Friday, 6 May 2011

(9.15 am)

THE CHAIRMAN: Good morning. Yes, Ms Dunlop.

MS DUNLOP: Thank you, sir. This morning, sir, we do have Professor Ian Hann with us from Cork.

PROFESSOR IAN HANN (sworn)

Questions by MS DUNLOP

MS DUNLOP: Professor, we normally start by looking at the curriculum vitae of a witness and I would like to look at yours, if I may. Do you have a hard copy of that?

A. I am afraid I don't.

Q. I was just going to say that I don't imagine that that's a problem because you will know everything in it. If we could perhaps have it on our screens, it is WIT0030296. Could we look at the first page in, please?

Professor, we can see that you took an MB BS at Bart's in 1971 and you developed your career in haematology, and we know from later in your CV that you moved to Glasgow and obviously that's the period of your career in which we are particularly interested.

If we look at the next page, please, where your previous positions are listed. And like most of the doctors whose CVs we have been looking at, you have taken us through your house jobs. We can see that you worked in paediatrics in Liverpool and indeed in

Manchester.

Then on to next page, please. You had a spell in Great Ormond Street, towards the end of the 1970s. Then you went to Glasgow. We can see that's position number 12. You tell us that the position that you held in Glasgow involved not just looking after the hospital at Yorkhill but also the Queen Mother's Maternity Hospital, which, for those who are not so familiar, geographically was next door. Yes, you are nodding. But also there were facilities at Strathblane, the children's home hospital at Strathblane, which is outside Glasgow, and in those days also there were some paediatric beds in the hospital in Drumchapel. Is that correct?

A. I'm not sure about that, to be honest. I think it was mainly for the elderly.

Q. Yes. At one time, certainly, there were paediatric beds in the hospital in Drumchapel but it is very difficult to know exactly when. You held that position between January 1983 and August 1987. You then went back to Great Ormond Street?

A. Could I just interrupt, sorry.

Q. Yes.

A. There is a doubt over that latter date. You will know from Dr Brenda Gibson's evidence that the data that she has been given was that I left in 1988. What I'm

quoting there is what the personnel department at Great Ormond Street told me. I am afraid I can't verify it either way. It is either August 1987 or August 1988 depending on who you believe.

Q. We have seen other material, professor, but I don't think anything is going to turn on it. Can we look at the next page, please, where we see set out a description of your work in London, then finally, your move to Cork.

If we move on, on the next page, charity committees, research bodies and committees and editorial commitments. Then recent research projects. This is on to page 8. Professor, you have told us you are a house husband, and I'm sure that's very full-time, but are you still working in haematology in any respect at the moment?

A. No, I was running a laboratory until mid-March and like many things in Ireland, it went into liquidation. So at this moment in time I'm just a house husband, but I'm also an editor of the British Journal of Haematology and I do medico-legal work, mainly in the clinical field.

Q. Thank you.

Just to look at your publications, which begin on page 10, I did notice a very large number of publications connected with leukaemia, childhood

leukaemia. Would it be right to describe that as your principal interest?

A. Principal scientific interest, yes.

Q. Among the list, however, I noticed, for example, number 44, if we could go to that. This is page 14.

A. Yes.

Q. Psychological disturbance in children with haemophilia. We see your name and indeed Dr Brenda Gibson, and then 53 on the next page, "Children with haemophilia: same or different?" On the following page, 68, "The impact of prophylactic treatment on children with severe haemophilia". These articles might suggest an interest in haemophilia in a holistic sense, so not purely the science of it but also in the psychology of it; would that be correct?

A. Yes, that is correct, in fact research in the haemophilia area outside of the genetic aspects is very difficult to perform.

Q. Why is that?

A. Basically it's a lifelong disease and a relatively rare disease and therefore there is an extreme paucity, until very recently anyway, of, for instance, randomised trials or metanalyses, which would be the gold standard of clinical studies, particularly in leukaemia.

Q. Number 96, which is on page 21, a publication relating

to a survey of treatment of children with haemophilia in Europe. So 20 centres in 16 countries. Was that across the whole of Europe?

A. No, it basically was a thing that was established by Professor Rolf Ljung(?), who was the director, and still is, I think, in Sweden for many years who set up for the first time a group of paediatric centres, which was called "Euro Ped Net"(?), and it basically was large centres that were prepared to take part in that and to do epidemiological studies mainly.

Q. So was it more western Europe?

A. Almost entirely western Europe, yes.

Q. If you look at what is beyond your list of publications, which is a lengthy list, we can see you also have some case reports and we understand that, and communications. Is that where you have written to journals?

A. Yes, letters to journals, basically, which were published.

Q. That was page 32. Well, it is in my copy anyway. I'm sorry, it doesn't seem to be page 32 on the screen. Special dissertations come next. I noticed some publications on the genetics of haemophilia. We can see that if we go on. It might be page 34 here. It is page 36 in the hard copy.

Yes, "Genetics of haemophilia". Then again on the

page two pages on, what looked to be another presentation on the psychological aspects of haemophilia entitled "Haemophilic children, more or less disturbed". We can see that on the screen in the 1980s.

Not taking up too much time but I noticed also page 42, which might be page 40, presented to European Haematology Association on Recombinant VIIa therapy. This is Factor VIIa. Is that correct?

A. Correct.

Q. One of the things that one notices as a layperson reading about haemophilia is that sometimes deficiencies in particular factors seem to be treated by increasing the dose of what might be thought to be adjacent factors, like using Factor IX, sometimes, to treat people with perhaps inhibitors to Factor VIII. This looked to be using Factor VII to treat children with Factor VIII inhibitors. In very general terms, is that one route to treatment using different factors?

A. Yes, I think we gave up using Factor IX in that circumstance a long time ago, but VIIa, or activated Factor VII, which is what that means, is still a standard treatment for patients with inhibitors, so-called bypassing activity. So you bypass the Factor VIII defect or attempt to.

THE CHAIRMAN: I'm not sure how much we need to know at this

stage, but VIIa is the carrier protein, is it, or what?
A. No, it is the activated form --
THE CHAIRMAN: It is the activated.
A. In fact, all clotting protein factors become activated through what used to be called the clotting cascade, and this is an activated form which doesn't require much in the way of Factor VIII to activate it, so it bypasses that defect to an extent.
THE CHAIRMAN: Yes. I think one can see activation in the sense of putting something into gear when there is a demand for the clotting process, but is this a characteristic of the particular protein that exists independently of that? Is activated independently? Or what?
A. It is activated within the body during the clotting process, the clotting pathway. It is an initiator, if you like, and also a bypasser of the defect in Factor VIII mainly, although it can help with Factor IX sometimes.
THE CHAIRMAN: I don't know how far it's necessary to follow any of these things, Ms Dunlop, but of course just having a reference to Factor VIIa doesn't necessarily enlighten us or me.
MS DUNLOP: I just wondered, professor, and this may be completely wrong but to try to have a sort of lay

understanding of how these treatments work: if there is a gap in the cascade, so something is missing, would it be reasonable for us to think of the idea of using a different factor as being an attempt to introduce more momentum at another stage of the clotting process to enable the body, as it were, to bridge the gap that's there?

