Friday, 28 April 2011

(9.30 am)

PROFESSOR CHARLES FORBES (sworn)

THE CHAIRMAN: Good morning.

Questions by MS DUNLOP

MS DUNLOP: Good morning, sir, we have Professor Charles Forbes with us today.

Good morning Professor Forbes.

A. Good morning.

Q. Before I ask some questions of a witness, we usually start by looking at their curriculum vitae, and we have your CV. I don't know if you have a hard copy with you. We didn't print it out because it is very long, but I just wanted to pick up one or two of the things that are in it and it will appear on the screen in front of you. It's WIT0030203.

If we go to the first page in, please, just to confirm some details, which I'm sure you will have no difficulty with. But we can see that you graduated MBChB from Glasgow University in 1961 and that you did an MD at Glasgow in 1972. What was your MD?

A. It was on blood coagulation and related areas of coagulation.

Q. Your current appointment is shown as professor of medicine at the University of Dundee and honorary

consultant physician, Tayside University Hospitals, as the first. That is true as at today, is it?

A. No, I have now retired seven years ago from that but it was true until then.

Q. Yes. The visiting professorship in the department of bioengineering at Strathclyde University, I just wondered, really for our interest, if you could explain what aspects of bioengineering you were involved in?

A. This is a very basic department, which looks at the engineering aspects of some medical problems, and I was deeply involved with them and we looked at things like bedsores and why bedsores happened. We looked at the flow of blood and the stickiness of blood. So it was all very relevant to the job I was doing at that time.

Q. Can we move to the next page, please? You have listed for us your medical career. We can see your house appointments in 1961 and 1962. I think we will come back to this, but we notice particularly that between 1968 and 1970 you were a Fulbright fellow doing research through the American Heart Association with Dr Oscar Ratnoff, and we heard a bit about Dr Ratnoff yesterday and his particular insights into the developing problems of HIV in haemophilia.

Then, if we can move to the next page, we see that you have held a number of different roles and

responsibilities in The Royal College of Physicians and Surgeons of Glasgow. Perhaps we could just scroll down and look. On the following page, The University of Glasgow. You have obviously, throughout most of your career, had quite a heavy teaching commitment. Is that correct?

A. Yes, yes. Undergraduate and postgraduate.

Q. Yes. Then the Royal Infirmary of Glasgow, you were the director, Regional Haemophilia Reference Centre, 1983 to 1987.

Just pausing there, Professor Forbes. The centre in Glasgow, at least the centre at the Royal Infirmary in Glasgow, appears to have had co-directors for quite a lot of the period we have been looking at. I think you were a co-director with Dr McDonald for a while?

A. Yes.

Q. And also a co-director with Dr Prentice. Is that right?

A. Yes.

Q. I have noted from other papers that it looks as though Dr Lowe succeeded you. I think you went to Dundee in 1987 or 1988 and then Dr Lowe took over. Would that be correct?

A. That is correct, yes.

Q. He succeeded you?

A. Yes. He had worked with me for many years before that

but he became director in 1987.

Q. Right. Perhaps from the other papers we have, we can put in the dates when other people held various roles. In general terms what was the reason for having co-directors?

A. Well, it was a very large centre and very busy. All of us did it as an addition to our normal duties, which were first of all teaching undergraduates and postgraduates, and also the clinical care; we took a share of the acute medical receiving rota. So it was a very busy job and it was better to have somebody else there so that holidays were covered and so on.

Q. When Dr McDonald was there, what was his particular role?

A. He was involved in the organisation of the department of haematology. So he was in charge of the lab aspects of the care of patients of all kinds of haematological problems, in addition to haemostasis, clotting disorders.

Q. I'm asking you that, Professor Forbes, because I don't think Dr McDonald is going to be coming to give evidence.

A. I believe that.

Q. I thought I would just ask you that while you were here. We can see that you have also had an number of roles in

the Scottish Home and Health Department. Then if we look to the next page, we can see your career at the University of Dundee, where you moved in 1987. First of all your university career and then also your roles and responsibilities in Dundee Teaching Hospitals NHS Trust.

Moving to the next page, you have plainly had a lot of experience as an examiner, and we can also see listed on that page your particular responsibilities within the area of haemophilia. That is as a member of particular groups and organisations. We can see you are a member of the reference centre directors' group between 1978 and 1987; a member of the committee on home therapy, 1976 to 1982; chairman of the AIDS subcommittee between 1985 and 1987 and the chairman of reference centre directors at that time too.

On to the following page. Your editorial posts. A number of different journals and then other appointments. We can see, for example, the Advisory Committee on Dangerous Pathogens, UK Expert Committee on Vascular Disease, a founder member and secretary of the Scottish Heart and Arterial Risk Prevention Group or Society. Haemophilia Society of Great Britain and at the bottom too, the Chest, Heart and Stroke Association. Then if we look on to the following page, one that caught my eye, Professor Forbes, was the Aesculapian

Club. Perhaps you could tell us a little bit about that. Aesculapius was a physician, wasn't he?

A. Yes, a long time ago, but this is very much a social club, associated with The Royal College of Physicians of Edinburgh.

Q. I see:

A. So it is very much social?

THE CHAIRMAN: It's a dining club, isn't it?

A. It is a dining club.

MS DUNLOP: Now we know.

Then there is the American Heart Association. I guess these are in alphabetical order because there are a lot of them on this page. Then if we look on to the following page.

A. The American Heart Association was to do with being in America for two years.

Q. I see. And you have even found time, if we go right down on to the following page, to be a governor of the RNLI?

A. Yes, that's very much a honorary thing.

Q. Yes. Then a very -- if I may say so, Professor Forbes -- impressive list of publications and contributions, and we can only note a small proportion of them as we look at them but it's intriguing to see that in the 1960s, you seem to have done some work on

snake venom.

A. That was associated with being in East Africa, where we were based very near the serpentarium, and we therefore could get venom from various types of snake. Most of these venoms actually affect blood coagulation or thrombosis. So they were very relevant to what I was interested in.

Q. We see too, perhaps slightly more directly connected to what we have been looking at, number 11, an article in the Scottish Medical Journal in 1969 on cryoprecipitate therapy. Can you tell us a little bit about the Scottish Medical Journal. When did that start?

A. Well, it's a very ancient journal. It is about 200 years old. I became editor and obviously some of my contributions were with them. This one was an early local use and preparation of the cryoprecipitate, which was done in Glasgow with blood transfusion. As you recognise, some of the names here are the senior members at BTS.

Q. Yes. Is the Scottish Medical Journal still going?

A. Yes.

Q. Right. Sorry, maybe I shouldn't have asked that. But just to check that it's still alive.

A. No, it is one of these journals that has survived. It has changed a lot but it's still going.

Q. Right. Moving through, we see on the next page, another really very wide-ranging succession of articles.
I noticed, if we go on to the following page at number 28, the publication in Italian for a symposium, an international meeting on haemophilia in Rome. Did you write it in Italian or did you have to have it translated?
A. No, I did not write it in Italian; it was translated for us.
Q. I see. I was offering you the chance to note that you were able to write these papers in Italian as well as in English.
A. No, difficult enough in English.
Q. Yes. Then just really scrolling through. If we move on, the next one that caught my eye was actually number 66 because it's one of a number of papers. This one is connected with pre-eclampsia. It is one of a number of papers which seem to be connected with obstetrics. So you have had an interest in, I suppose, particularly thrombotic conditions in pregnancy, have you?
A. Absolutely. We had colleagues in the department of obstetrics who were particularly interested in and collaborated with us. So that was why it came about.
Q. And indeed, a number of articles in that area feature in your list. 73 would be another one and so on?

A. Yes, Peter Howie became the professor of obstetrics in Dundee in fact.

Q. Yes. Then number 89. You have written an article in the Scottish Medical Journal on students and their health. That must have been an interesting piece of research?

A. Well, the problem is that the health problems of students totally determined what becomes of them and how well they do in their academic studies. So it was, I thought, very relevant to the job I was doing.

Q. I notice too that number 95 was an article on renal disorders in haemophilia. Going on through the list, we can actually see a notice number 135. We have to go on a few pages. One called "Self-perception of employed and unemployed haemophiliacs".

A. Well, at this time I had become involved with a group of psychologists at Stirling University, and Ivana Markova there was the professor of psychology, and many of the problems we saw in our patients had psychological backgrounds which were very, very relevant and potentially changeable. So we explored many of their problems over many years with this group.

Q. Yes. I think, Professor Forbes, that it is really part of a wider impression that I had as I looked through this list -- for example, there is that article on the

self-perception of employed and unemployed haemophiliacs, then there is another one on the next page, "Integration of haemophilic boys into normal schools", "Impact of haemophilia on child-rearing practices and parental cooperation" -- that you have taken an interest really in all aspects of haemophilia. So a very holistic approach. Am I right about that?

A. Well, I think these things are so important because what happens in early youth determines what happens in later adult life, and we spent a lot of time looking at their education. Catherine MacDonald in 146 there was a teacher and she became a psychologist as well, and that's the reason that some of these are in.

Q. Yes. Another one, I suppose we perhaps can note, because we can see it there, you have also looked at the effects of age and cigarette smoking on blood and plasma viscosity in men; another, I suppose, thrombosis-related interest, I would guess?

A. Yes. You will notice as the CV goes on, it becomes more interested in thrombosis and the causation of thrombosis, which is a much bigger problem in Glasgow and Scotland.

Q. I did notice that, professor, it looked as though you had moved really past or out of haemophilia more towards the other end of the spectrum, if one can put it

crudely, to look at cardiovascular problems --

A. Absolutely.

Q. Just noting another few of your articles as we look at the list. I notice 196, which I think is part of the same subset as the one we looked at a moment ago, where you told us about Ivana Markova, "The haemophilic patient's self-perception of changes in health and lifestyle arising from self-treatment."

I think we all already know enough to understand that at that point the sorts of self-perception you must have been encountering would have been very positive.

A. We were always very struck by the fact that many of these young men had behavioural problems, taking part in activities that were, to the normal person, very dangerous and that was why we started looking in depth at a cohort of young people with haemophilia.

Q. And predictably perhaps, towards the bottom of that page, we start to see articles on a different theme. "Immunological abnormalities in haemophilia: Are they caused by American Factor VIII concentrate?" BMJ (1983).

A. We were always very intrigued as to how all this happened. I don't think we even, after all the investigations and papers, clearly know what happened. But it clearly, at that time, seemed to be associated

with American concentrate, although I would probably have to say that maybe that's not totally true.

Q. Yes. The next page, 219, you looked at coronary artery disease in severe haemophilia. What is the extent of that as a problem?

A. This was the great paradox that here was a man -- it was a single case report --

Q. I see, sorry?

A. -- in which he would bleed and bleed and bleed, as many haemophiliacs did until they were treated, and yet when he died, he died with coronary artery disease due to atheroma and thrombosis. So it was a great paradox and we wrote this up as an interest paper. It has been reported elsewhere since then.

Q. So in fact a rare occurrence?

A. Rare.

Q. Then 268, an article that we refer to in the preliminary report: "Acquired immune deficiency syndrome: an overview," Scottish Medical Journal (1985). I think it was January 1985?

A. Yes, that was just to bring everyone up-to-date with the state of play of the problems in haemophilia.

Q. Yes. Jumping to 314, I noticed an article entitled "Haemophilic arthritis". Is that a direct consequence of the bleeding that we have heard people experience in

their joints?

A. This is the major clinical problem of all young haemophiliacs, that they bleed into their joints and after a time, a series of events continue in which they rebleed and they continue to destroy their joints. So that was part of our studies, looking at this particular aspect. But it's a very common problem in haemophilia.

Q. Right. You have also looked -- 336 -- at liver dysfunction in haemophilia?

A. Again, that's a reflection of the fact that it was such a common problem. We were aware of it happening. We didn't understand why it happened. We presumed it was a virus or viruses of some kind and no doubt we will come back to that.

Q. Yes. Moving on, one or two further articles I noticed about themes we have mentioned. Arthritis in haemophilia. Really very many more publications, professor; one on thrombosis in airline passengers, something that we have all heard of too. I'm not sure if this is the next number in our database or if we can just keep going. No doubt I'll find out.

There is another section at the end of the articles headed, "Chapters and related educational publications". 457 publications. Then we see that you have also written a large number of chapters and other

publications, many, obviously, on coagulation defects. Then, after we have noticed 55 entries in that section, you also have books and other publications, and I noticed from the list of books that you have worked with both Dr Evatt and Dr Aledort. Is that correct?

A. Yes.

Q. I think we are all very aware, particularly since yesterday, that those individuals don't see eye to eye nowadays. I'm not sure if they ever did.

A. No, I don't think they ever did but ...

Q. I don't think I need to ask you, professor, to say anything particular on that. It is just in the context of everything we looked at yesterday, it was quite striking that you had worked with both these individuals.

Thank you for expanding on some of those entries for us, professor. With that exercise completed, I would like you now to go to your statement, which is [PEN0150254].

A. Yes.

Q. And you have, I think, a hard copy of that?

A. Yes.

Q. You tell us that your interests in haemophilia started in 1961 and on qualification you started at the RHSC in Glasgow. That would be a house job?

A. Yes.
Q. Yes. So six months?
A. Six months.
Q. Yes. And that was actually a surgical position and you were looking after children with haemophilia, who had surgical problems, especially joint disease, and I suppose in those days really very young children had joint problems?
A. Indeed, they did. Also abdominal problems like appendicitis and so on. So all the routine of young children was seen there, and obviously in those with haemophilia the problems were compounded by their bleeding tendency.
Q. Then you tell us that you were seconded to the University of East Africa, the Kenyatta National Hospital. I'm guessing from the name that that might have been in Nairobi, was it?
A. It was. It used to be called the King George VI Hospital but on Africanisation it became the Kenyatta National, and still exists as their main medical facility.
Q. You say this secondment was in association with Professor Douglas. How did Professor Douglas end up having a connection with the hospital in Nairobi?
A. Well, the British Government were wanting to provide

help to Kenya because when things were divvied up at independence, Kenya didn't have a medical school, and it was thought by the Government that it would be quite easy to make a medical school there quickly and get it up and running within a year. So a team from Glasgow were selected to go out and that was led at that time by Professor Douglas.

Q. Right.

A. He was appointed head of the team for the medical school and I came along as a boy at that time.

Q. A very interesting opportunity, no doubt?

A. A wonderful opportunity. Because we saw things we had never seen before; diseases we hadn't seen before or even dreamt about. So good medical experience.

Q. Professor Douglas. We have seen his name on some committees and working groups, particularly in the early 1970s. What was his chair?

A. His chair at that time was in the Royal Infirmary in Glasgow and his interest was in blood coagulation and thrombosis.

Q. Right.

A. He then was appointed to Aberdeen University, where he became professor of medicine, and he continued and built up a department in Aberdeen of the same kind as Glasgow with a lot of interest in coagulation and thrombosis.

That continues to this day.

Q. I see. You tell us actually, in paragraph 3, that Professor Douglas' work started in Oxford in the centre run by Professor McFarlane.

A. They were friends and he went down to work there, and at that time his main contribution was he divided the disease of haemophilia into two totally separate conditions. So that was his claim to fame.

Q. Right. Was that really the two of them together or was it more Professor Douglas?

A. Well, he had worked on it and Professor McFarlane was in charge of the unit at that time, in Oxford.

Q. You use the term "Christmas Disease". I suppose nowadays people say Haemophilia B more often than they say Christmas Disease?

A. Well, it depends on the age of the person you are talking to. It is Haemophilia B and it is due to a different defect, a different protein abnormality. Therefore there are major differences in treatment.

Q. A witness in our first block, Dr Norfolk, corrected what was certainly a misapprehension on my part. I thought Christmas had something to do with the time of year but he told us there was a Mr Christmas.

A. There was a Stephen Christmas who was the first patient described with this other defect.

Q. I see. At the end of paragraph 3 you talk about the set-up in Glasgow. You say -- and this is Professor Douglas:

"... was involved in the general treatment of adult patients. Children were treated separately At the Royal Hospital for Sick Children by the then director, Professor Michael Willoughby."

We know that Professor Willoughby is dead. In fact he went to Australia.

A. He did. He went to Perth.

Q. I wonder, Professor Forbes, if you can help us a little bit about the organisation at Yorkhill in the 1970s. I'm fully aware that you were working in adult care at that time but certainly in this block you are our only witness who was in practice in haemophilia care in Glasgow in the 1970s.

I can't put this up on the screen because it's only a hard copy, but this book, which is called "The Yorkhill Story" -- I don't know if you have ever seen it?

A. No.

Q. Right. Well, it happens to be something that I possess. It is published in 1972 and I think, sir, we will scan in the relevant pages in due course, but really the most significant thing about it is that there is nothing

about haemophilia in it.

