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Wednesday, 18 May 2011

(9.30 am)

PROFESSOR ANDREW LEVER (continued)

THE CHAIRMAN: Good morning.

MS DUNLOP: I think the point we have reached, sir, is that it's the turn of those in the front row to ask such questions as they want to ask.

THE CHAIRMAN: That was the position last night but I never retain the confidence that it will be maintained overnight.

Mr Di Rollo?

MR DI ROLLO: Mr Dawson is going to ask the questions.

Questions by MR DAWSON

MR DAWSON: Good morning, professor. Could I start by asking you a few questions about a period you were asked about yesterday. That would be the spring of 1983. Could we have up on the screen, please, a document which you weren't taken to yesterday but you did discuss. That's [\[DHF0014474\]](#).

This is the document to which reference was made yesterday, namely the Haemophilia Society letter of 4 May 1983 incorporating some advice from Professor Bloom. I think you are familiar with this letter. Is that right, professor?

A. I am, yes.

1 Q. And you will see in the main block that there is an  
2 opinion expressed by Professor Bloom to the effect that  
3 AIDS has not yet been proven to result from transmission  
4 of a specific infective agent in blood products. You  
5 spoke yesterday about the requirement that people should  
6 be reassured in the context of this letter.

7 If you had been asked in May 1983 for your view as  
8 to the aetiology of AIDS and the risks of contracting it  
9 from blood or blood products without the burden of  
10 having to reassure your audience, how would you have  
11 expressed yourself?

12 A. I think it's difficult to separate the two entirely, if  
13 I might say, in that giving completely unguarded advice  
14 without considering the impact that it might have isn't  
15 something I think I would want to do. So I think in  
16 this and other circumstances you could argue that it  
17 would be, not exactly reckless but inconsiderate to be  
18 giving advice without considering the consequences.

19 I think my wording would have been not dissimilar to  
20 Professor Bloom's, in that it was not proven. I think  
21 if I were speaking to an audience in whom it was not the  
22 case that I was trying to reassure, I would have  
23 probably implied that I thought it was quite likely that  
24 it was an infectious agent transmitted by blood  
25 products.

1 Q. Thank you. What pieces of evidence would particularly  
2 have influenced your view at that time?

3 A. I think the knowledge that there had been retroviruses  
4 already implicated in human disease in the form of  
5 HTLV-I and that that particular virus was known to  
6 target a cell population in the blood called the  
7 lymphocytes, and that there was evidence in this illness  
8 that there was dysfunction of the lymphocytes and the  
9 epidemiology, which has been visited quite extensively  
10 so far, of the fact that there appeared to be clusters  
11 in particular geographic areas and, of course, the fact  
12 that sexual transmission of infectious diseases is  
13 extremely well documented, as indeed is blood  
14 transmission of infectious diseases.

15 Q. I would like to come back to this document but could  
16 I just jump for the moment to your statement, in  
17 particular page 5. The statement is [\[PEN0150517\]](#). In  
18 the paragraph which starts with, I think, a reference to  
19 the preliminary report, 8.25, you discuss this letter,  
20 and you say there that:

21 "Whilst true ..."

22 That's the comment to which I have just made  
23 reference:

24 "... appears to ignore much circumstantial  
25 evidence."

1           Then you say:

2           "... and consensus opinion in the majority of  
3           doctors that a transmissible agent, almost certainly a  
4           virus, is the most likely aetiology."

5           I just wanted to flesh out a little bit who you were  
6           talking about when you said "the majority of doctors".  
7           Would that include haemophilia doctors and  
8           transfusionists to your knowledge?

9    A.   I think one's opinion is always coloured by the people  
10       one works with and certainly I work with infectious  
11       diseases people and have done for many years, and  
12       I think that may in part reflect the people I work with,  
13       and I would hesitate before assuming I knew what the  
14       haemophilia doctor population were thinking at the time.

15       But I think in discussion most doctors that I came  
16       into contact with and much of the published literature  
17       at the time as well, including articles in the Lancet,  
18       had suggested that a transmissible agent, which was  
19       blood-borne, seemed a very likely candidate. So I think  
20       that may be a consensus of many doctors in different  
21       disciplines but not every doctor in individual  
22       disciplines.

23    Q.   I understand. From what you have just told us there,  
24       would it be fair to say that the consensus opinion was  
25       not only as you say there, that a transmissible agent,

1 almost certainly a virus, is the most likely aetiology,  
2 but also that the virus could be blood-borne?

3 A. Yes.

4 Q. Thank you. While we are on that page, I just wanted to  
5 ask you about a comment that you make in the top  
6 paragraph of that page. You say in the final sentence  
7 there, under a reference to the period March 1983, so  
8 slightly before the letter we have been looking at:

9 "The connection between AIDS and blood products,  
10 particularly commercial blood products, from the US  
11 appears to be very strong."

12 I just wanted to ask you: in that sentence, is that  
13 you expressing your opinion of the state of affairs at  
14 that time or is that you referring, as I think you do  
15 throughout this passage, to what's contained within the  
16 preliminary report?

17 A. That's a reference.

18 Q. To the preliminary report?

19 A. Yes.

20 Q. Yes. Does that represent your view on that matter as at  
21 that time?

22 A. I think there was a general knowledge that the sourcing  
23 of donations for blood products in the UK and in the  
24 United States was very different and that it was known  
25 that paid donors as a whole were more likely to carry

1 infections. So I would say that would reflect my  
2 opinion as well.

3 Q. Thank you. If we could just go back to the Haemophilia  
4 Society letter, please, [\[DHF0014474\]](#), you will see,  
5 professor, that shortly after the sentence to which  
6 I have made reference starting "The cause of AIDS", the  
7 passage from Professor Bloom places some reliance on the  
8 fact that neither have any cases been reported from  
9 Germany, where massive amounts of American concentrates  
10 have been used for many years.

11 Can you be of assistance to us as regards the  
12 accuracy of the reference to Germany at that time, both  
13 from the point of view of the usage in Germany of  
14 American concentrates and also whether at that time  
15 there had been any cases of AIDS in the German  
16 haemophiliac population?

17 A. I have no information about the usage of concentrates in  
18 Germany. Similarly, I don't know any facts about the  
19 reported instance of immunodeficiency in the German  
20 population either. There was, I think, still at that  
21 time a lack of perception of cases which were developing  
22 into AIDS as I implied in my report. There may have  
23 been cases which were not recognised as such but that is  
24 speculation.

25 Q. Thank you. Had Professor Bloom chosen to look to other

1 countries in Europe at that time for examples of the  
2 extent to which there had been infection or suspected  
3 infection amongst the haemophiliac population, other  
4 than Germany, what information might he have found?

5 A. Again, I don't have information on the perceived or  
6 actual detection of AIDS cases in other European  
7 countries other than the few comments I have made in my  
8 report of Denmark and the single case in Italy.

9 Q. Thank you. It's true to say that there is no reference  
10 there to the question of how many haemophiliacs were  
11 infected at that time in the United States. Can you be  
12 of assistance just in pinpointing what the statistics  
13 might have shown at this point in time, had such  
14 a reference been made?

15 A. Is the question, had we had a test for HIV at the time?

16 Q. What the information was that was available at that time  
17 as regards possible infection amongst the haemophiliac  
18 population in the United States.

19 A. I would have to refer to the documents that have been  
20 quoted in the report to give you numbers because I am  
21 afraid I don't carry those in my head.

22 Q. I have got no difficulty with that at all.

23 A. It may take a moment or two.

24 Q. Thank you. (Pause)

25 A. It may be helpful if I have a hard copy of the report to

1 look at as well.

2 THE CHAIRMAN: What do you want to refer the professor to,  
3 Mr Dawson? I don't think it's fair to send him simply  
4 on a search through the documents. Do you have  
5 a specific date, the date of the letter? What are the  
6 source documents that you think you might like him to  
7 look at?

8 MR DAWSON: I don't have any particular source documents in  
9 mind.

10 THE CHAIRMAN: Mr Dawson, it is up to you to have them.

11 MR DAWSON: I understand that. I'll move on from that  
12 question, sir.

13 THE CHAIRMAN: As far as you are concerned, professor, do  
14 you have any concern about the accuracy of the  
15 references in the report, since you have read it, giving  
16 data at or about the time of this letter?

17 A. I don't have any concern with those.

18 THE CHAIRMAN: Well, Mr Dawson, unless you can point  
19 otherwise, we will simply take the report as it is.

20 MR DAWSON: Indeed, I'm obliged.

21 Could I ask you just one final question about this  
22 letter. There is a reference in the final sentence here  
23 to certain experts. It says:

24 "We should avoid precipitate action and give those  
25 experts who are responsible a chance continually to



1 assess the situation."

2 Can you be of assistance to us as regards who those  
3 experts who are responsible might have been in  
4 Professor Bloom's mind at that time?

5 A. Professor Bloom would have wanted as much information of  
6 an epidemiological nature as possible from as many  
7 countries as possible, as were using concentrates, and  
8 the sorts of sources of information would have been the  
9 MMWR reports and the CDSC reports.

10 Without good statistical information about the  
11 development of what turned out to be an epidemic, one  
12 would have trouble predicting it but those were the  
13 primary sources that he would be hoping to get it from.  
14 In addition, he would also be wanting information from  
15 people who were striving to actually isolate an  
16 infectious agent.

17 Q. So --

18 A. Scientists and virologists.

19 Q. So virologists would be amongst those who would be  
20 responsible for looking into the situation at that time?

21 A. They would be beginning to be involved at that stage,  
22 yes.

23 Q. Who in particular would have been involved in the  
24 virological community?

25 A. There are at that time not many people actually in the

1 world who are very much experts in retroviruses but  
2 there were quite a lot of people who were experts in  
3 virology, some of whom are named here. So people like  
4 Dr Tedder, for example, people who had connections with  
5 the Blood Transfusion Service from investigation of  
6 other viruses and those who investigated hepatitis  
7 viruses, for example.

8 Q. Do you think it would be fair to sum up the content of  
9 Professor Bloom's message as saying that at this stage  
10 we don't really know what the position is, so we should  
11 just continue as regards the use of blood products as we  
12 have before?

13 A. I think in fairness he is not ignoring the issue; he is  
14 saying that there is something we have to keep an eye on  
15 but at the moment we don't have enough information to  
16 inform action which we can confidently say is the  
17 correct way forward.

18 Q. Indeed. Thank you. You were referred yesterday to the  
19 views expressed at almost exactly the same time as this  
20 by Dr Galbraith and you gave us some explanation of  
21 that. Could we have up a document, please,  
22 [\[MIS0010001\]](#)? This wasn't a document you were taken to  
23 yesterday but was a subject matter upon which you made  
24 some comment. Is this a document that you are familiar  
25 with?

1 A. I am, yes.

2 Q. It is a letter, which although it is not entirely clear,  
3 I have gleaned from the preliminary report is dated  
4 9 May 1983, so five days after the document that we have  
5 just been looking at. In this document, Dr Galbraith in  
6 a letter to Dr Ian Field says:

7 "I have reviewed the literature and come to the  
8 conclusion that all blood products made from blood  
9 donated in the USA after 1978 should be withdrawn from  
10 use until the risk of AIDS transmission by these  
11 products has been clarified."