A. Yes, I mean it is a great deal more complicated than that, but in essence what you are saying is correct. It's a very complex network. It is not really a cascade. But what you said is essentially correct.

Q. Thank you.

We can also see, if we move on, that you have been involved in the production of a number of chapters in books and you have also contributed a number of invited articles. If we can move on a couple of pages towards the end of this list, we can see the heading. It is on the hard copy, page 52, which might be page 50.

I just noticed that you had written a chapter on paediatric haematology -- this is at number 12 -- a book called "Paediatric Speciality Practice in the 1990s." "Blood disorders", in a textbook of paediatrics edited by Forfar and Arneil, another professor of paediatrics in Glasgow. Is that correct?

A. Yes.

Q. Forfar. Was he in Glasgow too?
A. I think he was in Edinburgh. It was a long time ago.
Q. So it was an Edinburgh/Glasgow collaboration?
A. Yes, amazing.
Q. You also contributed -- number 17 -- "Growing up with haemophilia in the shadow of AIDS". Is that an article?
A. I think "Health trends" is a BMJ-like journal that comes out like a volcanos, on an irregular basis. I don't think it exists any more. So my memory isn't very good on it.
Q. Number 19, the use of blood products in paediatrics. On to the next page, number 23, "The use of factor concentrates in the management of Haemophilia A and B and other coagulopathies", in a book called Modern Transfusion Medicine. 24, "Haematological Diseases" in the Great Ormond Street Handbook of Paediatric Medicine and Surgery.

Professor, just lastly we also can see another list of books published. Again, what look to be general haematological textbooks, perhaps paediatric haematological textbooks, but obviously a long history of publishing in various different journals and books.

We have from you, professor, a number of different statements and I would like to look at them in a particular order; very, very roughly speaking it is

a sort of chronological order. Actually the first document I want to put to you is one that you have written very recently, and it's about the World in Action television programme. It is headed "Professor Ian Hann response to Penrose Inquiry re Blood Money", received 5 April 2011. It is a single sheet. It is [PEN0120205]. We were trying to remember, professor, did you just receive the transcript or did you receive the DVD as well? Did we send you the DVD?

A. I received the DVD.

Q. So you actually watched the programme?

A. No, I didn't, I preferred personally to rely on the transcript. So I haven't reviewed the DVD itself.

Q. I see. We can see for ourselves, you have told us where you were in 1975. You don't remember seeing these programmes, and you pinpoint your full engagement with the question of appropriate and available therapy for bleeding disorders as being in 1983. In paragraph 4 you make a reference to the emphasis in the programmes on the problems with Hemofil and the need to improve the donor pool and move towards unpaid donors, self-sufficiency. I simply wondered when you use the term "self-sufficiency" what are you meaning?

A. I'm meaning that the National Health Service would eventually produce enough Factor VIII and Factor IX

concentrate to treat all of the patients, including all of those that require prophylaxis.

Q. We will come back to ideas of prophylaxis shortly, professor. The other thing I wanted to ask you about paragraph 4 was in relation to your reference to the commercial companies being the main drivers for increased safety with regard to heat treatment. Really, the first part of that sentence. It may be that we are going to hear evidence later in the Inquiry about the efforts that were made at the protein fractionation centre in Edinburgh, the NHS facility, to improve product safety. Is it your impression that there were considerable efforts being made in that area too?

A. Yes.

Q. Right. So would it be fair to say that the need to achieve increased safety with regard to heat treatment was taken very seriously by the NHS in Scotland as well?

A. Very seriously indeed, yes.

Q. Then paragraph 5, you make further reference to UK self-sufficiency and the risk of viral contamination. Then in paragraph 6 you talk about the figures needed for prophylactic treatment, and we can see from your figures that you are recording a ratio really of almost 1 to 3 in terms of the numbers of amounts required for, on the first hand, on-demand therapy and then on the

second hand, prophylactic treatment. So prophylactic treatment really very much more demanding in your view, in terms of the amount required?

A. Very much so, and that was published from one of the very few randomised trials conducted by Manco-Johnson.

Q. We have seen a reference in the 1970s, professor, to prophylactic treatment being presented as something which could be achieved at almost the same cost as on-demand therapy. I suppose the thinking being that if you prevent bleeds from happening, then you don't have to use huge amounts of product in treating the bleeds, but that's not your view?

A. That was what we would be saying. To be perfectly frank, we wanted it. So, you know, it all comes down to the smoke and mirrors of cost-effectiveness and quality of life et cetera, and thankfully it was even more primitive in those days than it is now.

So, yes. There is no way that you can ever make this add up to being the same cost, no matter if you put in the cost of operations, the cost of disability and so on. And this is why cost-effective analyses, in my view, can never be wholly acceptable.

Q. Can we move on, please, to look at the next statement that you provided, which is headed "Preliminary outline of my time as haemophilia centre director at Yorkhill by

Dr, now professor, Ian Malcolm Hann", which for us is [PEN0120203].

Just to note for us all, professor, that the date which appears on the second page is 5 May 2010.

A. Can I interrupt, sorry. I have lost my vision of you.

Q. Oh, I don't think -- I don't know if that matters.

I don't think that matters, sir.

THE CHAIRMAN: I don't think it's terribly important that you see us, professor, provided that you hear us. We are not going to move around much. You can visualise us if it helps.

A. That's fine, thank you.

MS DUNLOP: We can see you.

Just noting from this account in the second paragraph, you explain about the haematology service to Yorkhill and the Queen Mother's as, I suppose, the maternity hospital, the haematology service would be for what? Both the mothers and newly born babies? Is that what was required?

A. Yes.

Q. You say you provided all of the paediatric haematology, malignant and non-malignant, service in the West of Scotland, and a large part of the oncology service too.

I think we come back to that in a later statement.

In relation to paragraph 3, you mention that during

your time at Yorkhill you:

"... worked very close by with the adult centre at Glasgow Royal Infirmary."

I know you didn't arrive until 1983 but do you have any knowledge of when the centre at Yorkhill had become a fully-functioning haemophilia centre?

A. I am afraid I don't know that.

Q. Was it in any sense a satellite of the centre at Glasgow Royal Infirmary?

A. I think we basically worked in conjunction with each other and provided each other with whatever help was required. Initially, for instance, because the laboratory at Yorkhill was in a terrible state, they often provided specialised clotting test help, and then at a later stage, if there were very specialised tests, they would help in that respect; but basically as a symbiotic relationship rather than a dependent one.

Q. Was help ever provided in the other direction? Were there ever situations where Yorkhill was helping the Royal Infirmary or did it tend to be mostly one-way?

A. Obviously we helped in so much as we organised the transfer of the patients' so-called translational care, nowadays, but basically Anna Pettigrew worked across the two units essentially in that respect. We always made our views -- I mean basically it was like

a multi-disciplinary team. We had fairly regular meetings and Anna had very regular meetings with them.

Q. So the translation you are talking about was when a young person would be moving from care at Yorkhill to care in the Royal Infirmary. Is that what we should understand by that?

A. Yes.

Q. Right. Within Yorkhill, when you worked there, the doctors who looked after children with haemophilia, was that just really you and Dr Pettigrew?