So it's published in 1972 and I looked up Dr Willoughby and there are two references. We learn from this that Dr Willoughby was undertaking intensive research into leukaemia. That's what's said about him. That's page 168. He is listed at the end of the book -- this is page 195 -- as a consultant certainly. He is listed as the only consultant in haematology and the general heading actually is "Laboratories", and then "Haematology, Dr M L N Willoughby".

I suppose there are a couple of points that arise from that. The first is that at that time haematology is listed under a heading "Laboratories". So in the early 1970s was it perceived more as a laboratory-based specialism than it might be today?

A. Yes. That was a time of change, in which people who were working in laboratories in haematology became more clinically orientated, and as the diseases became more specialised, it became absolutely mandatory that people who were looking after patients had the background of the lab as well. So that's a point of change in which the haematologists became very clinically-orientated.

Q. Yes.

A. Michael Willoughby was a great enthusiast and a very efficient and effective haematologist, but he did look

after the patients in the wards. So he was starting to become a clinician and certainly his interest was leukaemia, but he also had an major interest in bleeding disorders. So he looked after the patients very well. Before that, I would say Professor Douglas and his staff were often asked to go to Yorkhill, which happily they did, and did what was necessary for bleeding disorders. So the cover was there.

Q. Yes. You see, professor, we have had statistics supplied -- really very extensive statistics -- by UKHCDO, and in relation to Yorkhill the number of patients shown in 1970 is only three. In 1975 it is only eight. But in 1980 it is 69 for Yorkhill. So my question to you is: is it really the case that the centre at Yorkhill didn't get going until the second half of the 1970s?

A. Well, as shown by the figures that is true, but it was the fact that there were people there who were able to do what was necessary and to treat the patients from other centres. Up until then they had been scattered all over the West of Scotland, and local paediatricians would look after individual patients. But at this time, as things became more specialised, it was apparent that it was better that they all be looked after in one knowledgeable centre.

Q. Right. You are perhaps aware, professor, that in our first block we looked at statistics for the number of patients with haemophilia in Scotland who looked to have acquired HIV through their treatment and that the figure for Yorkhill is 21?

A. Per cent?

Q. No, 21 boys. The chairman, I think, pointed out at the time that that works out at around 35 per cent. It is difficult to be precise because we only have numbers for registered patients at five-year intervals, but it is really, compared to the adult centres in Glasgow and Edinburgh, very much higher.

We know from the UKHCDO statistics that a lot of commercial product was used at Yorkhill towards the end of the 1970s, around 1980, and we can also see from the minutes of meetings that it was known that a lot of commercial product was being used in Glasgow, particularly in the children's hospital. Do you remember Dr Willoughby having a preference for commercial products?

A. Well, I'm not sure I remember much about his preference but the fact is that the concentrate could be given in a much smaller volume and, as some of these were babies and very young children with a very low blood volume, it seemed very reasonable to use concentrate for them.

Q. Yes.
A. The problem with the cryoprecipitate is that you were having to deal with a big volume and many of these little children couldn't tolerate that.
Q. Yes. I understand that, professor, but I suppose I'm particularly interested in the choice to use commercial products rather than NHS products, because I think at the Royal Infirmary, and indeed at Edinburgh Royal Infirmary, there was a lot of use of NHS product. What was it that made the difference for Dr Willoughby?
A. He may have had money to buy it. Because all that would be bought expensively.
Q. Are you in a position to tell us anything about why he might have had money to buy that?
A. I have no idea.
Q. You have no idea. Was that different from -- sorry?
THE CHAIRMAN: Can you tell us anything about it, Professor Forbes? I think we do have to explore what may be seen to be an anomaly within Scotland in the approach at Yorkhill. So any help you can give us would be valuable.
A. I don't know anything about the purchase or anything of concentrate at this time. I was not involved at all.
THE CHAIRMAN: I see.
A. But if you look nationally there were many other centres

in the UK who were using wholly and totally commercial concentrates at vast expense, and the centres that were doing that or able to do it were Newcastle and some of the London centres. At the end of the day, their incidence of HIV infection in their haemophilic patients was enormous, 90 per cent.

MS DUNLOP: Yes. I appreciate that, professor, but we did do a calculation as at 1980, and all of this is rather approximate, but as at 1980 both in Edinburgh Royal and Glasgow Royal, out of the total concentrates used, the figure for NHS concentrate was around about 90 per cent in both these centres, whereas at Yorkhill, NHS concentrate only made up about 19 per cent of what was being used. At least to us, it appears quite a significant difference.

A. Yes, I don't know if I can instantly explain that. But the perception was that the NHS concentrate was maybe not as effective or as efficient as the commercial concentrates.

Q. Your reference to a possibility that Dr Willoughby had money to buy the material, would that have been in contrast to you. Did you not have a budget for anything like that?

A. We had no money whatsoever. So we used what was available all the time.

Q. Can we move to paragraph 4 of your statement, please? You say, at the end of the period of secondment -- of course, I have taken you rather off your track. I think that's the secondment in Nairobi. You were asked to go to work at the Royal Infirmary?

A. Yes.

Q. I read across from your CV that we are talking here about 1966 to 1968. Is that right?

A. Yes.

Q. Special job in the care of patients with haemophilia and related bleeding disorders. Then in 1968 you went to Cleveland with Professor Ratnoff?

A. That is correct.

Q. I expect that this was extremely valuable experience, was it?

A. Wonderful opportunity, and I stayed two years with him.

Q. I think perhaps we will come back to Professor Ratnoff. By paragraph 5, I think this period:

"1971 I returned to the Royal Infirmary in Glasgow."

You say, I think, by this point you are a senior registrar. Is that right?

A. Yes.

Q. I noted too -- and this is again from your CV -- that you became a senior lecturer and a honorary consultant in 1974?

A. Yes.
Q. Paragraph 6, you tell us:
"The West of Scotland Haemophilia Centre became one of the largest in the country with approximately 300 active patients."
It looks from what you go on to describe there as though you had a sort of open-access policy. Is that right?
A. We did.
Q. How exactly did that work? Was it a nine-to-five service?
A. No, it was a 24-hour service but we did try to encourage patients to come within reasonable working hours, but we had an open-access service 24 hours a day. And many of these emergency patients in fact did need to come in very urgently for treatment.
Q. I suppose the benefit of that would be that a patient who was having a bleed didn't need to go to ordinary casualty; they could come straight to you?
A. We tried to dissuade that. It was very difficult. It took a long time to get the ambulance people and the casualty people to agree that they could be bypassed.
Q. I see. And you say you had an on-call commitment every weekend, no doubt because people have these bleeding experiences at all times of the day and night?

A. Absolutely, any time.
Q. We asked you --
THE CHAIRMAN: Professor, when you took up these positions, was Dr Willoughby still in position?
A. Yes.
THE CHAIRMAN: I don't think we know much about the people who may have worked with him at this time. Do you have any recollection of who his colleagues would have been at Yorkhill? Directly relevant colleagues?
A. Yes. I think you are going to hear next week from one of them, who also worked with us in the Royal and then with him in Yorkhill, and that's Anna Pettigrew. So you are going to hear from her.
THE CHAIRMAN: Were there others?
A. Indeed there were, but the names have gone.
THE CHAIRMAN: The other question: now that you are involved in these roles yourself, the difference between your ability to fund commercial purchases, as it were, and Dr Willoughby's might have been more pointed in your own mind. Were there any particular factors that might have enabled Dr Willoughby to purchase commercial product? He was, after all, dealing with very young children, for example.
A. Well, it would be fair to say that dealing with young children is very much more emotional than dealing with

older patients. I suspect there were funds available within Yorkhill but I have no idea what and how much, and when and who had them and so on.

THE CHAIRMAN: Yes. You simply wouldn't have contact with that information?

A. No, but Dr Pettigrew might have when you see her next week.

THE CHAIRMAN: Thank you.

MS DUNLOP: Thank you, sir.

Professor, can I just backtrack a moment. I wanted to go back to an answer you gave when you said: it is possible that the NHS concentrates weren't seen as being as effective or efficient as the commercial concentrates. Was that your own experience?

A. I think that was a view that we had.

Q. Based on direct experience of a comparison or based on just a general understanding?

A. I think it was from experience that we thought that.

THE CHAIRMAN: Can you say in what respect? I can understand that there could be a whole range of differences, for example, efficiency of administration, the rate of response to the product, the percentage of active proteins as against the total protein content and so on. What would be the measure that you had in mind?

A. I think it was efficacy; I think it was the effect they

had. Maybe also the ability of them to dissolve as readily. So there were a whole range of things that we maybe felt were not as good.

THE CHAIRMAN: We have heard the expression "purity" in this context, which I rather took to mean that the commercial products at certain periods, may have had a lower level of proteins that were not actively engaged in the therapy.

A. I think that would be fair to say on occasions.

THE CHAIRMAN: Yes. Again, if you can help, it would be of great advantage because it's not easy for us immediately to understand what the differences might be unless we are helped.

MS DUNLOP: I suppose, professor, what you were saying about being able to dissolve the concentrate, if we can take that first, that's really a reason related to convenience, I suppose, is it?

A. It sometimes took a long time for the material to dissolve properly and sometimes there was always a residuum of insoluable and therefore wasted material.

Q. Right. And this is your own recollection of working with NHS product, is it?

A. Yes. On occasion.

Q. Right. The other word you used was "potency". So does that -- well, what does that actually mean about an

individual vial of Factor VIII from NHS production? In what sense would --

A. How much Factor VIII is there and is able to be given per vial.

Q. So a sort of percentage proof notion?

A. Yes.

Q. Right. Okay. Your recollection is that that was lower with NHS product, may have been lower?

A. Sometimes, sometimes.

Q. Right. Do you accept, Professor Forbes, that we will have to put these points to people from the protein fractionation centre and people who were directly responsible for preparation of the material, and that they may have other views?

A. Yes.

Q. Right.

A. I would expect them to have.

Q. You were talking about the open-access policy, or the open-access clinic in the West of Scotland centre, and you told us it was a 24-hour, seven days a week facility. Is that right?

A. Yes.

Q. Yes. We asked you if you had seen the World in Action programme in December 1975. We have all seen it because we watched it yesterday, and I think you have recently

watched it too?

A. I have seen it twice.

Q. Yes. You say in your statement:

"I'm not aware of seeing the World in Action programme in December 1975 and indeed did not watch much television at that time."

I just wondered, professor, even if you didn't see it, was it not the talk of the hospital?

A. It was the talk of the haemophilia part of the hospital. Very much so.

Q. Right. So when you say "I was not aware," in your statement, you do actually remember hearing about it, do you?

A. Absolutely.

Q. Yes. What did you hear about it?

A. I think there was a gasp of disbelief when they showed the types of donors that were being used to give plasma in commercial centres, and I think that was the dominant thing in the discussions at that time.

Q. Did you experience a sort of gasp of disbelief yourself when you watched it recently?

A. I did. I was appalled. I think that's a reasonable statement. There was no monitoring at all of these paid donors; and even if they were asked questions, they denied that they had any problems whatsoever but clearly

they did have, and to see them drinking alcohol immediately before they go in for their blood donations is incredible, but of course my view is now tempered by the passage of time, that one would say that is awful.

THE CHAIRMAN: Could you help us about a little bit more? It must have been the talk of the --

A. It undoubtedly was.

THE CHAIRMAN: Because part of the background would be that, at least at Yorkhill by then, there must have been a well established pattern of use of imported commercial material.

A. Well, I'm not sure what commercial product they were using. I think that most of the programme on television was about Hemofil.

THE CHAIRMAN: Yes, it was.

A. And that would be one of the products only that might have been purchased, but I don't know that so I can't comment on that.

THE CHAIRMAN: But if one had by then information from America that the incidence of transmission of hepatitis was much higher anyway in connection with commercial products generally, and if one then saw that programme, would it not have caused quite a stir among practitioners?

A. I think it probably did but I'm not aware of detail of

anything at that time, but I know that people felt that this was not the way to go. And that commercial concentrates of all kinds, probably not just the Hemofil but the other ones, were all tarred with the same brush.

THE CHAIRMAN: That's the sort of impression I thought one might have formed but... Ms Dunlop?

MS DUNLOP: I suppose, sir, going back to the figures in 1975, there are only the eight registered patients shown, according to UKHCDO, and the tables that we have showing usages of product for Yorkhill, only date from 1977. All the Scottish centres provide detail for the use of products from much earlier than that, but for Yorkhill the figures that they provide only start in 1977.

That may be because of some problem with data collection or data transfer; equally, it may be that it's around about 1977 that this sort of treatment on a large scale begins in Yorkhill. But I suppose, given what you have told us already, you are not really able to recall what the explanation might be.

A. I can't help on that.

THE CHAIRMAN: Would it be a consolation to you, Professor Forbes if Yorkhill took up significant usage of commercial products after 1975 in the light of the programme?

A. No comment.

THE CHAIRMAN: No comment.

MS DUNLOP: Well, perhaps we can leave your statement for a little bit, professor, and go back slightly in time. I wanted to ask you to look at a document from 1974. It's the minutes of a joint meeting of the directors of haemophilia centres and blood transfusion directors held in Sheffield on 31 January 1974. It's [SNB0072190].

A. Yes.

Q. You should have that, I hope?

A. I have it, thank you, and I was there.

Q. That was going to be my next question but you have answered that.

We asked Dr Winter about this yesterday but these were really very large gatherings, weren't they?

A. It varied a bit but this one must have been quite enormous.

Q. Yes. The first part I wanted to look at is on page 2194. We can see that at that meeting:

"... there was a wide-ranging discussion about the relative merits of cryoprecipitate and freeze-dried concentrates with regard to ease of manufacture. Some felt it was rather meaningless to ask doctors if they would prefer freeze-dried concentrate to cryoprecipitate when no freeze-dried concentrates were available to

them."

So I suppose when we see the question that was put at the end of that discussion -- "What would you prefer?" -- for some of those commenting it must have been hypothetical, but it is pretty clear, if we read on to page 6, which is 2195, that there was a unanimous preference for freeze-dried concentrate over cryoprecipitate. Do you remember that discussion at all? I mean, I know it is an extremely long time ago but I just wondered if you remembered.

A. I don't remember the discussion but I probably would agree what the conclusion was. But I don't remember it.

Q. Right. If we look at 2197, so if we go on to page 8, we see the sorts of comments with which we are quite familiar now:

"Cryoprecipitate was not ideal. For home therapy from many points of view some directors were buying commercial AHG."

As it was still sometimes known, I suppose, for use in home therapy.

I wanted to ask you about another document from around that time, Professor Forbes. It is [DHF0023161].

A. Yes, I have it, thank you.

Q. Good.

It's quite a heavily redacted document but we can

see it is the minutes of the meeting of the Expert Group On the Treatment of Haemophilia. We have seen this week a bit of information about the establishment of that group in 1973, but it's the minutes of their meeting on 11 October 1974.

If we can just go down, please, on to the following page. Not particularly illuminating minutes. On this page we can see that the list of reference centres was to be revised, and we can see various reference centres listed but there isn't anything about Scotland. So I suppose my first deduction might be that there wasn't actually anybody from Scotland at the meeting. That might be possible. You don't recognise it, I take it?

A. I don't remember.

Q. No. This issue about whether Glasgow and Edinburgh were or weren't reference centres, for example -- I'm not going to go to this, but in the minutes of a meeting of reference centre directors in October 1979, it says that Glasgow and Edinburgh unofficially acted as reference centres. Was that something that recurred over the years, whether Glasgow and Edinburgh were or weren't reference centres?

A. I think they were just accepted as being there and functioning as reference centres. I don't remember when they were first officially designated, but in general

terms we just accepted we were reference centres and functioned as such.

Q. Yes. Certainly in your CV, you showed that you had been a reference centre director. I can't remember the year but possibly in the 1970s. So de facto, as you say, it looks as though there was a kind of understanding that Glasgow and Edinburgh were. But do you think it ever affected the flow of information that the formal designation was missing?

A. I don't think so for one minute. We were in the loop for all the communications, and in fact, as often happens, we were overwhelmed by the amount of stuff that was coming in from all directions.

Q. Can we just look at the next page. As I say, the minutes are not very revealing, but there was a recommendation for spending on home therapy and then there is still some use, if we go down the page a bit. We can see paper 5. There has been some use of cryoprecipitate for home treatment.

A. I don't think we ever felt that we were out of the loop and were being neglected or ignored. So I don't think that's particularly important.

Q. Thank you. I just notice a section at the end of the page we are looking at just now, which is page 4, that:

"Members were of the opinion that many of the

advantages of home treatment could not be quantified, for example the reduction in the number of children crippled or the improvement in the quality of life for patients on home treatment. A costing study would be of little benefit at the present time."

Do you agree with the sentence that begins, "members were of the opinion ..."?

A. I think that that would be out of date now. I think that most people who were on home treatment programmes eventually had better joints and less crippling. So I'm in no doubt that home treatment was the way ahead at that time. While that may have been a very early view, I don't think that in the long-term that's acceptable.

Q. Right. I think the thrust of it, at least to me, appears to be that this was so good that, you know, the pounds, shillings and pence of it was maybe a secondary consideration because of the unquantifiable benefits of the treatment. That's, I think, how I would read it. Would you agree with that?

