17 October 1983. It's the 14th meeting of the UK haemophilia centre directors and it's a document we'll look at I have no doubt with a number of witnesses.

In the course of that meeting of haemophilia centre directors in October, the minutes record this:

"Dr Chisholm [who was I think the director in Southampton] raised the problem of patients refusing to take up commercial Factor VIII concentrate because of the AIDS scare. She wondered in view of the worry of the patients whether the directors could revert to using cryoprecipitate for home therapy. Professor Bloom replied that he felt there was no need for patients to stop using the commercial concentrates because at present there was no proof that the commercial concentrates were the cause of AIDS. Dr Chisholm pointed out that there was a further problem in her region because of problems in getting large amounts of commercial concentrates whereas she could get unlimited supplies of cryoprecipitate. Other directors reported that they had the same problems. After discussion, it was agreed that patients should not [and that's underlined in the minutes] be encouraged to go over to cryoprecipitate for home therapy but should continue to receive the NHS or commercial concentrates in their usual way."

Again, sir, one key question for you will be whether that was an appropriate response on behalf of the haemophilia centre directors as at October 1983.

SIR BRIAN LANGSTAFF: Just pausing there, it's an abbreviated record of the meeting so one doesn't know quite what was said, but as reported the words are "no proof that commercial concentrates were the cause of AIDS."

That's rather different than saying a virus was the cause of AIDS, is it not?

MS RICHARDS: It is, sir.

SIR BRIAN LANGSTAFF: Because whatever was the cause of AIDS, assume for the moment it is unknown, it might have appeared that commercial concentrates were transmitting it.

MS RICHARDS: Yes. It is not articulated in that way. It is of course a compressed set of minutes and not a verbatim record.

SIR BRIAN LANGSTAFF: So it may simply be a reflection of a much larger -- bound to be a reflection of a much larger discussion.

MS RICHARDS: It may be but the outcome, in any event, is clearly recorded in the minutes and the minutes were disseminated as I understand it is the usual practice to haemophilia centres, the outcome was don't encourage patients to switch to cryoprecipitate.

Could we then please have, Henry -- we're moving to the following month, November 1983 -- PRSE0002122,

thank you. I want to see the whole document.

Sir, you will see this is copies of two newspaper reports, one from the Daily Telegraph and one from The Guardian and then there's a handwritten entry at the bottom. We'll just zoom in on the Guardian item, "US blood caused AIDS". It says this:

"The British haemophiliac who died from AIDS almost certainly caught the disease from contaminated supplies of blood clotting agent Factor VIII, imported from the US, doctors report today. The man, aged 55, caught AIDS a few weeks after being given US Factor VIII for the first time. Hitherto, he had been treated exclusively with British supplies. It seems highly probable that the development of AIDS was related to this treatment. This case provides further evidence for a link between blood products and AIDS ..."

That's a quote from Dr Daly, Dr Helena Daly and Dr Jeffrey Scott from the Bristol Royal Infirmary from a report in The Lancet. There is a reference to that. I won't go to it, but The Lancet report is PRSE0004509.

Then it's referred to a haemophiliac in Cardiff having developed the disease. This was the Bristol case:

"Bristol man was given a large amount of US Factor VIII in December 1981, fell ill in January", et cetera, et cetera.

So that's reported in The Guardian. I think the actual date of the report is 18 November of 1983.

If we zoom out, please, to the handwritten entry. This is a Department of Health document, just slightly back, thank you. Someone's written:

"Have you seen? On X -- is it okay for me to continue to say there is no conclusive proof that the disease has been transmitted by American blood products."

Then we have an answer:

"Thanks. Yes, it is okay."

Now, our understanding at least of who wrote the answer is that it's Dr Diana Walford within the Department of Health and Social Security. If we zoom back out again, the X is, as we can see, an X that's marked by what Dr Daly and Dr Scott have reported in The Lancet.

We can see the handwritten note is not dated but I understand the Guardian report is to be 18 November. I will double-check that. It would fit with the date of The Lancet, I think. We can see a Parliamentary question just a few days before that, PRSE0000886,

14 November 1983, top right-hand corner, Mrs Currie asked the Secretary of State for Social Services what advice has been given to hospitals concerning the use of imported Factor VIII in the light of recent concern about its possible contamination with the causative agent of AIDS. Mr Kenneth Clarke:

"There is no conclusive evidence that acquired immune deficiency syndrome (AIDS) is transmitted by blood products. The use of Factor VIII concentrates is confined almost exclusively to designated haemophilia centres whose directors and staff are expert in this field. Professional advice has been made available to all such centres in relation to the possible risks of AIDS from this material."

That, as I say, may possibly pre-date the -- or may pre-date the handwritten note we've just looked at but if we then go to ARCH0000679, please, we can see now this is 16 December 1983, so on any view this would seem likely to post date the handwritten note, "Is it okay for me saying this", answer, "Yes, it is". It is a letter from Lord Glenarthur responding to an MP's letter addressed to Kenneth Clarke and it says in the second paragraph this:

"I can well appreciate the anxiety, particularly amongst haemophiliacs and their families which recent

press reports on AIDS may have caused and would, first of all, like to put matters into perspective: the cause of AIDS is as yet unknown and there is no conclusive proof that the disease has been transmitted by American blood products."

Then it goes on to give an assurance that the Government is committed to making the country self-sufficient and various factual information is there set out.

Sir, I am then going to move on to April 1984 and I should emphasise there is a vast amount of documentation from this time as one would expect both emanating from the Department and from --

SIR BRIAN LANGSTAFF: Just a moment. Before you leave that, just scanning down, it refers, does it, to "the imports prepared from plasma collected after March this year", the same paragraph, subject to new regulations initiated by the US FDA.

MS RICHARDS: Yes. So it refers to the expenditure on BPL, then it says:

"Meanwhile, in the absence of a satisfactory alternative, we shall be dependent upon imports from the USA for an adequate supply of Factor VIII."

Then there is reference to imports prepared from plasma collected after March being subject to new FDA

regulations designed to exclude donors from high-risk groups.

Then says:

"There is still a quantity of stock which has been made from pre-March plasma. The FDA has recently decided not to ban the use of such stocks because to do so would cause a crisis of supply. The same considerations apply here."

SIR BRIAN LANGSTAFF: So what that means is, is it, that a pre-March plasma collected from high-risk groups was still going to be made available here?

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: I see.

What's the next line?

"We are anxious to minimise the possible risk of the transmission of AIDS by blood donation."

MS RICHARDS: "... by blood donation."

So then there's reference to the leaflet.

SIR BRIAN LANGSTAFF: So that's talking about something different?

MS RICHARDS: Yes. Let me just check the full text of the letter. Yes, it just finishes with the leaflet, and it encloses a copy of the leaflet.

So, sir, the next document is from April 1984. Obviously, there continues to be a significant amount

of material generated by Department, Regional Transfusion Directors, Haemophilia Centre directors and the like, but that will all be further examined in the course of the Inquiry's hearings. For present purposes we move to 23 April 1984 and the press conference announcement by Dr Robert Gallo. That's at DHSC0000455.

I won't go through the entirety of it but we can just see there it's said that:

"Scientists have discovered that variants of human cancer virus are the probable cause of AIDS. This should make it possible for there to be a test. Dr Robert Gallo, who directed the research, isolated the new group of viruses. They are variants of a family of viruses known as HTLV of which HTLV-I and II are members. The new virus is named HTLV-III."

We will see in the documentation from then on until the name "HIV" is given that the virus is referred to generally as HTLV-III.

May of 1984, then.

PRSE0001094.

This is one of various Haemophilia Society communications, and again these are documents we're going to be looking at, I've no doubt, time and again. This is, we'll see, May 1984.

We go to the second page -- and you saw this, sir, in the course of evidence from individuals last year -- it's an update on AIDS by Dr Christine Lee, then Senior Registrar in the Royal Free.

We'll see it says:

"The occurrence of AIDS in haemophiliac patients has strongly suggested transmission of the order by blood products, and epidemiological studies have suggested it may be related to a transmissible agent."

Then she refers to the report that we've just looked at and also to the work in Paris, and then says this in the second paragraph:

"In Great Britain the number of haemophiliacs who have been reported with AIDS remain at two, thus the incidence is less than 1 in 1,000 patients at risk."

Then she goes on to -- if we go further down, Henry, in the third paragraph -- talk about:

"The prospects for resolving problems are brighter for haemophiliacs since improvements in plasma fractionation are likely to make it possible to remove or inactivate causal agents from therapeutic products."

She refers to the prospect of heat treatment. So that's The Haemophilia Society publication.

Again, no doubt when we hear from relevant clinician witnesses, including Professor Lee, we'll be wanting to consider with her the terms in which that articulation of incidence and risk was expressed.

Sir, if we go briefly to DHSC0000443, page 233, sir, we're now in August of 1984. If we go to the second page, this is an internal DHSS document. It's commenting on the publication of a paper in The Lancet and a publication in The Guardian on the use of a screening test for AIDS devised by the Institute of Cancer Research in the Middlesex Hospital.

So in August 1984 it was reported that a test in relation to detecting the HTLV-III virus was underway, and details are given of that.

Then if we go to the third page, please, Henry, so the next page, we see under the heading "Haemophiliac patients with antibody to HTLV-III":

"The proportion of haemophiliac patients amongst the relatively small total number tested ..."

I'm skipping over but there had been a number of tests undertaken:

"... is high. It must be stressed that at present the significance of this finding is not yet clear. However, in all the studies carried out on groups of patients so far there does seem to be

evidence that haemophiliac patients are a group at risk, presumably because of the therapy they require with Factor VIII, most of which is derived from human blood."

They then say at the last sentence of that paragraph:

"Until a test is developed that can be used to screen all blood donations, no guarantee can be given that donations are free from the AIDS agent."

If we then move to November 1984, picking up on this issue of the development of a test, at DHSC0000435 we see this. It's a minute dated 23 November 1984 from one departmental official to another:

"The briefing session last night with MSH [which is presumably still Kenneth Clarke] for his ITV interview revealed that he has strong views on spending money on the blood test for HTLV-III. He felt that to spend around £2 million was not cost-effective when there were so few AIDS cases and the money could be better spent elsewhere. I paraded a number of arguments, including that widespread use was a virtual certainty in the US, demonstrating publicly we were doing all we could to show that our blood is safe, the parallel with hepatitis. Clearly

we will need to play a strong devil's advocate role with the working group next week. I would be grateful if we could look out some figures about hepatitis testing."

Then further reference to a donor leaflet.

It may be that's a revised version of the leaflet, I'm not sure.

Then if we go, please, to DHSC0002309_057. This is dated 30 November 1984. Again, it's an internal departmental minute and it says:

"Ministers will wish to be aware of three incidents of UK blood being given by donors found positive by the screening test for HTLV-III antibody. In one case the infection had been transmitted to a number of recipients, none of whom has yet developed AIDS but this is a possibility."