A. Mainly, yes. We sometimes had assistance from the other trainee doctors. One of the problems and one of the reasons Dr Willoughby left was that there was a paucity of medical assistance at trainee level at that time, but Anna was only part-time. So obviously I needed other help at times.

Q. Yes. And again this is something you discuss in your other statements as well.

A. Yes, and Dr Gibson of course, when she came -- who was quite an expert in coagulation and took over from me eventually -- was also very helpful on-call, et cetera.

Q. I just wanted to ask you a little bit about the differences involved when you are treating children with haemophilia from what you might experience when treating adults. I suppose one of the things that is

particularly striking is the notion that these are largely young boys, small boys, and they will, in many cases no doubt, want to be very active?

A. Yes, and it was a particular problem in Glasgow. I have to say, even more so than elsewhere -- well, Liverpool as well, when I worked there. It was just impossible sometimes to dissuade them from taking part in contact sports, especially football. It was a constant discussion; a question of them adapting to a different lifestyle, if possible.

Q. Yes. I expect, professor, we could take quite a lot of time in looking at that as a topic in itself. We have seen, particularly in the 1970s, really quite detailed debates about what sort of a life a young person with haemophilia should have. There is a reference in one set of minutes to whether people should take up dancing, for example. Were these debates quite significantly to the fore around that time?

A. Very, very much so, although I have to say it would be difficult to persuade boys in Glasgow to take up dancing.

Yes, I mean, basically we had a lot of discussion about what was right and what was wrong, and eventually the World Federation for Haemophilia provided an extremely good book, mainly derived from Australia,

which then categorised sports by risk and by how you could reduce those risks. So for instance, without going into great detail, we would strongly encourage swimming, tennis, running, to a certain extent gymnastics and so on, and discourage contact sports, particularly boxing and Karate and things like that.

THE CHAIRMAN: I'm fascinated by the suggestion that gymnastics might be appropriate, having done that at a certain stage in my life, I would have thought that some types of vaulting and jumping off parallel bars and horizontal bars might present a difficulty.

A. I can't hear.

MS DUNLOP: Can you hear us, professor?

A. It has gone.

MS DUNLOP: I guess not.

A. I don't know if you can hear me.

MS DUNLOP: We can hear you. (Pause)

THE CHAIRMAN: My question about gym of course can be put briefly. What sort of gymnastics did you have in mind as appropriate?

A. As I say, I didn't go into a lot of detail because that would be one of the difficult areas, which would be categorised as having some risk but that that risk could be ameliorated by avoiding certain aspects. In other words, if you like, you could do yoga-like gymnastics or

similar sorts of things, but you wouldn't be allowed to climb ropes or the ladder-type things or jump over horses, or do much in the way of hand-stands, et cetera. And actually we organised school visits, which Anna usually went on. I went on a few, where all of these things were considered. The whole idea being to try to integrate them into normal school activities as much as possible and not just be the person who ran the line with a flag.

THE CHAIRMAN: You have comforted me. We can ignore the five Olympic disciplines which I had in mind.

A. Yes.

MS DUNLOP: I wondered too, professor, whether further issues developed as the treatment became successful. So that bleeds became something of a distant memory or perhaps even something that an individual had never experienced. Did that bring a different set of issues?

A. Yes, and people worried about this a great deal.

The patients who received home treatment or prophylaxis had, for various reasons, all experienced at least one joint bleed. That was what we developed as the national policy, which I wrote with Dr Hill in Birmingham a few years later. So they had all experienced that, although at a very young age. The fact is that you get better at treating a chronic

disease if you are chronically ill than if you aren't. So there was always a worry that they wouldn't present.

In fact that turned out, except in very rare circumstances, not to be a major issue. We very rarely ran across difficulties of parents not presenting their children, say if they have had a head injury or if they had a joint bleed at a very late stage, because apart from anything else, treating things early is always much more effective and leads to less damage to joints.

Q. So I understand what I think you are saying: that the parents remained vigilant, but did the children grumble?

A. Yes, and this is a problem with prophylaxis that we have recognised in recent years and that the Swedish recognised many years ago, in that they -- you are speaking there about three times a week probably treatments, and difficult veins sometimes and lots of attempts on occasions. There were certainly quite a few episodes where people would hold off treatment and hope that things got better.

You have mentioned Dr Fiona Logan's work. What we were looking at there, comparing them to diabetic children and to so-called normal siblings, was a chronic disease and how parents and children come to terms with that eventually.

Q. You mention in paragraph 4 the Haemophilia Society. You

say:

"The main contact then ..."

I guess that should be:

"... and for many years afterwards was Philip Dolan."

I suppose parents might themselves be members of the Haemophilia Society?

A. I apologise for the Freudian slip by the way. It wasn't deliberate. Yes, I was involved with the Haemophilia Society as a medical adviser for a long time, starting around about 1987.

Q. But even in your time in Glasgow from 1983, the Haemophilia Society would be very active and very involved, I take it?

A. Yes, and that came as a surprise to me because they were nowhere near as involved in England, and I thought that Philip Dolan provided excellent liaison and we had a very good relationship with him to my memory.

Q. Thank you.

A. It wasn't a paternalistic one by the way. I notice in some of the evidence people saying that they think the Haemophilia Society were just almost ruled by us or were like patsies in a way, and it wasn't like that. When I was asked to become a medical adviser, it was made very clear to me that I was supposed to be their

advocate, not some sort of person who dictated events to them. They were a very well-informed group.

Q. You don't really think they were entirely dependent on medical input?

A. No, not at all, and I'm talking about Scotland, of course, at the time. No, they were certainly not.

Q. When it came to perhaps discussing issues about use of concentrates and so on, would it be correct to say they were partly dependent on medical input?

A. Oh, definitely, yes.

Q. But not totally?

A. Not totally, no, they had their own views, and they were of a view (inaudible) views that were passed on to them through the Haemophilia Society itself.

Q. At the end of paragraph 5 you say -- and this is in relation to hepatitis more -- that:

"Our energies were first and foremost to prevent serious bleeding and secondly to find ways out of the awful situation of virus risk."

It seemed, if I can say so, Professor Hann, that that was a very succinct encapsulation of a sort of ranking. Are you really saying that at least in this context of non-A non-B hepatitis, the virus risk was not seen as something which dwarfed the risk of serious bleeding?

A. It didn't dwarf it for the simple reason that all blood products and certainly all concentrates, both commercial and NHS, were known to carry a very high, or total virtually, risk of transmitting hepatitis, non-A non-B hepatitis as it was then called, but obviously it was a combination rather than a ranking, actually.

Q. Right. But not something that ever justified giving up the use of the concentrates? The hepatitis risk?

A. Not for the reason of non-A non-B hepatitis, no.

Q. Then on to the next page. You say that you did everything you could to minimise pooled plasma product use and that that would not just be an issue for patients with haemophilia but also for cardiac patients, leukaemia patients and others?

A. Yes, sadly that was a problem that came to light later. But we always knew that there was that risk.

Q. We will look perhaps in more detail at some of these issues in subsequent documents. The next document I would like you to have is one headed "Professor Ian M Hann response to Penrose Inquiry, dated 5/6/2010". It's in a larger print. For us it's [PEN0150035].