12 I would just be interested to know your comment on  
13 the apparent difference between the position being taken  
14 by Professor Bloom and the position being taken by  
15 Dr Galbraith, both of which appear to be based on a lack  
16 of complete understanding of the position, but one of  
17 which appears to suggest continuing with the position as  
18 it was, and the other suggests that in light of the lack  
19 of complete understanding, something needed to be done.

20 A. Yes. They completely come from a very different  
21 background.

22 Q. Of course.

23 A. Dr Galbraith is looking at this entirely from an  
24 infection point of view, without, in many ways,  
25 considering the consequences of doing this and to some

1 extent doing perhaps what you requested I did, which was  
2 to give advice without necessarily thinking through all  
3 of the implications of it.

4 So from a purely objective point of view, if he  
5 feels that there is sufficient information to suggest  
6 that there is an infectious risk, his duty as the person  
7 that is acting in the public interest from an infectious  
8 disease point of view, is to apply a precautionary  
9 principle and say this is what one should do.

10 I don't disagree with his comments in terms of the  
11 likelihood of there being an infectious cause and an  
12 infectious risk. I suspect the difference between him  
13 and Professor Bloom is that he doesn't perceive what has  
14 happened to the haemophilia population over the previous  
15 20 or 30 years, the benefits of blood products, and the  
16 change in their lifestyle that this sort of action would  
17 incur and also the fact that nobody at that stage knew  
18 whether this was going to be a rather short-lived,  
19 relatively unexciting, epidemic, such as the SARS  
20 epidemic which burned out very rapidly and doesn't seem  
21 to have come back, or whether it was going to turn into  
22 something which was extremely tragic, as it did.

23 Q. It does appear that the position as regards the  
24 haemophiliac population in the United Kingdom is  
25 certainly something which Dr Galbraith is taking into

1 consideration here, in particular in the first sentence  
2 he says:

3 "Last week whilst you were away in Geneva, a case of  
4 the Acquired Immune Deficiency Syndrome in a  
5 haemophiliac in Cardiff who had received USA Factor VIII  
6 concentrate was reported."

7 So that would date it as before either of the  
8 letters we have looked at, the other one being five days  
9 before this. I think you were asked some questions  
10 about that case yesterday. But I would just like to see  
11 if you could give us a bit more information as to how  
12 well-known at that time the infection or the reports of  
13 infection in the haemophiliac in Cardiff actually were?

14 A. In the infectious disease field and certainly in the  
15 microbiological field, the CDSC reports, which were  
16 regularly issued, were generally looked at. So the  
17 infectious disease community would have been aware of  
18 it, other specialities probably not. The haemophilia  
19 doctors' community, I suspect, would have been but not  
20 necessarily from the CDSC report because that must have  
21 been reported after the actual event.

22 Q. Okay, thank you.

23 THE CHAIRMAN: Mr Dawson, could I go back just a little and  
24 pick up a point that you made?

25 MR DAWSON: Of course.

1 THE CHAIRMAN: You have indicated that in May 1983  
2 Dr Galbraith would have been required to follow  
3 a precautionary approach. Was the precautionary  
4 principle well established at this time in the way it  
5 came to be established by the early to mid 2000s?

6 A. Dr Galbraith does not know what's going to happen when  
7 he says this. There is no doubt about it, and I think  
8 he is being very cautious, which is an understandable  
9 position from his point of view, in that if his position  
10 is to warn the population of risks of infection, then  
11 it's his duty to do so as early as possible and to be  
12 relatively unequivocal about it, rather than to imply  
13 that there is a new infection and we don't really have  
14 to worry. But he does not know the unfolding of the  
15 epidemic as it occurred.

16 THE CHAIRMAN: But his duty would derive from the particular  
17 nature of his office.

18 A. Exactly.

19 THE CHAIRMAN: And the obligations that went with it?

20 A. Very much so.

21 THE CHAIRMAN: Does that imply that from his point of view  
22 a balance would be less important as between the  
23 possibility of an emerging risk and the benefits that  
24 might attend it?

25 A. I think everyone is coloured by their own particular

1 perspectives. So his perception of an infectious risk  
2 would be dominant in his mind as he thought this  
3 through. And more so than the consequences to the  
4 population that he would be influencing, were his words  
5 to be translated into actions.

6 THE CHAIRMAN: I'm anxious, Mr Dawson, that we don't get the  
7 balance wrong and I don't think I fully appreciate the  
8 point of view that would be held by each and every  
9 specialist around this time. But if you want to follow  
10 this and tighten up on just exactly what Dr Galbraith's  
11 office would have required him to do, it might help.

12 MR DAWSON: Indeed. What I intended to move on to was a  
13 slight refinement of this position, which was to ask  
14 about the contact between the different specialities.

15 THE CHAIRMAN: That might be fine.

16 MR DAWSON: You gave some very interesting evidence  
17 yesterday about the history of infectious diseases as  
18 a medical speciality, if you like, and its recognition  
19 varying over the history.

20 To what extent was virology a recognised medical  
21 speciality at this time, in the early 1980s?

22 A. Virology is and always has been part of clinical  
23 microbiology but it was certainly an independent  
24 discipline within clinical microbiology. So there would  
25 be consultant virologists at all of the larger hospitals

1 and there would be access to virological expertise in  
2 all hospitals. So virology was in the health service  
3 certainly an established discipline, and of course  
4 outside of that there was and is a very large amount of  
5 basic research going on in virology.

6 Q. I think you touched on this, but at that time how easy  
7 would it have been if a haemophilia doctor or a  
8 transfusionist wished to seek the opinion of  
9 a virologist on these important matters? How easy would  
10 it have been for such doctors to do so?

11 A. I don't perceive there would have been significant  
12 difficulty at all.

13 Q. You referred yesterday to the development, I think, in  
14 the aftermath of the HIV outbreak of the development of  
15 multidisciplinary teams and my understanding of your  
16 evidence was that you thought that they were rare at  
17 this time but they had developed subsequently and that  
18 their advent was something to be welcomed.

19 Even if the support of a virologist had been  
20 available, do you think at that time that it would be  
21 likely that a haemophilia doctor would have sought out  
22 the opinion of a virologist on these matters?

23 A. Yes, in answer to your first point, just to clarify,  
24 I think probably multidisciplinary teamworking started  
25 with the cancer world, which was the major driver behind



1           that. I don't think it would have been difficult or  
2           unreasonable for somebody in the haemophilia field to be  
3           discussing this with a virologist. Virological  
4           expertise at the time was still relatively rudimentary.  
5           I don't mean to insult my colleagues from the time but  
6           there were a limited number of viruses that one could  
7           grow in culture in the laboratory and it was a common  
8           observation that virologists tended to give you a result  
9           long after the person had either got better or not.

10           That was partly because the viruses are difficult to  
11           isolate and they are difficult to grow. They are very  
12           fussy. And partly because a lot of diagnoses were done  
13           in retrospect by detecting antibodies against the virus  
14           that had been there. So quite commonly it was a post  
15           hoc diagnosis.

16           However, for infections such as Hepatitis B, then  
17           involvement with virological laboratories was very close  
18           in fact. So chronic viral infections did involve  
19           a large amount of interaction between, for example,  
20           doctors looking after patients with liver disease and  
21           the virological community, doctors looking after  
22           patients who were having transplantation, who were  
23           immuno-suppressed and were prone to viral infections,  
24           and certainly, as far as I'm aware, doctors who were  
25           looking after patients with haemophilia would consult

1 with virologists in the diagnostic laboratory at regular  
2 intervals.

3 Q. Thank you. One of the haemophilia doctors from whom we  
4 have heard evidence in this section told us in his  
5 evidence, in the context of there requiring at a later  
6 stage to be a designated physician in each area for  
7 AIDS, that in his area he seemed to be the only doctor  
8 who knew anything of AIDS and therefore they suggested  
9 that he should be the nominated AIDS physician.

10 It seems to me that that paints a picture of there  
11 being little local expertise. Perhaps there might have  
12 been some difficulty seeking out and receiving the  
13 opinion of a virologist, even if one felt that way  
14 inclined as a haemophilia doctor.

15 Do you think that that paints an accurate general  
16 picture or do you think that may be just a local  
17 exception to the general rule?

18 A. I think you have to distinguish between laboratory  
19 virology and clinical infectious disease expertise.  
20 Most laboratory virologists would work in the laboratory  
21 doing diagnostic work and would rarely if ever, venture  
22 onto the wards and consult with patients or see illness  
23 in the round. They would be dealing with specimens  
24 rather than people. To some extent that's still the  
25 case; to a large extent that's still the case.

1           Then laboratory virologists were very much the norm.  
2           They would be consulted but would not necessarily  
3           involve themselves in management of infections to that  
4           extent. Clinical infectious disease expertise, as  
5           I expressed before, was relatively patchy and there were  
6           relatively few, compared to other disciplines,  
7           infectious disease physicians, and at this stage, of  
8           course, there was almost no expertise at all in the UK  
9           on HIV/AIDS amongst clinicians and that was reflected  
10          over the following five or ten years by the fact that  
11          in, not the minority but in the small majority of  
12          hospitals which did have some sort of infectious disease  
13          expertise, which tended to be large teaching hospitals,  
14          the infectious disease physicians did get involved in  
15          managing patients with HIV/AIDS. But in many hospitals  
16          up and down the country, it was what is termed an  
17          organ-based specialist who became involved. So people  
18          who were gastroenterologists or respiratory physicians,  
19          who took an interest in these particular things.

20          I think you have had Professor Gazzard here. He is  
21          a gastroenterologist originally. But there wasn't an  
22          infectious disease physician in his hospital so he  
23          became interested in AIDS and took it on and became  
24          a world expert on it. In other hospitals it was the  
25          local respiratory physician who became interested

1 because of pneumocystis, and took it on.

2 So there was a relative lack of clinical infectious  
3 disease expertise. There was access to laboratory  
4 virological expertise but these were not people who  
5 would be involved usually in the management of patients  
6 directly.

7 Q. Do you think that at this time an infectious diseases  
8 expert would be better placed to form a view on the  
9 risks of AIDS, and in particular the risks of  
10 transmission of HIV by blood products given perhaps  
11 greater understanding of the topic, perhaps greater  
12 access to materials, and given the fact that as you  
13 said, such experts, unlike haemophilia doctors, would be  
14 unburdened by the types of considerations that you  
15 mentioned as being in the mind of a haemophilia doctor  
16 at this time?

17 A. I don't believe that infectious disease doctors are all  
18 powerful and vastly superior in their skills to other  
19 physicians. I can perhaps quote one of my colleagues,  
20 just to reflect this, and this is somebody who was  
21 a haemophilia doctor at the time. He pointed out that  
22 their understanding of infection was such that, when  
23 they saw patients who were developing AIDS or patients  
24 with haemophilia had antibodies, they thought everything  
25 was okay and there wasn't a common perception that you

1           could have antibodies and still not be okay, because  
2           they didn't have the breadth of exposure to patients  
3           with other infectious diseases.

4           So it would be reasonable to say that an infectious  
5           disease physician would have a broader perspective and  
6           perhaps a deeper understanding of an infection. Even  
7           so, at the time this was such a new and such an unusual,  
8           and as I have said before, such a unique infectious  
9           disease phenomenon, that I don't believe anybody would  
10          have predicted accurately what actually happened.