A. Yes.

Q. Is that the view that was widely held at the time?

A. Yes, I would.

Q. I think you are saying you would agree with that?

A. Yes.

Q. Right. Can we look at another document from around this

time? I think we can deduce from the material in it that it's around about 1974, probably about half way through. It is [DHF00023406].

A. Yes, I have it.

Q. I can give you a minute to look at it. I just wondered about what people really meant by the term "home therapy" at that time. We can see from the first page, again number 5, this preference for lyophilised concentrate to cryoprecipitate, and then different classes of requirements:

"Routine treatment of early bleeding, cover for dental extraction, routine surgery, cover for heroic surgery and major trauma, management of serious bleeding and the growing requirement to provide home treatment."

If we can look on to the following page, paragraph 11 sets out what seems to be envisaged as a kind of holding position until there is enough NHS material. This is for the whole of the UK. But there is a plan or a suggestion that commercial material should be used in three areas and it's the third one I wanted to ask you about:

"... for the immediate provision of home treatment in suitable cases who lived too far from a haemophilia centre to be adequately treated there."

Was it the case in the 1970s, when home treatment

came in, that it was originally really envisaged only for people who lived a long way from the centre?

A. No, it was literally what it says "for home treatment", and the advantage of that was that patients who had bled, let's say into at joint or abdomen, could in fact give their treatment instantly, whereas in days gone by they would have to have phone for an ambulance, wait, get taken to an inappropriate casualty department, wait again, be assessed and then many hours later they would get their treatment.

Q. Right.

A. So the advantage of home treatment was it could be given immediately by the person involved or their family.

Q. Right. So you certainly don't recall in the mid 1970s some sort of principle or criterion that the only people on home treatment should be people who lived a long way away from a haemophilia centre?

A. No, I don't remember that and I don't think that would be a good idea.

Q. Right. I wanted to ask you another question about this period and the use and introduction of the commercial concentrates in particular. We looked yesterday at an article, which I think you may have in front of you -- or possibly not actually. But I can simply highlight two facts from it. It's one we looked at from a journal

called "Transfusion" in 1993, and it's about the evolution of clotting factor concentrates. I don't think you do have it, professor, because I think I can read out the only piece of information I want or need from it. Its reference is [SGH0021947].

What interested me from this was that the first concentrate described appears to have been a Hyland product and it was licensed by the FDA in May 1966. I'm taking this, sir, from page 429 of the article, which is 1954 in the signature reference.

So Hyland had a product licensed by the FDA in America in May 1966 and then the first one called "Hemofil" appears to have been in 1968. Do you remember why it took until 1973 before they came to Britain?

A. I have no idea.

Q. Right. I just thought you might know. I didn't want to miss a chance of asking you.

A. I presume all these would be commercial products.

Q. Yes.

A. And therefore would require money to be found but I have no idea.

Q. They weren't licensed in Britain until 1973.

A. Oh, right.

Q. I suppose the possibilities would be that the companies or the company didn't want to market its product in the

United Kingdom or that for some reason they didn't acquire a licence to do so until 1973, but you don't recall what the story was?

A. No, no.

Q. If we look at our preliminary report at page 568. The signature reference for this is page 16 of [PEN0131433].

I just wanted to look at this, Professor Forbes, because the first mention of commercial product that we can see for Glasgow Royal Infirmary appears to be 1976. There is a reference to Hemofil there. Does that accord with your recollection, that that would be about the time when American commercial products started to be used at Glasgow Royal Infirmary?

A. Well, I have no memory that helps me in this but it must have been.

Q. Right. And actually, over the next few years we don't have any quantities but we can see products from other manufacturers. We can see a product Koate, from Cutter; Factorate, which was from Armour; Cryobulin, which I think was actually from Immuno, the Austrian company. So various commercial products as well as Factor VIII from PFC?

A. I think that was only due to the system we had in Glasgow that, when we wanted something to give, we had to approach the people in blood transfusion, who then

ordered it, and then it depends on what deal they could make with the various companies.

Q. So when you said earlier about not having the money they must have had some sort of resources that they could use to buy it?

A. I'm sure there was some budget for emergency use.

Q. I just wanted to ask you one or two questions now about hepatitis, Professor Forbes, but given that it is five to 11 and it's a new topic, it might be better to have a short break?

THE CHAIRMAN: I think we should have a short break. In terms of timing, would it help to keep it tight?

MS DUNLOP: I think if we could keep to 15 minutes that would help.

(10.56 am)

(Short break)

(11.17 am)

THE CHAIRMAN: Yes, Ms Dunlop?

MS DUNLOP: Professor, can I ask you a few questions about hepatitis and blood products. I take it really from the outset of your interest in haematology, you would be aware of the risk of transmission of hepatitis by transfusion or by the use of blood products? Would that be correct?

A. Yes.

Q. Can we look at a Scottish circular. This is [SNB0057275]. Do you see, this is dated December 1964. It is Scottish hospital memorandum number 89 of 1964. The subject matter is, "Hospital blood transfusion arrangement and the supply of blood products in clinical use".

Looking particularly at paragraph 11, which is on page 7277:

"All blood for transfusion must be regarded as potentially contaminated. The most important transmissible disease in this country is homologous serum jaundice, or serumhepatitis, the incidence of which is five per 1000 recipients of blood or small pool plasma. No transfusion should be undertaken unless the benefits outweigh the risk of hepatitis."

Then, as far as blood products are concerned, 13:

"As with whole blood, these products should be used only when there is a clear clinical necessity."

What's said is that:

"They may carry the risk of transmitting serum hepatitis."

That's the first identified problem. Do you agree with that as an analysis of the understanding of the dangers of transfusion or the risks of transfusion and the use of blood products in the 1960s and 1970s?

A. Yes, totally.
THE CHAIRMAN: Do we have the appendix available Ms Dunlop?
MS DUNLOP: Yes, it is the next page. It is a list of blood products, that's all.
THE CHAIRMAN: Yes, that's what I would like to see just in passing.
MS DUNLOP: Well, we do.
THE CHAIRMAN: Item number 3 is Factor I. It is fibrinogen. So what does that imply as to what's happening in the blood products world at that stage? This is the Cohn fractionation that would be carried out at every blood transfusion centre, is it, Professor Forbes?
A. Yes.
THE CHAIRMAN: It is just to get a starting point because we know that there are some other references that don't quite recognise it as early as that.
MS DUNLOP: Yes, number 7, which is on the next page, is antihaemophilic fraction.
THE CHAIRMAN: Yes.
MS DUNLOP: I think we know from evidence that we heard in the first week of the Inquiry, professor, that there were early attempts to make products specifically for patients with haemophilia, and I think Dr Foster when he comes will be able to chart the history of how these efforts progressed.

THE CHAIRMAN: But someone who had read all the evidence would remember that Dr Colvin didn't acknowledge that this could happen in Scotland as early as this, and that it was only Oxford who could produce the material. It is simply to fill a gap, Ms Dunlop. I'm not interested in pursuing it further.

MS DUNLOP: We know that there was a symposium in Helsinki in 1975, more particularly between 27 July 1975 and 1 August. That was Joint World Federation of Haemophilia and International Society of Blood Transfusions Symposium. Did you attend that?

A. I have no recollection of being there.

Q. Right.

A. But I have been in Helsinki so I may have been.

Q. Right. We have an article which, I think, looks to have been the introduction to the published volume of papers from the symposium. It is [LIT0010150]. We have already noted, I think, that this comes from the Scandinavian Journal of Haematology, in which it was published in June 1977 by Dr Mannucci. Who is, I think, a very well-known name in this area. Is that correct?

A. It is correct, highly respected.

Q. Yes. We can see just from the summary that he is recording that:

"Liver disease after thromboembolism are the most

frequent and severe side effects associated with the use of clotting factor concentrates in haemophiliacs."

Is thromboembolism specific to a particular treatment in haemophilia?

A. It is not a common complication with the treatments available now. There were one or two products that did stimulate the clotting process, causing thromboembolism but from memory it wasn't a major problem.

Q. Was it nor a problem with Factor IX?

A. It was a problem with Factor IX, which could be activated and might cause clotting within the veins and then thromboembolism.

Q. Right. We can see, just staying with the summary, that Dr Mannucci is saying that:

"Complications do not justify withdrawal or limitation of the very effective and life-changing use of concentrates."

But one has to be aware of their occurrence.

A. That was a view we held.

Q. So that would have been your view around the mid 1970s?

A. Absolutely.

Q. How then does the reaction to the television programme fit with that?

A. In what way, sorry?

Q. Well, if the risk/benefit assessment, which seems to be

being described in this article, and which you say was a widely held view, is that the complications of liver disease didn't justify withdrawal or limitation of the use of concentrates, would there be any sort of qualification to that, based on what people were starting to realise about the commercial products from America?

A. Maybe slightly, but at the end of the day the risk of dying of bleeding was always much greater and that was what drove all of us to use these products despite the possible downside.

Q. These international meetings -- I assume you have attended some. You say you were not sure if you were at the Helsinki one but you must have been at some over the years -- were the drug companies usually there? Did they have stands? Can you describe it for us?

A. Yes, I have been to many of them. They are sponsored often by the companies who are involved in the production of materials relevant to the theme of the meeting. Certainly the Factor VIII and IX producers would be at a meeting like that in Helsinki.

Q. Right.

A. And they would be giving hospitality to some of the centres that they were friendly with and not to others. So it was a mixture.

Q. Of course, if they were looking for customers in Helsinki, it doesn't look as though they were successful from what we know about the position in Finland. Do you know that to be the case?

A. No, I don't know anything about Finnish treatment. We did visit one or two of the haemophilia centres there and were very impressed by the Finnish standards of care.

Q. Right. Douglas Starr's book on blood, to which I have already made quite a lot of reference; have you read it?

A. I don't think I know of it even.

Q. Right. Well --

A. Sorry.

Q. We have a lot of it, in fact, in our court book database but he says on page 244, and I don't think we need to have it in front of you:

"Most of the World Federation of haemophilia's budget was paid for by the fractionation companies who picked up the tab for its lavish annual meetings."

Did you know that?

A. I have never been at any meetings that were lavish. So I must have missed out on that.

Q. Right. Just sticking with the theme of sponsorship, if we look at [SNB0016951], this is a symposium of the 19 September 1975 in Glasgow, and if we look right at

the very bottom, in quite small print, we can see that:

"... the Council of the Royal College of Physicians and Surgeons of Glasgow are thanking Travenol Laboratories for their generous support towards the sponsorship of this symposium."

What sort of form would that sponsorship take?

A. I don't remember any detail but I must have been there and probably organised the symposium, but they would support the travel of some of the speakers and they might even have paid for some of the accommodation. I suspect, looking at the timescales here, this would be a day meeting. So one or two of the people would have to come and stay the night before and the sponsorship may have been for hotel or whatever.

Q. I see.

The other thing I noticed from the programme, like many these days, and lawyers have them too, the conference starts with registration at nine and then there is a succession of talks. And there is one on virus hepatitis. It is called, "Virus hepatitis: complicating replacement therapy by Dr Craske". It is not until 4 o'clock?

A. Yes, I see it.

Q. Does that reflect some sort of relative sense of where this stood as a topic, that you discussed a lot of other

topics first and then viral hepatitis towards the end of the day?

A. I think there was a lot to discuss in these meetings. I don't think there is any reason to think this was being dumped to the end of the symposium for any reason. I would have thought that probably was the highlight of the afternoon session. Certainly a very important area.

Q. Okay. We have already mentioned the television programme and the effect it had, and you certainly, I think, recall it being discussed among you and your colleagues. I suppose a number of people would have seen it and you hadn't seen it, so they would be explaining to you what was in the programme. Is that roughly what happened?

A. That's as I remember it.

Q. Right. Do you remember Dr Cash writing to the BMJ about it in January 1976?

A. No, but no doubt I will be getting a bit of paper in front of me in a minute.

Q. Yes, indeed. It is [LIT0010245]. It's the British Medical Journal of 24 January 1976. Here it is.

A. Yes.

Q. You see in the first paragraph Dr Cash is saying that these sorts of programmes can be misleading, I suppose because of editing. Then he says:

"There is no doubt that the import into the United Kingdom of Factor VIII concentrates derived from external sources, however well screened for hepatitis viruses, represents an unequivocal pathway by which the level of a potentially lethal virus into the whole community is being deliberately increased."

What's your response to that?

A. Well, I'm not sure I agree with the wording "deliberately increased", I can't agree with that. But he is certainly very firmly making a statement about how he views the content. I'm not sure I would agree with the words.

Q. Perhaps if we tone it down slightly and said that undoubtedly the import of concentrates is also bringing with it a potentially lethal virus into the whole community, would that be right?

A. I think one would have to say that might be true.

Q. Yes.

A. I'm not sure it was deliberate, though.

Q. No. Well, obviously we are going to get the opportunity to ask Professor Cash about this as well. Actually he goes on to say that:

"The absolute magnitude of the problem was exaggerated."

A. That may have been his view at the time but I'm not sure

if he could look back and say that it's exaggerated or not.

Q. That would be because of everything that has happened with Hepatitis C?

A. Absolutely. It is with the wisdom of hindsight.

Q. Yes. You can put the letter aside, thank you.

I was going to say do you remember but actually this is a meeting that you didn't attend. So it would be very unlikely that you would remember it, but there was a UKHCDO meeting on 13 January 1977 and the minutes of that are [SNB0017117]. We can see that there is a long list of participants, and by now we are recognising more and more of the names. Dr Craske is there. Obviously Dr Bloom, as he then was, Dr Davies from Edinburgh. Then on to the next page, please. Another continuing list of those who were in attendance and down. We can see Dr Peter Jones. Dr Peter Jones was a firm believer in the advantages of home therapy, was he not?

A. He was, he was a great advocate. In fact we wrote a paper on home therapy together.

Q. I suppose you will have had quite a lot of contact with him over the years?

A. Over the years, not recently.

Q. No.

A. I think he has now retired.

Q. Professor, I think I need to ask you about this even though you weren't there. If you look at page 10 of these minutes, which is SNB0017130, if you look at the bottom of the page, where the meeting is talking about supplies of products for treatment, did you know that Dr Jones at that time was a paid consultant to Hyland?

A. No, I have --

Q. Is that the first time --

A. I didn't know that and that's the first time I'm seeing that.

Q. Right. But plainly if you had been at the meeting, you would have known because he declared that as a potential conflict of interest, when the meeting was going on to discuss supply of products.

Also at this meeting a hepatitis working party was formed. Do you remember around about that time the feeling being that it was necessary for the UKHCDO to have a hepatitis working party?

A. Yes. And that was set up and I think it was under John Craske.

Q. Yes. It was suggested by Dr Winter, who gave evidence yesterday that, that he wasn't actually the chairman but I think actually looking at all the paperwork, it does looks as though he was the chairman of the hepatitis working party. Is that your recollection?

A. I think from memory that he was the chairman.
Q. There is a lot of discussion at this meeting about the consequences of the introduction of home treatment and there are passages -- if we go to page 14 which is SNB0017134 -- about the organisation of care and really what was happening for people with haemophilia.

Perhaps if we just read on for ourselves from 14 about the organisation of haemophilia care, and then a Mr Prothero is speaking on page 15, and I think he was from the Haemophilia Society?
A. He was a very active member of the Haemophilia Society committee.
Q. Yes.
A. He was also a haemophiliac.
Q. We can see from the middle of page 15 that the Society felt that the treatment of many haemophiliacs had been much improved. Looking on to the next page SNB0017136, I think it's very useful perhaps to read the passage from 16 onwards because of the snapshot it affords of what life was like for people with haemophilia around about that time.
A. I think these statements from John Prothero are actually very relevant because they are the other side of the coin, that we are looking at the problems but he was saying what a wonderful change to his lifestyle all

these treatments have brought.

Q. Indeed, on to 17 and 18, perhaps it's best if we just read this for ourselves but, as I say an interesting synopsis of many of the changes that were taking place.

I referred to working parties. Can we look at page 21. We can see item 10. This is SNB0017141. Item 10 is:

"Working parties to study problems of interest to haemophilia centre directors and patients."

It was Dr Rizza who felt that means should be found to streamline proceedings and suggested, in the third last line, that:

"A small number of working parties should be set up ... and give only brief reports at the annual meetings."

If we look on 22, we can see that, exactly as you recall, what was being proposed was that the chairman of the hepatitis working party should be Dr Craske, although there seems to have been a little bit of dissent because it has been suggested the meeting should have had prior warning of this proposal. The recommendations had to be circulated for comments. But certainly it looks, at least insofar as that specific detail is concerned, as though the recommendation of Dr Craske to chair the hepatitis working party did become formalised.