The background is then set out. Then it says at (3):

"Knowledge of these incidents is becoming more widespread and is likely to reach the media before long. Haemophilia Centre Directors managing the haemophiliacs involved may well feel that they have to inform their patients of the situation."

It seems to be left to the clinicians to make that decision. Then if we go please to TYWE0000048,

this is a document internal to Newcastle District Health Authority, report of an *ad hoc* group to consider the use of heat-treated Factor VIII concentrate, so heat treatment is now potentially available.

If we go to the second page under the heading "Acquired immunodeficiency syndrome", if we just go down please to the second paragraph:

"90 individuals are believed to have died from AIDS in the UK including two heterosexual haemophiliac patients. Because of the known haematogenous transmission of AIDS, haemophiliacs are at clear and special risk of contracting the disease. 74 per cent of haemophiliacs in the USA, 53 per cent of West German haemophiliacs and 34 per cent of London haemophiliacs have antibodies to the putative AIDS virus. It is not known at present what proportion of haemophiliacs attending the Northern Regional Centre have antiviral antibodies but the information will be available soon. There is no reason to believe that the incidents will be less than that in London haemophiliacs and we know that one patient has contracted the disease in Newcastle."

Then if we go to the last but one page, please, there's then under the heading "Conclusions and

advice":

"Our conclusions and advice are as follows: from the available evidence a change from using conventional commercial Factor VIII to using commercial heat treated Factor VIII appears to carry little risk but offers substantial advantages. It should be appreciated however that these advantages, though likely, are not proven and we cannot exclude the possibility that even heat-treated commercial Factor VIII concentrates do not transmit AIDS."

SIR BRIAN LANGSTAFF: That should be "do" transmit AIDS, shouldn't it? "Can't exclude the possibility that they do transmit it".

MS RICHARDS: That's probably right, yes, sir.

SIR BRIAN LANGSTAFF: So the "not" is misplaced.

MS RICHARDS: Then:

"We believe on balance that the use of NHS Factor VIII should be discontinued until after April 1985 when material from this source will also undergo prior heat treatment."

Then if we carry on:

"We advise the continued use of cryoprecipitate. We cannot identify groups of haemophiliac patients who would be likely to benefit from heat-treated commercial Factor VIII or would be likely to be at

special risk from conventional commercial Factor VIII, apart from those without previous exposure to any Factor VIII concentrate."

Then they say they have not taken into account the economic consequences of change. That's for the authority and its officers. Then if we go to the next page, please, there the recommendations are there set out, and we can see it's a note authored by Professor Rawlins, Dr Jones the director of the Newcastle Haemophilia Centre, and others. So by December or in December, early December of 1984, the Newcastle District Health Authority it would appear has recognised what it calls this clear and special risk to haemophiliacs and proposes to take action to use heat-treated products. Again, the timing of that decision and decisions of that kind will be a matter explored in due course with relevant witnesses I hope.

Then two further key documents from December 1984. I am not going to put them on screen, sir, in the interests of saving time but we will be looking at them again I've no doubt with witnesses.

It was on 10 December 1984 that a special meeting of Haemophilia Reference Centre directors and a handful of others was held at Elstree and recommendations were drawn up as to what products

should or should not now be used.

The references for that, sir, are -- Henry, there's no need to put it up but HCDO0000394_117. It's the note of the 10 December 1984 meeting and then the guidelines drawn up as a result of it which are dated 14 December 1984 is at HCDO0000270_007. So it's in December of 1984 that the Haemophilia Centre Directors finally take some form of decision and action and one key issue for you, sir, will be whether that was too late.

Two further references, sir, again without needing to go to the documents. In January 1985 two new groups were formed and began to meet: the Haemophilia Centre Directors set up its AIDS group and they met for the first time on 11 January 1985, and then 29 January 1985 was the first meeting of something called the Expert Advisory Group on AIDS, EAGA, which was an advisory group set up by the Department of Health and, again, one question for you, sir, will be whether those are steps that should have been taken at an earlier stage and, if so, when.

In January 1985 one of the pressing issues, and again this will be explored at a later stage, is the question of the introduction of a test to screen blood donations. We will just, I think, look at two

documents in relation to that. DHSC0000562, please, Henry.

This is a submission to ministers on the question of screening or draft submission, in any event, screening blood donations for AIDS antibody. It's dated 11 January 1985.

If we go to the second page we can see the purpose of the submission. It describes the public health problem that the spread of AIDS presents and the need to reduce it as far as possible the risk of its transmission by blood and blood products. It seeks ministers' agreement in principle to the introduction of a test to screen all blood donations for evidence of infection with the AIDS virus.

It then gives background in terms of numbers of cases, routes of transmission. We see at 2(c) it is now said in terms:

"AIDS can be transmitted by sexual contact and by transfusion of blood and blood products."

Then top of the next page under the heading 4, "Need for a screening test":

"While the campaign to dissuade high risk groups from donating blood is an important interim measure, it is not enough. Experience has shown that people with the active disease and others who are infected

have been donors. The confidence of patients will be lost if they cannot be assured that they will not contract AIDS infection from transfusions."

Then various facts and figures are set out in relation to the introduction of a screening test.

Then if we look at one further document from this month, DHSC0002482_012 this is I think a fairly well known document now. It's from -- it's dated 22 January. It's authored by Kenneth Clarke, the then Minister of State for Health. It refers to the submission and says this:

"This looks inevitable I suppose. Could I have drafts please of the proposed public announcement. Could I have a draft of a letter to go to all chairmen of all RHAs explaining our proposals, how did Wellcome corner this market", et cetera, and then in the last paragraph this:

"Before we all panic further, it is presumably the case that the ending of the collection of blood from homosexuals greatly reduces the risk from blood collected in this country? Also, as only haemophiliacs have died and they may have had Factor VIII from American blood, is it the case that we have not had one AIDS fatality from blood donated in this country yet? Do we need this and heat

treatment of the blood?"

Sir, there is then I think at MDIA0000039 a document that you may find useful in relation to knowledge of risk. This is a letter in The Guardian from Professor Hardisty who was director of the haemophilia centre at GOSCH. He is responding to a letter from the mother of a 9-year old haemophiliac boy. He says this in the second paragraph:

"The facts are these. AIDS was first described early in 1981 and the first case in a haemophiliac was reported to the Center for Disease Control in the United States later that year. Medical intelligence travels fast and these facts were well known to this, as to all British haemophilia centres at that time. Although the occurrence in haemophiliacs provided strong evidence that the disease could be transmitted by blood products, however, it was not until 1984 that the causative virus was identified."

So, sir, I just draw attention to that for the statement from Professor Hardisty that medical intelligence travels fast and that these facts were well known to haemophilia centres.

SIR BRIAN LANGSTAFF: That time would be July 1982.

MS RICHARDS: Yes, it would. That is the date of the first report from CDC in relation to a haemophiliac.

SIR BRIAN LANGSTAFF: He does say the first case was reported later that year, '81, but he has got that date wrong, has he?

MS RICHARDS: He has.

In the course of 1985, again there is a significant amount of important material relating to the speed or lack of speed in introducing or making available tests and expressions of concern at delays or limited availability of heat treated product and centres still using non-heat treated products. Those are all matters that will be explored over the coming months, so I'm not going to go to those documents now.

I do just draw your attention, I'm not going to ask to put it up on screen, but picking up upon the issue of non-A, non-B hepatitis, research by Professor Preston was discussed by the Haemophilia Centre Directors' Hepatitis Working Party in February of 1985 and reported in -- I'm trying to find the publication -- The Lancet in June of 1985 authored by Professor Preston and Professor Haye and, obviously, that's material that we will be exploring further with appropriate witnesses.

Sir, I'm going to then pick matters up now in 1986 in relation to non-A, non-B hepatitis. If we have up on screen PRSE0004555 we see if we -- thank

you -- we can see:

"Blood Bank Week American Association of Blood Banks publication 21 February 1986", and this gives us sufficient information for what we need:

"FDA advisory panel recommends surrogate testing for non-A, non-B hepatitis."

We'll obviously again in due course be exploring the UK consideration of whether or not to introduce surrogate testing.

There's an editorial in August of 1986 in The Lancet that it may be worth looking at, PRSE0001137 called "Safer Factor VIII and IX." We will just see that it says in the opening paragraph:

"The risk of contracting non-A, non-B hepatitis from Factor VIII and IX concentrates was first recognised ten years ago."

Then reference again to large pools of plasma. I can't, I'm afraid, find the reference at the moment but there is a reference in here to it now being clear that there's a substantial risk of chronic sequelae in relation to non-A, non-B hepatitis.

Then if we look at PRSE0002109, still on the topic of surrogate testing for non-A, non-B hepatitis, this is Dr Cash to Dr Fraser of the Bristol Regional Transfusion Centre, 28 August 1986:

"Dear Ian,

"Non-A, non-B hepatitis surrogate testing. I have a feeling that as the drums are beating louder and louder in other parts of the world on this topic the Brits remain fast asleep. I may be wrong but I would like to be better briefed on the matter."

He suggests planning a consensus meeting, inviting a number of experts and transfusion service directors to make some recommendations to the Department of Health.

If we then, please, have -- I'm not sure whether this is the right reference but we will try it.

Henry, BNOR0000323.

This is in extract from Hansard, 20 November 1986. The question is asked of the Secretary of State when the Department first became aware that AIDS could be transmitted through blood and blood products, and it's instructive to see the answer of Mr Newton for the Secretary of State:

"We became aware in 1982 of reports from the USA that haemophiliacs were contracting AIDS. Although the mechanism of infection was not known, it was presumed that it had been transmitted through the use of blood products such as Factor VIII. Evidence that the AIDS infection could also be transmitted by blood

transfusion emerged from the USA in 1983."

Whether there was a tension between that and the public statements of the Department and of ministers in the course of 1983 will no doubt be a matter, sir, that you consider further.

Then, returning to hepatitis, in November of 1986 there was a -- Transfusion Hepatitis Working Party reconvened. I will give you, sir, the reference but won't go to it. It's NHBT0000023_007. That's 24 November 1986.

There are various publications in 1987 which look at the issue of surrogate testing and the non-introduction in the United Kingdom of surrogate testing.

Then we get to April 1988. If we could have, please, PRSE0003126, we will see there:

"Hepatitis non-A, non-B virus discovered.

"Researchers at Chiron Corp announced Tuesday they have isolated and cloned proteins from the virus responsible for non-A, non-B hepatitis. If true, this discovery is a major breakthrough for transfusion medicine because 90 to 95 per cent of patients with post-transfusion hepatitis are considered to be infected with the non-A, non-B strain, and we're told that a screening test (an ELISA test) to detect

antibodies is being submitted for approval."

December 1988, so December of that year -- PRSE0002580 -- we see a publication in The Lancet:

"Chronic liver disease and haemophilia."

Sir, in what perhaps may be thought to be an understatement:

"These are difficult times for haemophiliacs. Initial optimism in the early '70s that introduction of clotting factor concentrates might restore patients to good health with normal life expectancy has given way to an increasing appreciation of the hazards produced by the contaminants of these preparations."