11        Q. Sir, I was going to move on from that topic to another  
12          topic now.

13          Would it be correct to say, professor, that at the  
14          beginning of the 1980s it was known that the use of  
15          blood products would involve transmission of certain  
16          viruses?

17        A. It was known that there was a risk of transmission of  
18          viruses with blood products, yes.

19        Q. What viruses at the beginning of the 1980s would there  
20          have been a risk of transmitting through blood products?

21        A. Hepatitis B was well established and at that stage the  
22          other hepatitis viruses had not been classified. So  
23          they were called non-A non-B but there was already  
24          epidemiological evidence that there was more than one  
25          non-A non-B virus because people had documented more

1 than one episode of acute hepatitis and jaundice in  
2 transfusion recipients in the past, but the exact  
3 numbers of agents was not known, nor were they  
4 characterised.

5 Q. Right. Are there any other viruses that would have been  
6 on the mind of clinicians at that time?

7 A. That's a good question. Somewhere around that time --  
8 and my memory fails me -- I think parvovirus was  
9 identified as being in blood products or in blood.

10 Q. If it might be of assistance, professor, I have  
11 something particular in mind here. This isn't from the  
12 beginning of the 1980s, and I did ask the question about  
13 the beginning of the 1980s. This is something from an  
14 article to which the Inquiry has had reference, by  
15 Barbara and Tedder from 1984. There is a list there of  
16 viruses which are deemed to be transmitted by blood and  
17 its blood products.

18 Perhaps it might be useful to have that up. It's  
19 [\[LIT0013739\]](#). We are looking at the second page of that  
20 document, which is LIT0013740.

21 Just to be very clear, this is an article which is  
22 written in October 1984. My question is directed to  
23 earlier than that, ie to the beginning of the 1980s, but  
24 there is a list there in table 1 of viruses transmitted  
25 by blood or its products and you mentioned some of

1 those. Hepatitis A, Hepatitis B and delta agent, non-A  
2 non-B hepatitis, parvovirus, cytomegalovirus, Epstein  
3 Barr virus and HTLV-I, to which you made reference  
4 yesterday.

5 A. Yes.

6 Q. This is obviously from a different time but these were  
7 the types of viruses that I was wondering about and  
8 whether there will be a known risk of transmission of  
9 these viruses at the beginning of the 1980s.

10 A. So there is a slight nuance here in that Hepatitis B,  
11 non-A non-B and HTLV are normally transmitted by blood,  
12 in that that is their route of transmission.  
13 Cytomegalovirus, Epstein Barr virus, if they are present  
14 in blood, are, but that's not their normal route of  
15 transmission. I perhaps misinterpreted your question as  
16 to what can or what is usually in the natural course of  
17 events.

18 Hepatitis A is, as it says, rarely; that is  
19 transmitted by the faecal/oral route. It's an orally  
20 acquired agent. Parvovirus. I confess to not knowing  
21 a great deal about parvovirus transmission because it is  
22 not clinically very important, apart from in patients  
23 with sickle disease in whom it causes a red cell  
24 aplasia. So I presume that says it's in the blood and  
25 then therefore can be transmitted by blood products, but

1 I don't again believe that's its natural route of  
2 transmission.

3 Q. Right. Okay. What I'm thinking about in particular was  
4 some evidence you gave yesterday about the risk/benefit  
5 analysis of administering blood products but which  
6 I understood you to mean the balancing of, first of all,  
7 the risk of viral transmission, as against the clinical  
8 benefits of using certain products. Is that a correct  
9 interpretation of what you describe as the risk/benefit  
10 analysis yesterday?

11 A. Yes.

12 Q. As I understood your position, you were of the view that  
13 at the start of the 1980s, the position was that despite  
14 the risk of certain of these viruses possibly being  
15 transmitted by blood, the general consensus was that the  
16 risks of viral transmission were outweighed by the  
17 benefit of treatment. Is that right?

18 A. Yes, and I can run through that list and point out why,  
19 if you like.

20 Q. Well, I'm less interested in knowing particularly why  
21 but what I'm interesting in knowing is what happened  
22 when HIV came along against that background. First of  
23 all, could I just clarify that it would be correct to  
24 say, would it not, that from its earliest  
25 manifestations, one of the defining characteristics of



1           AIDS was the suppression of the immune system? Is that  
2           right?

3    A.   So the earliest characteristic was evidence that the  
4           lymphocyte populations were affected. That was the  
5           earliest sign before people developed overt disease.  
6           But the disease manifestation is exactly that: it's  
7           evidence of a suppression of the immune system or  
8           depletion of the immune system.

9    Q.   And I think you referred yesterday to opportunistic  
10           infections.

11   A.   Yes.

12   Q.   Which I understood to mean infections which would be  
13           more likely to cause difficulties for patients with  
14           a suppressed immune system than they would in a healthy  
15           patient?

16   A.   That's correct, yes.

17   Q.   In light of the threat of an immuno-suppressant virus,  
18           do you think that there required to be a reassessment of  
19           the risk/benefit analysis in light of the risks of the  
20           transmission of various viruses at the time when HIV  
21           came along?

22   A.   It becomes another exercise of retrospective view.

23   Q.   Of course.

24   A.   Because risk/benefit is a combination of risk/benefit to  
25           individuals and to the population as a whole. Whereas

1 all of the viruses that had been mentioned here in your  
2 previous list are ones in which it was established that  
3 the benefit from the treatment far outweighed the risk.  
4 It's now clear, very clear looking back from this  
5 perspective, that the risk/benefit was against the  
6 continuing use of blood products if they were  
7 transmitting HIV.

8 I think there probably was a reassessment in  
9 people's minds as to whether or not this was going to be  
10 more serious, as there would have to be because there  
11 had been deaths. But there was still no knowledge of  
12 whether this was going to be an isolated, small number  
13 of deaths amongst a very large majority of people who  
14 had no disease whatsoever. The difficulty that the  
15 physicians at the time were in was the fact that the  
16 virus takes so many years to manifest itself through its  
17 incubation period to producing full-blown disease. But  
18 I think your statement is correct in that if there is  
19 evidence of immuno-suppression and there is evidence of  
20 death from immuno-suppression, it should, and I'm sure  
21 did, trigger a reassessment of risk/benefit.

22 Q. Thank you very much.

23 Could I just ask you, in relation to the evidence  
24 you gave yesterday, about the various theories related  
25 to AIDS in the early days? In particular I want to ask

1 you about a comment that you made on page 3 of your  
2 report. Could we have that up, please? That's back to  
3 [\[PEN0150517\]](#) at page 3. I'm looking at the very bottom  
4 paragraph of that page.

5 This is the section, professor, in which you have  
6 just started your analysis of the emergence of AIDS and  
7 you are telling us about the information or the evidence  
8 that was available and the theories that were starting  
9 to spring up. You say there:

10 "There was speculation at the time ..."

11 This is in the early days in the middle of 1981:

12 "... that cytomegalovirus or Hepatitis B, possibly  
13 a new, more virulent strain of one or the other, might  
14 be responsible for this disease as all of the  
15 individuals were positive on testing for both of these  
16 viruses."

17 Is there an explanation as to why the individuals  
18 who were exhibiting the signs of HIV were also positive  
19 for these other viruses, with the benefit of hindsight?

20 A. The homosexual population?

21 Q. I think you are talking here about people who are  
22 exhibiting signs of HIV infection, and a theory sprung  
23 up that it might be something to do with these two  
24 viruses as all the people had tested positive for these  
25 two. I just wanted to know whether there was an

1 explanation as to why it was that they were positive for  
2 these viruses as well.

3 A. Well, both can be sexually transmitted and this was  
4 a very sexually promiscuous population.

5 Q. You were also asked yesterday and gave evidence on what  
6 was described as the antigen overload theory. Could you  
7 just explain for me at what point in your chronology the  
8 antigen overload theory, on a balance of probabilities,  
9 become not the most likely explanation as to the  
10 aetiology of the virus in haemophiliacs, if indeed it  
11 ever was judged by that standard to be the most likely  
12 explanation?

13 A. Yes.

14 THE CHAIRMAN: I think the double-headed hypothesis here is  
15 a bit difficult. Perhaps we should unpack it just  
16 a bit.

17 I think that I know, from Professor Ludlam's  
18 publications, the sort of period over which his  
19 particular subjects were studied and found to be  
20 immune-suppressed, and that might give us a timeframe  
21 for one aspect of it, Mr Dawson, unless you can take it  
22 further back.

23 MR DAWSON: Perhaps an easier way of putting it would be  
24 first of all to say: was the most prevalent theory the  
25 antigen overload theory at any stage over this period?

1 A. I think it was a competing theory. It's difficult to  
2 give statistics but one might remember that the antigen  
3 overload theory probably originated in New York amongst  
4 the physicians looking after patients with HIV and  
5 amongst the gay population in New York themselves,  
6 because they felt that if it was perceived that there  
7 was an infectious cause -- this is again hindsight --  
8 that the gay population might be more stigmatised for  
9 transmitting agents which caused disease.

10 I think the first reference goes back to  
11 a physician, whose name escapes me, in New York, putting  
12 this forward as an alternative, less stigmatising  
13 theory. The stigma is very real and occurred right the  
14 way through in the Montreal conference. There was  
15 a series of unprecedented takeovers of the stage by  
16 different pressure groups protesting about what had been  
17 seen to be media perceptions or medical profession  
18 perceptions. I remember the prostitute population  
19 taking over the stage and complaining very much that  
20 being referred to as vectors of disease was a very  
21 demeaning thing.

22 So that's, I think, where it came from and would  
23 have established itself in a lot of people's minds who  
24 had vested interests in there not being a virus,  
25 similarly to, I think, the phenomenon in South Africa,

1           where it was deemed to be politically better for there  
2           not to have been a virus produced in Africa which caused  
3           the infection. That carried on, as you know, until very  
4           recently.

5    Q.   One could have asked oneself the question at any stage  
6           in this chronology: on a balance of probabilities, which  
7           is the most likely to be accurate of all these theories?  
8           Was there any point at which this competing antigen  
9           overload theory would have been the most likely?

10   A.   I don't think at any stage it was the most likely.  
11           I think it was competitive but I don't think at any  
12           stage it was the most likely. Largely because it was  
13           based on a speculation as to the effect of protein  
14           overload, for which there wasn't precedent.

15   Q.   I think you gave some evidence about that yesterday. Is  
16           there a point in the chronology where the antigen  
17           overload theory becomes no longer sustainable?

18   A.   To my mind, when the virus is isolated.

19   Q.   But not at any stage earlier than that?

20   A.   I think, as I mentioned yesterday, there is a gradation  
21           in belief that some people will have been very convinced  
22           after the Montagnier/Barre-Sinoussi isolation, others  
23           wouldn't. Others, particularly Americans, would have  
24           been convinced after the Gallo. So there would have  
25           been a slow change.

1 Q. So the point at which the antigen overload theory would  
2 have been put to one side would depend on how convinced  
3 one was about the discovery at those two different  
4 points?