A. That is my memory, that he was the chairman.
Q. Yes. The other topic that is discussed at this meeting is the topic of prophylaxis. Do you remember that coming along as a kind of natural development from home therapy?
A. It was a natural development and one that we supported.
Q. Sorry, this is going backwards, but if we look at page 6 -- and this is SNB0017126 -- it is in the context of a trial of prophylactic treatment, that firstly a Dr Kirk is emphasising that the patients selected for prophylaxis were all very severely affected haemophiliacs and there is a question about which regime the boys preferred, on demand or prophylaxis:

"Dr Kirk replied that the two boys with the best results, reduced number of bleeds, wanted to stop prophylactic treatment. The others want to go on. Possibly the two boys with good results had forgotten what a bad bleed was like. Professor Stuart felt that prophylactic treatment for haemophiliacs should not be entered into on a large scale until there was sufficient evidence that it was beneficial to the patients."

What were the reservations about it? I mean, certainly reading here, professor, it seems as though not everybody was convinced it was the way to go.
A. I think the concern was that it was the huge amount of

exposure to plasma products that it would entail. I think the upside is that they would have less bleeds, probably that would be the main thing. But the downside was that the exposure would be so much greater to plasma products.

Q. There was no mention in those minutes of the home treatment working party, but you agreed earlier, and I think we saw it in your CV, that you yourself were on the home treatment working party?

A. Yes.

Q. There is another source of confirmation about that in an article in the BMJ in 1978, if we look at [LIT0010258].

A. We wanted to document the enormous advantage to individual patients in the long-term, who had been on self-therapy, home therapy.

Q. Yes.

A. There is absolutely no doubt in my mind how advantageous it was in terms of a reduction of complications and bleeds.

Q. Just for the record, it's on the last page, which is 1450, LIT0010261. It's on that page that we see recorded that:

"The authors are members of the working party on home therapy of the UK haemophilia centre directors."

So I think Maureen Fearns was a haemophilia nurse?

A. She was in Newcastle. She was the Sister and organised the patients on a day-to-day basis. A very effective lady, I have to say.

Q. Who was John Stuart?

A. John Stuart was the director -- haemophilia director in Birmingham, I think from memory.

Q. Just to look at the second page of the article, so page 1448, which in our database is 0259, it's quite interesting to see the results of your survey set out there. Questionnaires, both in 1976 and 1977, say that 39 of the 48 centres had started home treatment by the end of 1975, and 46 of the 71 centres by the end of 1976. Over that two-year period, the number of haemophiliacs on home treatment or in training rose from 267 to 488. Two patients on prophylaxis in 1975 and 38 in 1976.

You say:

"At the end of 1976, there were 729 haemophiliacs either on or awaiting home treatment in the United Kingdom."

A. Yes, it was a very popular move and this, of course, is before all the horrendous complications came on stream. So this was the golden age, in which we actually seemed to be doing something valuable for these patients.

Q. There is an interesting table showing all the various

products that were in use, and it's evident that if Hemofil and Kryobulin were the first, that they have fairly swiftly been joined by products from other manufacturers, and there is also reference to the NHS concentrates from Edinburgh, Elstree and Oxford.

A. Yes.

Q. At the end, on the following page, 0260, and this is the right-hand side column at the bottom, you say:

"Both the need to carefully monitor the use of blood products and the need for a continual surveillance of patients, because of the possible long-term side effects, demand adequate follow-up procedures. Perhaps the most disturbing aspect of the 1976 inquiry was the lack of adequate follow-up in some centres."

What sort of follow-up do you think you were really meaning?

A. Well, obviously we were looking at follow-up of the particular physical problems of the haemophiliacs, their number of joint bleeds and the deterioration of joints and so on, and so we are looking at that aspect but of more concern was: could giving all these plasma products have a downside, and clearly it did have and that's for the future.

Q. Yes. Actually you refer on 1449 -- that's 0260 -- on the left-hand side under a subheading "Follow-up", one

of the particular tests described as being carried out in centres that were performing follow-up is liver function tests. So at that time, in your opinion that would have been a part of good follow-up, would it?

A. Absolutely. I'm pleased that we had put that in. We had no idea what would happen. And that was major concern for hepatitis and for perhaps other infections that we didn't know about.

Q. Yes. Another piece of information that I noticed, Professor Forbes, about this period, the golden age, the golden moment, relates to the Lord Mayor Treloar School. Do you remember it?

A. Yes, indeed, I went to visit it at one time.

Q. Was it actually called "college", rather than "school"?

A. "College", yes, I think it was a college.

Q. It's just I noticed that by October 1977 the number of boys who had applied within the past year to go to the college was only four. I was just asking you if the school was called a college; I wasn't sure whether there was a school and a college but on any view the numbers were declining sharply and that, I think, was attributed to the change in treatment that had come about. Is that right?

A. Absolutely. And that was a very positive aspect of this time.

Q. Did boys from Scotland go to the school?
A. Yes, they certainly did.
Q. Right. Do you remember some?
A. Yes.
Q. Now --
THE CHAIRMAN: Are you leaving the article?
MS DUNLOP: Yes.
THE CHAIRMAN: Can I ask one question, professor? At this stage, as you recollect it, were there particular indications for starting prophylactic treatment?
A. We felt that most patients would benefit from home treatment and prophylaxis. So the answer is, yes, but it had to be done with care. But this was against a background where we were not aware of the potential number of complications we have subsequently seen. So it looked as though the products were relatively safe, and that we could give them and give them in quite large amounts for prophylaxis or home care.
THE CHAIRMAN: But you don't remember any particular indication such as very severe haemophilia --
A. They were always included particularly, because they were the ones who were going to get maximum benefit from stopping bleeding.
THE CHAIRMAN: Yes. Thank you.
MS DUNLOP: Thanks.

Professor Forbes, could you just have another look at the preliminary report, please? Particularly some paragraphs in chapter 6, 6.69. Sorry, I'm missing the first page of the chapter. I think it is 2431. 6.69, which is on page 153 in the hard copy, is a discussion of a paper in August 1978 from Dr Mannucci about chronic active hepatitis in patients with haemophilia.

Over the page, 6.71, we see a reference to one of the papers from Sheffield. This is 1978, "Chronic percutaneous liver biopsy and chronic liver disease in haemophiliacs". Then 6.72 Dr Craske publishing evidence for existence of at least two types of Factor VIII, associated non-B transfusion hepatitis. Then 6.79 on the following page, 155, there is actually also a work relating to Factor IX by a team including Professor Zuckerman. Taking a particularly cautious line on the use of concentrates.

6.79 says:

"Throughout this period a debate was taking place in the medical community. On one side the view was held, mainly by virologists and public health doctors, that haemophilia patients should not be given concentrates because it was not known what viruses were being transmitted to them. The contrary view, mainly held by the Haemophilia Society and haemophilia doctors, was

that concentrates should continue to be given because they transformed the lives of haemophilia patients and hepatitis appeared to be a relatively benign condition."

According to your recollection of the second half of the 1970s, does that really summarise the differing points of view?

A. All these papers were highlighting something that we did know and understand, that hepatitis was a problem. How much of a problem we didn't really grasp initially, and it's only as these papers came out -- the first was Eric Preston, and I think it was liver biopsy he used, and we were appalled that so many of these patients clearly had liver disease and that was then confirmed by the Mannucci paper and so on. So we were gradually becoming aware that the use of all these blood products was not as benign as we thought it was.

Q. Yes.

A. That was a dawning realisation at this stage and this precedes HIV disease.

Q. Well, indeed.

A. We started to feel anxious about the use of the products that we gave, which were so wonderfully life-changing for the patients, and that's why, of course, the Haemophilia Society didn't want to change anything. They wanted to go on and give as much product as

possible. Because it was thought that the hepatitis that clearly was there was a pretty benign disease, not so eventually, but there we are. That was the state of play.

Q. So these are really just some of the pieces of evidence that were starting to emerge --

A. Absolutely.

Q. -- about what the nature of the problem might be, yes.

Just to look into 1979, back to the UKHCDO. These are actually only draft minutes but they appear to record what happened at the meeting in November 1979, which is [LOT0035015]. Because I think we should note this, Professor Forbes, that you appear to have gone for the first day and not the second day; we can see that from page 3.

A. The problem in life was that one was doing a full-time other job and to get away for meetings was actually quite difficult, but I'm glad I went for the second day.

Q. No, I think it was the first day.

A. Well, the first day.

Q. I think we can all understand the point you make, professor.

Just to look some of what happened at the meeting and some of what was discussed, if we could look firstly at 5024, which is page 10, Dr Craske is bringing

everybody up-to-date about the hepatitis working party, in particular a collection of data, and no doubt he was always very interested in good quality information.

We can see this discussion about the collection of data going through the succeeding pages and on to page 5028, which is real page 14, and also if we look at 5032, which is page 18, we can see the reports of the working party chairman, and perhaps just incidentally to note that this seems to be further confirmation that Dr Craske was the chairman of the working party.

A. Hm-mm.

Q. I suppose the unusual feature of it was that he was chairing a working party of UKHCDO but isn't a haemophilia centre director. Is that why it was unusual?

A. No, but he was an acknowledged expert and a very pleasant man; a great enthusiast for his topic as well.

Q. Just noting from that page that he is reporting the working party's feeling that it was important for the incidence of chronic hepatitis to be assessed, much discussion. I suppose this was a subject which occupied everybody's thinking around this time, was it?

A. It dominated everyone's lives.

Q. Right. Dr Craske is saying, at the bottom of the page, that most patients thought to have developed chronic

liver disease had not previously had an overt attack of hepatitis.

A. Well, it's sometimes very difficult to know. These things are often minor and then with time they change.

Q. In other words, is this really saying that the disease non-A non-B hepatitis was being recognised as having rather an insidious onset?

A. A very benign onset it would seem and then, as we go through time, it changed quite dramatically.

Q. Yes. Then on to the following page, page 19, 5033, there is a statement that there were two types of non-A and non-B hepatitis. I think --

A. I think that it was just a matter of time and we realised that there were different types of hepatitis that hadn't been discovered or explored.

Q. Yes. I think we know enough about hepatitis, professor, to know that it was true that there was more than one other type of hepatitis than A and B but, as far as what was causing post-transfusion or post blood product hepatitis was concerned, almost all of that was actually just one. Is that not the case?

A. Well, there was a lot of debate about that, about the incubation period of this different virus, and I think no one quite knew what was going on but time would sort that out.

Q. Yes. When time sorted it out, the culprit was Hepatitis C. Is that correct?
A. Absolutely.
Q. Yes. Then we can see there is the home treatment working party reporting. So your working party. Interestingly on page 20 -- this is LOT0015034 -- some discussion of prophylaxis again. Actually there has been a trial at the Lord Mayor Treloar college?
A. That was carried out by Dr Erinstan(?), who was the doctor in the college.
Q. Professor Stuart is the one who is quoted as raising the problem of prophylaxis and then the question is posed:

"Had there been any move to find out if prophylactic treatment really did any good?"

Was Professor Stuart really a bit of a sceptic?
A. I'm not sure what word would one apply to him but he was very argumentive. He liked to be the devil's advocate.
Q. Well --
THE CHAIRMAN: Was he unique in that respect among your colleagues?
A. No.
THE CHAIRMAN: No.
A. Plenty of them.
MS DUNLOP: I don't think for a minute, professor, that we could pretend that the medical profession is unique in

that either. But we can see Dr Jones responding to the question and saying that:

"For haemophilia A patients, limited prophylaxis was very effective indeed but it must be for a very good reason."

Perhaps that reflects the point that you made yourself about the exposure that it brought. Then a statement which is perhaps surprising to lay people that:

"One could spend less on prophylactic treatment than on on-demand treatment in some instances."

Do you remember that being thought?

A. This was a very interesting concept because people thought it would be very expensive giving routine treatment but in fact it reduced the amount of bleeding so that over a period of time the number of units of Factor VIII given reduced, and of course, the joint damage and the other things reduced as well. So it seemed to be a very efficient and effective way of proceeding.

Q. Right.

THE CHAIRMAN: The point that's made there by Dr Jones, that prophylactic treatment must be for a very good reason, is part of what lay behind my question about particular or specific indications for its use. Does this help

focus the point in any way, that there may have been particular indications?

A. Well, I think people were still concerned about the volume of blood products being given in prophylaxis and home therapy. So all these things, there was a little question mark in all of them.

THE CHAIRMAN: Yes. It did transpire, professor, that there was a very high infection rate indeed with blood product concentrates. Is that the case?

A. That's how it worked out.

MS DUNLOP: Just one of a number of publications. If we could look at [LIT0010239].

This is an article in the BMJ actually, eventually published on 10 December 1983, although it's evident from the minutes of the UKHCDO meeting in September 1982 that the data was ready by then. We referred to this briefly yesterday, but just looking at the abstract, we can see that what Dr Craske and others had done at Oxford was to look at 30 patients who had not previously received treatment with Factor VIII concentrate or who had been treated only infrequently, and to study them after a transfusion of Factor VIII:

"Tests of liver function were performed frequently. Four of them actually had evidence of chronic liver disease before transfusion but of the remaining 26, 17

experienced raised liver enzymes and ten patients developed jaundice."

Perhaps most interesting of all:

"All of the nine patients who had not previously received Factor VIII transfusion developed non-A non-B hepatitis."

A. Again, this was an early warning paper, which turned out, I think, to be totally true and particular applied to those who were infrequently treated and, of course, they were likely to get, I think, a more severe disease.

Q. Yes, and we should look too at what's said in the discussion on page 1756, which is LIT0010241. You see the discussion in the third line that says:

"All of those who received commercial concentrates developed hepatitis regardless of their transfusion history. Those who received NHS Factor VIII were less likely to develop hepatitis if they had been treated before and all nine patients who received NHS Factor VIII for the first time developed hepatitis."

This is quite a small study, professor, isn't it?

A. Well, it's a small study but it actually is quite alarming and does show that even the NHS product is likely to cause hepatitis.

Q. I suppose --

A. Despite the small numbers, I think that's very

significant.

Q. Yes. I mean, is there a reason why it would be a small study?

A. It's just the problem of getting patients together and doing these studies which are very time-consuming for the people doing them.

Q. Yes.

A. And the follow-up and so on.

Q. They have to be previously untreated patients as well.

A. That was the problem. That always made the studies much smaller.

Q. Yes. You did some work, I think, in this area yourself, and perhaps we can just look at a letter, which is [SNF0012890]. I'll just let you read it. (Pause)

A. As you say, it's very difficult getting patients together who are willing to take part in studies at this time. So I'm not sure just how successful this project was.

Q. Well, it does looks as though you have run a study of your own because Professor Cash is saying at the end of the third paragraph:

"You will recall you advised the working party that you had data which indicated that the results from the Oxford study ..."

That's the one at which we have just looked at:

"... were identical to yours."

A. Yes. I don't remember the detail of the study but it would be very small, with virgin patients.

Q. Right. So in light of the fact that we have searched and not succeeded in finding a letter going back from you to Professor Cash -- and I intend no criticism in that, and it may exist somewhere but we haven't found it -- you are not able --

A. I may not have written back to him.

Q. You are not able from your own recollection to give us any details of your study --

A. I have no details in my mind at all about that, I'm sorry.

Q. Right. But we can at least take from the letter that it does look as though your research was along the same lines as Dr Craske's?

A. Indeed, yes. I will certainly ask colleagues at the end of the session.

Q. Right. Your research and your results, I think.

A. Yes.

Q. Yes. Thank you.

That was a very long digression, professor, but we need to go back to your statement, [PEN0150254], and look at 0256. In paragraph 7 you are answering a question about sponsorship again. We should just look

at the document, [SNB0017296]. This is actually not a programme like the previous seminar, this is actually the UKHCDO minutes. It looks as though what happened in 1980 was that the UKHCDO came to Glasgow.

A. That is correct.

Q. Then at the end there was --

A. We organised a day symposium on the current problems of haemophilia and that was published.

Q. Yes. "Unresolved problems in haemophilia". We have actually got the book, professor. All the papers were published as a book with that title but I just wanted to note that from the minutes -- that's [SNB0017296] at 7310 -- you had obviously had to organise the UKHCDO meeting and then there is the one and a half day symposium organised by you --

A. Yes.

Q. -- and the Royal College, and again sponsored by Travenol. In your statement you really say, I think, the same as you said in relation to the 1975 symposium, that:

"There was no payment to individuals. Speakers no doubt got travel expenses but as far as I am aware, there was no direct payment of any kind, certainly not to ourselves."

That's paragraph 7. Sorry, I need to go back to the

minutes because there were one or two other points of interest in the minutes of that particular meeting.

THE CHAIRMAN: Before you do that, can I just have one follow-up?

Professor, was sponsorship of this kind peculiar to companies providing blood products or was it something that happened generally in relationships between the pharmaceutical industry and the medical profession? Do you know?

A. This was the general way of organising and funding symposia. So whether it was about peptic ulcers, something like that, it would be money from the pharmaceutical industry because these educational symposia, there was no other way of funding them. So this was normal.

MS DUNLOP: Thank you. Why did and do the drug companies oblige?