And reference there to HIV and then it says:

"Less dramatic but no less prevalent has been infection with hepatitis viruses."

Then it refers to non-A, non-B as the major problem.

"Acute post-transfusion hepatitis and chronic increases in liver enzyme concentrations have long been associated with Factor VIII and Factor IX concentrate infusion, but those caring for haemophiliacs were slow to accept chronic progressive liver disease as an important complication."

Then it goes on to consider the further discussion of that. If we look in the right-hand

column, second paragraph, the last two sentences:

"The evidence that chronic progressive liver disease is an important complication of haemophilia treatment is, therefore, becoming increasingly persuasive. Furthermore, experience with other types of viral hepatitis suggests that cirrhosis and hepatocellular carcinoma may first appear decades after infection."

Then the question is asked about what can be done, and then the next paragraph:

"Recognition of the seriousness of liver disease in haemophiliacs demands action on several fronts" and various matters there then set out, which again, sir, you will no doubt be considering.

Then we come to 1989. I don't think I need to take you to the documents but we will see, for example, in April of 1989, in the Science journal, the announcement of development of a test for HCV antibodies. In the course of 1989, we see various studies evaluating competing tests. A key question, sir, for you will be obviously whether there were delays in implementing any of that knowledge in the United Kingdom.

Without going to it --

SIR BRIAN LANGSTAFF: So I have two separate questions

I have to answer: the question whether we should have introduced surrogate testing, which we never did; and secondly, whether there was a delay in testing for the virus itself once it had been cloned by Chiron and a test was available.

MS RICHARDS: Precisely. Sir, I won't take time going to it but there's an important study in November 1989 published in the New England Journal of Medicine by Alter and others. It's PRSE0002501 and it looks at what the benefits could have been of the introduction of surrogate testing.

There is then in the course of 1990 and the dates and references, all given in the chronology that core participants have, a series of meetings of the advisory committee on the virological safety of blood which consider the introduction of screening. There's a deferral of decisions. We get to July 1990 and there's a recommendation of the meeting that the UK should introduce hepatitis C testing and then we have in October of 1991 an 11th meeting of that committee, the Advisory Committee on the Virological Safety of Blood considering recommendations in relation to HCV testing and the results of the first HCV test trials and the possibility of look-back study although no decision then taken.

That brings us effectively to the autumn or close of 1991. I've galloped fairly quickly through those materials but they are all available and will all be considered in due course, sir, with relevant witnesses at suitable hearings.

I wanted to finish, sir, this presentation with looking at a documentary in 1995. It's called Bad Blood. It's a Panorama documentary. It will take us probably to 1.05 or thereabouts but I think it will be instructive, not least because of what is said by Dame Sheila Sherlock and others in the course of the programme about the seriousness of non-A, non-B hepatitis, now known as hepatitis C.

Henry, it's BBCO0000003.

(Documentary, Bad Blood, played)

MS RICHARDS: So that's what I propose to finish this presentation with. As I hope has been obvious from the presentation, it is intended very much as an introduction and not as a conclusion on any of the issues that have been raised.

The knowledge of risk chronology that we've shared with Core Participants is a document that will no doubt develop and be added to as more and more evidence is heard, and so if Core Participants have any particular material they wish to draw to our

attention we would invite them very much to do so. But, sir, that completes this and we'll turn after lunch to Professor Bloom and Cardiff.

SIR BRIAN LANGSTAFF: Thank you very much. You have posed a number of questions for me to answer. There will undoubtedly be other questions which come from this material and whatever other material is joined to it, so that I have a full view of everything that there is to see by the time I come to write my report. Thank you very much.

Ladies and gentlemen, 2.10 if you please.

(1.12 pm)

(Luncheon adjournment)

(2.10 pm)

SIR BRIAN LANGSTAFF: Just so that you know, what we shall do, we shall aim to have the next break at 3 o'clock as usual or thereabouts but, because the numbers are smaller than they were yesterday, I think perhaps half-an-hour should be long enough for you to have refreshment. We can come back then, we won't lose any time off the hearing, but then finishing at or just after quarter past 4, so that if any of you have arrangements for travelling on tonight you know what time we are likely to finish -- sometime between 4.15 and 4.30 but probably much nearer quarter past.

MS RICHARDS: Sir, the purpose of this next presentation is to look at Professor Bloom and the Cardiff Haemophilia Centre. I will start that this afternoon but I don't expect to finish. We will then pick this topic up next Wednesday, when the Inquiry sits again, complete the presentation on Professor Bloom, and start the presentation on the Oxford Haemophilia Centre.

If we don't have enough time to finish it, we will complete Oxford the following week, the next day when we don't have a live witness but have a presentation on St Thomas'. So there won't be any compressing of the material. It's just some of it is taking a little longer to map out than when we originally set the timetable.

SIR BRIAN LANGSTAFF: Well, there is a lot of it.

MS RICHARDS: There is, and even this is a selection rather than the entire material.

Professor Arthur Bloom was director of the Cardiff Haemophilia Centre from 1966 until 1992. He died in November 1992. He played a hugely significant part in the events which the Inquiry is investigating in three key respects. Firstly, and in many respects of course most importantly, he was consultant at and director of the Cardiff centre, and so he was the

doctor with ultimate responsibility for the treatment of patients with bleeding disorders at that centre.

Secondly, his decisions and actions, in particular in his capacity as chair of the Haemophilia Centre Directors Organisation between 1979 and 1985 -- critical years -- influenced the decisions and actions of other haemophilia clinicians.

Thirdly, his influence clearly extended beyond haemophilia care because he was involved in, belonged to or advised a number of other bodies, committees or groups. The documents suggest he therefore played a particularly influential role in shaping the response at a national level, or, in any event, in relation to England and Wales, to the arrival of AIDS.

To give a flavour of the groups of which he was a member or a participant, at some time at least, he joined, in 1976, an expert group on the treatment of haemophilia and allied conditions, which was a group advising the Department of Health and Social Security. He was a member of The Haemophilia Society's medical advisory panel from 1979 to 1992. We'll see in the materials that we look at, he also played a broader role in shaping and advising The Haemophilia Society's response to the AIDS crisis.

He was, as I've said, chair of the Haemophilia

Centre Directors Organisation between 1979 and 1985. He was not a member of its hepatitis working party but he did join one key meeting in January 1983. He was on the Haemophilia Centre Directors Organisation's AIDS group from its inception, in January 1985, to 1991. He was a member of the CBLA, the Central Blood Laboratories Authority, from 1982 to 1984 or '85, and it would seem he was on its research and development committee in blood transfusion, or played some part in that committee, between 1982 and 1985. He was part of the MRC working party on AIDS between August 1983 and 1987 and he was a member of EAGA, the Expert Advisory Group on AIDS, advising the Department between January 1985 and 1987.

He was also on the Working Party on AIDS of the British Society for Haematology from October 1983, and between 1987 and 1988, it may be other years as well, he was president of the British Society for Haematology. He played a part on the AIDS Medical Advisory Committee to the World Haemophilia AIDS Centre, which seems to have been partly under the auspices of the World Federation of Haemophilia, at least in 1984 and 1985.

He was on the NBTS, National Blood Transfusion Service, Advisory Committee Working Group on AIDS from

November 1984, and he played a role in the National Blood Transfusion Service, or the NBTS Technical and Scientific Working Group on Viral Contamination of Blood Products, at least in 1988. There may have been some overlap in this latter two groups.

So it can be seen that his influence was extremely wide, and we will look at interactions that he had with The Haemophilia Society, with the Department, with the National Blood Transfusion Service and others.

The presentation will fall into three parts. I'm going to start by looking at what we've learnt from or managed to pull together from documents dating back to the 1970s, and I'll go through those in a largely chronological order. They are drawn from a written note that has been provided to core participants. It's pretty long and detailed, it's 150 pages of material with multiple references, and I am not going to cover all of it but it is available to all core participants. So that will be the first part of the presentation.

I'm then going to look at back at some of the evidence heard from individuals about their experiences of treatment by Professor Bloom or under Professor Bloom's care at the Cardiff Haemophilia

Centre.

So that, sir, will be a reminder of just some of the key parts of the evidence that we heard last year. That's because the documents, the contemporaneous documents, tell only a partial picture, and the evidence of patients and their families helps complete that picture.

Then thirdly, I will look at the litigation report prepared by Professor Bloom in the course of the HIV litigation. He was retained as an expert witness and prepared a fairly lengthy report. Again, it's disclosed and available to all core participants, and it would take some days to go through it in its entirety but I will deal with certain key issues set out in that report and relate that back to what we learn from the documents.

First of all, looking at the materials, I will set out what we have learnt so far from those documents. I say "learnt so far" deliberately because, as with all presentations that we undertake during the hearings, these aren't intended to be the last word on the subject. They are really intended to be the first word on the subject. No doubt more material will be provided or will be gathered by the Inquiry or received from witnesses or received

from core participants over the coming weeks and months.

Sir, I am going to start, as indeed we do in the written note, with a brief description of the facilities and staff of the Cardiff Centre.

Henry, could we have, please, HCDO0000279_011, I hope.

This is The Haemophilia Society's publication, The Bulletin, from 1990.

Henry, if we could go to -- I think it's page 10. We have an article there headed "The Cardiff Haemophilia Centre". This is an article authored by Professor Bloom in 1990, but it gives a little flavour of what the facilities and staffing may have been like in earlier years. So we see there it's said:

"The development of The Cardiff Haemophilia Centre really dates from the invention of cryoprecipitate in 1964. 11 patients were seen in 1963 at the Cardiff Royal Infirmary, where treatment was then undertaken under the direction of the late Professor Harold Scarborough. At that time the life expectancy of a person with severe haemophilia was 23 years.

"We moved to the University Hospital of Wales in 1971 and the number of treatments rose to over 1,000

in 1979. At first, day patient treatment was undertaken from the haematology or children's wards, but with the development of freeze-dried concentrates and home treatment, this system became inadequate and a room adjacent to the coagulation laboratories was adapted as a treatment room.

"A haemophilia sister was appointed in 1977 to supervise and co-ordinate treatment."

Then we're told later on that in 1987 the space problem was partly solved by expansion of the clinical facility to a suite of three rooms and a secure laboratory.

On the next page we see a description of a number of the staff. I won't go through the details of it but we are told there are nursing staff.

At the point in time at which this article was written, which was 1990, we're told that:

"At present there are about 50 patients on home therapy and Professor Bloom says, 'Most are severely affected or require frequent treatment during the year. We like to start this therapy at an early age, as soon as a child is co-operative, venipuncture access is good, parents feel able to cope and home circumstances are satisfactory'."

Then there's reference to social work and other

staff, and I'll come back to that in a moment.

Then in terms of research, we're told that the research group within the Cardiff Haemophilia Centre has been in existence for over 20 years.