5 A. Very much from ones own personal perspective and where  
6 one lived and worked, yes.

7 Q. You talk at length in your statement about something  
8 which I have referred to already, which is the balancing  
9 exercise which requires to be carried out in haemophilia  
10 care between the risks of products and the benefits of  
11 products. I just want to ask you about one of the  
12 things that you say on page 5 of your statement, so two  
13 pages from where we are at the moment. Looking at the  
14 second bottom paragraph. I'm looking at line 7 of that.  
15 A sentence which begins:

16 "To maintain ..."

17 Do you have that, professor? It's the second bottom  
18 paragraph, line 7 of that. There is a sentence  
19 beginning:

20 "To maintain ...

21 A. Yes.

22 Q. It says there:

23 "To maintain the factor concentrate availabilities,  
24 the directors knew that they had no option but to  
25 continue to source blood products from the USA."

1           This is in the context of you discussing, I think,  
2           what I have described as the balancing exercise and  
3           pointing out your understanding of the considerations on  
4           one side and the considerations the other, as to whether  
5           to continue to use certain products. I just wanted to  
6           ask you what the source of that comment was about  
7           continuing to source blood products from the USA?

8    A. This was my impression from the documentation that  
9           I received with the preliminary report.

10   Q. Right, okay. Was that comment then made with the  
11       United Kingdom in mind or Scotland in mind?

12   A. Both.

13   Q. Okay, thank you.

14           I would just like to jump back now to something  
15       which you were mentioning earlier and this is another  
16       component, I think, in what I have described as the  
17       balancing exercise, but this is one of the factors that  
18       you have brought out. One of the things that you refer  
19       to -- and I think this is probably best described at the  
20       top of the next page, on page 6. Perhaps it would be  
21       easier just to go to that and read out the second  
22       paragraph. Again in the context of this balancing  
23       exercise:

24           "Although AIDS itself clearly had a very bad  
25       prognosis, there had not been enough longitudinal data



1 to say what percentage of individuals, who were infected  
2 with the putative agent, actually went on to get the  
3 disease. It might, as with some diseases, for example  
4 HTLV-I, be a very small percentage who became ill and  
5 the risk/benefit ratio of being infected versus not  
6 receiving clotting factor concentrates was not  
7 clearcut".

8 I think you have mentioned this already this  
9 morning. I think there you are talking about two  
10 different considerations. One is the number of people  
11 who might go on after infection to become ill and that  
12 was the thing that wasn't known at that time. Is that  
13 correct? That's the first thing?

14 A. That's true.

15 Q. The second thing you are talking about there is for  
16 those who do become ill, that there was -- and it was  
17 known at that time -- a very bad prognosis?

18 A. That's true.

19 Q. Those are two separate considerations in this balancing  
20 exercise. Is that correct?

21 A. They are both part of a balancing exercise but they are  
22 separate considerations, yes.

23 Q. Thank you very much. I just wanted to ask you a couple  
24 more things. The first was something that I think you  
25 talked about yesterday. I just want to be clear that my

1 understanding of it is correct. One of the other  
2 witnesses who has given evidence in this section in the  
3 context of talking about transmission of HIV via blood  
4 products used the expression "viral load". What's your  
5 understanding of that expression?

6 A. It's a mathematical estimation of the number of viruses  
7 per unit volume of the plasma. And we use it clinically  
8 to judge whether or not a person has early or advanced  
9 disease and also the success of antiviral therapy. The  
10 methodology is an amplification technique, but one  
11 effectively counts the number of viruses or the number  
12 of genomes of the virus, the number of pieces of RNA of  
13 the virus in a unit of blood, usually 1 millilitre. So  
14 that somebody who is uninfected is zero. In somebody  
15 who is very well treated it is less than 50 because  
16 that's the limit of detection of the assay. People who  
17 are unwell may have many thousands or many million  
18 copies of the virus per ml of blood.

19 Q. I'll move on from that topic. The final thing I wanted  
20 to ask you was at what point in the chronology did it  
21 become known that HIV could be sexually transmitted?  
22 I think yesterday in the context of the correspondence  
23 between Dr Craske and Dr Ludlam you made some reference  
24 in connection to the fact that there had been some  
25 studies done amongst the haemophiliac population, which

1           were of assistance in reaching the conclusion that HIV  
2           could be sexually transmitted. I was just interested in  
3           knowing what it was you had in mind and whether that was  
4           in fact the point in time when sexual transmission  
5           became accepted?

6    A. No, sexual transmission was believed to be the case from  
7           very early on, both in terms of homosexual transmission  
8           as clearly a risk factor but also evidence of infection  
9           in the heterosexual population.

10                 It's actually a very good and difficult question to  
11           answer as to when it was absolutely certainly known that  
12           a virus was transmissible from one person to another and  
13           that probably occurred in the late 1980s. I can  
14           remember the paper because it was in Science, but  
15           I can't remember the exact date when the virus was  
16           isolated from somebody who was newly infected and shown  
17           to be, with the techniques that were then available,  
18           identical to the virus from the person who they appeared  
19           to have acquired the virus from.

20    Q. Was that when it definitely became --

21    A. That's when you could not deny there was any other way  
22           that it had been transmitted. But, as for many virus  
23           infections, the epidemiology is often as indicative.  
24           So, for example, if you look at the antibodies in people  
25           to a virus like herpes simplex type 2, which is HSV-2,

1 genital herpes, then they are very uncommon in people  
2 under the age of 12. And if you look at the population  
3 as a whole, then the percentage of people with  
4 antibodies to herpes type 2 rises in the late teens. So  
5 the implication there is that sexual transmission is  
6 occurring.

7 In fact I don't think any virus has been as  
8 accurately analysed as HIV. I don't think anybody has  
9 actually taken a herpes simplex type 2 from a donor and  
10 compared it to herpes simplex type 2 from a recipient  
11 and said they are the same virus. So all of the  
12 evidence of sexual transmission comes from the  
13 epidemiology.

14 Q. The reference that I picked up yesterday about there  
15 being a study amongst haemophiliacs in this regard, what  
16 was that about?

17 A. Again I would have to refer back to the report but there  
18 was a case of a spouse of a haemophiliac becoming  
19 infected.

20 Q. You have described the point at which it became  
21 certainly known that the virus could be transmitted  
22 sexually. The documentation we looked at yesterday,  
23 I am thinking of this letter from Dr Craske to  
24 Dr Ludlam, was more in the mid 1980s, and there was  
25 reference there to Dr Craske's understanding at that

1 point that the virus could be sexually transmitted. Of  
2 course, we went through that list and some of the things  
3 were right and some of the things were wrong, but that  
4 was one of the things that you had said was correct. At  
5 what point was it the prevalent view that sexual  
6 transmission was a possibility with HIV?

7 A. I think from the word go actually. It was believed it  
8 was sexually transmitted.

9 Q. Thank you very much, Professor, thank you.

10 Sir, I have no further questions.

11 THE CHAIRMAN: Professor Lever, I'm going to have to come  
12 back to the very early stages of the development of the  
13 antigenic overload theory and it may be there is some  
14 literature that I will have to have Professor James dig  
15 out for me to make sure that I understand it, but is it  
16 right to understand the position generally to be that  
17 after a reasonably significant number of cases of AIDS  
18 in homosexual men had been recorded, there was an  
19 extensive study in New York of a large number of  
20 homosexual men and in particular a study of their immune  
21 indicators? Is that a starting point?

22 A. Yes, and my memory for the literature isn't perfect  
23 either. As I recall, there was evidence of immune  
24 dysfunction but also the presence of anti-sperm  
25 antibodies, indicating perhaps that there had been

1 exposure to proteins which the immune system wouldn't  
2 necessarily normally have encountered.

3 THE CHAIRMAN: So leave the anti-sperm antibodies aside just  
4 for the moment. One element that did emerge was  
5 depression of the T4:T8 ratios right across a broad  
6 spectrum of homosexual men. Out of that did the theory  
7 develop that it might be a progressive sort of  
8 condition, as it were, leading to immuno-suppression in  
9 this population that might not be associated with an  
10 infective agent but with the accumulation of exposure to  
11 things like sperm and other factors? How does one  
12 explain it?

13 A. I'm not a career immunologist. So I would have to give  
14 you my understanding of this but you can influence  
15 lymphocyte populations, you can manipulate the immune  
16 system in rather specific ways, as I mentioned before,  
17 by things like desensitising procedures. One could  
18 construct an argument that abnormal exposure to proteins  
19 would do something but the details of it, I think, would  
20 be very difficult to tease out and be very specific  
21 about and say this had a precedent that would  
22 specifically do what happened to the lymphocyte cell  
23 populations. I'm sorry, that's not a very satisfactory  
24 answer.

25 THE CHAIRMAN: Not very satisfactory. I don't need all the

1           answers at the moment and perhaps --

2       PROFESSOR JAMES: I mean, my understanding is that they were  
3           obviously faced with the first 20 or 30 AIDS cases,  
4           let's say, in a population of gay men in New York,  
5           casting around for the first beginning of ideas as to  
6           the possible cause. They screened a pretty large number  
7           of gay men and I think one of the studies is in the New  
8           England Journal but I'm going to check these references  
9           for the Inquiry.

10           Among other things but principally they found this  
11           suppression of T4:T8 ratios in otherwise well  
12           individuals and then obviously it was a matter of, if  
13           you like, casting around for theories which might  
14           explain this. One of the theories that was put forward,  
15           in a rather inchoate fashion but perhaps with greater  
16           immunological expertise, certainly greater immunological  
17           expertise than I have, even then, was that it could be  
18           due to antigen overload as witnessed by the presence of  
19           anti-sperm antibodies and so on. I believe that in  
20           those papers obviously they also mentioned, well, this  
21           could be an infectious agent, we just don't know but  
22           that's my understanding of how that theory originated  
23           pretty early on in the game.

24           I mean, we will check on that but would that fit  
25           with your understanding as well or is that not correct?

1 A. No, it's correct but it also reflects what I said  
2 yesterday, that the initial manifestations of HIV don't  
3 look like a normal infection.

4 PROFESSOR JAMES: Yes.

5 A. They look like something is leading to a degeneration or  
6 a deterioration in the immune system and there hadn't  
7 been another infection which clearly did that, and  
8 that's why not only theories of protein overload but  
9 theories of specific drug abuse like amyl nitrate were  
10 brought up because it could be a toxic effect in the  
11 immune system, and all of those were as plausible as  
12 each other. I don't think any one of them had  
13 a majority view at the very beginning.

14 THE CHAIRMAN: To bring in Professor Ludlam's work here, he  
15 in effect did the same sort of screening of a large  
16 number of haemophilia patients and found a pattern of  
17 suppression that seemed at least to have some parallels  
18 with that that had been reported from New York. Is that  
19 a correct understanding?

20 A. That's correct. Again, in the absence of an illness  
21 that looked like conventional infection, one would look  
22 around for competing theories.

23 THE CHAIRMAN: I think it is going to be quite difficult to  
24 get any precision out of this at the end of the day. If  
25 the two or more theories are running in parallel, then



1           they will continue until some event or some discovery  
2           emerges that effectively puts an end to one of them?

3    A.   They have continued beyond that.

4    THE CHAIRMAN:  They continue beyond that?  Yes.  You mention  
5           the South African situation where possibly a political  
6           explanation is to be preferred over any sort of medical  
7           explanation.