A. Well, they are very dependent on the goodwill of the profession. You must speculate on their own reasons for funding but usually these are done for altruistic reasons.

Q. Well, do you think that benefits do accrue to them from this sort of activity?

A. I think they must. They wouldn't have done it otherwise. But there is no hard sell in any of these

scientific symposia like this. There is no immediate rushing off to prescribe drugs from the sponsoring company. But I'm sure that in the long-term they must feel there is a benefit. Certainly medical education would not have occurred to nearly the extent it did and had to without the help of the pharmaceutical industry.

THE CHAIRMAN: But some others might know that, for example, in relation to a drug like the statins, Astro-Zeneca and Pfizer are, and have been for a long time, in direct competition. There surely would be some commercial objective on the part of either of those companies in sponsoring --

A. I'm sure there must be but, so long as it is not overt in the forum of the symposium, that, I think, is acceptable.

THE CHAIRMAN: So it would be unacceptable if there were overt marketing --

A. Absolutely.

THE CHAIRMAN: -- techniques adopted.

A. Absolutely, and the pharmaceutical companies, to give them their due -- I know that we love to hate them -- but in fact they were always very good and very sensible about this kind of area.

MS DUNLOP: I suppose there might be different types of benefits to them. There might be a general sense that

those attending would get the benefits of a type of product. So if there is a new kind of drug that has arrived, then this might be an opportunity to disseminate information and then if we are not really in that area, there is maybe an opportunity to promote your own drug as distinct from a competitor's drug. Is that a reasonable hypothesis?

A. I think that is possibly true. However, in this particular area, with this new disease, or diseases, I'm not sure there were any particular drugs that they were proposing or sponsoring. So ...

Q. Yes. Certainly we have seen that, although initially in 1973 there were the two concentrates, two commercial concentrates, they were reasonably quickly joined by concentrates from other companies. So was there a degree of jockeying for position?

A. Oh, certainly.

Q. Professor, we were looking at the minutes of the UKHCDO meeting in Glasgow in 1980. Just to go back to those minutes, [SNB0017296], and to look at page 6.

Professor, we are trying, for reasons I think you understand, to find out a bit about Yorkhill and about Dr Willoughby's practice, but do you see there is a quote towards the bottom of that page from Dr Willoughby. Does that ring any bells for you? Do

you remember him being particularly committed?
A. He was a very committed clinician and this I can accept would be what he would believe, and I would also think that that's a very reasonable statement to make, that the commercial concentrates, if given often enough in sufficient volume, might well have resulted in less crippled adults.
Q. Yes.
A. So I'm endorsing that statement of his.
Q. It's actually interesting also to look -- reminding ourselves that this is 1980 -- at where Dr Craske was in his thinking at this time. If we look at page 9, we can see, as usual, a report from Dr Craske as chairman of the working party on hepatitis and reading on to page 10. I did take you out of chronological order to look at the article we looked at, that was published in 1983, but do you see there at line 4:
"Dr Craske felt that increased usage of small pool concentrates would help to reduce the incidence of hepatitis. First-time exposure resulted in many cases. Professor Bloom [is] wondering about cryoprecipitate for mild haemophiliacs ... he pointed out there was a problem over the amount of Factor VIII in these materials. [Then] Dr Craske agreed and said that the NHS product was certainly better than the commercial

products because of the screening of the blood donors and the regular donor panels which were used in the UK."

Firstly, what about Professor Bloom's question:

"Cryoprecipitate is a better product for mild haemophiliacs."

As at 1980?

A. Yes, well, that was his view and indeed it was probably our view because that's the product that we had readily available and so we would endorse that view. The problems of cryoprecipitate we have talked about before and it still was a problem. It's the volume, the number of donations needed, the method of making it up, the time involved and so on. So that's why it fell out of favour.

Q. Yes. How did you happen to have it readily available?

A. We had a very good relationship with our blood transfusion people and if we asked for 20 or 30 donations, they would have it available within half an hour or so. It was a good relationship thing.

Q. At that time, this view of Dr Craske's about the NHS product being better than the commercial products, I mean, is it your impression -- and I suppose I'm alluding again to the material we just looked at from 1983 and 1984 -- that that was an accurate feeling?

A. I'm not sure it was right. Looking back, I'm not sure

that what he is saying is accurate.

Q. Yes. But maybe it was something that certainly a number of people believed?

A. It certainly was.

Q. Yes.

THE CHAIRMAN: Professor, how could the Glasgow BTS produce 30 units in half an hour? It suggest a sort of captive donor population.

A. These were not donations that were taken. They were stored in deep freezes, and in fact the blood transfusion in the West of Scotland had a very active programme of their donation sessions, of asking people if they were willing to give for this purpose. So we had a huge deep freezes full of material in little bags that could be frozen, defrosted and used. So it was a big effort but they did it.

MS DUNLOP: And this would be something that was not coming from the West of Scotland headquarters at Law Hospital. It was more local than that, was it?

A. Yes, we had a section of blood transfusion within the Royal Infirmary.

Q. I see. Can we look at the minutes of a Scottish meeting now, rather than a UK one, [SNB0015055].

A. Yes, I have it.

Q. Good. This is one you were at?

A. Yes, I was at it.
Q. Yes. Firstly, perhaps we shall note before we look at the minutes that Dr Pettigrew is at that in place of Dr Willoughby.
A. Yes.
Q. But commercial purchases of Factor VIII are referred to at the bottom of the first page. 1979 and 1980 figures seem to have shown that a significant and apparently increasing quantity of commercially produced Factor VIII was being used. I'll just let you read on.
THE CHAIRMAN: Could we see the following page on the screen?
MS DUNLOP: Of course, yes. (Pause)
This is a meeting, professor, where the haemophilia directors are represented but also the Blood Transfusion Service. What was the kind of tone of the discussion, particularly as far as the BTS representatives were concerned? The increasing commercial purchases are being referred to. What's the sort of tone coming from the Blood Transfusion Service?
A. We always had very good relationships with the blood transfusion people. There were no overt hostilities, and I think it's just a statement of the situation as of this time, but I certainly don't remember any antagonism.

Q. Were they disappointed?
A. I think they were working uphill all the time, trying to keep ahead of the game, but a very difficult thing to do. But we had, as I said, very amicable relations and we usually got enough of some product to treat. So there was never a shortage like that.
Q. Professor, I understand that for the haemophilia clinicians, they are, of course, thinking of how best to treat their patients, but what was the wider policy context of these kind of discussions?
A. Well, there were obviously major financial implications but also implications in terms of policy regarding the taking of blood and getting enough donors to give the blood for the product. But at the end of the day I think we muddled through, and maybe I'll not say it any higher than that. But there were times where there was a great shortage of product.
Q. I just wondered, in referring to the policy background, if there was a policy imperative in favour of self-sufficiency?
A. Well, it was always in the background. I think we all thought that unless a huge investment was made in the plant for SNBTS that it wouldn't happen. I'm not sure it ever did happen until much later on.
Q. Well, what, as far as you can remember, was the attitude

of the haemophilia clinicians towards these sort of ideas about one's choice of product?

A. Well, the attitude is, "Give us enough of a good product". That's always what we were at them about and it was a constant theme. It wasn't just one meeting that there was a conflict of interest. It was to get enough effective product.

Q. Were you aware of any kind of policy being set from outside or above?

A. I think nothing but help. The chairman of that meeting was Dr Bell, who was an old friend of mine; in fact my class mate. We had nothing but help. But there was only so much they could do about it.

Q. Do you think they had a particular view as to what they wanted to see or were they essentially neutral?

A. Oh, I think they were totally neutral and probably very helpful. So not just neutral in sitting with their arms folded but trying to get on with it.

Q. So you don't think that there was any kind of steer coming from SHHD as to what ought to be happening in this area?

A. Not at all.

Q. If we look down a little bit, we can see discussion of home therapy, unsurprisingly, and then cryoprecipitate yields and use. Dr Cash is saying, by reference to

a paper, that cryoprecipitate could be very important:

"The increase in home therapy would place such a strain on resources that all options had to be studied, including serious consideration of the use of cryo for this form of treatment."

Well, could cryo be used for home therapy?

A. Well, the answer is, yes, it could be, but it was a much more difficult thing to make up, to store so many bags, to have a water bath to defrost them, to then pull them all together into one pack and then to take the pack, draw it up and give it. So it was possible but not the ideal material.

Q. Right and people could do that at home?

A. They could do it, and did do it at home but with difficulty.

Q. Right. Look on to the next page, so on to page 3; this is SNB0015057. There is a reference to a Council of Europe paper, a Council of Europe recommendation concerning blood products for the treatment of haemophiliacs. Does that paragraph, paragraph 6, ring any bells?

A. Not at all. I wasn't aware of it. At the time.

Q. What about attitudes to recommendations of the Council of Europe more generally?

A. I don't think we had any problem with the

Council of Europe. I didn't know anything about it, to be quite honest, at this time.

Q. Did that change?

A. I don't think so. I'm not sure what part they were playing in it. I have subsequently looked at the papers which have been provided in retrospect and I'm sure that they were saying the right things but I wasn't aware at the time.

Q. Can we look on to the next page, please, paragraph 9. This question of designation of the Edinburgh and Glasgow as reference centres seems to be rumbling on, doesn't it?

A. Yes, I'm surprised. I never at the time thought of it as any problem or concern. We certainly didn't feel slighted or anything like that. So we just accepted we were reference centres, whether we were or not is another question.

Q. It's interesting to note from the next page, the final page, that there is a decision to have a smaller body, a working group, chaired by Dr McDonald, and comprising Dr Cash, Mr Watt, somebody else from SNBTS and directors from Glasgow and Edinburgh.

Just to look, again around this time, at UKHCDO -- this is October 1981 -- [SNB0017354]. If we look down the first page, we can see quite a lot of names we

recognise and then on to the following page, please. I think this is one, professor, where you weren't there and I don't think your apologies are there either, but, please, I don't want you to take that as a criticism. No doubt if you did not manage to attend one of these meetings, it was reported back to you what had happened?

A. Yes.

Q. Perhaps we can note without comment that the designation of Edinburgh and Glasgow -- actually not perhaps so obviously Glasgow -- certainly Edinburgh and Belfast is cropping up at 7361 if we look at page 8. Yes. By this time it seems to be under discussion at SHHD. What would there be to discuss?

A. Well, I have no idea.

Q. No, right. Page 9, SNB0017362, there seems to have been a bit of debate about arrangements for purchasing, holding and distribution of blood products stocks. This is something that has been raised by the Department of Health. So obviously a primarily English initiative, but it says that the reference centre directors were very disturbed at this suggestion. Do you remember controversy in this area?

A. No, no, no.

Q. Well, perhaps to prompt you slightly, there is the comment that it has been agreed at the last meeting

that:

"Responsibility for the control of stocks of coagulation factor concentrates should not be moved from the haemophilia centre directors to the Blood Transfusion Service."

Do you have any memory of what the fear was?

A. No, but I can guess what the problem was: that the haemophilia centre directors were the people who were responsible to individual patients to provide treatment at the drop of a hat often, when they had a major bleed. So they were the people who were liable to be approached at short notice, and therefore if stocks were held elsewhere, then it might take a long time for them to be delivered. So I presume that's the background.

Q. Right. Hepatitis, of course, featuring again. This is page 19, SNB0017372 --

THE CHAIRMAN: Do you have any comment on the note at the last paragraph that:

"In accepting the decision, the Department of Health had insisted on proper records being kept of purchases and use."

A. Well, I think that had been a problem because people would come into the centre and they would get treatment and no one would document the batches and so on. So there was little documentation of individual things.

That was tightened up greatly, and correctly tightened up.

MS DUNLOP: Why else did there need to be records of what the usage was?

A. Well, one had to know how much was being used and who had got it and we were very aware of the problems that there may be complications so that we could always refer back to the individual batch numbers that had been given to an individual patient, and if there was hepatitis or something else, then we could follow it up back to the donor.

Q. Right.

A. So good record-keeping was absolutely mandatory.

Q. But records of usage would be useful in a wider sense to the Blood Transfusion Service, would they not?

A. Oh, of course.

Q. Would it not enable them to plan for the future? They could get an idea of total usage?

A. They had to plan all the time.

Q. I think I had asked you to look at page 19, SNB0017372.

A. Yes.

Q. This is a multi-centre prospective study of hepatitis and first-time treated or seldom treated patients was planned:

"These patients seemed to be running a higher risk

of contracting non-A non-B hepatitis whatever type of material was used."

And we have discussed that. And then on page 20, 7373, Dr Craske is again reminding the directors of the importance of reporting?

A. Again, he is emphasising the importance of keeping good records with the batch numbers of the material given. So it is important.

Q. Just to look at the home treatment working party, page 21, SNB0017374, mention of prophylaxis again, and then interestingly on page 22, 7375, we can see Dr Jones posing questions from the report on the 1980 annual returns and the first is why some mildly affected haemophiliacs were receiving home therapy. So why has that struck Dr Jones?

A. Mild patients would not normally bleed frequently and it would seem that that is not the right use of home therapy. And I would endorse that. Mild patients shouldn't need to have home therapy.

Q. Then the second question, whether all patients who should be on home therapy were now receiving it. I think we can understand the thinking there.

There is rather a change of tack, professor. If we look back at your statement, and the number of that is [PEN0150254]. We are now looking at paragraphs 8 and 9.

I wanted to leave the first sentence of paragraph 8 for the moment. Well, in fact leave most of it for the moment and look at paragraph 9. One of the things you say in paragraph 9 is that you were looking at immunity in patients with haemophilia:

"It is quite apparent that there was an association between the administration of large amounts of Factor VIII concentrate and the immune process, which was suppressed in many patients. A variety of other investigators are finding the same kind of abnormalities. What [did] this mean? Was there something in the Factor VIII or IX concentrates that did suppress these tests of immunity?"

This is an area in which Dr Ludlam in Edinburgh was interested too, is it not?

A. Yes, it is.

Q. I'm certainly planning to ask Professor Ludlam about this whole topic but I don't know if there is anything that you would want to add on the question of immunological abnormalities in haemophilia patients generally?

A. We became interested because of the ability to measure so many of the factors in blood. And we were kind of thrown off the scent at this time by finding that a lot of our patients who had been highly treated, a lot of

protein given to them, had abnormalities of various kind, not all the same kind, and we thought that it must be that their immune system was being suppressed by something in the plasma that they were given, and that was a view we took and explored for several years. And I think it was probably accurate to say that there were abnormalities but what they meant, we didn't know, and of course, some of it probably was that they were infected with the unknown virus, HIV. So we were looking for something but we didn't know what we were looking for at the time.

Q. Right.

THE CHAIRMAN: Could I follow this because I find this quite a difficult and interesting area.

MS DUNLOP: Yes.

THE CHAIRMAN: I get the impression from some of the literature that there was a developing thought that the progressive deterioration of immune response, however measured, might have been, as it were, part of a progressive condition that could eventually result in the sort of immuno-deficiency that was associated with AIDS.

A. That was our thought. The problem was to try and prove what this was all about, and that was why we followed it up for many years. Whether it was HIV or not, I don't

know. I suspect some of it was. And it may well be that the immunity of individuals was depressed and then they got infected with HIV. And I'm not sure that anyone has explained that fully yet.

THE CHAIRMAN: But the obvious point of interest is the conflict that there was as to whether the aetiological agent was a virus or whether it was simply the end product, the end stage, of a progressive development that was not related to an external virus.

A. I think we don't know the answer to that yet. Not all the patients that we were studying became HIV-positive.

THE CHAIRMAN: No.

A. So it may be that there was something else going on which was not yet fully defined.

THE CHAIRMAN: But you don't think that even now the issue has been finally resolved?

A. I don't think. So I think there is lots to know about this yet.

THE CHAIRMAN: I think Professor James is suggesting to me it never will be. It is just something that will not be resolved.

A. Maybe the time has slipped by and we will never be able to revisit in the same state.

THE CHAIRMAN: The source material has gone and that's that.

A. Absolutely.

THE CHAIRMAN: That may be as far as I can take it.
MS DUNLOP: Yes, I was just going to ask, Professor Forbes, and this is, I appreciate, going a little bit further forward in time, but if it had been the explanation for the sorts of illnesses that started to develop in patients with haemophilia in the 1980s, when they began to suffer from pneumocystis pneumonia and some of the other diseases that were associated with AIDS, if that had been caused by the concentrates, rather than caused by a virus, it would still not be at all reassuring, would it?
A. Not in terms of treatment and the need for treatment.
Q. Professor Forbes, you do say in paragraph 8 that you received a phone call some time in 1980 from Professor Ratnoff, and you say that he was asking if you had seen any unusual types of haemophilia. I should have given the reference. I'm sorry. We are back in your statement at [PEN0150254] at page 3. So 0256:

"Oscar Ratnoff was asking if [you] had seen any unusual types of haemophilia in which patients were clearly ill with various opportunistic infections and tumours."