"During the 1970s, procedures were developed in order to examine the clotting factors in tissues and in blood, special assays were developed. Detailed studies on the genetic defects started in 1982, and a series of genetic defects within Factor VIII and IX and von Willebrand factor genes have been detected and studied in detail."

That's a brief outline of the physical facilities.

In terms of staffing, we do have a handful of statements, witness statements, that the Inquiry has obtained from nursing or social work staff who worked at the centre. I'll explain what we have. I'm not going to go to any of them but, again, this is material that's available to core participants and indeed will be, no doubt, more widely available in due course.

We have a statement from Jennifer Jones who was a nursing sister 1972 to 1977 and then again from 1981 to 2003. We have a statement from Christine Loran who was a nurse at the centre from 1992 to 1995 and then

more recently when it was under the direction of Professor Collins. We have a statement from a nurse Kerry Thomas who worked on a central children's ward but had some dealings with the treatment of children with bleeding disorders between 1980 and 1982, and we have a statement from Mary Dykes who was a social worker who worked at the centre in the 1970s from 1974 to 1977 and in the period 1987 to 1992. Those are all materials, as I say that core participants will be able to consider.

We also have a statement from the current director of the Cardiff Haemophilia Centre, Professor Peter Collins who took over in 1996 and it may be that the Inquiry hears oral evidence from Professor Collins in due course. But obviously he can't give much of a light on the years when the centre was under Professor Bloom's direction.

We don't have a complete set, currently at least, of the annual returns submitted by the centre to give us data for every year of the number of patients and the types of treatment but we do have two snapshots that we can look at. We'll look first at a set of returns from 1976. Henry, it's HCDO0000072_006, please.

We can see from this it's the annual return for

1976. These were the returns that were submitted to the Oxford Haemophilia Centre and we'll hear a little more about that process when we look at Oxford next week.

Centre Cardiff, director Professor AL Bloom, and so we see the number of haemophilic patients treated during the year, 57; number with Factor VIII antibodies, 6; number of Christmas disease patients treated during the year, 15; number with antibodies, zero.

Then if we go down the page we can get a sense of the different treatments as at 1976. We see there cryoprecipitate is the type of material used, the number of Factor VIII units is 909,020 so it seems at that stage to have been still the main treatment, cryoprecipitate. We then see in terms of the volume of NHS Factor VIII 23,750 and then we see smaller amounts of profilate, Factor VIII and Koate. In terms of Hemofil we see a larger amount, 101,160 units, and in terms of Kryobulin a larger amount of 319,775.

If we go on to the next page, please, we can see there in terms of carriers of haemophilia we have one carrier identified as being treated with cryoprecipitate.

We can skip over the next page, Henry, and go on

to the fourth page. Here we have the annual return in relation to patients with von Willebrand's disease. We're told that there's 12 patients treated during the year and we can see there that the bulk of the treatment as at 1976 was with cryoprecipitate with a smaller amount of NHS Factor VIII concentrate.

I think that's all we have from 1976.

We can then move forward a decade to 1986. This is HCDO0000349_002, please, Henry. So here we have the annual returns for 1986 of materials used to treat haemophilia A patients, carriers of haemophilia A and von Willebrand's disease patients. I'm not quite sure what has happened there in relation to haemophilia B patients, but anyway we see the centre is centre number 150, but it is Cardiff; director, Professor Bloom; total number of haemophilia A patients treated in 1986, 71; total number carriers of haemophilia A treated in 1986, 3; total number of von Willebrand's disease patients treated in 1986, 15.

Then if we look at the types of material used, we can see, and I won't go through all of the figures, but much, much smaller amounts of cryoprecipitate now in use, except for von Willebrand's disease patients. NHS Factor VIII is used both for hospital and home treatment in the figures we see there set out, but

then the treatment which appears to be most used in hospital and to a roughly equivalent level for home treatment is the alpha Factor VIII profilate.

If we go to the third page -- sorry, the fourth page please, Henry, we also have figures here for materials used to treat patients with haemophilia B. Total number of haemophilia B patients treated in 1986 21. Then if we look at the material used, we can see it's predominantly NHS Factor IX concentrate both for hospital and home treatment, but also some usage of alpha commercial Factor IX and a very limited amount of usage of fresh frozen plasma.

That's a snapshot both in terms of numbers and in terms of the materials used. We need to then piece together from other documents how the treatment practices and the materials used changed over the years.

You'll see that in terms of the number of patients, in some respects it's a relatively small centre for the reference centres. There are centres with much larger numbers of patients but Professor Bloom's influence nonetheless, as I have already outlined, really was very extensive indeed in the world of haemophilia care.

I'm going to look now at some of the materials

we have, first of all, from the first half of the 1970s; so from the period 1970 to 1975. Henry, could we have please on screen DHSC0100019_042. This is a letter, we don't see who it's from but we know from a subsequent letter it's from Dr Maycock to Dr Biggs at the Oxford Haemophilia Centre, but it's providing information about cases of serum hepatitis as at 22 April 1970 and we can see there it gives details of five individuals treated in the late 1960s who developed serum hepatitis at Cardiff.

If we then, please, Henry, have HCDO0001014, please. This is now April 1971 and these are the minutes of a meeting of Haemophilia Centre Directors and we can see from the list of attendees that Professor Bloom was there.

If we go to the second page, please, we can see that the issue of incidence of jaundice was, and we see this from pretty much every meeting of Haemophilia Centre Directors over the years, a topic of discussion at the directors' regular meetings. So under agenda item 3 were told Dr Biggs gave a summary of the report on the incidence of jaundice and then we see the action is, amongst other things, to ask directors to give figures about Australia antigen and antibody testing to send her these results. So that would be

what we would now call hepatitis B.

Then we can see the top of the next page is a record that each director, each centre, so including Cardiff, are agreeing they will maintain and send to Oxford each year: detailed records of material given to patients who developed jaundice, the full list of names of patients treated so their names are being shared with Oxford and the total amount of material used in a year in terms of the number of donor units.

Then we can see under the heading "Hepatitis and Australia antigen", there's a discussion about the incidence of Australia antigen and antibody in the haemophilic population and the precautions which should be taken to prevent the spread of infection in the wards and among laboratory staff. It's recorded that donor blood will in due course be screened for that.

Then if we go on please, Henry, to it should be page 7. There is then a brief discussion about the availability of Factor VIII concentrates, bottom half of the page. We'll see this again as a theme in haemophilia centre directors' meetings:

"There was discussion about the presentation of cryoprecipitate to single donor packs. This presentation was not convenient, in general it was

felt that some steps ought to be made to provide the cryoprecipitate in a pooled form. It was agreed that although the supply had improved in the last two years, there was still a shortage of material."

So identification there, as a general observation, shortage of cryoprecipitate.

Then if we go on to page 11 we see under the heading prophylactic therapy and home treatment there's a discussion and we can't tell from this any particular contribution of Professor Bloom but we're told the directors described their experience in prophylaxis home treatment and self-administration of factors VIII and IX by patients:

"It was generally felt that the regular administration of Factor VIII to severely affected Christmas disease patients was beneficial."

So it appears to be a favourable view of prophylactic therapy in relation to Factor IX. Then it says:

"For the classic haemophiliac Factor VIII deficient patient such treatment was more difficult. More frequent treatment could be necessary. The supply of material was not adequate. A number of centres were treating a limited number of patients in this way. It was felt that a controlled trial might

be helpful. If agreed, the trial could be of regular weekly treatment for six months and on demand treatment for six months."

So an early discussion there in 1971 of prophylactic therapy. We'll see as we go through the documents the extent to which we have been able to discern the usage or home therapy and prophylactic therapy at Cardiff.

If we then please, Henry, have DHSC0100026_118. This is a letter which looks at the supply of cryoprecipitate. We're in June 1971. It's a letter from the director of the Welsh Regional Transfusion Centre to Dr Maycock at the Lister Institute and it refers to the ever-increasing demands for cryoprecipitate for haemophilia treatment at the CRI, so Cardiff Royal infirmary, where all haemophiliacs in the region are treated:

"I was obliged to point out that we were producing proportionately more cryoprecipitate than most other regions and asked why the haemophiliacs should need so much more cryoprecipitate here than in other regions. I think my note has had some good effect at any rate making the CRI unit realise they are getting their fair share. I have had to write to tell Professor Jacobs and Dr Bloom that if they want

even more cryoprecipitate it can only be done if they send a technician to assist in cryoprocessing done one or two evenings a week. We can easily get the donors but handling the blood here is too much for our small staff."

Then there's a suggestion in the next paragraph that Dr Maycock should perhaps put this issue down for discussion at the next directors' meeting and Dr Drummond says the object of the analysis is to show the wide variation in practice by the clinicians. Then we see bottom of the page the issue virus hepatitis flagged up and an issue of Australia antigen testing of blood donors. Picking it up on the last word of the page and then to the next:

"Clinicians are increasingly demanding blood tested for Australia antigen", and there is concern expressed about the ability of the Cardiff transfusion centre to cope with that demand.

If we move then, please, to WITN2554013. This is a document from a patient record. We saw it during the witness' evidence last year. It's from January 1972 and it's again just to see the extent to which the issue of developing hepatitis featured in the early 1970s:

"This patient with Christmas disease has during

the last six months received treatment with Factor IX concentrate for various bleeds. The concentrate is prepared at Oxford. I understand that one of the donors of blood from which the concentrate is prepared has since developed jaundice, which could be due to infective hepatitis. Your patient is therefore at risk from developing hepatitis. But in view of the fact that he has received so much treatment in the past and has probably been previously exposed I think the risk is a small one."

We'll then move on please, Henry, to HCDO0001015 this is picking matters up now at the Haemophilia Centre Directors' meeting in October of 1972, 27 October, it was attended by Dr Bloom. We can see that in the fourth line. If we go please, Henry, to page 9 we can see also there is an earlier discussion about home treatment. Here we pick up the issue about halfway down the page of supplies of therapeutic material, and if we look at the last three lines, this is Dr Biggs' probably speaking at this point but it's not clear from the minutes:

"The desirability of increasing home treatment and the availability of good commercial material make the question of increased British supply very urgent."

If we go over the page:

"The cost of preparing concentrate was discussed. It was emphasised that material made by the NHS was unlikely to be more expensive than the present commercial material."

There's then a discussion about units initiated by Dr Maycock. Then it says this:

"Two main topics were discussed. One concerned the purchase of commercially available Factor VIII preparations and the other was the more long-term problem of increasing the supply of a good quality soluble British product. Many directors were pressing for permission to purchase the good commercial products manufactured overseas."

Again, we can't discern from the minutes whether those many directors specifically included Dr Bloom, but we can see that the general mood, as at the autumn of 1972, is Haemophilia Centre Directors asking effectively to be able to use commercial material and identifying an insufficient amount of NHS concentrate.