A. Can you just give me the title again, sorry.

Q. Yes. It's the one that's in the biggest font of all and is says:

"Professor Ian M Hann response to Penrose Inquiry dated 5/6/2010".

A. Thank you.

Q. You have it?

A. Yes.

Q. Nothing really from the first page, professor, save to say that I think we do now know that the starting date was January 1983. So where we read "1982", we should read it as "1983". On to the next page you say you were director of the West of Scotland Children's Comprehensive Care Haemophilia Centre. This was an extremely burdensome role, and this is really the totality of your position:

"It was an extremely burdensome role which was partially recognised by the appointment of Dr Gibson within the next year."

When Dr Gibson was appointed what was her brief?

A. Basically we worked together but I was the haemophilia director, and her main interest initially was leukaemia and bone marrow transplantation. Obviously we worked one in two, if you like, on-call and weekends, and those were our specific areas of interest. I, mainly in haemophilia, but also I took half the patients with leukaemia, for instance.

Q. When you say you worked one in two, does that mean you

were on-call on every second night?

A. I spent a year on-call to start with and then one in two.

Q. Every second weekend?

A. It was a very tough time.

Q. If you were a year on-call and then Dr Gibson came and you were doing a one in two, for how long were you doing it as a one in two?

A. Until I left. The first year I had one week's holiday.

Q. Right.

A. It is one of the reasons Dr Willoughby left because he was in a similar position.

Q. Yes, coming to Dr Willoughby, professor, to ask you some questions about him. But just to follow this statement through, this is actually a statement addressing questions about systems, but I did notice a mention of something I didn't recognise in the following answer, the one that's in front of us on the screen. You say that you used topical thrombin. How does it work?

A. This is basically at the end. In the old description of a clotting pathway or a cascade, thrombin is near the bottom just before the production of fibrinogen. It's been used a lot in footballers and such like, for instance. Particularly useful in children because of the mouth bleeds and such like from bottle feeding and

so on. You just place it on the bleeding area and it stops the blood. It assists blood clotting basically.

Q. Right. You mention also --

A. It's a Factor II, if you like.

Q. All right, thank you. You mention tranexamic acid and we have had some explanation of that from Professor Ludlam, but just to confirm so that we have this clear in our mine, does tranexamic acid have any role in Haemophilia B?

A. Yes, again, Haemophilia B is often a much less severe disorder but basically tranexamic acid is an antifibrinolytic agent which basically, in simple terms, means it stops the blood clot breaking down too quickly, which is one of the problems in haemophilia. So it is actually a very useful drug which is still used extensively, and one of the very useful aspects of this is that it stops bleeding when the deciduous teeth fall out.

Q. So does it have some part to play in what might be thought of as the first aid treatments, or when there already is a bleeding problem? That tranexamic acid may sometimes be useful?

A. It has been used but not very effectively prophylactically in children who have had recurrent nose bleeds.

Q. The other notion that I think we understand is the planned intervention. So where a child is going to perhaps have a tooth out, or something like that, is it a drug that you could use for that?

A. Yes, and sometimes you can avoid the use of factor concentrates or cryoprecipitate altogether in mild to moderate haemophiliacs and occasionally in severe haemophiliacs too.

Q. You go on to tell us on the next page -- if we can move to that please -- that within a few days of taking over your post you produced a protocol and guidelines for therapy of bleeding disorders as such documents had not previously existed.

We understand that you had worked with Dr Peter Kernoff in London. I wondered if that had been his approach. Were you applying what you had learned in London?

A. Yes, and also from the leukaemia area. This was an era when we had gone from basically each doctor doing it his own way almost to a much more protocolised approach to things. It was in its very early inception, but because Dr Pettigrew wasn't always there, because I had many other things to do, it was important that there was guidance for those people who weren't particularly expert in this area. So we followed the best practice

at the time, if you like.

Q. So more a question of guidance for other people who might not be so familiar with the condition than a question of standardising treatment in some sort of way.

A. I think both, actually, yes.

Q. Both. You say:

"I noted that my predecessor had what appeared to be a preference for commercially, as opposed to NHS produced products."

How did you come to realise that?

A. My memory was that I had one discussion with him. Do you want me to go into the detail about that?

Q. Yes, absolutely.

A. I may be wrong, it may have been more than one discussion, but this is what I can remember. I can remember it well because without being in any way, I hope, pejorative, I was being told that this was some sort of poisoned chalice that I was taking up and I was worried that as a young man who hadn't been a consultant before, I was taking on a massive amount of responsibility, and I wasn't sure that I would be adequate to deal with it.

So I do remember it well and I can go into a lot of the detail of why he felt that he had to leave and such

like, but basically, with regard to the haemophilia management, he was well ahead of his time in one respect and that is with regard to prophylaxis. There was a great deal of scepticism, which I to some extent shared I have to admit, and I was wrong over whether it was efficacious or practical or not. He believed that prophylaxis was the way ahead and he was right, actually.

But he was generally disillusioned with the health service throughout the UK, with industrial action and many other things. He felt that he had been let down with regard to supplies. He said that I had been used to being in England, to having to use commercial concentrates. He said this is a better option. It's available. You don't get let down at the last moment. You can go ahead with surgeries that are required. You can treat patients who have very severe bleeding or life-threatening bleed problems and not have to rely on cryoprecipitate, which was extremely difficult to use in children.

He felt that the Scottish product suffered from being very low purity, difficult to draw up, with significant wastage and significant problems with reactions, infusion-related reactions, and what we call in clinical terms "recovery"; in other words, the amount

of Factor VIII that they actually get and is measurable in the blood stream.

We did discuss the problem of supplies from America and his view was that the problem of Hepatitis B had largely been overcome and it was also my experience that we were not seeing new cases.

He felt -- and again that was the experience of the Royal Free, which was a major hepatitis centre -- that non-A non-B hepatitis was a minor disorder and that all products, all plasma products, were susceptible to that.

So basically that's why he used it.

That, to the best of my knowledge, was our discussion on the subject.

Q. Who contacted whom? Did you contact him or did he contact you?

A. I think the most likely -- I approached him. I think that we may have had one telephone conversation and one discussion at a meeting that we were both attending. I'm not sure of that, but I definitely instigated that. He did not.

Q. Professor Hann, it is certainly an issue now and it's an issue in the Inquiry, but I'm also interested in the fact that it was obviously an issue then too. So we must be thinking about what, towards the end of 1982 and into 1983? Was there some kind of sense in which he

felt he had to explain or justify why he was using commercial product?

A. I think probably so.

Q. Do you want to explain that a bit more?

A. You know, it's a very long time ago and I don't want to make things up or have clever memories that I would like to think was the truth. I remember him saying that, you know, there needed to be a move within the NHS to self-sufficiency and we both agreed that that would be the ideal.

Q. You go on to say that you did not express that preference. I was just going to ask for a start, did you inherit a stock of commercial product?

A. Yes, not a very large stock but there was certainly products that was being used, yes.

Q. And did it continue to be used after you took over?

A. Yes, and there were periods of time when, as far as I remember, we had to call in extra commercial products because, I would agree with Dr Forbes, it was not the case that we were ever able to use exclusively Scottish product.

Q. But you say you did not express that preference to the best of your knowledge. I appreciate everything you say about how long ago it was but doing the best you can, can you try to recapture your thinking at the beginning

of 1983?