We did ask you: do you think it could have been later than 1980?
A. Well, I was doing this from memory but it was before the

whole AIDS story started to come into the public arena. So 1980 probably was about the time that we spoke.

Q. When would you say the whole AIDS story started to come into the public arena?

A. It was the first publications in Morbidity and Mortality Weekly, and that's another two years or at least a year.

Q. Right. It seemed to us -- and obviously we are not medically qualified -- that most accounts of the period begin with the report in the MMWR in June 1981, of the opportunistic infections in five homosexual men, and are you saying that Oscar Ratnoff was in touch with you before that?

A. Yes, he was in touch about a particular patient he had been referred, who was a haemophiliac and it was clear that there was some funny immune problem in this patient's blood and he was obviously ill and eventually died. So this was an early warning of what was to come.

Q. What did you think at the time?

A. I was astonished. I had never seen anything like it in any of the patients I looked after.

Q. This is a phone call. So was there just the one contact. He telephoned you and you had a discussion or was there more than one contact?

A. No, there was one contact at that time but it rapidly was followed by a publication in which he described all

the features of this man.

Q. Right. I think perhaps we need to try to find that. I wasn't aware that he had published on it. He wrote up the case, as doctors say, did he?

A. Yes.

Q. Right?

A. And it was a multi-author publication. It must have been in 1981 or 1982 or something like that.

Q. Right.

THE CHAIRMAN: Can you remember where it appeared?

A. I think it was New England Journal of Medicine. I have to say it should be easily identifiable.

MS DUNLOP: Yes. It is just that, professor, again, as outsiders in all of this our impression has been that the first reports of something like the new syndrome in people with haemophilia were in the summer of 1982, but if you are right, you think it might have been published later.

A. I think it would be published by that time but I have to say that we all accept that the first revelation was in these Mortality and Morbidity Weekly. So 1981/1982. But if you go back into the literature, you will find several case reports of funny diseases which were well described, which almost certainly were AIDS, long before the official date of 1982.

Q. Quite. But would that be true of patients with haemophilia? Would you find reports of funny diseases in patients with haemophilia?
A. I think this may be the first one.
Q. Right.
THE CHAIRMAN: I think we know of a case in 1960.
MS DUNLOP: Yes, but I don't think in haemophilia.
THE CHAIRMAN: No, indeed.
MS DUNLOP: No.
THE CHAIRMAN: But the difficulty, I think I see at the moment, is that if the case were fully written up in that way in 1981, then the disclosure of AIDS syndrome in haemophilia patients in 1982 and 1983 might have been expected to, as it were, resurrect the earlier case and I'm not sure we have seen anything that suggests that.
MS DUNLOP: No, we haven't but equipped with the name of "Oscar Ratnoff", we can have another look.
THE CHAIRMAN: Indeed.
MS DUNLOP: That's certainly so and we will report back to that.
A. I think the lead author of that Ratnoff paper was a man, Manitove, and I'm sure it was the New England Journal of Medicine.
Q. Thank you for that, Professor Forbes.
You go on to say in your statement -- and this is

looking at paragraph 10 -- about the growing awareness. I think initially you had said that, subsequently it became apparent that plasma concentrates of all types could be contaminated with a virus which was generally known as "HTLV-III" and later as "HIV". We asked you what period you were really referring to here and you have added a bit into the statement in answer. You have said:

"This was meant to be a global statement of the next few years, probably five years, from 1983."

In the preliminary report we referred to a report in MMWR at the end of 1982 of AIDS in a 20-month old infant, who had received platelets from a man who went on to develop AIDS. That's one piece of evidence but I think we have already heard other witnesses suggest that that was an important piece of information. There was more information in the succeeding months. So I wanted to suggest to you that actually what you say in paragraph 10 about the idea of an infective agent being transmitted, was pretty clear by the first half of 1983. Would you accept that?

A. There was still a lot of doubt about it and many people didn't believe it was an infective agent. There was a lot of argument: so it wasn't hard and fast at that date. But it rapidly became so and most people in fact

did think it was an infective agent that was transmitted.

Q. Professor Forbes, I'm asking you to think back 28 years, and that's a challenge that would defeat many of us, so please say if you don't want to answer this, but around this time -- and I mean early 1983 -- what did you think?

A. I was absolutely astonished by what was coming out and it was clear that there was something happening. We didn't know what. I personally, and most of my colleagues, guessed it probably was some kind of virus that we had never encountered before, which I think was right, but it took a long time to get the proof of that and therefore all this was speculation at the time. But one had to do something to try and stop the spread of it or find out more about the spread of it, and that was very difficult.

Q. Thank you.

Perhaps, sir, we could carry on after lunch.

THE CHAIRMAN: Yes.

(1.00 pm)

(The short adjournment)

(2.00 pm)

MS DUNLOP: Professor Forbes, we have really looked at your statement up to about paragraph 10. I think we can pick

up there. You say in paragraph 10:

"It was certainly not possible to stop the use of concentrate as bleeding would have resulted in death, and the general reaction of most haemophilia directors at that time was to continue to treat the bleeding with concentrate."

Then you return to the immunological abnormalities. You say:

"It was speculated that something in the concentrates suppressed the immune system."

I suppose, if, you know, at that time, in another world, if concentrate treatment had not begun and all of these other developments had been apparent from the United States, would you have wanted to begin treatment with concentrates in Glasgow?

A. It's a very difficult question. I think you have to take into consideration the use at this moment of time and not think about what has subsequently happened, and I think that probably one would have wanted just to continue to use concentrates.

Q. So really a factor in the decision was that one was maintaining the status quo, carrying on what patients had got used to?

A. Well, there is that but they certainly were used to being treated, and I think the decision rightly was made

to continue treatment with concentrates.

Q. You say in paragraph 11:

"The subsequent history is well set out, chapter 8."

Then:

"In 1982 the first documented cases of patients with haemophilia with AIDS were recorded. The progression of the disease ... range of symptomatology ... typical of other patients in other risk groups."

Then you say in paragraph 12, and you have already mentioned this:

"It is worthwhile noting that in retrospect other patients who probably had AIDS had been recorded intermittently."

A. Yes.

Q. You say at the end of paragraph 12 that:

"The reported incidences in the third group, people from Haiti, has never been satisfactorily resolved."

A. I think that's right, I think there is no very good explanation as to why people coming from Haiti had an high incidence, and one can speculate obviously about lifestyle, but I don't think there is any proof even now as to what went wrong there.

Q. Certainly we have seen a number of references from those years of the groups all beginning with "H", and this is certainly one of the "Hs" that one sees in a number of

the articles, in terms of the high risk groups.

Paragraph 13. You say:

"The report in MMWR ..."

You are meaning July 1982:

"... was the first report of transmission in blood products."

I suppose it was a report of AIDS in haemophilia rather than definitively a report of transmission in blood products. That might be more accurate, would it?

A. Well, they kind of came together at that time but when I wrote this, I was meaning haemophilia. I should have said transmission in Factor VIII but they came at the same time. Like a bolt from the blue, I have to say.

Q. Yes. Then you say:

"Over the month to come ..."

And this is paragraph 14:

"... it became clear that AIDS was not limited to the United States but was now present in the UK with small numbers of patients being diagnosed."

One thing I was going to ask you about was an event in 1982, one of the other haemophilia clinicians drew our attention to an international symposium that was held in Stirling in June 1982. It is the second international symposium on infections in the immuno-compromised host.

And according to him Acquired Immuno-deficiency Syndrome was the talk of the symposium. Were you at that?

A. No, I have not heard of this at all. Stirling in Scotland?

Q. Yes, our Stirling.

A. Our Stirling, okay. No, I don't know anything about it.

Q. You say at the end of paragraph 14:

"We in the West of Scotland continued to use cryoprecipitate for both routine treatment in the centre but also for distribution to people on home therapy."

So I suppose that really picks up something you said this morning, that cryo was in some instances used for home therapy?

A. Yes.

Q. What sort of patients with haemophilia would be having cryo at this point for home therapy, rather than concentrates?

A. Well, in reality, we had to give them what we could and they had to accept that that was what was available. They had to be pretty intelligent to use it correctly and effectively and make it up themselves, and I think that that was a limiting factor.

Q. Did you increase your use of cryo?

A. I'm not sure that I can answer that accurately, whether

it was increased or not. But the figures were there and were collected annually at that time. So the information must be available somewhere.

Q. Yes. On 22 March 1983 there was a meeting of the haemophilia and blood transfusion working group at St Andrew's House, and the minutes of that are [SNB0015183].

A. Yes, and I was there, I see.

Q. You were there. I think this is the group we saw being set up in 1981.

A. Absolutely.

Q. So a smaller number of people than met at the annual meetings. I think it was to look at issues of interest in between the annual meetings. Chaired by Dr MacDonald. We see a number of issues were discussed including heat-treated Factor VIII:

"The development of new heat-treated Factor VIII at PFC."

Mr Watt was there and gave a progress report. On to page 2. It was suggested that the new products should now be given to a small number of patients for clinical evaluation and you and Dr Ludlam expressed willingness to take part in trials.

A. I think the clinical trials were the only way ahead at this time. So we were happy to do that.

Q. And then AIDS was discussed. We can see that if we go a little bit further down the page. Dr Ludlam reported that in the UK a letter and questionnaire had been sent to haemophilia directors:

"AIDS was an emotive issue in the USA and Canada and was causing a move away from factor VIII to the use of cryo with the resultant supply problems. There was concern that AIDS might appear in the UK and the Haemophilia Society was attempting to reassure its members and put fears of infection from blood products into perspective."

Do you have any memory of this meeting, Professor Forbes?

A. Well, I have to say I don't remember the meeting but the sentiments were quite clear, that there was a wave of tremendous anxiety about HIV infection and its transmission. And a lot of depression in the group of patients who were being exposed to the chance of infection.

Q. That particular recorded concern, as at March 1983, was a concern that AIDS might appear in the UK; do you think that was the extent of the concern?

A. I think most people thought that it undoubtedly would appear in the course of time, and already we were starting to look rather differently at our patients to

see if they had any of the features that might be an early warning of AIDS.

Q. If we look on to the next page, we can see the transfusion directors are considering how best to ensure the safety of plasma supply, and you were conducting a sample study of the immunological status of haemophilia patients.

A. Yes.

Q. And it's that work that we saw, I think, mentioned in your curriculum vitae, work with Dr Karen Froebel and others, Dr Melbye, is it?

A. Melbye.

Q. Melbye, sorry. So that would be that work, would it?

A. Yes.

Q. Now, you were also asked --

THE CHAIRMAN: Could I ask a question?

MS DUNLOP: Yes.

THE CHAIRMAN: Professor, I get the impression from what you have said so far that the use of cryoprecipitate in your area was largely a response to what was available. Is that right?

A. Yes.

THE CHAIRMAN: I have read some comments that suggested that there was a more positive preference for cryoprecipitate in the West of Scotland from time to time. Do you have

any recollection of that? That it was the product of choice rather than simply what was available?

A. I think that often we had no choice but to take what was available at that time, provided by SNBTS and that was usually cryoprecipitate. There were concentrates coming on stream, made locally in Scotland, and for all kinds of reasons we worried about the efficacy and safety and so on. So our preference was still for cryoprecipitate.

THE CHAIRMAN: Yes. I'm not sure if that helps resolve all of the issues that there might be.

MS DUNLOP: No.

THE CHAIRMAN: But we may simply have to leave it at that.

MS DUNLOP: I think perhaps we can leave it at that for just now.

I wanted, Professor Forbes, to look at a meeting that was held in May 1983. The minutes of it are [DHF0014384].

A. Thank you, I have them but I'm not sure I was actually at it.

Q. Well, I have the advantage of you, Professor Forbes because I actually have a copy in my hand which is unredacted.

A. Oh, right, was I there? In body if not in spirit.

Q. You weren't there.

I think perhaps, professor, I should explain to you

that when we wrote the preliminary report, this is all we had. So a piece of paper with a very large blank in it, and we deduced, wrongly as if turned out, that there wasn't any Scottish representation, which is partly why the questions about the designation of Glasgow and Edinburgh as reference centres arose.

However, having now had a further batch of documents, or more recently had a further batch of documents, which contained an unredacted copy of these minutes, we now know that Dr Ludlam was there. But you weren't there. No one was there from anywhere else in Scotland. I suppose you wouldn't expect anybody from Dundee or Inverness or Aberdeen perhaps if this is reference centre directors?

A. I don't think they would be there. I have no recollection of being asked to the meeting or refusing to go.

Q. Or sending apologies?

A. Or sending apologies.

Q. It is slightly puzzling, wouldn't you agree, Professor Forbes, that if a meeting is being held of reference centre directors in May 1983, solely to discuss the problem of AIDS, it is slightly puzzling that there isn't any representation from Glasgow?

A. Well, I can't explain why that was but clearly it's how

it happened.

Q. Why or how, I suppose. But you don't know whether you were invited. It is really just one of these questions we may never be able to answer.

A. I have no recollection.

Q. Right. We do know that a letter was sent on 24 June 1983 by Professor Bloom, outlining the recommendations from the meeting, and no doubt you will have received that, but if we look firstly at the recital of what has happened to date on the first page. It is Professor Bloom who briefly outlined the background to the meeting and its purpose:

"Recent publicity raised in the press, radio and television about the problem of Acquired Immunodeficiency Syndrome, AIDS, has caused considerable anxiety to haemophiliacs and their medical attendants, as well as to the Department of Health. There is clearly a need for haemophilia centre directors to discuss what should be done with regard to the surveillance and reporting of suspected cases and the management of patients. To date in the United Kingdom, one haemophiliac is suspected of suffering from AIDS and in London there are reported to be ten cases of confirmed AIDS in homosexual males."

There has obviously been quite a bit of discussion

of events to date, and then on the second page issues about reporting and then in a paragraph beginning:

"The steps to be taken ..."

Is discussed the scenario: should a patient with haemophilia develop AIDS, what should happen about their haemophilia treatment. Then:

"With regard to general policy ... it was noted that many directors have, up until now, reserved a supply of National Health Service concentrates for children and mildly affected haemophiliacs. It is considered it would be circumspect to continue with that policy."

You weren't looking after children at that point but as far as mildly affected haemophiliacs were concerned, what was the practice in Glasgow in May 1983?

A. Well, we did have for mild haemophiliacs an alternative treatment which is a chemical called DDAVP, and that was the agreement that we would use that in preference to giving them blood products of any kind.

Q. Right.

A. But it wasn't as straightforward as that, as no doubt we will come to.

Q. Yes. I'm certainly going to ask you about DDAVP in a moment, but we do understand -- and please correct me if this is wrong -- that DDAVP wouldn't be any good in a patient with mild haemophilia who was suddenly

suffering a bleed; you need something more immediate with which to treat that?

A. We tended to use it in elective situations, where we were doing some minor -- and I emphasise minor procedure -- like tooth extraction of one or two teeth. We did use it occasionally for acute bleeds as well because it did raise the level of Factor VIII in the blood of the recipient and would stop minor joint bleeding. So we did use it a bit but with some caution.

Q. It says:

"It was also agreed that there was as yet insufficient evidence to warrant restriction of the use of imported concentrates in other patients in view of the immense benefits of therapy."

Did you have any memory of receiving a letter telling you what the recommendations were? I suppose it would be better if I let you see the letter as well. It is a letter of 24 June 1983. I'm sorry, I don't think we have a hard copy of it for you.

A. Okay, if you put it up on the screen.

Q. It is [SGH0022175]. This is actually the copy addressed to Dr Ludlam, but assuming that you in Glasgow would have received the letter also --

A. I presume so.

Q. Yes.

A. The communications in haemophilia were very good. So we must have.

Q. And we can see the recommendations set out there:

"Treatment with DDAVP ... children and mildly affected patients or patients unexposed to imported concentrates ..."

Using NHS concentrates instead.

A. Yes.

Q. I mean, will receipt of that letter have caused you in Glasgow any difficulties or made you have to change anything you were doing?

A. Well, there is another problem that we haven't touched on, but in your previous statement of two or three statements ago, you indicated that in the UK community there had been found so many patients with HIV positivity, and potentially they might be blood donors. So we had no problem in saying that there was a potential for contamination of blood products even from local, home-grown sources. So that was always the concern, that HIV would come into the donor population of the UK. And that has already happened.

Q. Well, are you saying that that altered your practice in Glasgow in 1983?

A. Well, it was a concern.

Q. Right. And recognition of that as a concern, what

effect did that have?

A. Well, we were scratching our heads and asking: what is best to give patients? Many took the view that the major problem was not something that would happen in the future, like HIV disease or AIDS, but the concern was would the patient bleed and die at that point. So the tendency was to come down on the side of using whatever concentrate we had available or cryoprecipitate. So treatment was still the option of choice.