If we then please, Henry, have CBLA0000098. Here we are at November 1972 and get a sense from Professor Bloom of the treatments being used at that time. It's his letter to Dr Maycock and he says this, picking it up in the second line:

"You may have noticed we have not used much

freeze dried concentrate of AHF recently. This is not because we were ever unhappy with it but is mainly because the supply of cryoprecipitate produced locally is quite good."

Then skipping down a few lines he says:

"I note that you are changing over to a high-potency preparation. I would imagine this would be easier to give by simple injection. For this reason on completing the form I have now assumed we would optimally like to use freeze-dried concentrate, if available."

So the suggestion there appears to be the predominant usage at that time cryoprecipitate and that's no doubt reflected in the 1976 return we looked at, but a preference to start being able to use freeze-dried concentrate. That obviously in relation to the letter to Dr Maycock would be Elstree produce.

It is perhaps instructive just look at Dr Maycock's brief reply which is at CBLA0006294 where he says this to Dr Bloom:

"I hope that one day there really will be sufficient material to treat all the haemophiliacs in an ideal manner but I doubt whether that will be in my time."

Henry, could we then have, please, HCDO0001016.

We've moved forward now to January 1974 and again we see what we can pick up from the minutes of the -- this is a joint meeting of directors of haemophilia centres and blood transfusion directors, 31 January 1974. We see Dr Bloom was in attendance and we can see he is a faithful attendee of pretty much all of these meetings.

If we go to page 5 please, Henry, picking it up in the last paragraph, again this is in a discussion about supply and self-sufficiency:

"What kind of material was best for treatment? There was a wide ranging discussion about the relative merits of cryoprecipitate and freeze-dried concentrates with regard to ease of manufacture, recovery from the original plasma, ease of administration, and recovery of activity in patients. It was generally felt that larger supplies of concentrated preparations were required now and urgently and some felt that it was rather meaningless to ask doctors if they would prefer freeze-dried concentrate to cryoprecipitate when no freeze-dried concentrates were available to them. When the discussion was completed, the meeting was asked to indicate whether anyone would in fact prefer to have cryoprecipitate if freeze-dried concentrate were

freely available. It was clear that none of those present would prefer cryoprecipitate."

So we can infer that by January 1974 Dr Bloom's stated preference is to be able to use concentrates in place of cryoprecipitate.

Elsewhere in the document there is emphasis on the need for the UK to become self-sufficient in products and if we go then on to page 8, there's then a discussion about home therapy. We don't know whether one of the directors involved here is Dr Bloom or not. It said:

"Several directors said they did not treat all the patients at their centres since this was too inconvenient for the patient and too difficult. On the other hand, they were aware that the materials might not be used properly. This raised the question of home therapy. It was stressed that home therapy was becoming more accepted widespread and was improving the quality of the patients' lives. Cryoprecipitate was not ideal for home therapy from many point of views. Some directors were buying commercial AHG for use in home therapy."

As we've seen from the 1976 annual return, certainly Cardiff, although still using a very significant quantity of cryoprecipitate, was buying

some commercial concentrates.

Could we then please have WITN0047002. If we go to the next page this is an extract from a patient record from February 1975 and it gives us some idea of how Dr Bloom's approach to treatment is developing. He says:

"This patient who suffers from haemophilia has been selected for home treatment", and there is a description of the instruction that's been given to the patient's wife in that regard.

Then in the next paragraph it's said that the risks from the use of this preparation, especially allergic reactions and hepatitis, have been explained. Then if we skip over the description of allergic reactions it said this:

"A small percentage of these freeze-dried preparations contain, unavoidably, the virus of serum hepatitis and therefore potentially dangerous to the patient, his relatives, et cetera."

Whether by serum hepatitis in 1975 Dr Bloom had in mind hepatitis B, non-A, non-B hepatitis which had begun to be recognised, or was using the term to cover both we don't know.

SIR BRIAN LANGSTAFF: The term then, certainly when used before the 1970s it covered both, didn't it?

MS RICHARDS: We now know it covered both, but some -- some clinicians we see, from some doctors, seem to use it more to describe hepatitis B. We've no way of knowing what Dr Bloom necessarily had in mind, save it's clear from this he regarded it as an unavoidable fact that serum hepatitis would be found in concentrate and he regarded it as potentially dangerous not just to the patients but to the patients' relatives.

Then if we could have, please, HCDO0001019, please.

This is Haemophilia Centre Directors' meeting September 1975. Again, we can see that Dr Bloom was present.

If we look at the discussion on "Progress towards self-sufficiency" -- sorry, I haven't noted down the page number. If we just scroll down I'll hopefully find it. Next page. Next page.

Sorry, just pausing there, we'll see there, again, as we see, it's essentially at all these meetings discussion of the incidence of jaundice in haemophiliac patients.

If we go to the next page please, Henry. Next page.

There's a hepatitis survey being established

there.

The next page, please. Next page. No. If we carry on -- I'm sorry, Henry.

There's reference there to a proposed pilot study of hepatitis in haemophiliac patients.

Then if we go on to the next page, there is somewhere reference to a discussion about self-sufficiency which I will find, I hope. If we carry on -- if not, I will come back to it on Wednesday.

Ah, page 12. Thank you. That's what happens when you don't print off the page.

So if we pick it up towards the bottom of the page, thank you, "Supply of Factors VIII and IX":

"Dr Maycock said an expert group had met at the DHSS on 20 March 1973."

That's the group that we considered briefly with Lord Owen during his evidence on Tuesday, and we'll look at again when we look at the Oxford Haemophilia Centre.

If we go to the next page, please, if we scroll down there should be a reference to Dr Waiter from the DHSS.

Yes, so pick it up here.

Various directors having set out their views on

insufficiency of supply, we see Dr Waiter saying that she hoped that the haemophiliac patients would realise that the supply of Factor VIII was not inexhaustible and they should not undertake activities of excessive physical danger.

I am just going to pick matters up from 1976 onwards. If we could have, please, WITN0047003.

Again, this is an extract from a patient record and it's just again insight into Dr Bloom. He is now described as a consultant haematologist. He had previously been described as a senior lecturer. This is 21 January 1976:

"Just a note to let you know that the last blood test on Mr H showed that he was positive for hepatitis-associated antigen."

So that's hepatitis B.

"Presumably, he has picked this up from the Factor VIII concentrates from which he is treated and we are keeping an eye on his liver function."

So again, there, clear knowledge that -- and we're now, as I say, in the early part of 1976 -- incidence of hepatitis B in the haemophiliac patients known clearly to be transmitted by Factor VIII concentrates. We are told "keeping an eye on his liver function". We can't tell exactly what tests are

being done or what significance was being attached to it at that stage by Professor Bloom.

In 1976, Professor Bloom was invited to join the reconvened Expert Group on Haemophilia. He didn't in fact attend the 1976 meeting so I'll look at that document next week when we look at Oxford Haemophilia Centre, because both Dr Biggs and Dr Rizza did.

If we then go, please, to CBLA0000473.

This is what's described as an exploratory meeting of blood transfusion directors and Haemophilia Reference Centre directors in October of 1976. We can see from the agenda that the issue of self-sufficiency is high on the agenda.

If we go to the second page, please, Henry, we can see from the list of attendees that Dr Bloom is there. We're told in paragraph 3 it's supposed to be an informal meeting. Only Haemophilia Reference Centre Directors and the Blood Transfusion Directors related to the Reference Centres, along with fractionation experts, have been invited.

Representatives from the DHSS, Welsh office, Northern Ireland Health Authority and Scottish Home and Health Department have not been invited at this stage.

Then we can see under the heading, "Reason for

calling the meeting". Picking it up three lines down:

"The reference centre directors [so that will include Dr Bloom] believe that the Haemophilia Centre Directors in toto are able to offer much assistance in expediting the adequate production of Factor VIII concentrate in the UK by Blood Transfusion Centres eg by outlining the amount of cryoprecipitate needed or not needed, and by purchasing Factor VIII concentrate from abroad for a set period of time to allow increased plasma availability for fractionation. The view of the haemophilia reference centre directors is that there should be no need to import expensive Factor VIII concentrate from abroad."

Then picking it up a few lines down we see that:

"Since the introduction of commercial Factor VIII there's been a steady increase since 1973 in the usage of Factor VIII concentrate probably both due to the patients and haemophilia reference centre directors becoming aware of the commercial preparations."

If we pick it up over the next page, about a third of the way down it's said:

"There's an urgent need to convert plasma used for cryoprecipitate to a freeze-dried preparation."

It's said that:

"There are five commercial companies licensed and supplying very satisfactory Factor VIII in the UK. It will be surprising if doctors and patients do not come to prefer these very convenient preparations as compared with cryoprecipitate."

Then over the page we see a discussion and some interventions from Professor Bloom. So, about three-quarters of the way down, Professor Bloom is recorded as saying:

"We use cryoprecipitate for ordinary bleeds, eg into joints, but we need the treatment of inhibitors and home treatment freeze-dried material."

So concentrates for home treatment.

Top of the next page he's recorded as saying that NHS material compared very well with commercial products.

Then if we look towards the bottom of that page, the question is asked what's the target for how much freeze-dried and how much cryoprecipitate and Professor Bloom's answer is 100 per cent freeze-dried. So that presumably his target or aim as at 1976 to move to entire usage of concentrates in place of cryoprecipitate.

If we then just look in 1977 at documents which explore again the issue of jaundice, HCDO0000072_005,

we see here the continued reporting to Oxford in what are now formalised hepatitis survey forms of patients developing jaundice. So we see that Professor Bloom is being asked to supply particular information about patients receiving a specific batch of Hemofil.

The second paragraph then explains a particular patient being found to be mildly jaundiced following treatment with Elstree Factor VIII concentrate and then reference in the last paragraph to three patients developing asymptomatic hepatitis and receiving, in addition to other materials, Elstree Factor VIII.

Then there's further exchanges of correspondence which we need not look at in which it makes clear that there's a system in place for supplying information about patients developing jaundice to Oxford and information being supplied to Dr Maycock at Elstree in the event that there is hepatitis that develops following the use of Elstree Factor VIII.

It's clear that at least some of this material is patient identifying material, the material that's sent to Oxford certainly is. Whether the information that was provided by Professor Bloom to Dr Maycock also specified patient names is not entirely clear from the correspondence. Equally, what's not clear of course is what was being told to the patients

themselves about these matters.

Then one final document before we break at -- no just a short series of documents I think very quickly. We see some interactions between Professor Bloom and pharmaceutical companies in the late '70s. We can just get a flavour of them from a couple of documents.

IPSN0000334_018, please. This particular interaction, and it's just an example, there are various documents that we refer to in more detail in the note. This is August 1978 and it's the director of Speywood communicating with Professor Bloom:

"Thank you for sparing me some of your time last week. I found our discussion most interesting. We will keep you in touch with progress on the animal product."

He then offers to let Professor Bloom have a small amount of polyelectrolyte to help with research that is being undertaken at Cardiff into the biochemistry of human Factor VIII. There's then reference to an offer to send some of the animal product to Professor Bloom for laboratory testing against blood from inhibitor patients. Just pausing there again, we've not currently been able to construct from the documentation the extent to which patients themselves were aware of any of these matters

in terms of, for example, laboratory testing against their blood.