A. I think my thinking is twofold. I don't think I ever met a haemophilia director who didn't want -- sorry about all the double negatives -- there to be self-sufficiency in the UK. That was our aim. That was what we all wanted. We went to many meetings where we said, "Do this for goodness sake, do this". And we knew it had been going on for at least six years before.

So there was that aspect of it.

With regard to preference, I had been used to using commercial product and NHS product in England. My impression was that there was not as much difference there as there was when I came to Scotland, where there were certainly cases of children who had reactions and where there was certainly difficulty with what appeared to be a low purity product. I would have definitely preferred to move away from commercial concentrate because of the perceived risk of other viruses.
I wasn't thinking of HIV but other viruses, like cytomegalovirus for instance, and so on.

So I would have preferred to be able to use NHS concentrate.

Q. You started in Yorkhill at the beginning of 1983. You say you weren't thinking of HIV, as it was to become known, but how long was it before you were?

A. Yes. I read a lot of the Inquiry depositions with regard to this. My belief is that the directors who were directors in 1983 had a great deal of (inaudible) still when I took over at the beginning of 1983. We didn't know what was the cause of AIDS, we didn't know that it was going to be a major problem in haemophilia. We didn't know many things.

But it did become clear later, probably in 1983 some time or early in 1984, when the cases were reported from Europe, but you have already heard from various people who have different memories of the time. My memory of the time is that it was not clear in early 1983 that this was going to be a problem, a significant problem.

Q. Thank you. To move to the next paragraph, I just wondered if you could briefly explain what you mean by short-term prophylaxis. I think we have been imagining prophylaxis as an indefinite treatment, three times a week injections or something like that?

A. The problem was that we never had sufficient product to carry out long-term prophylaxis. There was also some doubt -- and I carried some of that doubt myself and as I say, I turned out to be wrong -- that long-term prophylaxis would work in these patients.

The fact is that it didn't work initially -- and we published on this, you have already mentioned those

publications from Great Ormond Street. It took several years in severely affected haemophiliacs, for prophylaxis to actually achieve its aim. So short-term prophylaxis was used in patients who had bursts of bleeding problems or a very severe bleed, like in the knee or some such, which did not settle down.

So we carried out short-term prophylaxis, usually for several months or a little longer, during which we could verify a supply and then, in almost all of those cases, we had to discontinue prophylaxis.

Q. In the next paragraph, or the next bullet, you say, in relation to commercial product:

"The plan would always be to use that which was available and which had a good track record."

I just wondered what you meant by a good track record.

A. There were -- and I think you have had evidence of this -- episodes, during that period of time, where specific products seemed to be associated with a more dramatic hepatitic pattern in a patient, and those products were recalled.

So basically we would use the concentrate which had not been associated with that type of problem. But obviously, all of the products to an extent turned out to be transmitting Hepatitis C as it came to be called.

Q. Can we just move to the next page, please, and a question was posed about systems. Just one thing, professor, in that answer. We can see it's on our screen about six lines from the bottom currently:

"My recollection ..."

Do you see that section about two thirds of the way down the paragraph. Your recollection is that:

"The supplies were kept in the blood bank."

That's the blood bank in Yorkhill?

A. Yes, I think so. I'm not at all sure of that.

Q. Who ran the blood bank?

A. I did.

Q. You? Yes?

A. With many other tasks.

Q. I think we can leave that statement now to one side, thank you, Professor Hann.

Just quickly to dispose of something else you have sent to us, if we could. It's a recent letter and it's the one about funding from drug companies, if you can find your copy of that. It's [PEN0150330].

Yes, we asked you, as we have asked, I hope, all the other directors, about connections with pharmaceutical companies, and you say that to the best of your knowledge your centre, Yorkhill, did not receive any pharma company funding for staff employment or for

research.

A. That's correct, yes.

Q. Although you recognised the possibility that drug company funding may have facilitated attendance at international meetings.

A. It's possible, yes.

Q. Yes. And you say that's something that continues today.

A. It does.

Q. And in fact at Great Ormond Street you say there was a practice of approaching commercial companies in rotation to ask for such funding, the rotation bit presumably being so that there was no particular connection with any one. Is that right?

A. Absolutely, yes.

Q. Yes.

A. And obviously we looked for study leave NHS funding or local charitable funding, if that was appropriate, first and then we approached them.

Q. Right. We can put that to one side now, Professor Hann, thank you. Something else we asked you about -- and it is really because you drew our attention to it -- is the symposium in Stirling.

Actually, before we go directly to that, we should go to the document that's actually entitled "Professor Ian Hann's statement", so that we have that,

and we can see where the Stirling symposium fits in. "Professor Ian Hann's Statement to the Penrose Inquiry", dated 30/9/2010. That's [PEN0150370]?

A. Yes.

Q. Just to check we haven't missed anything from the first page of that, but I think we have already covered the commencement of your work at Yorkhill in 1983, and you have developed a little further the conditions that had applied immediately before you arrived with Dr Willoughby. You say:

"The reasons were aired in the media at the time."

So the difficulties must have been really quite well-known, at least in Glasgow?

A. Yes.

Q. You say:

"He was very disaffected with the general lack of resources and in particular a lack of trainee medical NHS-funded posts and the funding for a second consultant."

Was that something you really had to start asking for as soon as you arrived, more help?

A. Yes. I am afraid it was an era where those who shouted loudest were the ones who probably got the resources. So I had to spend a great deal of time fighting our corner, both for buildings, which we eventually built,

and for a bone marrow transplant unit, which was built, and also, even more importantly, for staffing.

Q. The combination of responsibilities, Professor Hann, in involving, as it did, children with leukaemia, which I hope can be described as malignancy of the blood?

A. Yes.

Q. Children with solid tumours and children with haemophilia, does sound, I think, to lay people to be a particularly harrowing one.

A. Yes, and the attrition amongst my colleagues at the time throughout the UK was significant.

Q. That was commonplace, was it, to be combining all these different, very challenging and serious medical problems? I suppose they belong together, do they?

A. I don't think there was any other job where the volume was great as that in the UK.

Q. You mean in Glasgow specifically, there was no other job where the volume was as great?

A. No, there was no job throughout the whole of the UK where that volume of work would have been placed upon one person with very little funding to --

Q. Sorry, I'm just trying to be clear. The weight of the load in Glasgow, are you saying that was heavier than any other such post in the UK?

A. If you look at it as a centre, it was one of the larger

and certainly not the largest centre. With regard to haemophilia, there would have been two or three others that were larger. It depends on population size essentially, and we were looking after roughly 3 million people, 1 million or less children. And there would be centres in Manchester and Birmingham that were bigger and we were similar to the next size in population for haemophilia, if you like.

Q. Right. But was the combination in Glasgow, the combination of all these different factors, particularly onerous even within an onerous specialism?

A. I was the only consultant in the UK who had all of those responsibilities in the one job.

Q. Can we move to the second page and look at your reference to the meeting in Stirling. This is obviously something you attended before you became the director at Yorkhill?

A. Yes.

Q. We traced the papers from that meeting, and I think just so that we can put them into the record, we should look at them briefly. I think you have a hard copy because we sent you a hard copy. It's [LIT0013668]. So you can get your hard copy and we will have our virtual copy.