Q. Can we go back to your statement, please, Professor Forbes? I wanted to look at paragraph 16, [PEN0150254], paragraph 16. Thank you. You were asked, if you remembered the meeting -- and this is the meeting of the biological subcommittee of the Committee On the Safety of Medicines -- in July 1983, the meeting where Dr Galbraith is said to have recommended that blood products from the USA not be used. So you don't have any recollection --

A. I have no recollection of that at all or indeed of Dr Galbraith, and it's just a total blank, I'm sorry.

Q. Right.

A. I think his advice was not positive, in that one could not stop treatment of patients because of the dangers of bleeding and the consequences of bleeding. So I'm not sure that one would have been able to take his advice.

Q. Right. Well, I think specifically what Dr Galbraith was very concerned about was American concentrates, and he was suggesting that perhaps the time had come to stop the import of blood products made from blood donated in the United States of America after 1978. As far as Scotland was concerned at that time, with the particular supply available in Scotland, would it have been possible practically to cease all use of American products?

A. I'm not sure there was enough locally produced Scottish -- if you wish to call it such -- Scottish Factor VIII available to fulfil all the needs of the haemophilic population, but I can agree with his sentiment, and maybe having seen the two videos of World in Action of the donor pools they were using, one emotionally would say, "That's the right thing to do, stop this stuff". But at the end of the day, it wasn't true to say that all the material produced in the UK was free of infection. So maybe at this moment of time that was perfectly fine to say, but could one do it? I'm not sure.

Q. Right. Just on that theme, I thought I might ask you to look it up, a Government memo, [SGH0026764]. Just that heading "Imported Factor VIII":

"Scotland is virtually self-sufficient in

Factor VIII."

A. That was cloud cuckoo land. I don't think we were ever self-sufficient in quality Factor VIII at all at that time.

Q. So if witnesses were to testify from the Blood Transfusion Service, particularly from protein fractionation centre, that there was enough product for the treatment of all patients with haemophilia in Scotland at that time, you would think they were mistaken, would you?

A. I would be surprised they would so testify.

Q. You referred to DDAVP. And in your statement you actually drew our attention particularly to an article on DDAVP. I'm referring here particularly to paragraphs 19 and 20 of your statement. There has been a suggestion and various comments about DDAVP and you say:

"It's not without its own problems."

Then the following paragraph you were, I think, going to be given a reference from Professor Lowe but I think the article is "DDAVP in haemophilia", and it is from the Lancet of September 17, 1977?

A. Yes, that's correct.

Q. We have it as [PEN0150368]. So that's it. That's the article you were meaning?

A. Absolutely, and we wrote this up as a warning to other groups that DDAVP did have potential other effects and to be used with caution.

Q. What was the nature of the difficulty?

A. It was fluid retention after the use of DDAVP in which blood pressure changed, and also the amount of fluid retained in the body rose. So we were concerned about that.

Q. Was that an actual contra-indication or was it just something to be attentive to?

A. I don't think it would be a contra-indication because you would only be aware of it after it had happened but it was something that we flagged up to warn people to look for, and quite straightforwardly to look for it.

Q. Right. And as long ago, as we see, as 1977.

Paragraph 21, you are responding to questions about -- this is back to the WFH -- the WFH and ISTH meeting in Stockholm at the Karolinska institute. ISTH, International Society of Thrombosis and Haemostasis. Is that correct?

A. Yes.

Q. Karolinska in June 1983. I just wanted to put to you what we actually found out about this from papers of someone else who was at the conference. You think you were there?

A. I think I was.
Q. Right.
A. But I couldn't -- I have no documentation.
Q. I see. Can I ask you to look at paragraphs 8.37 and 8.38 of the preliminary report. This is page 197. I actually have a reference for it too. It is page 12 of [LIT0012479]. These paragraphs are written with reference to some reports prepared by Dr Peter Foster. Did you know Dr Foster?
A. Yes, I had met him many times.
Q. It's really his comments in 8.38 that I'm interested in but just for context we can see at 8.37 that he was there. I don't know quite how we managed to write that ISTH stood for the International Society for the Treatment of Haemophilia. I'm not sure where that came from, but we do accept that that's wrong. The Karolinska institute -- that Dr Foster prepared two memoranda for Mr Watt of PFC on his return. I suppose you knew Mr Watt very well too?
A. Yes, yes.
Q. Right. In 8.38, Dr Foster's impression -- and this comes from these reports -- I'm not going to trouble you by taking you to the actual reports but Dr Foster's impression was that:
"There had been a concentrated attempt from the US

delegates to play down the situation and an attempt to suppress the AIDS hysteria."

Do you have any memory of this?

A. There was no doubt that there was huge hysteria in the whole field of haemophilia about AIDS and related illnesses.

Q. But do you have any particular memories related to that meeting in Karolinska?

A. I have to say I have little memory of it.

Q. Right. We then took you on through events in your statement. If we can go back to that please, [PEN0150254], looking at 22. That's the meeting of the biological subcommittee. We have already covered that. That's where they discussed Dr Galbraith's paper. And there is a meeting in Aarhus, and then the UKHCDO in Manchester.

You say you are not sure it is correct to say the emphasis was on maintaining use of commercial concentrates. You had made an effort to provide cryoprecipitate from small pools for mildly affected patients and even those on home therapy, and that's, I take it, the position that Glasgow Royal Infirmary --

A. It was.

Q. You say:

"This may be the reason that when we eventually had

a test for HIV only 16 per cent of our treated patients tested positive."

A. Yes. This was one of the very early studies of numbers of patients infected, and we had been collecting samples and storing them and eventually, with the help of Dr Melbye, whose name is in one of the papers, we found that only 16 per cent of our patients were positive with HIV compared with the other big centres that collaborated, and, like Newcastle, their incidence of positive HIV in the patients was 90 per cent. And applied to all the big centres who had large numbers of patients who had been treated with concentrates.

Q. I think --

A. So we were very lucky.

Q. I think the particular writing-up of this material that might be most useful to run past you is [DHF0026016]. I think that's the second reference you mention in paragraph 23, I hope. Can we go to that? 6016. We have to look at page 4 of this, which is obviously 6019. So that's actually the first page. The first page is actually I think the editorial. Does this look like the article that set out your experience in Glasgow?

A. That is correct. With a variety of collaborators who later had a major role in this but our contact was Dr Melbye, who was a virologist from Denmark.

Q. Yes.
A. So we were very pleased at this in some ways, that fate had determined that, because we weren't using the huge amounts of concentrate that other people were using, that so few of our patients had been exposed to the virus.
Q. Just look a little bit further down the summary. We can see that from these two groups, the Scottish patients and the Danish patients, we can see 15.6 per cent of Scottish and 59.1 per cent of the Danish patients were antibody-positive. Two of 30 subjects treated with locally produced concentrate only were antibody positive compared with 23 of 58 subjects who had been treated with commercial concentrate. I think if we read on, these two patients are your patients -- well they were Glasgow patients.
A. Hm-mm.
Q. Right, if we can perhaps go back to your statement, and to understand your paragraph 26, we should look at the schedule of questions you were sent. That's [PEN0120225].
A. Yes.
Q. I think you have a copy of that?
A. I do, yes.
Q. Yes. You are commenting in paragraph 26 on 3(v), which

is on the last page of the schedule. It is actually on a page headed "Page 8", but I think will probably be page 6 of the court book reference, if that makes sense. That might be 0230.

The question was:

"More generally was there an awareness of Scottish patients with AIDS?"

Perhaps this links into what you have been saying, professor, about feeling anxious about the Scottish blood supply:

"We are aware of a comment from an unnamed genito-urinary specialist to the effect that in 1983 patients were arriving in his/her clinic with symptoms of AIDS."

Just so that we are all clear about the question, I think I should show you the actual page from the thesis concerned, which is [PEN0160457]. There, right in front of us on the screen, and I hope you have a hard copy of it as well, Professor Forbes?

A. Thank you, I have.

Q. It is really that quotation we can see beginning:

"We were aware of it as physicians because of medical literature but really we started seeing our first patients with clinical evidence of HIV infection in 1983. When I felt these glands and saw some of the

skin complaints, I realised what was going on and related it to HIV."

Then just to let you see the results of our research into that, can you also look at [PEN0140102]? This is a statement from Dr Sandy Macmillan. Do you know Dr Sandy Macmillan?

A. Yes, indeed, he worked in Edinburgh.

Q. Yes, in genito-urinary medicine?

A. Yes.

Q. And he is not sure whether those are his words or not. He says:

"I can't recall when I first saw a patient with presumed HIV infection."

But he thinks it was likely to have been early to mid-1983. So with that amplification of what was in the minds of the questioners, when we asked you that question, you said in your answer:

"I don't know what evidence or where this came from."

Well, that's where it came from. Did you, as a haemophilia clinician in Glasgow, have any knowledge perhaps from genito-urinary colleagues or from talk amongst doctors that there were already patients in Scotland with these kind of symptoms, lymph node enlargement and so on?

A. Yes, they were starting to appear and we were aware of them, and we did often consult with our local genito-urinary specialist and indeed he became part of our little team, looking after the haemophiliacs.

Q. Can we go back to the statement, paragraph 26. When you said:

"I actually don't believe it either."

What was it that you didn't believe?

A. I was referring to the appearance at genito-urinary clinics at that time. They certainly did appear later, as I have agreed.

Q. Right. So you --

A. I was just quibbling about the suggestion that everyone knew about it but us.

Q. I'm sorry if that appeared to be the implication of the question. I think the question was really just wondering if you were aware of any patients in Glasgow reporting to genito-urinary physicians in 1983 with symptoms that looked very like AIDS?

A. The answer is: I can't put the timeframe together here.

Q. Right. I quite understand. I think, given that it was Glasgow, however, the other thing we wondered -- and can you look at [LIT0010219] -- this is a report of an AIDS case in Scotland. You see, this is the BMJ, I think, if we go right up, we will see it is 11 February 1984:

"Pyrexia of undetermined origin, diarrhoea and primary cerebral lymphoma associated with Acquired Immuno-deficiency."

It is the story of a Scotsman who had been working in East Africa who had returned and become ill, and in fact had developed symptoms of AIDS. If we look at the end of this article, if we could move on to the next page, please, we can see it was accepted for publication on 3 October 1983. In fact, from the article we can see, if we go back to the page before, this is The Western Infirmary, and if we go back to the page before, once we have seen a slightly bigger print. Can we scroll down, please, you see from the summary that he died on 24 December. So drawing, I suppose, the obvious inference is it was accepted for publication in October 1983, 24 December must have been December 1982. Do you have any recollection of hearing about this case in Glasgow?

A. I don't think I ever heard about it but it does underline the fact of the point I was making before, that before morbidity and mortality reports, there were individual cases like this and several others, where clearly this looked like we could go back and say that probably was AIDS, although we didn't have the proper identification with the antibody tests and so on.

So there are a number of these people who were diagnosed and that's one of them.

Q. Right. Can we go back to your statement, please, at paragraph 27? I think we already know your position on the proposition that Scotland was self-sufficient or nearly self-sufficient. But I just wanted to ask you in this paragraph when you are talking about "self-sufficient", what would be your definition of "self-sufficiency"?

A. I think the definition would be that at the drop of a hat, at any moment of time, if a patient required treatment, you could go to your people and say, "We need to treat this patient, we need X, Y and Z," that it would be available and I'm not sure that we ever were in at that position.

Q. Right. I suppose that involves all sorts of issues beyond simply production, does it?

A. Absolutely.

Q. Right. And, 28, I wanted to ask you just a little bit about heat-treated concentrate. Your view was -- and you think in common with quite a lot of others -- that you were pretty sceptical about the notion of heat-treated concentrate. Is that right?

A. Yes, we had worked with Factor VIII for many years and the problem was that it was a very short half-life, and

even as you worked at the bench with it, it would disappear in front of your eyes. So the fact that someone would want to actually raise the temperature and to kill a virus, I thought would never work and I was very doubtful about it. And in fact, many of the initial attempts did destroy most of the Factor VIII potency in the concentrates but clearly I was wrong and I accept that because now it is undoubtedly proven to be of value.

Q. I suppose in modern parlance, Professor Forbes, it would be described as counter-intuitive. Is that correct?

A. That would be a very good term. I'm not sure I could say that.

Q. We know that some heat-treated concentrate started to come through in 1983. Perhaps you could just have a look at firstly [SNB0074604]. This is back to Hemofil. The quest for safety in the treatment of Haemophilia A, and this is heat-treated from Hyland Therapeutics, and there actually is a date on this; the date of this material is March 1983. If we look at the next page, please, I think the date is at the very end in fact. Yes, a bit of narrative about Hyland Therapeutics introducing the first commercially AHF concentrate in 1966, and then acknowledging that the chief source of risk in concentrate therapy stems from

the possible viral bioburden. I actually hadn't come across the word "bioburden" until I saw that leaflet, professor.

A. I'm not sure I have ever come across it since then.

Q. Right. I suppose it just means it's infectious?

A. Yes.

Q. Yes. Anyway:

"bioburden of the large pools of source plasma. One of the most significant threats is that of viral hepatitis. In fact, that haemophiliacs would eventually contract one or more forms of hepatitis has long been considered inevitable."

So it has been a longstanding Hyland Therapeutics goal to find a solution to the problem, we see.

A. I think it would be pertinent just to make the point that the heat treatment, we all hoped would work. It raised the additional problem of changes in the other proteins which were in the container, and certainly if you looked at the vials that had been heat-treated, often they had changed colour to little bit of brown appearance, as clearly much of the protein or some of it had been denatured, and the concern was that this might be a new antigen that had been created by the burning of the protein, the crisping up of it. And there was a lot of anxiety and a lot of time went into trying to prove

that that was safe to use. So it wasn't all straightforward, saying we will heat it to such and such a temperature and that will be the viruses destroyed. It was thought other problems might arise.

Q. Right. Do you remember in general terms these commercial heat-treated products starting to come through?

A. Yes.

Q. And how then in summary would you characterise the reaction in your haemophilia centre to the news that there were these heat-treated products, not, I take it from what you have said, one of total enthusiasm?

A. No -- well, I think we were enthusiastic that things were being done. Whether they were the right things, is another question, and people were anxious that suddenly we would be inducing a new disease due to new antigens in this crispy brown material. So there was a lot of anxiety still.

Q. There were, of course, moves going on at PFC at this time as well, heat treatment projects at PFC. Do you remember that?

A. Yes, indeed.

Q. Right. What was it that they were trying to do? Do you remember?

A. Well, they were trying to do a pretty similar thing, to

look and see how best to heat treat, whether it should be a dry product that was heated or whether it was a wet product. What the loss of Factor VIII would be and what the penalty would be with perhaps new antigens being produced with the crispy brown material that was available.

I would also add that there was a time where one of the companies that had produced a heat-treated material, their concentrate was shown to be still infected so it hadn't been successful.

Q. You mean with hepatitis or with HIV --

A. No, with HIV. So there was concerns about the efficacy and the heating process, the temperature, duration of temperature and so on.

Q. Yes.

A. So all the anxieties didn't disappear overnight.

Q. Well, just to move sideways to look at what was happening in the NHS fractionation world in Scotland at the time, can we look firstly at [SNB0015242]? You see this is a letter from Professor Cash to Dr McDonald. I'll just give you a minute to look at it. (Pause)

So it looks, Professor Forbes, as though you were helping with trials?

A. We were very keen to see trials carried out and with a protocol that had been agreed between everyone. So we

got the most information from patients who were going to receive this product.

Q. And the other letter is [SNB0074335].

A. And that's an agreement letter from myself.

Q. I think you are ahead of us, professor.

A. I have got a very good helper here who is producing it all right in front of me.

So they started using whatever their technique was at that time to produce the material and we were testing it on our patients.

Q. Yes. This is obviously something that we can ask Professor Ludlam about, but one of his patients, I think, had a reaction to a product towards the end of 1983, but your trial seems to have run more smoothly?

A. Well, it did, for whatever reason.

Q. Yes. Of course, we do know that there were some very significant developments in 1984 in relation to infection with NHS product but the focus of that was in Edinburgh and not in Glasgow. But I expect you remember that?

A. Yes.

Q. Just in conclusion, professor, can we go back to your statement and to paragraph 29? You express a view that:

"The attention, anxiety and distress associated with HIV infection made us take our attention from the

equally important, and in retrospect, perhaps more important aspect, of other infection, which is Hepatitis C."

You say:

"It is apparent that Hepatitis C in the long-term has become a lot more serious and sinister disease with many fatalities."

I think you mean a lot more serious and sinister than it was at first thought to be?

A. Absolutely. It was thought early on to be a benign, almost irrelevant condition, which we could document by liver function tests and so on, but clearly, looking back, and I have to say that my opportunity of now looking back at what we thought 20 years ago, it was clearly a very sinister disease that was insidious and fatal in many patients.

Q. Do you think it stopped you -- by "it", I mean the attention paid to the HIV infection -- doing something in relation to hepatitis that you otherwise would?

A. I'm not sure what else we would have been doing but it certainly was a surprise going back after all these years to see how much the population had been devastated by hepatitis, as opposed to HIV.