Then the last main paragraph, turning to Koate, so one of the commercial concentrates here we certainly would like to be restored as a partial supplier of your needs and the price is there set out and guaranteed delivery within 24 hours.

Then just before we break, if we go to IPSN0000334_019, we have an internal note from the same gentleman of his meeting with Professor Bloom and again it gives us a flavour of the kind of discussions that took place and some of Professor Bloom's preferences for treatment. So this is a meeting with Professor Bloom August 24, 1978:

"There are 250 haemophiliacs attached to this centre of which 100 are regular attendees and 13 inhibitors. Until recently human Factor VIII purchases have been split three ways, Hemofil, Factor VIII and Elstree."

So two commercial products and one NHS product.

"They have now stopped using Armour following the hepatitis problem."

Then it said:

"Bloom used to favour Immuno but as this is now 16p he never buys."

Then if we skip down a paragraph:

"I offered Koate at 10p for 50,000 units lots and am reasonably confident we'll get some of the business. Bloom always likes to keep two suppliers but is reluctant to make frequent changes. Bloom is obviously not an animal lover, although he is interested in our work. He is prepared to look at the new material when available", and then there's a suggestion of providing him with clinical evidence as soon as possible.

"Bloom would like some PE to help with a new research project of his looking at the biochemistry of human Factor VIII. He has a research worker starting in January '79 to work full time on this subject."

Then over the page, it said:

"PPF was at one time rationed in his area but it's now issued on a first come first served basis. There is never enough available partly because the Health Service does not produce sufficient, partly because of the high price. Bloom felt there was a place for commercial material, if it could be produced more cheaply. We should obviously investigate."

So we get there, from that source, some idea of what was understood by pharmaceutical companies at

least to be Professor Bloom's approach to the use of commercial concentrates, and we see there obviously what appears to be a particular concern about their cost.

That, I think, takes us to just after 3 o'clock and time to break.

SIR BRIAN LANGSTAFF: Time then to break until 3.30.

(3.03 pm)

(A short break)

(A short break)

(3.27 pm)

MS RICHARDS: Sir, there are two further documents from 1978 which provide another small piece of the jigsaw that we're trying to assemble.

Henry, could we have HCDO0000400, please.

This is a meeting of the Reference Centre Directors on 27 January 1978, and again we see Professor Bloom in attendance.

We can see from the second page, seven or five lines down, he is proposed as chairman to succeed Professor Blackburn and he'll take up that post in the autumn of 1979.

Then if we go to page 7 please, Henry, under the heading "Price of commercial Factor VIII

concentrates", Professor Bloom says this -- or the minutes say this:

"Professor Bloom expressed concern regarding the number of companies now marketing Factor VIII. The different prices, along with fluctuating prices, made it difficult for doctors to establish their patients on any one preparation of Factor VIII for any length of time. Several directors expressed similar worries."

There's an agreement that Professor Ingram will write to the DHSS asking for advice.

Sir, just pausing there, you will see the concern that's expressed about the numbers of companies is one that's related to price and consequences of price, not an issue raised in relation to safety as a basis for concern.

Secondly, it doesn't necessarily follow from the fact of different or fluctuating prices that doctors can't establish their patients on any one preparation of Factor VIII for any length of time, because the concentrate is obviously there. It may be that's a reflection of what we pick up from the Speywood document, is Professor Bloom's desire to purchase the cheapest of commercial products, and that's the reason why his patients are switching from one concentrate to

another type of material, even though it's not regarded as being the most appropriate clinical course. That's just one inference that it might be open to you to draw from the material, sir.

Then if we go on, please, to -- different document, Henry -- HSOC0010549.

This is a meeting of the Haemophilia Centre Directors, so the reference centres meeting is the small number of leading clinicians and then we have the larger number of directors attending these bigger meetings, including again Professor Bloom.

If we go to page 13, please, Henry -- actually, we can pick it up at page 12.

So, under the heading, second half of the page, "Supplies of Factor VIII concentrate to the DHSS contract and the price of commercial Factor VIII", we see a question being posed to the Department of Health representative, Dr Collins, about the Department's policy regarding the supply situation, and it's said that the DHSS's original target had been reached and exceeded by 1978. They wonder now whether there was a revised target. It's said Scotland can't produce any more because of continuing problems over shift work. Department's target figures included cryoprecipitate which was used throughout the UK.

Then there's this observation from Professor Bloom:

"He said he had a feeling that there was complacency in the Department about the target situation. He appreciated that the DHSS had to have a target and wondered if the target should not now be set at 100 million units."

It's then said that that had been thought about by the Department of Health. Then, towards the bottom of the page, Professor Bloom flags up the question of funding of BPL. He asks if the Blood Products Laboratory was sufficiently well funded:

"If not, could the directors help with this matter in any way?"

It is not clear what kind of help he had in mind in making that suggestion, but the comment is going to be conveyed to Dr Lane.

We move then to 1979. Again, there were a number of directors' meetings where -- and I won't go to them, but the same issues of self-sufficiency, supply, use of commercial concentrates and discussion of hepatitis and jaundice are recurrent themes.

We'll pick matters up on 22 September 1980. It's at HCDO0000406, please, Henry.

Professor Bloom is now in the chair. If we go

to page 3, you can see, under the heading "Progress report on the 1979 annual returns from haemophilia centres", it's just a comment halfway down -- this is not specifically related to Professor Bloom but, sir, may pick up on a point you were asking about earlier.

It says:

"It was pointed out that there was now great difficulty in calculating the donor exposure in view of the many different brands of commercial products now used and the lack of information as to the pool size."

Then discussion of estimates.

Then if we go over the page, to page 4, we see Professor Bloom's contribution about eight lines down:

"Professor Bloom said the increased use of prophylactic therapy would also increase the overall cost of treating haemophiliac patients."

It's unclear whether he is talking there about an increased use of prophylactic therapy at Cardiff or whether it's a more general, national observation.

Sir, just for your note that on the next page, under the heading "Hepatitis Working Party", there's then a discussion about pool sizes again and the relative pool sizes used for Elstree and Oxford materials.

Then if we go toward the bottom of that page, so this should be page 5, about seven or eight lines up from the bottom it's recorded:

"Dr Craske said there had been a poor response from directors to the request for information about patients thought to have developed chronic hepatitis."

So, again, we see the issue of chronic hepatitis being very much on the agenda for Haemophilia Centre Directors.

Then if we go to page 11, please, Henry, about halfway down the page -- carry on a little bit further down so we can see the whole passage -- thank you.

"Dr Savidge -- so that's Dr Savidge, St Thomas's Hospital -- asked what the policy was of the Haemophilia Reference Centre Directors regarding the use of cryoprecipitate for the treatment of haemophiliac patients and for home therapy, and Professor Bloom said that it was a matter for the individual directors to decide. He referred to the minutes of the fifth meeting of Haemophilia Reference Centre Directors, January 1978 [which we've looked at], when the matter of cryoprecipitate versus Factor VIII concentrates for home therapy had been discussed at considerable length and the Reference Centre Directors had agreed that Factor VIII

concentrates were preferred for home therapy."

So something of a tension, potentially, there. He's saying it's a matter for the individual director rather than for the UKHCDO or for Professor Bloom to give any guidance. Then there's a reminder: well, there's been an extensive discussion and you should be using concentrates rather than cryoprecipitate.

Now, also in September of 1980 we have some extracts from an international symposium that was held in Glasgow which a number of directors and others attended. I think by this time next week I'll have a full copy of the document but I've just got the extracts very kindly provided by a core participant.

If we could go to JEVA0000001 please, Henry.

So what we have are some extracts from this symposium which set out some of Professor Bloom's interventions and we can see as at September 1980 a key topic is the impact of hepatitis on haemophiliac patients' livers. So Professor Bloom asks the question:

"Could the appropriate members of the panel advise the Haemophilia Centre Directors and the clinicians who are present on what is the current state regarding the possible treatment of these various types of hepatitis? Should we be doing liver

biopsies in practice on our haemophiliacs and, if we do, can we correlate possible treatment to the liver biopsy appearances?"

Then there's a response from Dr Thomas. I don't need to take you to the detail of that. This is just really looking at the kind of questions that were in Professor Bloom's mind.

So if we go to JEVA0000002 we can see that later in the discussion Professor Bloom comes back to the same topic:

"To come back to my earlier question, what should the people who are not associated with a specialised liver unit be doing when they are faced with a young man who has persistently abnormal liver function tests, a spleen tip palpable, and an enlarged liver? Should we be doing a liver biopsy? Is there any value in it? Or is there any possible treatment available?"

It's not I think unreasonable to infer that this is an issue that Professor Bloom may have been presented with in clinical practice for it to be a topic of particular interest to him.

If we could then please, Henry, have JEVA0000003. A later part of the symposium is opened, the same event but a later part of the day, there are

opening remarks by Professor Bloom and I'll just pick it up in the last paragraph on this page. Having talked about cryoprecipitate and concentrates he says:

"Successful though this treatment has been, many problems remain to be solved, notably the high incidence of abnormal liver function tests and various forms of hepatitis discussed in detail elsewhere in this symposium ..."

Then if we go on please, Henry, to -- it should be the second page of this, I think. Do you have a second page? Last paragraph, we then see a reference again by Professor Bloom to the issue about self-sufficiency. Four lines down that paragraph he says this:

"The usage of Factor VIII concentrates in the UK has been assessed accurately because of the organisation of Haemophilia Centre Directors and the returns effectively collated at the Oxford Centre. The current usage of 50 million units was forecast in 1975. The most recent data indicate that the annual requirement will rise to 85 million units by 1985 due, perhaps, to developments such as home treatment and limited prophylaxis."

Then he says this and again this perhaps gives us an insight into his own treatment practices:

"It is the experience of most haematologists that crude cryoprecipitate is not a suitable material for home treatment ..."

He then goes on to talk about the likely shortfall in Health Service-produced concentrate.

Then if we go please, Henry, to PRSE0003946, please. We're now in a haemophilia centre directors' meeting on 30 September 1980, so not long after the Reference Centre Directors' meeting had met the bigger meeting takes place chaired by Professor Bloom. If we go, please, to page 5 we can see towards the bottom of the page, last ten or so lines:

"Professor Bloom said that all the directors were aware of the very severe shortfall in national health concentrate, which was a worrying situation. One of the directors commented that he was not sure that the idea of a commercial firm taking over the manufacture of Factor VIII would be a good idea because the situation might change with a change in Government."

This is presumably a response to the proposed or potential takeover by Beecham of BPL.

He thought it would be better to recommend the Department of Health look urgently into increasing the production of Factor VIII concentrate in NHS

laboratories."