I don't know, can we juxtapose Professor Hann's comments specifically on this meeting, if we could,

please. That's [PEN0150270]. If we could have that aside. So your document relating specifically to that as well, please, Professor Hann, if you could have that. Your comments.

THE CHAIRMAN: Professor Hann, what interest took you to Stirling?

A. Throughout my career, one of my main interests was infection in immuno-compromised patients. This was the main meeting in the world -- it just so happened to be in Scotland at that time -- dealing with such infections. Immuno-compromised patients basically being patients who have either immune deficiencies, or more commonly leukaemia and cancers, requiring treatment which made them very susceptible to infection. Throughout my career, that was probably my main research interest.

MS DUNLOP: Can we get 0270 beside the book?

THE CHAIRMAN: Do we have it set up as you want?

MS DUNLOP: No, there is a specific document dealing with this symposium. That's [PEN0150270].

Just to explain, sir. We did go to this organisation to try and find exactly what the dates were and the best they have been able to tell us is that it was June 1982. We do have correspondence to that effect.

THE CHAIRMAN: The reason, professor, for asking about your interest is that we have heard from haemophilia specialists who were not at the meeting and some of whom knew nothing about it. Does that surprise you?

A. No, I think, you know, without bleating on too much, we were extremely busy at the time and really couldn't get away to lots of meetings. This was a meeting which would have been attended mainly by leukaemia treaters, bone marrow transplant doctors and if you like, malignant haematologists, and there were, if you like, many other meetings for haemophilia directors, et cetera. It would have been unusual for clotters, if you like, to attend this meeting.

MS DUNLOP: Right.

THE CHAIRMAN: Thank you.

MS DUNLOP: Sir, just without taking too much time, we can see from the preface, which I think will be 3671, the relevant pages from what is a published book, sir, which have been scanned in, and I think it's the fourth page in. The preface says:

"There was a special lecture by Dr Donald Armstrong on Acquired Immuno-Deficiency in homosexuals and drug addicts. A topic which came to the fore after the plenary sessions had been planned."

Was it the talk of the meeting, professor?

A. Yes, very much so.
Q. We can see a long paper on the topic at 3685.
A. Do you have the page number of the actual book?
Q. I'm sorry, I think it will be page 105.
A. The numbers are on alternate pages. Usually anyway.
Q. It is the presentation headed "Acquired Immuno-Deficiency Syndrome: infection and neoplasia in homosexual men and intravenous drug addicts."

A long list of contributors. We see one of them was Dr Curran, whose name has cropped up in other publications.

A. Yes. CDC.
Q. Yes. And just to look at what was being said, there is a reference to an alarming epidemic, and at the bottom of the page:

"AIDS patients are regularly seen in Los Angeles, San Francisco and other large cities in the United States. Cases have also been reported from Europe. In addition to ..."

Then we move past a table that appears in on the next page, two tables in fact, of data so far, information to date. We find the text:

"In addition to AIDS with its complications, another syndrome, lymphadenopathy, of unknown aetiology has been recognised in the same population."

Then the reference to persistent weight loss and then the history of some of the lifestyle factors of homosexual men involved.

Onto the next page, which is 109, 3689 for us, we can see at the bottom:

"Acquired Immuno-deficiency disease has a high mortality rate. Thirteen of 42 patients in our series have already died."

Then on 3691, page 111, some description of attempted treatments and then a statement is made:

"The aetiology of this Acquired Immuno-deficiency disease is not known."

Some reference to cytomegalovirus. Some questions posed towards the end of the paragraph:

"If CMV or other known virus is causing this disease, why is it happening now?"

So was there an atmosphere at the meeting of great puzzlement?

A. Extreme.

Q. And if we look on to the next page, 112, a reference at the top to:

"Many people being exposed but only a few people developing symptoms."

Then the final paragraph:

"Those who take care of these patients realise how

devastating this illness is. The early events need to be identified by prospective studies of high risk groups."

So is the thinking there, the reference to prospective studies of high risk groups, is that a reference to the need to acquire more knowledge about this by looking at how it starts? That would be the notion of the prospective studies?

A. I think we just needed to know a lot more -- I mean, there was a lot of description here which initially was puzzling because it appeared to be a series of different diseases almost. People started naming them, things like Slims disease, and so on and so forth. So what I think they are saying there is we just need to understand the natural history, obviously the aetiology, the cause, over which there was a great deal of puzzlement; why it was making people immune deficient or were they immune deficient and therefore getting these things.

This is a very short summary of a great deal of discussion over all the various possibilities with regard to research needed to be done, and especially for the first time. Although we knew some viruses, like Epstein Barr virus, the glandular fever virus, other Herpes viruses like cytomegalovirus, could cause immune

deficiencies, nothing remotely like this had ever happened before.

So we needed to prospectively study apparently normal gay people at that time, intravenous drug abusers et cetera, and see what it was that was making them immune deficient.

Q. Can we look then at the document on the right? That's your notes of your memory of this symposium. You say you remember it well because you were ill yourself.

A. Ironically, yes.

Q. You say:

"The meeting was very gloomy, with eminent doctors expressing their dismay at the dramatic new problem."

Ignorance and impotence, was that the sort of dominant feeling?

A. Yes.

Q. Then in paragraph 3 you talk about -- page 111 -- a very good insight to your memory on aetiology at the time. In paragraph 6 you say:

"There is no mention of haemophilia persons in the documents I have recently seen. My memory is that there was corridor discussion of possible other affected patients including a very small number with haemophilia."

I just really wanted to ask you two things,

Professor Hann. When you left this symposium in Stirling, among the various possible explanations, do you have any memory of what you yourself thought was likely to be causing it?

A. The preferred belief of people in discussions, if you like, with the experts -- I did know Dr Armstrong a little so I think I may have discussed it with him -- was that it was mainly a coincidence of factors, such as the use of recreational drugs, so-called, making these people immune deficient and making them very susceptible to cytomegalovirus and the cause, which was not known at that time, of Kaposi's sarcoma, such that we know to be due to a herpes group virus.

So it was thought most likely that there may have been a new agent, a new viral agent, but that that may well not be the only cause and it may be due to several viruses. In fact one of the virology experts in the UK at the time, Professor Tyrell, certainly later in 1983 was still of the view that that was most likely to be the case, and I remember either a lecture or a discussion with him saying that it was unlikely to just be one agent. Like quite a lot of things in medicine, it turned out to be simpler but not easier than we first imagined.

Q. The other thing I wanted to ask you was: did you leave

thinking that it was going to be relevant to your patients with haemophilia?

A. I thought that there is a possibility. But this was mainly a problem of sexual transmission and possibly intravenous drug abuse.

Q. Can we revert to the statement that we were looking at, please? That's [PEN0150370]. Just because that's the one that mentions your trip to Stirling. On to the second page under that heading in bold, "The situation in January 1983". You say you are trying to answer the questions in chronological order and you point out that it would be useful to see actual amounts transfused and also whether or not any HIV conversions occurred in the children after 1983. I don't know, Professor Hann, if you have seen a spreadsheet. I'm not sure if we sent it to you, but there is a spreadsheet.