8    A.   Indeed.

9    THE CHAIRMAN:  Do you want to follow that in any way?

10   MR DAWSON:  No, thank you, sir.

11   THE CHAIRMAN:  Mr Anderson?

12   MR ANDERSON:  I have no questions, sir.

13   THE CHAIRMAN:  Mr Sheldon?

14   MR SHELDON:  No questions.

15   MS DUNLOP:  May I ask --

16                               Further Questions by MS DUNLOP

17   THE CHAIRMAN:  I thought you might.

18   MS DUNLOP:  Sorry, Professor Lever, just that last point.

19           Professor Ludlam's work in discovering this altered  
20           immunology in his patients who had been treated with  
21           concentrates, he is able to tell us that these were not  
22           people who went on to develop AIDS.  Do you know if that  
23           end of the story is also possible for the population of  
24           homosexual men that was studied?  In other words, was it  
25           possible to go back afterwards and say, "Well, in

1           retrospect they were all going to develop AIDS"?

2   A.   As far as I'm aware, everybody who developed

3           a lymphocyte subset mismatch in the gay population, who

4           were HIV-infected carried on and progressed and

5           developed immunodeficiency.

6   Q.   I just wondered if there was a parallel with the

7           haemophilia patients because the situation in the

8           haemophilia patients, as we understand it, is that the

9           altered immunology turned out to be

10          a freestanding phenomenon, and whether that is also true

11          of gay men. Did it turn out that independently of AIDS

12          they had altered immunology?

13   A.   I don't know for certain of any publication on

14          non-HIV-infected gay men looking at their lymphocyte

15          subset proportions, and I'm sure there is published data

16          on that. So I confess my ignorance. I don't know.

17   Q.   Right.

18   THE CHAIRMAN: It's likely to be quite a complicated

19          position, isn't it, with cytomegalovirus and Epstein

20          Barr virus having an impact on the immune system?

21          Perhaps you have a very complex situation that would be

22          very difficult to unravel; I don't know. Would there be

23          immuno-suppression in most homosexual men because of

24          other virus and other attacks on their systems?

25   A.   It has certainly been talked about but I don't know for

1 certain of accurate epidemiological evidence to show  
2 that. One of the difficulties is, of course, that if  
3 you are in a group of individuals who expose themselves  
4 to a very wide range of infections, then statistically  
5 you are more likely to get infections. So actually  
6 quantitating whether the immune system was compromised  
7 by simply looking at how many infections the population  
8 get would reflect probably more exposure than innate  
9 immunity.

10 MS DUNLOP: Just a couple of other points not on that.

11 To go back to an answer that you gave to Mr Dawson  
12 towards the beginning of his questioning, you said that  
13 your own view around about May 1983 would have been that  
14 it was quite likely that there was an infectious agent  
15 transmitted by blood products and you imagined the  
16 situation of speaking to an audience where you would be  
17 trying to reassure. So I suppose the position I have  
18 just sketched, that this is quite likely to be an  
19 infectious agent transmitted by blood products, you  
20 would have expressed that view to a room full of people  
21 that you weren't aiming to reassure? But if you had  
22 been in a room full of patients with haemophilia,  
23 perhaps, and you held that view, objectively held that  
24 view, which is not a reassuring one, would you still  
25 have felt the need to reassure?

1 A. I think, as a medical practitioner, you should not  
2 unnecessarily alarm people. So it would be  
3 irresponsible just to give a message which simply  
4 frightened individuals without also expressing  
5 alternatives or covering statements, such as there may  
6 be an infection but we have no idea of the severity or  
7 how many people who get the infection would actually  
8 develop illness.

9 So as a general term, if one is dealing with  
10 a population -- and all patients to one extent or  
11 another are a vulnerable population -- we are all  
12 vulnerable populations -- I think it's one's duty to  
13 give information but in the least alarmist way one can.

14 So I think, if I was talking to a room full of  
15 people in whom the news might cause unnecessary alarm --  
16 and at that stage one didn't know whether it was  
17 unnecessary alarm -- one would indeed have tried to  
18 cover one's message with as much reassurance as one  
19 could at the time.

20 Q. Just finally, this in a sense, follows from that.  
21 Mr Dawson developed with you the two different aspects  
22 of the risk/benefit analysis: one being the risk/benefit  
23 analysis as applied to the whole population and the  
24 risk/benefit analysis for an individual. On the  
25 question of the latter risk/benefit analysis, at that

1           time, I suppose, would it have come to, on the one hand  
2           the risk of getting this infectious agent which had  
3           a very high mortality versus, on the other hand,  
4           reverting to the risk of spontaneous bleeding, such as  
5           accompanies severe haemophilia? Would that be the  
6           choice?

7    A. Well, at the time one didn't know that the infection  
8           itself carried a high mortality. One knew that AIDS  
9           did. One didn't know that 100 per cent of the people  
10           who were infected developed AIDS and there wasn't  
11           a precedent for that in infectious diseases. So that  
12           would colour one's judgment slightly.

13           But if you look at perhaps comparable situations,  
14           and we are talking about a situation where the lifespan  
15           of the population had been extended by some 20 years  
16           over the course of not a dissimilar period of time, you  
17           would be looking at a situation similar to that in the  
18           treatment of many of the leukaemias, where again there  
19           had been massive increases in life expectancy. But  
20           people going into the treatment of leukaemia would know  
21           and would be told that there was a percentage risk of  
22           them not surviving.

23           So I think there are parallels in other situations.  
24           I don't think this is necessarily a unique situation,  
25           whereby the worst case scenario is not surviving.

1 I think there are a lot of other medical parallels where  
2 the worst case scenario is not surviving, but if that's  
3 for a very, very tiny proportion of the population, then  
4 the individuals take a decision for themselves as to  
5 whether they want to take that risk.

6 Q. That, in the early 1980s, would have been the principle,  
7 would it, that because there is a risk, albeit a small  
8 risk, of a fatal outcome, the danger is mentioned to the  
9 patient so that the patient can take the decision?

10 A. I think it depends on the history of the field you are  
11 dealing with.

12 Q. Right.

13 A. Certainly in the treatments for malignancy that would  
14 almost certainly be the norm.

15 Q. Thank you.

16 THE CHAIRMAN: Professor Lever, thank you very much indeed.  
17 It will take time to digest it all because some of  
18 the answers are very precise but the effort that you  
19 have put into it is really tremendous and I'm very, very  
20 grateful.

21 MS DUNLOP: Perhaps we could have our break now, sir.

22 THE CHAIRMAN: I think that might not be a bad idea.

23 MS DUNLOP: Yes.

24 (10.49 am)

25 (Short break)

1 (11.22 am)

2 Presentation of additional material by MS DUNLOP

3 THE CHAIRMAN: Yes, Ms Dunlop?

4 MS DUNLOP: Sir, at this point, which is obviously the  
5 conclusion of block 2, there are still one or two loose  
6 ends. I hope I have kept sight of all of them, although  
7 it's possible that I have missed something and other  
8 parties can always raise that, if they spot something  
9 else.

10 But to start with, something that I mentioned at the  
11 beginning of block 2, which is really I suspect, not  
12 a significant point, but it relates to a letter which is  
13 dated 11 January 1982. I had imagined that it could be  
14 seen as a significant letter because it refers to the  
15 arrival of heat-treated concentrates. The Inquiry team  
16 has come to the view that the date on the letter is  
17 probably wrong and that it's one of those January  
18 letters where someone has forgotten that it's a New Year  
19 and that the correct date is probably 11 January 1983.  
20 Could I very briefly run through the reasons on that?

21 The actual letter itself is [\[DHF0030892\]](#). It's  
22 a circular letter and I can see that from another copy  
23 of it that we have, it is signed by Professor Bloom and  
24 Dr Rizza. We can see that it relates to at least four  
25 commercial companies who are about to introduce

1           preparations of Factor VIII, possibly Factor IX, that  
2           have been processed in an attempt to reduce the risk of  
3           transmitting Hepatitis B and non-A non-B.

4           The points that are particularly made, the numbered  
5           points, relate to the need for properly conducted  
6           clinical studies. Then onto the next page, if we could,  
7           please. There is data on the efficacy of the products  
8           and then at the end of paragraph 2 we have  
9           a reinforcement of the point that formal trial is  
10          important and, three, that use of products on  
11          a named-patient basis bypasses these regulatory  
12          controls.

13          If we look back to another document, [\[DHF0030059\]](#),  
14          this document is the minutes of a meeting at BPL on  
15          15 December 1982. Again, this is a document of which we  
16          have another copy and we know certain personnel who were  
17          there: Dr Lane was there, Dr Cash was there and  
18          Professor Bloom was there certainly. This was a meeting  
19          discussing the advent of heat-treated concentrate. If  
20          we look on to the second page, we can see at the top  
21          a similar sort of thinking:

22                 "The need for centralised, fully-controlled  
23                 prospective trials of HS, hepatitis-safe materials, best  
24                 operated through a properly executed national clinical  
25                 trial."



1           And so on:

2           "Proposals. Random exploitation of the haemophilia  
3           service by commercial organisations for the study of  
4           hepatitis-safe products should be discouraged ... formal  
5           basis for controlled clinical trial."

6           And so on. Then the final document in this little  
7           chain is [\[SNB0135265\]](#). Can we bear in mind that that  
8           meeting is 15 December and it's actually a meeting  
9           that's going to feature in block 4, when we come to  
10          study viral inactivation as a topic. But on 21 December  
11          there has been in fact an exchange of correspondence  
12          between Dr Cash and Dr Lane. This is Dr Lane writing  
13          back to Dr Cash. All I would like from this letter at  
14          this point is that one of the agreements at the meeting  
15          at BPL had been that Messrs Bloom and Rizza would be  
16          writing out to the haemophilia directors.

17          So putting all these things together, in fact there  
18          had been this meeting on 15 December, they had been  
19          discussing the need for properly controlled clinical  
20          trials. There had been an agreement at the meeting that  
21          Messrs Bloom and Rizza would write to all the  
22          haemophilia directors. The view of the team is that the  
23          letter of 11 January is that intended letter and that it  
24          only makes sense then if the date, 11 January 1982, is  
25          seen as a mistake and it's in fact 11 January 1983.

1 THE CHAIRMAN: At the moment in the preliminary report,  
2 paragraph 7.13 takes the date just as it is but  
3 paragraph 7.14 sets out the dates on which applications  
4 were made. They don't fit terribly well with a date of  
5 11 January 1982 but I'm not sure they fit terribly well  
6 the date of 11 January 1983 either.

7 MS DUNLOP: Well, actually it was this that started the  
8 train of thought in the first place, that  
9 11 January 1982 would have been very early to be saying  
10 there are four companies which are about to introduce  
11 products. If they were only applying for licences in  
12 America from June 1982 onwards, it seemed to us that on  
13 balance, January 1983 fits better than January 1982.

14 THE CHAIRMAN: Any views on that?

15 MR ANDERSON: I agree. I have nothing to add.

16 MR DI ROLLO: It does look as though there are no other --

17 THE CHAIRMAN: It is a possible explanation even in the  
18 absence of the circumstantial material.

19 MR ANDERSON: It cannot be January 1982 whatever else it is.  
20 I don't think it can be January 1982.

21 THE CHAIRMAN: Just far too early, really.

22 MS DUNLOP: Yes. I should say, I had anticipated that this  
23 letter might feature and it hasn't really but it seemed  
24 possibly misleading in suggesting that heat-treated  
25 commercial products were available as early

1 as January 1982. So that was really the only purpose in  
2 saying that the team has come to the view that the date  
3 is probably wrong because it doesn't fit with the other  
4 evidence. Because I said at the beginning that I was  
5 going to return to that, I wanted to return to it.