Then over the page, page 6, about six lines down:

"Professor Bloom proposed that the meeting should press the Department of Health to provide more Factor VIII. It was agreed that a strong resolution should be sent from the meeting to the Department of Health that the Department view with grave concern the increasingly inadequate supplies of NHS Factor VIII concentrate."

Then if we go to page 10, please, in this same document, this is in the context of a discussion about hepatitis and the presentation of material by Dr Craske. Picking it up four lines down from the top:

"Dr Craske felt that increased usage of small pooled concentrates would help to reduce the incidence of hepatitis in the haemophiliac population. First time exposure to large pooled Factor VIII concentrate resulted in many cases of hepatitis, especially in von Willebrand's disease patients. Professor Bloom wondered whether cryoprecipitate would be a better product to use for mild haemophiliacs and von Willebrand's disease, but pointed out there was a problem over the amount of Factor VIII in these

materials."

So, again, a very clear live issue for Professor Bloom and his fellow directors: the issue about pool sizes and the risk of hepatitis, and the recognition that cryoprecipitate would bear a lower risk.

The resolution that a message would be sent from the haemophilia centre directors to the Department resulted in Professor Bloom, along with Dr Rizza, writing a letter to the Secretary of State and we see that at HCDO0000394_049.

It's dated 12 November 1980, addressed to the Right Honourable Patrick Jenkin, the Secretary of State for Social Services, and it says this:

"Dear Secretary of State,

"At the recent meeting in Glasgow of the UK Haemophilia Centre Directors, disquiet was again expressed at the shortfall of freeze-dried concentrates of anti-haemophilic factor provided by the NHS manufacturers for the treatment of haemophilia and at the consequent need to purchase large quantities of Factor VIII from foreign commercial sources.

"There's general agreement amongst experienced haematologists and physicians that freeze-dried

intermediate or higher purity Factor VIII concentrate is the material of choice for the treatment of haemophilia.

"Statistics collected by the Haemophilia Centre Directors show that 50 million units were used during 1979, a figure accurately forecast in 1975. Medical progress, increase in the number of patients and changing patterns of treatment are reflected in the arithmetic increase in the annual use of Factor VIII seen since 1969 when those statistics were first collected. If this trend continues at the present rate, the annual requirement will rise to about 85 million units ..."

Then he goes on to set out what the current production is of NHS fractionation.

"It's generally agreed that cryoprecipitate is not suitable for home treatment and has limited medical indications for use. Nevertheless, even taking into account this latter material, there is still a shortfall of 25 million units of Factor VIII per annum, and this amount is currently purchased from commercial sources at a cost to the NHS of 2.5 million."

Then there is the expression of concern in this next paragraph about the possibility of licensing the

commercial production of Factor VIII by private enterprise within the UK, and reference to it being contrary to the spirit of voluntary blood donation and eventually to treatment.

Then over the page it is said:

"The problem of supply of Factor VIII cannot be divorced from that of these other aspects of the Blood Transfusion Service, and in our opinion should be solved by improving NHS transfusion resources within the UK, both centrally at the fractionation laboratories and peripherally at blood transfusion centres. We feel that the future of blood transfusion practice and plasma fractionation in this country is too important to be exposed to the vagaries of national and international commerce. Moreover, once expertise in plasma fractionation has been lost and staff dispersed, it may prove difficult to set up plasma fractionation again within the NHS should the commercial organisation withdraw."

So effectively a request not to proceed with commercial takeover of BPL from Professor Bloom and Dr Rizza and effectively a cry for greater investment in NHS production.

There is a response from Sir George Young on behalf of the Secretary of State. I'm not going to go

to it but it is dated 18 December 1980, and reference is made to the fact that the Minister for Health had now said there's no question of a commercial company taking over BPL.

If we move then to April of 1981 and we go please, Henry, to CBLA0001346 we can see this is a joint meeting of representatives of haemophilia centres and Blood Transfusion Service directors 23 April 1981.

Again, we can see Professor Bloom is there. The purpose of the meeting is set out under the heading summary of the main points discussed, four lines down, the meeting had been convened in order to consider the foreseeable requirements for blood products containing coagulation factors used in the treatment of haemophilia.

Without going into the detail, at the first page there's agreement as to a projected figure for Factor VIII usage for the mid-80s. Then over the page I just want to pick up the references there to hepatitis risks under the heading:

"Types of material required frozen cryoprecipitate.

"Even if this were largely phased out for the treatment of severe haemophiliacs, there would still

be a small requirement for its use in patients with von Willebrand's disease and in mild haemophiliacs and some carriers with low levels of Factor VIII. In the last two categories the small pool size with its lesser risk of hepatitis transmission was the main reason why frozen cryoprecipitate was preferred to concentrates."

So again a clear recollection both of the risk of hepatitis transmission and of the relationship as it was then understood to be with pool sizes.

Then there's a reference again in the next paragraph to that. This in the context of discussing the possibility of freeze-dried cryoprecipitate but it said four lines down:

"Unless the pool size for the freeze-dried cryoprecipitate was small, the advantages of such a product in terms of lessening the hepatitis exposure would be lost and it would be difficult to standardise and expensive to produce."

Then if we look, please, at DHSC0002209_049 we see here a letter from Dr Napier Medical Director of the Welsh Regional Transfusion Centre to the Advisory Committee on the National Blood Transfusion Service. It's not entirely clear what all of the answers mean because we haven't, I think, yet matched it up with

the questions but for present purposes what's relevant is paragraph C:

"I understand that Professor Bloom wishes to continue independent purchase of Factor VIII for the Cardiff Haemophilia Centre."

The context here is that there was an ongoing discussion at this time and it appears repeatedly in Haemophilia Centre Directors' meetings a suggestion that the transfer of decision-making for the purchase of Factor VIII would move from Haemophilia Centre Directors to Regional Transfusion Directors or Regional Transfusion Centres, and that was vehemently opposed by Professor Bloom and, indeed, by other Haemophilia Centre Directors. They did not want to lose control over the decision-making in terms of the purchase of products.

One further document, this is in 1980, at HCDO0000274_028. It's a letter from Dr Kernoff at the Royal Free to Professor Bloom, dated 20 October 1980. It describes what he characterises:

"... as a disastrous series of events following a liver biopsy carried out on one of our haemophilic patients who developed severe and uncontrollable bleeding and the resulting complications causing his death a week later."

For my purposes however if we could just go, Henry, to the second page last paragraph, we can pick it up five lines down:

"The seriousness of the hepatic problem in haemophiliacs cannot be ignored."

Then there's reference again to the question of liver biopsies. But there's a communication from Professor Kernoff to Professor Bloom in those terms, the seriousness of the hepatic problem with haemophiliacs, a clear recognition of the significance of the issue.

Then if we could look please at TREL0000145_084. This is one of a number of letters from Professor Bloom to Dr Aronstam at Treloars. The purpose of this is just to see that as at February 1980 what is being said by Professor Bloom is:

"Most of our home treatments patients are on Elstree Factor VIII, although we must supplement this with other products from time to time during periods of shortage."

How that matches up with some of the other material we have seen would suggest that Elstree Factor VIII is certainly used but so too are a number of commercial products is unclear but that --

SIR BRIAN LANGSTAFF: The return which you showed me for 1976 I think it was showed a hugely greater use of imported concentrate than it did of local concentrate. Was it '76 or is it the other one?

MS RICHARDS: I think it might have been '86 but it is right to say '76 shows a significant amount of Elstree product being used, but it also shows a not insignificant amount of a range of different concentrates being used. Then we have, for example, the insights we see in the note of the meeting with the managing director of Speywood which show that Professor Bloom clearly does use commercial concentrate, I suppose it's conceivable it's not for home treatment but it doesn't quite fit this statement here with what we pick up again from the different pieces of the jigsaw.

Then if we could -- again, it's really within the 1979/1980/1981 period we're looking at here. If we could pick up please, Henry, another Speywood communication. It's ISPN0000334_006.

Sorry, I said it the wrong way round. It's IPSN0000334_004. I'm not sure that is the document I want, sorry. I think it should be 006 at the end.

Yes.

So this is a letter from Professor Bloom to

Speywood Laboratories, 19 November 1979. He says this:

"I'm trying to rationalise purchasing policy of Factor VIII concentrate for the treatment of haemophilia and I would be very grateful if you could bring me up-to-date on your current price lists and marketing policy."

What the relevance of marketing policy is and what is meant by that is opaque. Price lists, again, is consistent with what we've seen earlier, that an important factor for Professor Bloom in choice of product appears to be its cost.

Precisely what is meant by rationalising purchasing policy is not clear but clearly the purchase of commercial concentrates is here being contemplated.

The response is at IPSN0000334_004. It's in these terms from David Williams of Speywood:

"Dear Arthur,

"I enclose formal reply to your recent request for human Factor VIII prices. It would be great if we can get back onto your list of suppliers, and I believe that our correct price structure is competitive. I have to confess we're a bit short of sales at the moment and, with research expenditure of

the polyelectrolyte programme mounting, life is a bit difficult for Speywood. Anything which you can do to help will be greatly appreciated."

Then there's a reference to Hyate:C being available for clinical use:

"We are anxiously waiting for the first suitable case. If you have an inhibitor crisis, perhaps you will consider using the product. I will come down to Cardiff early in the new year to update you on the rest of our projects."

There are other communications we see as well from Professor Bloom with other pharmaceutical companies.

That brings me to 1982, which is a key year, clearly, because of AIDS first being reported in haemophiliacs.

I'll start, if I may, with a letter that may be from 1982 or may not. I'll explain why I say that in a moment. It's at HCDO0000252_042.

It's a fairly well known letter. It's dated 11 January 1982. For reasons I'll come back to when we look at some documents, probably on Wednesday, from late 1982 and early 1983, it is at least possible that this document has been incorrectly dated and that it was sent on 11 January 1983. But for present purposes

I'm going to focus on its content rather than the date.

It's addressed to all Haemophilia Centre Directors:

"You are no doubt aware of at least four commercial companies are about to introduce preparations of Factor VIII and possibly Factor IX that have been processed in an attempt to reduce the risk of transmitting hepatitis B and non-A, non-B.

"As far as we know, the products have been subject to a heat treatment process."

Then there's reference to the possibility of other methods of treatment having been used."

"Although initial production batches may have been tested for infectivity by injecting them into chimpanzees, it is unlikely that the manufacturers will be able to guarantee this form of quality control for all future batches. It is therefore very important to find out by studies in human beings to what extent the infectivity of the various concentrates is being reduced. The most clear-cut way of doing this is by administering those concentrates to patients requiring treatment who have not been previously exposed to large pool concentrates."

So, pausing there, the suggestion is in those

who have been previously not -- PUPS as they are often referred to -- previously not exposed to large pool concentrates, that those patients are treated with these suggested new products to see whether they have reduced the infectivity of non-A, non-B hepatitis.