A. Yesterday.

Q. Right. So you have now seen the spreadsheet that has been prepared, which lists 21 boys who are considered by the haemophilia directors, when they analyse the data today, to have been most likely to have acquired infection at Yorkhill. You have seen that now?

A. I have seen it, yes.

Q. It's [PEN0120160]. What are your thoughts on the spreadsheet, professor?

A. Several. The first is -- again this is memory and others may remember better -- I don't recall 21 patients that I was looking after being HIV positive. My memory is that it was nearer to ten. I have no means of checking that but that is my memory.

I accept that this has been looked at and drawn up and I can only accept it.

The seroconversions which basically are in those patients who between the last negative and the first positive test, where those two tests are available, occur when I would expect, which reflected the experience at the Royal Free, where I have just come from in 1983. In other words, they occurred between 1981 and 1982 largely.

I don't recall any episodes that definitely occurred at the beginning of January 1983.

The first patient on the list and several others, where there is no negative test available, could have seroconverted since subsequent to my starting there, but I just don't know.

Where there is definite evidence, it occurred mainly during 1981/1982.

Q. Yes. Just to explain, professor, and because time is short, I'm not going to go to it, but when we looked at statistics, which we did in March, it did seem as though

the Glasgow total, if we can put it like that, which UKHCDO had had, was 34 and that the allocation within Glasgow, according to their data, had been 23 to the Royal Infirmary and 11 to Yorkhill, but that as a result of the discussions and the analysis that the directors have now applied, it looks as though a proportion of the Royal Infirmary patients have been allocated back to Yorkhill. So although they were perhaps being treated at the Royal Infirmary, their infection is being regarded as having occurred while they were still, as it were, within the Yorkhill catchment. So that may help to explain why it is beyond your recollection.

A. Yes, I'm sorry to interrupt. Yes, that is much more my recollection.

Q. Right. Do you remember in your tenure at Yorkhill, any sense of how this had happened? What as doctors, when you were discussing it within the hospital, to what in particular -- and I'm really thinking of blood products -- it was being attributed?

A. The HIV infection?

Q. Yes, within the children in Yorkhill?

A. Yes, well almost certainly related to the factor concentrates that they had received.

Q. Commercial or NHS?

A. Well, I'm not sure that I had all the negative tests

available at the time in order to be able to let me know. This look back procedure is something I have wracked my brain about and I find it very difficult to remember how it happened, but obviously what we wanted to know initially was was a patient HIV positive or not, and what did that mean. And then obviously from the blood transfusion safety, et cetera, point of view, one needed to know if there was any way of allocating that seropositivity to particular batches or whatever.

That would have been extremely difficult to do because there was no batch allocation in those days, although that did come in at some stage. In other words, you know, trying to allocate specific batches to specific patients so that you could then go back and say, "Right, you know, that batch needs to be tested", or withdrawn or whatever it might be. So they had been exposed to a whole series of different products.

Q. Can we put the spreadsheet down, please, or close it and go back to the statement just to ask you another couple of questions, I think, professor, maybe three. If you go on to page 4 at the top, and this is in the autumn of 1983, one of the things you remember is a very reassuring statement from Ken Clarke.

A. I'm sorry, my pages are different from yours.

Q. I'm sorry.

A. Heading or a paragraph?
Q. There is a question in bold:
"What did I do to reduce risk of virus transmission?"
A. Right.
Q. Can you find that? Immediately above that you have told us that you recall a very reassuring statement from Ken Clarke and you refer to our paragraph 8.63 in the preliminary report. We know, because we have been over this with other witnesses, that what was being said was that there was no conclusive evidence that AIDS was transmitted by blood products, or something like that. But when you heard that, your interpretation of it was that it was very reassuring?
A. I haven't written that very well, to be honest.
It was intended to be a very reassuring statement and is scientifically correct, and I think it had that effect on a number of people. But by this time we were very concerned obviously, about the risk of transmission and the fact that at least one case had been reported in the UK by this stage.
Q. Yes.
A. So I wasn't personally very reassured. It was intended to be a very reassuring statement.
In retrospect a rather political statement, if you

like, which is correct without really transmitting the fears and worries that we had.

THE CHAIRMAN: Could you tell me what you mean by it being scientifically correct?

A. I think I'm right in saying that by this stage Montagnier had produced some virological evidence which was controversial only in so much that we didn't know how to interpret it. You can't be sure about transmission of an agent until you know what that agent is. I haven't read all of it in detail but I think what Mark Winter said to you about Koch's Postulates summarises all of that.

THE CHAIRMAN: One of the problems is that everybody is reading what everyone else said, of course, professor, but if scientific proof means the exclusion of all possible particular negative propositions that might challenge it, it is a very high standard indeed. Is that what you have in mind?

A. Yes, I would agree with that. It was not scientifically, conclusively proven.

THE CHAIRMAN: Do you think that politicians understand what they are saying when they use an expression like that?

A. My experience over the years is that they say things that could easily be misinterpreted but mean that they can't be pinned down, if you see what I mean.

THE CHAIRMAN: But, of course, Mr Clarke will be passing on information that was provided by his Civil Service advisers, one would imagine.

A. Yes, I'm sure that it was a Yes, Minister-type situation.

MS DUNLOP: Just looking further down that page, Professor Hann, if you still have the hard copy, you do say that there was a constant need for vigilance. I'm reading from a paragraph that begins:

"I am asked if haemophilia doctors followed advice. There was a constant need for vigilance in this respect as there was inappropriate use of blood products on a regular basis, particularly by surgeons, who often attributed near-magical properties to products such as fresh-frozen plasma and cryoprecipitate and whole blood."

Do you think sometimes the surgeons were keen on the advantages and didn't always appreciate the disadvantages?

A. I think that's remained the case for many years, yes.

Q. Then finally, Professor Hann, on the last page, just to go straight to the very end, you say that:

"The treating consultant had to deal with the patients in the middle of what can only be called a maelstrom of uncoordinated events. Means have to be

found to coordinate crises at a high level and to bring all agencies together. This really didn't happen and there was a dislocation between the parts of the UK which I hope has not continued."

There was, it seems to us, looking back at the period, certainly a proliferation of committees and working parties and working groups. Is that your recollection?

A. There was. I won't go over all the ground that you have already heard. This is a pre-Internet, pre-computer era, when access to journals and all the rest of it -- you habe heard all of that before. But I think I would just like to emphasise what Mark Winter already said to you, that what we needed was a bit less democracy and a bit more guidance from experts. What tended to happen in this era was that a group of doctors would get together with often civil servants or whoever, or public health doctors, and would discuss things. I hope this doesn't sound too bad but it's a bit like putting 20 lawyers in a room; you will get 20 different views. Basically that's exactly what happened. You will see that one very good example of many was that what happened with regard to testing and giving out results to people.

I went to any number of meetings on that, where the

conclusion was we can't agree, therefore it's down to individual clinical responsibility. Or whatever.

What we needed and what came later with prions, and to a certain extent Hepatitis C, was an expert committee that came to a conclusion, that gave us guidelines that could be regularly updated. Having a dozen committees doesn't solve the problem. And even if you are in contact with real experts, as I was, in London and in Glasgow and Edinburgh, you still need some sort of guidance. You need somebody to say, "This is the way you should be doing it". And we got virtually none of that.