Q. I see. Professor, I said in conclusion but I shouldn't forget to put to you one final document, which is your

own. It is [PEN0150223]. Just to record that you were just one of a large number of people who were asked about funding from pharmaceutical companies and this is your response, I think prepared earlier this year. You have no recollection of any financial inducements, payments or incentives being given to your haemophilia centre by any blood product manufacturer.

A. I'm not aware of it. Certainly there were no personal fees ever given by any of the companies for whatever reason but they certainly did support the symposia, the scientific aspects of these symposia, and they were very good. We couldn't have done that without them.

Q. Thank you for giving us your response on that and thank you for your evidence today, Professor Forbes.

THE CHAIRMAN: Mr Di Rollo?

Questions by MR DI ROLLO

MR DI ROLLO: Professor, can I just ask you about the situation as far as the decision-making in relation to acquiring concentrates and prescribing them to patients. Were you responsible for making the decision as to whether to use concentrates? Was that one of your responsibilities?

A. I don't think it ever was. The only time that we insisted on a concentrate was where there was major surgery. For all the other situations, which were not

as severe as that, we were happy to be told what was available.

Q. Right. And as far as what concentrates to use were concerned, was that your responsibility or --

A. No, never.

Q. Am I right in thinking that it was NHS concentrates that were used in your hospital?

A. Mostly. Very little of the commercial material was ever purchased, I'm told.

Q. And again, that's as a result of being told by others as to what was being used or not being used?

A. Well, we were guided by SNBTS.

Q. Right.

A. We were told what they had in store and in stock.

Q. Right. When you were being asked about self-sufficiency, I think you said in your evidence that you don't think that there was ever self-sufficiency in quality Factor VIII, or words to that effect. What do you mean by that? In terms of quality? What do you mean by that?

A. I mean stuff that you could rely on as to what it said on the bottle was actually in the bottle. So potent, effective therapy was the difficulty because there was such variation. So every time we gave a material, we measured it in the blood of the patient to ensure that

there was enough to make them safe for whatever the procedure was. So if they were having major surgery, we would work out the dose require, we would give it and then we would check by a blood test after 20 minutes or so that we had achieved a haemostatic level of the Factor VIII or IX.

Q. And if you hadn't, what would happen then?

A. We would give another dose.

Q. Right, and that would still be NHS concentrate?

A. It would be.

Q. Again, would you have to give more than two doses? Would you sometimes have to ...?

A. Well, we would then be on a plan of giving doses twice a day. So there would be another dose. And by this time, by the time you had floated about giving a second dose in the morning, they would have the surgery and then we would be into a scheme of twice-daily testing.

Q. It wasn't a case of saying, "The NHS Factor VIII isn't working, we had better get some commercial stuff", or something like that? You would just carry on with the NHS?

A. No, we continued with what we had.

Q. Yes. So insofar as self-sufficiency is concerned, if we look at the document [SGH0026764], Scotland is virtually -- it says:

"Scotland is virtually self-sufficient in Factor VIII."

If by that was meant that the hospitals are being provided with Factor VIII and that is sufficient for their needs; in other words, they don't require to use commercial concentrate, that may not be as good as or it may not be of the same quality but they don't require to use other material; is that not a reasonable statement to say that it is virtually self-sufficient in that sense?

A. I think you would have to put a date when you say self-sufficient. Clearly, at the beginning of the period that we are all discussing, that was not true. I'm not sure it was even true at the end of the period we are discussing. I am rather sceptical that we were ever self-sufficient in this time.

Q. I'm trying to tease out the senses of self-sufficiency that we are talking about. The date on this document is 6 May 1983.

A. I would suggest that that -- I don't think -- is the way I would see it.

Q. But just to understand how you would see it, what you are saying is that you have to live with the material you have been given, which is the NHS concentrate. Is that right?

A. Yes.
Q. So it wasn't a case of you getting anything else; it was the NHS concentrate that you were using?
A. That would be true. The problem is that you never knew that you had enough.

Let us say that you are going along and you are treating the routine patients as they come through and you have got enough, of course, but all you needed was some patient who had been in a major car accident or some major trauma, or bled into his brain, and would you have enough for that? That was always the anxiety. So we were on a knife edge of having enough or not having enough. And I think that my response would be we were always worried about having enough.

Q. Right. My understanding is that it wasn't your responsibility to acquire this material for your hospital. That wasn't your job?
A. No, and -- We were lucky that we had embedded in the Royal Infirmary in Glasgow a little section of blood transfusion and that was their job.
Q. So who would make the decision as to whether to acquire for the hospital any commercial material?
A. I think that would be at that time Dr John Davidson, who was the doctor in charge of that area and has since died I have to say.

Q. How would he make a decision as to whether or not to acquire commercial material?
A. Well, he would look and see what they had available in store, and he would be calling in every day in any case from Law Hospital where the main store was; enough for what he thought would be needed for that day.
Q. How would he decide which commercial material --
A. I have no idea what his decisions were. I'm not sure that we ever used much commercial material.
Q. If we look at the preliminary report, there is some material for Glasgow Royal Infirmary. If we go to page 569 we will see that, I think, from 1980 onwards a number of different manufacturers of commercial products have been used in Glasgow, obviously much smaller amounts, in relative terms than the PFC concentrate. These are the figures that have been produced by the Inquiry in the preliminary report. So it does appear from that that a number of different manufacturers were supplying commercial material at Glasgow but, as you have indicated, in relative terms it's mainly NHS product that is actually being supplied.
If we go to Yorkhill on the other hand, and go to page 566, I think the point has already been made by my learned friend that there was considerably -- in proportionate terms, considerably more commercial

material used at Yorkhill in 1980 and 1981 and the following years, but it does appear quite significantly -- at least from this information -- that it's just one commercial product that has been used there, which is the Armour Factorate product, as opposed to the different manufacturers that we saw in the Glasgow Royal Infirmary.

Are you able to give us any information as to why that might be, not the question of the different proportions but the reason why you have got only one manufacturer?

A. I have no idea. I was not at all involved in the decisions about the Yorkhill situation.

Q. In terms of the responsibilities for acquiring and the decision to use that particular --

A. I don't know how they did their ordering. I presume they must have gone through the SNBTS but I have no idea. I don't know.

Q. Are you saying that the commercial material was actually supplied through SNBTS as well as the NHS material?

A. I think it may have been purchased. The commercial material was often a bulk purchase to get the price down, but I'm not at all and have never been involved in that so I'm not sure that that's even accurate. But the usual thing, certainly in the other centres, was that if

money was available, they would negotiate a separate price.

Q. When you say "they", who is "they"?

A. The people involved, and it may be SNBTS.

Q. It sounds to me as though you are not going to be able to help us with this.

A. No, I don't think I can.

Q. Right. When you were involved in actually giving a product to a patient, did you actually know where it had come from? Were you aware whether it was a commercial one or NHS?

A. Only when it arrived on the ward and I was about to administer it.

Q. Right. Thank you.

THE CHAIRMAN: Professor You have made it fairly clear you weren't involved in the actual procurement processes. I wonder whether I could draw your attention to one very colourful comment that came from Glasgow. It is in the preliminary report at paragraph 10.163. I don't know if you would have your attention drawn to it before.

A. No.

THE CHAIRMAN: Page 374. It is written by a Dr Hopkins. Do you remember him?

A. No.

THE CHAIRMAN: No. We see that he makes a comment about the

apparent failure of people south of the border to recognise that the United Kingdom includes Scotland and points out that there is not enough English produced Factor VIII, and then he says:

"In the midst of all this, a bunch of uncivillised Picts in the misty marches north of Hadrian's wall want to sit on a great big pile of their own local, home-made heat-treated Factor VIII in order to limit certain batches to certain Pictish patients."

I think the implication was that there was indeed, at the date of that letter at the end of 1984, enough material available in Scotland to supply English needs. Is that something you would know at all?

A. No. I have never heard of Dr Hopkins, I have to say. I have no idea where he came from.

THE CHAIRMAN: I think we also know that in due course Scottish material was, as it was put, decanted to England, but are you really in a position to know what the overall supply position was in Scotland relative to demand?

A. Absolutely not.

THE CHAIRMAN: Mr Anderson?

MR ANDERSON: No questions.

THE CHAIRMAN: Mr Sheldon?

Questions by MR SHELDON

MR SHELDON: Sir, there is one matter I wanted to clarify with the professor.

Professor, you were asked some questions by Ms Dunlop about the policy background to discussions in relation to the purchase and supply of commercial concentrate. And in particular I think you were asked whether any steer was given from above, particularly from SHHD, about these matters.

I just wanted to take you briefly, if I can, please, to a document, [SNB0015252]. We will see this was minutes of the meeting of the directors of the SNBTS and the haemophilia directors, 2 February 1984. Do you see that?

A. Yes.

Q. I think this was a meeting that you were not present at. I certainly can't see your name there. Would that be right?

A. No, I don't see it.

Q. Dr McDonald, I think is there from Glasgow but not yourself.

A. Yes.

Q. If we look, please, at the second page of that document.

A. I see that I had apologised to the meeting so I wasn't there.

Q. On page 2 there is an item at the very foot of that

page, (v):

"Dr Cash asked members to consider whether, given the present SNBTS production level of Factor VIII concentrates, it was necessary to purchase commercially unless exceptionally a superior product was available."

Do you see all that?

A. Yes.

Q. Can we go over the page, please.

We can see that there are contributions from Dr McDonald and Dr Ludlam, and there is then a paragraph:

"Dr Bell emphasised that the aim of the SNBTS and of national policy was for Scotland to be self-sufficient, and although the department would not wish to intervene in what clinicians prescribed, it was not sensible to purchase imported material when suitable NHS product was available."

Do you see all that?

A. Hm-mm.

Q. There is perhaps two aspects to that. The first is the issue of self-sufficiency, and Dr Bell is emphasising that that is an aim of SNBTS and national policy. Was it your understanding that was an aim of SNBTS and national policy?

A. Yes, it was the aim.

Q. Yes.
A. Whether it was ever achieved or not.
Q. That's perhaps a matter for other witnesses, but that presumably was the whole idea behind efforts made by SNBTS and PFC to produce domestic product. Is that fair?
A. Hm-mm. Yes.
Q. The second aspect is the question of purchase of imported material. Dr Bell prefaces that by saying:

"Although the department would not wish to intervene in what clinicians prescribed ..."

Why do you think Dr Bell was emphasising that matter?
A. I have no idea at this time.
Q. All right. He then goes on to say:

"It is not sensible to purchase imported material when suitable NHS product was available."

That does seem to be a steer about the purchase of particular sorts of material. Is that fair to say?
A. Yes, that's a fair comment.
Q. Just following on from this then, was that a suggestion that had been made previously or made to you, that you were aware of?
A. I think that was the general view. I'm not sure that we ever believed that it actually had been achieved at this

time.
Q. I'm sorry, just to be clear: are we talking here about the purchase of imported material?
A. No, about self-sufficiency.
Q. I'm sorry, I'm asking you about the purchase of imported material now, whether the suggestion had previously been made, ie before this meeting in 1984, that that would be a sensible policy?
A. Yes, but it wasn't followed by all the centres.
Q. I understand. And just to be very clear: this was a suggestion which had been made previously?
A. Yes, all right.
Q. Do you recall when?
A. No.
Q. Thank you, sir.
MS DUNLOP: I wonder, sir, if I may ask one supplementary question.
THE CHAIRMAN: Of course.
MS DUNLOP: I don't know if I'm allowed a re-examination.
THE CHAIRMAN: Let's not use the phrase "re-examination". Yes, you may ask a question.

Further questions by MS DUNLOP

MS DUNLOP: Thank you. Professor Forbes. I just wanted to pick you up on something you said to Mr Di Rollo. You were asked what you meant by quality of the product and

you said:

"Stuff you could rely on as to what it said on the bottle was actually in the bottle."

I suppose I should ask you firstly: is that something you want to say about the PFC product that what was in the bottle wasn't necessarily what was on the bottle?

A. I don't think I was attacking the PFC.

Q. Right.

A. It was important to know that what you had given the patient was the amount of material which had entered their blood stream at the right level? Was it high enough, in other words, to make them free of bleeding? The problem is that we were doing a lot of elective surgery at this time, especially joints, and to bleed if you have put a new hip in or a new knee is a catastrophe. So we were very keen to ensure that we had made them as haemostatic as possible and that their blood value achieved was high enough to be happy that they wouldn't bleed.

Q. I see. Thank you. I suppose the only other question was, given that reference to quality, did you ever complain to PFC about the quality of their product?

A. I think that would be a fair comment, that we did.

Q. You did?

A. Yes.
Q. All right. What would be the nature of those complaints?
A. That maybe it wasn't accurately defined on the bottle or so that the unitage that we were giving was in fact maybe spurious. So we were concerned that we were doing the right thing and the proper thing for our patients.
Q. And who did you complain to, can you remember?
A. Well, the usual people were the ones nearest by, and that would be Dr Davidson and Dr McDonald and the people at Law, at the blood transfusion at Law. But these were passed on, I have to say, and Dr Cash knew of our concerns about the amount of Factor VIII in the bottle.
Q. Right. Should we understand this to have been at a particular point in the story of the use of concentrates? Is there a particular time period you can put on this?
A. It was always very early on.
Q. Very early on, right. So roughly when?
A. I would have thought in the early 1980s.
Q. All right. So not early in the production of PFC material?
A. No.
Q. Thank you.
THE CHAIRMAN: Could I follow that just a little to make

sure I do understand. The word "quality" can have a huge range of applications in a context like this, professor. I think the only particular point you have pointed to so far -- you may wish to change this -- is, I suppose, the therapeutic value of the bottle, the number of IUs of Factor VIII in a bottle that would normally be presumed to have a certain content. Is that the right --

A. Absolutely.

THE CHAIRMAN: I can't remember the precise figures but I seem to remember something like 400 IUs per bottle being an indication of what should be expected.

A. And the other concern was the amount of additional protein that was there in a crispened form, in a denatured form.

THE CHAIRMAN: I want to ask you separately about "denatured" and what it means. So there are the two factors. One is the relatively high concentration of proteins other than Factor VIII, and the other was the variable Factor VIII content.

A. Yes.

THE CHAIRMAN: I think I have seen both of those referred to.

A. Yes.

THE CHAIRMAN: But is that the extent of the quality comment

that you make or is there something else that one should understand?

A. Well, we would also be concerned about the solubility of the preparation.

THE CHAIRMAN: Yes.

A. Has all of it dissolved, and the answer was often not.

THE CHAIRMAN: Is that different from the high concentration, or allegedly high concentration of fibrinogen and other material in it?

A. I think it probably is. It depends on the amount of denatured other proteins that are there.

THE CHAIRMAN: That brings us back to denatured which I think you will have to explain, and we haven't had an explanation.

A. A protein is denatured when some chemical or physical process happens to it. For example, you denature a protein by heating, and the protein that was in our little vials of Factor VIII was often quite brown and crisp in colour and often that wouldn't dissolve when we tried to dissolve it. So that was a concern.

THE CHAIRMAN: Because if it was denatured material other than Factor VIII, you wouldn't want it in your syringe anyway, would you?

A. I don't think so.

THE CHAIRMAN: So I'm not immediately sure that that's

a disadvantage. But the other expression that I think comes up in this context, though you have not used it, is "neoantigens". I have seen a reference to that in this wider context. What's a neoantigen?

A. A new antigen.

THE CHAIRMAN: That's just what that means.

A. Literally, and it might mean that the heating process had caused molecules of the particular thing in the bloods to come together as a cluster. So that might actually be a new antigen if it was injected into a patient.

THE CHAIRMAN: Professor James is suggesting induce antibody formation in the patient.

A. That was the concern.

THE CHAIRMAN: I have seen that discussed over time in documents as a possibility. I don't think I have ever seen it suggested that it actually was established as a real risk.

A. I think at the end of the day I have not heard of anyone who has identified it as a particular problem.

THE CHAIRMAN: It was something that was thought by those involved --

A. It was a concern.

THE CHAIRMAN: A possibility?

A. Yes.

THE CHAIRMAN: I don't know if I have put further fibrinogen into the bottle.

MS DUNLOP: The only thing, sir, just to be clear. This is my understanding, and I hope it's right, that the references to things being perhaps slightly brown or denatured or something, all relates to heated product. In other words, if it is heated PFC product, it must be after December 1984.

A. Yes.

MS DUNLOP: Okay, just so long as we all understand that too.

THE CHAIRMAN: I have no doubt you will remind me. Professor, thank you very much indeed.

Ms Dunlop?

MS DUNLOP: We have no other witnesses today.

THE CHAIRMAN: I'm required not to sit tomorrow.

MS DUNLOP: So I'm told. I gather that Highland Council is not taking a holiday tomorrow but I think every other public body in Scotland is.

THE CHAIRMAN: Ladies and gentlemen, I hope the weather is good for the garden but otherwise I'll see you on Tuesday.

(3.38 pm)

(The Inquiry adjourned until Tuesday 3 May at 9.30 am)