6 THE CHAIRMAN: Right.

7 MS DUNLOP: So that's the first point. The second matter I  
8 wanted to close off, if I can, is the whole question of  
9 the funding of haemophilia centres, or more widely  
10 haemophilia treatment in Scotland, by drug companies.

11 The haemophilia directors who have given evidence  
12 were asked about it and they provided their own letters  
13 or statements. Those who haven't given evidence but who  
14 were also asked about it are for Aberdeen,  
15 Dr Bruce Bennett and Dr Audrey Dawson. Dr Bruce  
16 Bennett's letter is [\[PEN0150352\]](#). Dr Bennett and  
17 Dr Dawson seem to have been co-directors in Aberdeen and  
18 he has provided a letter saying that to the best of his  
19 recollection:

20 "We received no funding whatever from commercial  
21 producers of Factor VIII."

22 Dr Dawson's is in fact the immediately preceding  
23 numbered document, [\[PEN0150351\]](#). The other person who  
24 provided a letter about this topic is Dr George McDonald  
25 from Glasgow Royal Infirmary. His letter is

1           [\[PEN0150073\]](#). It seems from the second paragraph of his  
2           letter as though it's not an unknown concept, financing  
3           for staff provided by pharmaceutical companies, but he  
4           does say in the first paragraph that as far as he can  
5           recall:

6                     "No funding was received from pharmaceutical  
7           companies to employ staff in the department of  
8           haematology, Glasgow Royal Infirmary, for duties  
9           pertaining to the regional haemophilia centre."

10                    The team made similar --

11   THE CHAIRMAN: The last paragraph there does talk about  
12           grants received from pharmaceutical companies.

13   MS DUNLOP: Yes.

14   THE CHAIRMAN: So there was a system to handle some grants.

15   MS DUNLOP: Yes. I don't know whether that perhaps refers  
16           to the sort of funding that the directors have spoken  
17           about, grants to facilitate attendance at conferences or  
18           the holding of the symposia in Glasgow. There were the  
19           two, the one in 1975 and the one in 1980.

20   THE CHAIRMAN: Yes.

21   MS DUNLOP: The Haemophilia Society has also provided  
22           information. Just for the record their letter on this  
23           topic is [\[PEN0150365\]](#). Provided via their solicitors.

24           They have made such enquiries as they can at this  
25           remove and they have discovered one or two instances of

1 fundraising and a donation of £2,529 from pharmaceutical  
2 companies, a one-off donation for research purposes.  
3 Then perhaps we can go on to the next page, please.

4 So they are saying that they haven't found anything  
5 to suggest that there was general funding and they make  
6 the point that it's very unlikely that any funding from  
7 pharmaceutical companies would not be acknowledged  
8 within the bulletins.

9 With that letter they sent copies of various  
10 bulletins including the one that makes reference to the  
11 £2,000-odd donation. Perhaps we do not need to go to  
12 them but I think I should read out the numbers so that  
13 the numbers are in the transcript for anyone who wants  
14 to look at the bulletins. They are [\[PEN0150361\]](#),  
15 [\[PEN0150354\]](#), [\[PEN0150358\]](#), [\[PEN0150359\]](#) and  
16 [\[PEN0150360\]](#). And that order is, as far as I can make  
17 it, chronological. I think running over a period from  
18 1979 to 1985.

19 The third matter --

20 THE CHAIRMAN: Could I just find out what the reactions are  
21 to this?

22 Mr Di Rollo, do you have any position in relation to  
23 this material?

24 MR DI ROLLO: No. The letter, I think, is clear enough.  
25 There is nothing I would wish to add.

1 THE CHAIRMAN: I think that we do have material in  
2 Douglas Starr that perhaps is responsible for some of  
3 the questions around this arising but I have to go on  
4 evidence and I think it would really be for those  
5 instructing you to adduce evidence if you wanted to  
6 pursue this topic, but it may be that you simply accept  
7 the material that's here. I don't know.

8 MR DI ROLLO: Well, I don't think there is any other  
9 material that can be brought to bear or obtained. So I  
10 think it is as it stands at the moment.

11 THE CHAIRMAN: Mr Anderson, I'm almost tempted to not even  
12 bother asking you but do you have any point?

13 MR ANDERSON: No, sir.

14 THE CHAIRMAN: Mr Sheldon?

15 MR SHELDON: Nor I. The factual material speaks for itself.

16 THE CHAIRMAN: Thank you.

17 MS DUNLOP: I have four topics, sir, and that's the first  
18 two.

19 THE CHAIRMAN: You are suggesting that if I don't interfere,  
20 you will get on with it faster?

21 MS DUNLOP: Not in the slightest. I was going to apologise  
22 for the fact that number 3 is the longest one. It's  
23 just that it involves looking at some letters, I hope  
24 rather briefly. But I think it would be useful to look  
25 at them because they cast a little bit more light on

1           some of the mysteries about choice of products,  
2           particularly in Glasgow in the 1970s.

3           One of the team, still at Drumsheugh, has been doing  
4           a lot of research in this area and there is a series of  
5           letters, as always I suspect not quite complete, but if  
6           I could perhaps refer to them with apologies for not  
7           having supplied a list of them but they are all in court  
8           book.

9           The first is [\[SNB0070860\]](#). This is going back to  
10          1976. Dr Davidson, the haematologist at  
11          Glasgow Royal Infirmary, whose name has been mentioned  
12          on a number of occasions, is writing to Dr Wallace, the  
13          then director of the West of Scotland service, about  
14          Edinburgh intermediate Factor VIII. It certainly seems  
15          to be the name by which it was known in Glasgow.

16          It's referring to a rationing to 100 vials of  
17          Edinburgh concentrate per month. He says:

18          "We have had to supplement our Factor VIII with  
19          a fair amount of commercial product. We have recently  
20          started cautiously with home treatment using the  
21          Edinburgh product."

22          Essentially he is looking for more material.

23   THE CHAIRMAN: It is June 1976 of course, things are just  
24          getting into gear really.

25   MS DUNLOP: Yes, absolutely.

1           That letter was copied to Mr Watt and shortly after  
2           that Mr Watt writes to Dr Wallace. It's 15 June 1976,  
3           [\[SNB0070864\]](#).

4           Mr Watt, perhaps not being entirely encouraging  
5           about the suggestion of increased supply. Giving some  
6           explanations about some of the things that have been  
7           happening. Then going on to the second page, if we  
8           could, please. Dr Hopkins featuring also in this  
9           letter. He is hoping, at the top of the second page, to  
10          receive more fresh plasma from the West than has been  
11          possible and that could have a substantial effect on  
12          their ability to produce Factor VIII.

13 THE CHAIRMAN: Do you know whether at this time it was still  
14          on a population basis or was it pro rata to fresh-frozen  
15          plasma supplies or what? Or was it an artificial  
16          system?

17 MS DUNLOP: It's difficult to work out quite what the system  
18          was. If there was some sort of rationing of 100 vials  
19          a month, quite how that was arrived at, whether it  
20          correlated with population or number of patients or  
21          amount of plasma supplied. So far, we haven't found any  
22          information about that.

23 THE CHAIRMAN: The next paragraph, of course, deals with the  
24          cryosupernatant point which Glasgow resisted with all  
25          its vigour, so far as I can tell.



1 MS DUNLOP: But Mr Watt is saying that he finds it  
2 difficult -- this is the third paragraph:  
3 "... to understand why Dr Davidson has had to  
4 supplement with a fair amount of commercial product.  
5 This can only mean that he has a personal preference for  
6 the commercial product or the actual rate of usage of  
7 Factor VIII has increased again in the west."  
8 And wanting to know what sort of quantity is being  
9 referred to. Then at the end of the penultimate  
10 paragraph, a reference to self-sufficiency.  
11 THE CHAIRMAN: He looks to have been very frustrated:  
12 "We can hardly be accused of failure to meet  
13 clinical requirement if we are not allowed cover access  
14 to the information available."  
15 MS DUNLOP: I imagine that the wording of the letter might  
16 have been corrected before it was sent out. It doesn't  
17 look quite right but this, I suppose, is a file copy.  
18 THE CHAIRMAN: I suspect some of this is part of the dispute  
19 between Mr Watt on the one hand, and the haemophilia  
20 clinicians on the other, over whether there should be  
21 a haemophilia register and proper returns at that time  
22 of the products used. I get a sense that this is not  
23 a simple answer to the question of the volume of supply  
24 but --  
25 MS DUNLOP: No, and I think he is making his feelings plain

1           when he says:

2           "We have all attended far too many meetings in  
3           discussion of the problem to reach at the present time  
4           what appears to be a point of total confusion."

5           So a degree of exasperation certainly.

6   THE CHAIRMAN:  Yes.

7   MS DUNLOP:  Then we move to a letter from October 1976,  
8           which is [\[SGH0029295\]](#).  This is Dr Wallace to Mr Watt  
9           and interesting because it refers explicitly to there  
10          being currently considerable competition between firms  
11          supplying Factor VIII concentrate:

12          "Some of these firms are offering substantial  
13          reductions for large orders."

14          Dr Davidson has raised the implications with  
15          Dr Wallace.  Dr Wallace goes on to say to Mr Watt at the  
16          end of the second paragraph:

17          "Both he and I appreciate your many problems but we  
18          would welcome your present opinion."

19          Then in the last paragraph:

20          "I think they ..."

21          That's the doctors at the haemophilia centre and the  
22          Royal Infirmary:

23          "... would like to have a reasonable guarantee of  
24          200 vials per month with the prospect of even more."

25          This is interesting, sir, because doing the best we

1 can to work out when Yorkhill became up and running as  
2 a haemophilia centre, and Dr Pettigrew's reference to  
3 the lack of a guarantee of supply, this all seems to be  
4 part of the background at that time. I think also too,  
5 the reference in the autumn of 1976 in this letter to  
6 commercial firms offering substantial reductions.  
7 Then November 1976, Mr Watt back to Dr Wallace,  
8 [\[SNB0070943\]](#). Again, back to what were then current  
9 plans, recording his appreciation of the dilemma in  
10 which Dr Davidson may be placed by the competing  
11 interests of firms supplying Factor VIII concentrates.

12 Talking about current issues. Then on to the second  
13 page.

14 THE CHAIRMAN: Does that last paragraph suggest that there  
15 are process problems?

16 MS DUNLOP: Yes.

17 THE CHAIRMAN: That the capacity of the plant wasn't up to  
18 producing Dr Cash's estimate of the total amount  
19 required.

20 MS DUNLOP: It does look like that, sir, yes. I suppose  
21 yield, as so often yield is coming into it as well.

22 THE CHAIRMAN: Indeed. Yes.

23 MS DUNLOP: The second page, the reference you made a moment  
24 ago, sir, to the West of Scotland haematologists being  
25 reluctant to use the material produced by the processing

1 of the cryosupernatant. The puzzling reference perhaps  
2 to Dr Peter Jones. I'm not quite sure where he came in  
3 at this point.