Then the letter continues:

"Those patients are few in number but a study along those lines is being carried out at Oxford to determine the infectivity of Factor VIII concentrates produced by the Plasma Fractionation Laboratory Oxford, and Blood Products Laboratory Elstree. This study shows that it is possible to demonstrate infectivity using quite small numbers of previously untreated patients. It's very important also to find out as soon as possible whether the manufacturing methods used to reduce the hepatitis risk has resulted in a product with undesirable characteristics ..."

It gives examples of what those characteristics might be.

"Although there's no doubt that the introduction of hepatitis-safe products would constitute a major advance, we hope you will agree with us that their use on a named patient basis would be undesirable and might seriously hinder controlled studies in the future. There are several reasons for thinking this:

"1. The best way of assessing efficiency and observing recovery of activity, side effects, et cetera, is by properly conducted clinical studies. Since a number of products are likely to be introduced in the next few months, a core of at-risk patients will be needed for this assessment. It is for the treatment of such patients that producers will make their products available. If patients at risk are treated as on a named patient basis, they will be unavailable for clinical trials and the results will be of anecdotal value only."

If we carry on please, Henry:

"2. For the purposes of a product licence, the manufacturers are required to set out to the regulatory authority in the UK the evidence of product efficacy and safety and details of processing, et cetera ..."

Then various matters set out in relation to regulatory requirements ending with the sentence:

"Formal trial of efficacy and ongoing monitoring of quality control is thus important.

"3. Use of a product on named-patient basis is often justifiable but bypasses these regulatory controls which have been established in the interest of patients. We are therefore writing to let you know

that the Hepatitis Working Party [that's the working party of the Haemophilia Centre Directors' Organisation] are discussing plans for clinical trials of these products as they become available and will, if necessary, request exemption from a clinical trial certificate in respect of individual products in order to expedite trials. We hope the companies concerned will collaborate in these trials and will offer appropriate supplies of their concentrate as well as financial support. Unfortunately, there is insufficient time available to air these problems at the next meeting of the Haemophilia Centre Directors but if you have any observations we would be most grateful to learn of them as soon as possible. With best wishes ..."

Then we see it's from Professor Bloom and Dr Rizza.

Again, that's one of the key documents that I'm sure we will come back to both with witnesses and with submissions in due course.

That's January of 1982 potentially and we'll come back to that. September 1982 there is a Reference Centre Directors' meeting on 6 September. Henry, that's HCDO0000410 please, chaired by Professor Bloom.

We can pick up the issue about the Hepatitis Working Party on page 8 please, Henry. So bottom of page 8 there's a report from Dr Craske for the Hepatitis Working Party. If we go on to page 9, please, we can see reference to two matters hepatitis vaccine and then a surveyor that Dr Craske was conducting in collaboration with Oxford on the use of commercial and NHS concentrates for first-time or seldom-treated patients. There's a description of that study. Nine of the patients had developed non-A, non-B hepatitis. It appears that there was a 100 per cent attack rate for first-time treated patients who received NHS Factor VIII concentrate and more than an 80 per cent chance of contracting hepatitis following treatment within any type of concentrate.

Then if we go further down, we see and this is the issue to which the January letter alluded, Dr Craske said he'd advise caution with regard to the claims for hepatitis B-free materials which had been made by commercial firms. Only way to check this material was to test it.

Over the page, we then see a continuing discussion and then if we can go on please to page 11 the discussion goes from one topic to another and then

leaps back. We come back to an issue about non-A, non-B hepatitis about ten lines down:

"In the context of a discussion about the hepatitis B vaccine Professor Bloom wondered what value the giving of the vaccine was as it was only for hepatitis B when non-A, non-B hepatitis seemed to be the larger problem for the haemophilic patients."

Then we have the passage we've already looked at. This is the first reference in the Haemophilia Centre Directors' meetings to AIDS. This is Professor Bloom asking Dr Craske if he's got any information about AIDS and Dr Craske saying he'll find out more about this.

We've looked already at the update that was provided at the Manchester meeting a week later on 13 September. I won't go back to that, sir, but you'll recall that the minutes report this:

"It appeared there was a remote possibility that commercial blood products had been involved."

That's in the context of the development of AIDS in haemophiliacs.

We can then pick matters up in a communication directly from Immuno to Professor Bloom and that is at DHSC0001280. This is 13 October 1982, a month after the Haemophilia Centre Directors' meeting from Norman

Berry of Immuno:

"Dear Arthur, as I am sure you are aware three cases of PCP were reported in haemophiliacs receiving Factor VIII concentrate. This caused concern about the transmission of the disease by Factor VIII or possibly other blood products."

Then Immuno say this:

"As far as Factor VIII is concerned we very much doubt the likelihood of this and the organism wouldn't pass through the bacterial filtration process. We do however wonder if there's some unknown entity in the product which causes an immunodeficiency."

Then says this:

"I do not know if it will possible to discuss this problem at your next Haemophilia Directors' meeting but, if you do, we would welcome any information you acquire and we would especially be interested in any haemophiliac who has repeat occurrences of chest infection."

So Immuno asking Professor Bloom to pass on to them details -- or information, sorry, I should say, rather than details about anything they acquire about this issue.

There is a brief reply from Professor Bloom at BPLL0001351_116 and it's 15 October 1982:

"Dear Norman, thank you very much for your letter about pneumocystis and Factor VIII concentrates. As a matter of fact, we discussed this at the Manchester meeting of the Haemophilia Directors and also at the Reference Centre Directors' meeting. At the moment our advice from the virologists is not to panic but we will certainly all keep an eye out for this immunodeficiency syndrome. I am sure that if a case is discovered in the UK that all interested parties will be notified."

Whether as at October 1982 a suggestion not to panic but we'll keep an eye out is an appropriate response is obviously very much an issue that you will need to consider, sir.

Then we will just look at a couple more documents that we haven't looked at previously in the knowledge of risk presentation which just pick up upon communications on AIDS in November 1982.

So if we have next, please, Henry HCDO0000557.

This is a letter from Dr Craske to Ms Spooner in Oxford.

Sir, it encloses a paper produced by Dr Craske, and the paper is the paper we looked at this morning which has the three theories of the possible aetiology of AIDS, with the third involving possibly the

transfusion of commercial blood concentrates.

We didn't look at the covering letter. Can't say with confidence that Professor Bloom would necessarily have seen this letter. He might have done. He would have seen the report. We know that because of the reasons for which it was produced. But this letter says:

"I enclose a copy of a paper I prepared for the meeting of the MRC hepatitis vaccine working group which describes the most recent information available about this new syndrome. At Peter Kernoff's suggestion I wrote to the project leader of the team looking into the epidemiology of this disease at the CDC, Atlanta, Georgia. He telephoned me last week. The latest information is that there are five haemophiliacs who have been identified with this syndrome, two of whom recently died. All these cases are without the usual association of homosexual practices, drug addiction or treatment with immunosuppressant drugs, which are factors which have been found in other patients acquiring opportunistic investigations.

"The hypothesis at present being used to explain the acquisition of these cases is that one or two patients in the incubation period donated plasma which

has since been used to prepare Factor VIII or IX concentrates. All the haemophiliacs who have had the disease have had severe coagulation defects requiring regular treatment with Factor VIII."

Then Dr Craske says this:

"The likelihood is, therefore, that other cases will be identified amongst severe haemophiliacs, though, probably at a low prevalence."

Then there is a reference to proposed dates for meetings.

Sir, the covering letter perhaps provides a little further detail about Dr Craske's view. It would, I think, perhaps be surprising if Dr Craske's view was not known to Professor Bloom, given how closely Craske, Bloom and Rizza were working at this time.

Then the very final document for today is at BPLL0011138. This is a meeting at BPL on 15 December 1982. It's headed "The implications for the Haemophilia and Blood Transfusion Services of Commercial Introduction of hepatitis-safe Factor VIII and IX". We can see the attendees. They Include Bloom, Rizza and Craske.

If we pick it up under "Commercial Considerations":

"Factor VIII concentrates occupy 13 per cent of the gross operating turnover of blood products. Factor VIII lies fourth to ..."

Sets out the other three.

"Pricing stability in the world market on blood products has introduced many bizarre effects, particularly in Europe. The price battle for Factor VIII intermediate concentrate in the UK is an example. Intense competition and unacceptably low prices is alleged to have resulted in the withdrawal of Hyland Hemofil 2 from the UK market and the threatened possibility of a second major company withdrawal in 1983."

Then there are various predictions set out, and at (2):

"It's a clear-field entry for commercial hepatitis-safe Factor VIII, which by nature of its special product status (unproven) can command a price structure more in keeping with market expectations."

Then if we go over the page under the heading -- I should have said, this is a note prepared by Dr Lane, the director of BPL.

Under the heading "Current commercial approach to UK users":

"The random approach now being adopted by

commercial manufacturers to haemophilia directors in the UK to study H-S VIII has many severe disadvantages for the NHS and gives little or no payback to the UK in return for opportunistic and non-contractual use of the special potential of the UK haemophilia services as a collective entity."

Quite what that means, sir, happily is a matter for you to decide and not me.

Then if we go to the third page, under the heading "Efficacy and safety of HS VIII and HSIX":

"The above statement defines the need for centralised, fully controlled prospective trials of HS materials, best operated through a properly executed national clinical trial, and the proposals are that the random exploitation of the haemophilia service by commercial organisations for the study of hepatitis-safe products should be discouraged, that the haemophilia services should create a formal basis for controlled clinical trial of alleged hepatitis-self products, that the haemophilia services, PHLS and NBTS, should combine resources in a manner likely to advance economic treatment of NHS haemophiliacs with safe products."

Sir, pausing there, that is the issue which is the subject of the January 1982 letter that we looked

at, the chimpanzees infectivity humans letter, and that's why it seems likely that the themes that are picked up in that letter, which echo the themes here, follow on from this and why -- it's one reason why we think the letter may, in fact, be incorrectly dated and should be dated January 1983. There's another reason, which we'll look at on Wednesday when we look further into 1983, why we think that might be the case.

Sir, that I think may be a convenient time to stop for the day because I'm about to look at the key communications and advice given by Professor Bloom on AIDS in the course of 1983, and that will take some time.

SIR BRIAN LANGSTAFF: Yes.

Well, thank you very much, Ms Richards. We meet again on Wednesday at ten o'clock then.

MS RICHARDS: Sir, yes. We'll resume with this material relating to Professor Bloom and Cardiff. We will then, I anticipate, start looking at the Oxford material but probably not complete it that day, but then on the Thursday and Friday of next week we have our first haemophilia clinician witness, who is Dr Mark Winter, who will be giving evidence here in person.

SIR BRIAN LANGSTAFF: Yes. He is scheduled for Thursday and Friday.

MS RICHARDS: He is scheduled for Thursday and Friday, sir.

SIR BRIAN LANGSTAFF: Very well.

That is it for today, so that is it for this week. Those of you who are travelling or whatever your plans are, stay safe. Those of you who have plans to return, I look forward to seeing you again in due course. Thank you very much.

(4.20 pm)

(Adjourned until Wednesday, 30 September 2020 at 10 .00am)

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