4 THE CHAIRMAN: I have read this and the only inference  
5 I could draw was that in some way Mr Watt was in contact  
6 with Peter Jones to have the material trialed.

7 MS DUNLOP: Yes.

8 THE CHAIRMAN: It was clearly of lower potency than the  
9 other material but there is quite a lot of surrounding  
10 correspondence that suggests that even so John Watt  
11 believed that it could make a valuable contribution to  
12 the treatment of patients.

13 MS DUNLOP: Yes.

14 THE CHAIRMAN: That view was clearly not shared in the West  
15 of Scotland.

16 MS DUNLOP: Well, I think Dr Foster covers this in his paper  
17 as well and in the end it doesn't seem to have been  
18 something that was accepted.

19 Then he goes on to say, at the end of the  
20 penultimate paragraph, that:

21 "Both Dr Cook and Dr Cash ..."

22 I think this would be Dr Cash on behalf of  
23 Edinburgh, Dr Cook on behalf of Inverness:

24 "... are looking for increased supplies of  
25 Factor VIII concentrate."

1           Not a particularly easy sentence to interpret  
2           actually.

3   THE CHAIRMAN:  No.

4   MS DUNLOP:  "I suspect that initially the increased supply  
5           from the West of Scotland will be reflected to some  
6           extent by the increased satisfaction of the demand from  
7           the other two centres, since it will be less easy to  
8           resist their blandishment than hitherto."

9   THE CHAIRMAN:  It must be the increased supply of FFP,  
10           mustn't it, plasma?

11            "Increased supplies of plasma for production."  
12            He is going to have to use up some elsewhere.

13  MS DUNLOP:  Yes.  It looked to be saying: in the West of  
14           Scotland you may be going to supply more but I may have  
15           to use that to satisfy the requests from Inverness and  
16           Edinburgh.  So don't imagine that you will get back  
17           a pro rata share of that material.  It seems to be the  
18           point.

19  THE CHAIRMAN:  But Dr Cook and Dr Cash are using  
20           blandishments to get more, whereas Glasgow had a more  
21           direct approach perhaps.

22  MS DUNLOP:  Well, if nothing else, I think we can see that  
23           it was quite complicated.  There is then, on 5 November,  
24           a letter from Dr Wallace to Mr Watt, which is  
25           [\[SGH0029294\]](#).  Dr Wallace is trying to send as much

1 fresh-frozen plasma as possible:

2 "My staff, like me, are hopeful that we can break  
3 the back of this Factor VIII problem."

4 Then December 1976 --

5 THE CHAIRMAN: Could we just pause on that? Is this  
6 question of SPPS something that I have to pay a lot of  
7 attention to, particularly the reference to the  
8 requirement for that particular product for burns  
9 therapy? I think my impression is that in due course it  
10 was accepted generally that alternatives to SPPS were  
11 acceptable to the people with particular problems, but  
12 is it something I have to look at or is it just part of  
13 the history that one needs to note but not develop?

14 MS DUNLOP: I would have thought, sir, that it's the latter,  
15 that certainly plasma was not exclusively available for  
16 the production of Factor VIII concentrate and that's  
17 perhaps all we need to take from it.

18 THE CHAIRMAN: Indeed. It's just another element then in  
19 the general equation of use of the source material. But  
20 at the moment I don't have any feel for whether the SPPS  
21 element in it is greater or less than the desire to use  
22 cryoprecipitate in the West of Scotland or to process  
23 cryo at Law Hospital.

24 MS DUNLOP: No.

25 THE CHAIRMAN: I just don't know. Overall the letter

1 suggests a joint approach is being adopted at that stage  
2 to reach some sort of agreement on targets for F8  
3 products.

4 MS DUNLOP: Yes. Then Dr Hopkins comes in again. He writes  
5 on 22 December 1976 to Mr Watt.

6 THE CHAIRMAN: A typical letter?

7 MS DUNLOP: Not as colourfully expressed as some, other than  
8 the fact that he has had to do his sums by hand, which  
9 he remarks on. That's [\[SNB0070970\]](#).

10 This is another letter apparently dealing with  
11 shortfall really. The third paragraph:

12 "If we supplied 200 vials a month to Glasgow Royal  
13 and meet our current commitments to other hospitals, we  
14 may need a monthly average of something like 250 to 300  
15 vials. Mr Grant has told me our current regional  
16 monthly quota is 100 vials."

17 So obviously a bit of a gap.

18 THE CHAIRMAN: John Davidson, what was his discipline?

19 MS DUNLOP: He is a haematologist in Glasgow Royal Infirmary  
20 and he at this point seems to be, as far as one can  
21 tell, performing the same sort of job as Dr Boulton. He  
22 is a bit of a middleman. He is not, as I understand it,  
23 a haemophilia clinician. He is not directly involved in  
24 treatment but he is trying to help, I suppose, with the  
25 supply issues. I think, looking back at the evidence

1           too, the position seems to have been that he may have  
2           been the person who did the order forms in  
3           Glasgow Royal Infirmary.

4   THE CHAIRMAN:  But for the whole of the West of Scotland?  
5           Or for the infirmary alone or what?  Do we know?

6   MS DUNLOP:  The reference to other hospitals is puzzling  
7           because the only other hospital one can think of is  
8           Yorkhill.

9   THE CHAIRMAN:  Unless they are using satellites in Paisley,  
10           Greenock and all the rest of it, to do some treatment.  
11           But the relative volumes would then worry one, wouldn't  
12           they?

13  MS DUNLOP:  In terms of the contrast?

14  THE CHAIRMAN:  Yes, 250 to 300.

15  MS DUNLOP:  Yes.

16  THE CHAIRMAN:  I don't think a computer would have helped  
17           him solve the problem.

18  MS DUNLOP:  No.  I suppose the context of all of this is was  
19           there a place for the purchase of commercial material.  
20           I think certainly it looks as though anyone wanting  
21           a guarantee of stock in the hospital at any given time  
22           might well have had to resort to the purchase of  
23           commercial material.

24           There is then a bit of a leap to 1977.  The next  
25           letter I have is [\[SNB0071243\]](#).  This is



1           2 September 1977. Dr McDonald to Mr Watt. This is  
2           about the cancellation of a planned meeting to discuss  
3           the problem of the availability of plasma fractionation  
4           and the availability of Factor VIII products.

5           So quite what that reflects is really impossible to  
6           work out, I think, at this remove.

7   THE CHAIRMAN: Yes.

8   MS DUNLOP: Then Mr Watt contacted Dr Prentice when he saw  
9           the minutes of the haemophilia directors' meeting in  
10          1977, in which Dr Prentice was recorded as having said  
11          that he had to buy commercial product. That appears to  
12          have leapt out at Mr Watt and he wrote to Dr Prentice  
13          about it on 12 January 1978. [\[SNB0017242\]](#). Recording  
14          that he is actually distressed to discover that  
15          commercial Factor VIII has been purchased in Scotland  
16          during 1977.

17   THE CHAIRMAN: This is John Watt's theme really. "If you  
18          tell me what you want, I can do it but I need the raw  
19          materials", and so on. Yes.

20   MS DUNLOP: And I need information as well.

21   THE CHAIRMAN: Yes.

22   MS DUNLOP: Then very close in time, 18 January 1978,  
23          Dr Davidson to Mr Watt, [\[SNB0017237\]](#). This is, I think,  
24          a direct response to the letter to Dr Prentice.  
25          Dr Davidson is sending a table which we haven't found.

1           No doubt it's in the database somewhere but it is  
2           probably decoupled from the letter and it won't have  
3           a date on it. A table giving the  
4           Glasgow Royal Infirmary blood product statistics for  
5           1977. Actually the letter, I suspect, tells us much of  
6           what's in the table.

7           Interesting to note from the third paragraph that  
8           Edinburgh had supplied 1.2 million units to the  
9           West of Scotland in 1977. Of that, 0.7 million units  
10          had been used in the Royal Infirmary. So the remaining  
11          portion perhaps was largely used at Yorkhill. That  
12          would certainly be one explanation.

13   THE CHAIRMAN: Except that that's not really consistent with  
14          the last sentence in the third paragraph, that:

15                 "The use of commercial F8 outwith this hospital, my  
16                 guess is that it would be low enough to be left out of  
17                 your calculations."

18                 Where does that come from?

19   MS DUNLOP: Well, it looks as though Dr Davidson's  
20          perception of the situation then was that, whatever  
21          other hospitals than Glasgow Royal Infirmary were being  
22          supplied in the West of Scotland, were using mostly NHS  
23          material rather than commercial material.

24   PROFESSOR JAMES: This only gives Glasgow Royal Infirmary --

25   MS DUNLOP: Yes.

1 PROFESSOR JAMES: -- statistics. So presumably there is  
2 additional statistics for the Children's Hospital?

3 MS DUNLOP: Yes. He says:  
4 "It will be a happy day when Scotland is  
5 self-supporting for all plasma fractions. It would be  
6 nice if this was in 1978."

7 THE CHAIRMAN: Yes, this doesn't really tell us who was  
8 buying what, how much was being bought, whether and how  
9 it was being recorded and so on.

10 MS DUNLOP: Well, it gives us a total usage for NHS product  
11 in the West of Scotland in 1977.

12 THE CHAIRMAN: With respect, it doesn't. It shows you  
13 supply and it shows you how much was used in the  
14 Royal Infirmary. We don't know whether there were  
15 stocks being built up elsewhere. Having regard to  
16 Dr Foster's evidence, it is not possible to exclude that  
17 at the moment.

18 MS DUNLOP: I suppose it is possible that the 0.5 million  
19 units, the half a million units were not used. I take  
20 that point, sir. Frustratingly, the statistics for  
21 Yorkhill only refer to amounts from 1980 onwards.

22 THE CHAIRMAN: Yes.

23 MS DUNLOP: So it's very difficult to know actually what the  
24 breakdown was between NHS and commercial product being  
25 used in Yorkhill in the late 1970s.

1 THE CHAIRMAN: So far, rather unfortunately, all of this  
2 material seems to be strengthening the impression that  
3 there was a lack of accountability, right across the  
4 system.

5 MS DUNLOP: Certainly the impression seems to be that it was  
6 quite a complicated problem, that people were in theory  
7 supportive of the notion of self-sufficiency but that  
8 perhaps in practice the supply was sometimes inadequate.

9 THE CHAIRMAN: Yes.

10 MS DUNLOP: The next letter we have is another one from  
11 Dr Hopkins from 1980. I appreciate that's quite a leap  
12 in time but it's [\[SNB0072612\]](#). It's perhaps, sir, if  
13 you are wondering, medium colourful in its terms.  
14 I suppose, making the obvious point that fluctuating  
15 demand is always going to be a problem.

16 THE CHAIRMAN: Yes, could we just read it. I think the  
17 first paragraph is interesting:

18 "1,000 bags of cryo are issued each month, 200 plus  
19 or minus 100 to other hospitals in the region."

20 That indicates that the bulk of the material is  
21 being used in Glasgow and a relatively small proportion  
22 going to other hospitals, which contrasts quite markedly  
23 with the previous balance of 200 to 300 going out and  
24 100, isn't it, being used in Glasgow?

25 MS DUNLOP: I think that was the vials of Factor VIII.

1 THE CHAIRMAN: Yes.

2 MS DUNLOP: Yes.

3 THE CHAIRMAN: I'm not looking at the particular material  
4 but just in the balance of usage, which doesn't  
5 immediately look right. Dr Hopkins' information from  
6 the period could be of wider interest in the Scottish  
7 executive, couldn't it?

8 MS DUNLOP: Well, not a problem that has gone away.

9 Just to look at the second page, what Dr Hopkins is  
10 planning to do with the cryoprecipitate stocks, wanting  
11 to therefore send more fresh-frozen plasma to Edinburgh  
12 and then at the end asking for warning if there is  
13 a supply problem coming. I think really referring to  
14 twin pressures: one, a sudden increase in  
15 cryoprecipitate demand or, two, a sudden drop in  
16 Factor VIII supplies from Edinburgh.

17 Then Mr Watt, a slightly reassuring response,  
18 26 August 1980, [\[SNB0072614\]](#). He says that they are  
19 getting better yields with their Factor VIII and  
20 increased issue from PFC does tend to result in  
21 increased availability of fresh-frozen plasma:

22 "Supplies are reasonably secure. It should be  
23 possible, given some disaster, to let you have at least  
24 two weeks notice of a likely hiatus in supply."

25 THE CHAIRMAN: I suspect it's "absent some disaster," rather

1           than, "given some disaster".

2   MS DUNLOP: I wonder if he was meaning -- given the text of

3           Dr Hopkin's letter. Dr Hopkins was saying, "I need

4           warning if there is a problem about to hit us". Mr Watt

5           is saying that if something terrible does occur, "I

6           should be able to warn you that it will bite in two or

7           three weeks' time".

8   PROFESSOR JAMES: In the event of.

9   THE CHAIRMAN: In which case I really don't understand how

10          it can have been taken as any comfort at all. We have

11          a disaster. I will be able to tell you what's going to

12          happen in a fortnight from now. It hardly let's one

13          respond to the sort of incident that Dr Hopkins has in

14          mind.

15   MS DUNLOP: Dr Hopkins only asked for ten days or

16          a fortnight's warning. I suppose Mr Watt in that sense

17          is saying, "I think I can give you a fortnight's

18          warning".

19   PROFESSOR JAMES: This refers to a disaster at PFC, rather

20          than a disaster on the terraces.

21   MS DUNLOP: I think that was all Dr Hopkins was saying:

22          "If Factor VIII concentrate supplies were suddenly

23          going to fall, we would like to know about that and

24          could I have at least ten days or a fortnight's

25          warning?"

1           And Mr Watt seems to be saying, "I think I can  
2           manage that".

3   THE CHAIRMAN:  Yes.

4   MS DUNLOP:  Then 1981, a letter which I think we mentioned,  
5           sir, during the evidence, a letter of 24 April 1981 from  
6           Dr Crawford to Mr Watt, [\[SNB0071634\]](#).  This is the  
7           letter referring to Dr Davidson's policy of buying  
8           commercial products by rotation from a number of  
9           manufacturers.  Actually, the letter goes on to deal  
10          with a quite specific point about the commercial  
11          producers having changed the labeling of their product.  
12          Saying on the label now that it's possible to store the  
13          product at room temperature for a short period.  In  
14          essence, I think, Dr Crawford is saying it would be very  
15          helpful if you could say the same on your labels.

16                 That's on page 2.  He says:

17                 "John would like to know whether it would be  
18                 possible, on the strength of stability data you have on  
19                 file, to modify the label to indicate for how long  
20                 a period storage at room temperature would be  
21                 acceptable."

22                 A letter sent perhaps without much of an expectation  
23                 of a positive response, but sent nonetheless.

24   THE CHAIRMAN:  We can understand the difficulties.  Storage  
25           on the shelf possibly is much more likely to happen when

1           somebody is on holiday than when they are at home.

2   MS DUNLOP: This is again speculating, but if patients were  
3           saying, "I really prefer this product from the X  
4           pharmaceutical company because I know I can take it on  
5           holiday and I don't need to keep it in a fridge all the  
6           time", then that small point of itself is going to lead  
7           to a preference by patients for the commercial product  
8           unless the NHS product is seen to afford equivalent  
9           flexibility.

10           Then finally, just really because it fits with  
11           Dr Foster's evidence -- and it may be that he has this  
12           in his reference list in his paper anyway -- a letter  
13           from 1982, [\[SNB0073184\]](#). Dr Foster to Dr McClelland.  
14           This is a letter which is in the preliminary report as  
15           well, about quality considerations. Dr Foster says his  
16           initial reaction to the claim that PFC Factor VIII  
17           concentrate is a poorer quality than commercial  
18           intermediate purity products is that this is probably  
19           fair comment.

20           Referring to the need, which, as he explained  
21           himself, hit NHS producers in a way it didn't hit the  
22           commercial producers, to maximise yield in the pursuit  
23           of self-sufficiency.

24           Some very technical analysis on the second page of  
25           how the PFC product actually compared to some of the



1 commercial products.

2 I'm not sure, sir, in the end, how much light any of  
3 this material sheds, but perhaps it is no more than  
4 straws in the wind at the time about what the factors  
5 were, about the presence of the commercial suppliers in  
6 the marketplace and about concerns to do with  
7 reliability of supply, about the dynamic of how much  
8 plasma is supplied for what purpose and how much you get  
9 back in return. So I think all of these themes are  
10 reflected in the correspondence, but I suspect in the  
11 end it's impossible to put together a complete picture  
12 of what was happening.

13 THE CHAIRMAN: A factor that has been growing at least in my  
14 mind as one of importance is the way demand was  
15 changing.

16 MS DUNLOP: Yes.

17 THE CHAIRMAN: As the approach to therapy altered, it is  
18 fairly clear that the demand for products was changing  
19 in what perhaps was an unpredictable way, and if that is  
20 happening at the same time as there are independent  
21 factors affecting supply, then it could become extremely  
22 difficult indeed to correlate one with the other.

23 It may be that there is simply no resolution  
24 possible now to the problem. It's a great pity that  
25 Mr Watt didn't survive and that indeed he was too ill to

1 help us because I have no doubt he would have views  
2 which would probably be expressed quite forcefully  
3 but --

4 MS DUNLOP: I think one of the things that perhaps comes  
5 across from the correspondence is that in reality it  
6 would have been helpful to everybody to have a very  
7 large reserve stock at any given time because a number  
8 of these problems could have been alleviated by knowing  
9 that there was a decent amount of material held  
10 somewhere. Whether it was ever possible to receive  
11 plasma in sufficient quantities to set that up, I think  
12 is questionable.

13 THE CHAIRMAN: It looks as if it may have become possible,  
14 1983/1984, but that was on the back of very considerable  
15 alterations to the plant and equipment at PFC. It may  
16 not have been possible before that to do it.

17 MS DUNLOP: Yes, and a whole raft of quite imaginative  
18 measures to achieve every last drop possible and make  
19 the best possible use of every donation, which all  
20 I gather will have taken time to feed through.

21 THE CHAIRMAN: Yes.

22 MS DUNLOP: The fourth point, sir, in conclusion, was just  
23 that we did refer to not having had any input from  
24 Dr Mitchell in this area. It's our intention to write  
25 to Dr Mitchell and perhaps put some questions to him

1           about his involvement in securing an adequate supply of  
2           PFC product for the hospitals in the West.

3   THE CHAIRMAN:  The other two loose ends that I can think of  
4           immediately are Professor Hann and Dr McClelland; who  
5           were cut short, as it were one way or another.  Do we  
6           have plans in hand to bring them back or are they going  
7           to be sort of built in at some stage?

8   MS DUNLOP:  They are both on the timetable for block 3, sir.  
9           I can't, off the top of my head, give the dates but  
10          I know that they are pencilled in.  They are scheduled  
11          to return.

12   THE CHAIRMAN:  Gentlemen, this question of supply.  As you  
13          will know from the preliminary report, I at least had  
14          a sense of frustration that the flow of data around the  
15          system made planning of production and supply very  
16          difficult.  I'm not sure that the material is available  
17          now to resolve the difficulties.

18                Do you have anything to say on this at all,  
19          Mr Di Rollo?

20   MR DI ROLLO:  Not at this stage, no.

21   THE CHAIRMAN:  No.

22   MR DI ROLLO:  I don't think there is anything I can usefully  
23          add to the material that you have.

24   THE CHAIRMAN:  Out of this, I think, comes an impression  
25          that one way or another those at the front end had

1 a perceived need to use commercial products, which might  
2 be attributable to a whole number of things, starting  
3 with personal preference and ending up with the need to  
4 plug a gap in the public supply. I just don't know  
5 where we are on that. I would like you to think, not  
6 immediately, but think where you want to take me in that  
7 area. Again, it's Yorkhill that becomes the particular  
8 focus for it.

9 MR DI ROLLO: Yes, certainly.

10 THE CHAIRMAN: Mr Anderson?

11 MR ANDERSON: I don't think I have any comment at this  
12 stage.

13 THE CHAIRMAN: At this stage.

14 MR ANDERSON: I will clearly bear in mind your comments.

15 THE CHAIRMAN: It is a problem area. Unless one can find  
16 some credible explanation for it, then it's going to  
17 hang in the air --

18 MR ANDERSON: One thing I will do is to ask those  
19 instructing me to make further investigations to see if  
20 there are any other individuals who may be able to cast  
21 light on that. I suspect that may be a fruitless --

22 THE CHAIRMAN: We are looking a long time into the past and  
23 it may be fruitless but those instructing you do have to  
24 remember that John Watt made a very serious effort to  
25 persuade the haemophilia doctors in particular to

1 provide him with the sort of information that would have  
2 given us an audited trail of all the material needed and  
3 its use. The inability to answer questions now may not  
4 be entirely unconnected with that. The additional  
5 information that when commercial supplies were  
6 eventually returned, they were returned through the  
7 offices of Dr Ludlam, who in effect seems to have  
8 aggregated information and therefore deprived it of any  
9 real meaning, doesn't help. So if those instructing you  
10 can look at this again, I would be very grateful.  
11 I would rather have an answer than a considerable hole  
12 that can only fuel speculation.

13 MR ANDERSON: I simply say that I will discuss it but  
14 without being terribly optimistic about it. We will  
15 certainly do it.

16 THE CHAIRMAN: We have been at it for a long time. I would  
17 be surprised that you would express optimism now that  
18 hadn't already been satisfied in other ways.

19 Mr Sheldon?

20 MR SHELDON: Nothing I can add at this stage, sir, thank  
21 you.

22 THE CHAIRMAN: Ms Dunlop, I still look forward with some  
23 hope, if not optimism, to finding an answer. But let's  
24 wait and see.

25 MS DUNLOP: We have no further business at the Inquiry

1           today, sir.

2   THE CHAIRMAN: Thank you all very much.

3   (12.21 pm)

4   (The Inquiry adjourned until Tuesday 7 June 2011 at 9.30 am)

5   PROFESSOR ANDREW LEVER (continued) .....1

6           Questions by MR DAWSON .....1

7           Further Questions by MS DUNLOP .....41

8   Presentation of additional material .....47  
9           by MS DUNLOP

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