Q. When you say at the end of this passage that the problem needs to be dealt with at the highest levels, you are thinking, I take it from your answer, of something like EAGA, the Expert Advisory Group On AIDS that was established in 1985. Was that the sort of body?

A. To be honest with you, I can't remember that body at all.

Q. Right.

A. You need an expert body that comes to the best possible conclusions at the time, which are practicable and are, if you like, a means of doing things, as opposed to just setting out the list of the problems which we already knew about.

Q. Who has to make that happen?
A. I think there was too much deferring to doctors in that era. We all had our views but somebody had to come to a conclusion, and therefore it has to be a group of people who are held to account by the people in the Home and Health Department, as it was called then, or the health departments, and senior doctors and virologists. We had a desperate lack of virological input in that era.
Q. Who has to bring everyone together in that way?
A. Yes, and they have to come to conclusions. We needed guidelines, you didn't need a list of problems.
Q. Does it really have to be government taking the initiative on an issue like that and bringing people together?
A. I believe that it does. I really believe that it does in the end because otherwise who is going to follow it? Who is going to follow it up? Who is going to transmit the information to public health doctors, to GPs, to everyone else? We don't have the resources to do that sort of thing.
Q. Thank you, Professor Hann. My colleague, Mr Gardiner is going to ask you some questions about direct doctor/patient or perhaps doctor/parent interactions, but we do also need to have a short break.

Sir, we only have the facility in court to 11.45. Perhaps if we keep the break as short as possible.

THE CHAIRMAN: We will try to do that.

Professor, the area that Ms Dunlop has been covering is one of very significant interest to me and I will have to look at it. One of the things I would like you to think about while we are having the break and see if you can help us on is this: I think in current research areas, the notion of cross-cutting between disciplines is becoming very well established, but at the time you are talking about, I have the impression that the separate professional groups perhaps didn't join together to reach conclusions or to discuss issues. Could you deal with any aspect relating to that problem that might be of help to us when you come back.

(11.06 am)

(Short break)

(11.17 am)

MS DUNLOP: I'm sorry, sir, I'm sorry, professor, there is one thing I completely forgot to ask Professor Hann.

THE CHAIRMAN: Can I ask my question first?

MS DUNLOP: Yes.

THE CHAIRMAN: Professor Hann, the reason for asking is that you have spoken generally about doctors and the need to coordinate thought, and that is what triggered in my

mind the question whether it went beyond that and raised the issue of the co-ordination of the expertise of different groups. Do you have anything to say about that?

A. Yes, I think we learned a great deal from the HIV era. So a small amount of good did come out of that time; which is a very dark time, and that was the need for two main things. One which we took on board fairly quickly, which is the need for multidisciplinary teams, and I think that we did that in paediatrics long before the adult field took it on, and it's now standard, for instance, in breast cancer and all the rest of it. But certainly it took a very great deal of time to come in.

We, for instance, set up a multi-disciplinary brain tumour group over the next months and so on. So that involves all persons: psychologists, radiotherapists, nurses, doctors and social workers and so on. So it became much more the team approach rather than a pyramidal setup, which it had been recently.

Secondly -- you are absolutely right, there are two problems really. First of all, virology was in many ways in its infancy. There was only really one antiviral drug and that was really just treating cold sores. So basically what had needed to happen was a development of virology and infectious diseases, both

of which were pretty much in their infancy, and for those groups then to form co-ordinated groups when it was necessary. I do believe that that has happened. I'm obviously not involved in it any more and wasn't for quite some time, in managing patients with these type of problems, but there certainly is better direction nowadays, and I hope that that continues and that it is done in a way that they would deal with other emergencies within government, for instance.

THE CHAIRMAN: Thank you.

A. So, yes, there is a major problem with co-ordination, which has been over come by the use of the internet, much readier availability of publications and the formation of multi-disciplinary groups.

THE CHAIRMAN: Thank you very much.

Ms Dunlop?

MS DUNLOP: Yes, sir.

Just quickly Professor Hann, because I know we are running out of time, but I forgot to ask you about an exchange of letters in December 1984. Just for the record, Professor Hann, I don't think we need to go to them. You have them. If I just paraphrase for everyone what they are and we can look at them in the transcript.

Professor Cash's letter to all haemophilia directors of 17 December 1984, [SNB0074685], and a handwritten

response from you on 19 December, [SNB0074689]. In short, Professor Hann, it looks as though you were unhappy with the speed at which the heat-treated product was introduced and all the tests that you were being asked to conduct. Is that right?

A. Yes, to give everyone their due, and Dr Cash his due, there was a great deal of urgency in this situation and they were responding to that. I think there was, to a certain extent, a failure to discuss what was appropriate in children in particular. Certainly I was very nervous about this approach. Without going into great detail, one normally does not launch a product or a drug in children with very, very limited information. Especially when there is a risk of neoantigen formation, therefore severe reactions which could be even life-threatening. There could be a significant risk of the development of inhibitors, which is a disaster, making patients not responsive to treatment, et cetera.

As it turned out, everything was okay, but I just wanted to express the fact that (a), it was very impracticable to do what was being asked, (b), it wasn't necessarily covering all the types of checks that I would like to see with regard to the liver function tests, et cetera and (c), that it really ought to have been instituted, and I would have preferred to see a bit

more evidence that there were no neoantigens, et cetera, and that there was some evidence of safety rather than, "Here it is, get on with it".

Q. Thank you.

Questions by MR GARDINER

THE CHAIRMAN: Yes, Mr Gardiner.

MR GARDINER: Thank you, sir.

Professor Hann, can you hear me all right?

A. Very well.

Q. Thank you.

I'm going to ask you some questions about the information that was given to patients about the risk of AIDS before treatment with blood products, about tracing and testing of patients and the information that was given to patients who were found to be infected with the virus. That's B5 topic.

The Inquiry wrote to you on 31 March this year. That document is [PEN0160472]. Could we just get that up on the screen.

That included a schedule which set out the things we were interested in. At page 4 of that schedule, if we could just go there, which is 0475.

A. Which question, sorry?

Q. I don't think you have copy of this, do you?

A. No, I have a copy of my report, which is in bold but not

the --

Q. Yes, I'm going to come to that in a minute. We can see at page 4 question 1, 2, 3, 4 and 5. If we go to your report, your response, which is [PEN0120270], which I think you have a copy of.

A. Yes.

Q. We have that on the screen and we see there question 1, which is the question that you have taken from our letter. Is that right?

A. As far as I remember, yes.

Q. Yes, thank you. So the question that you are being asked there, number 1 is:

"When the possibility that AIDS was a blood-borne disease which affected haemophiliacs became apparent (around December 1982), did Professor Hann discuss the implications with his patients (or their parents) before continuing to use factor concentrate therapy."

In your answer you say:

"I can't recall the detail of discussions with regard to risks of therapy."

Then you go on to say:

"The situation at Yorkhill was that we had a completely open approach and questions could and were asked on many topics in the day care area, in the clinics which Dr Pettigrew and I set up for this purpose

and clinical review for the first time, and in the patient/parent support groups that we set up for the first time."

Just before we look at the detail of this, could you give us a description of the physical set-up at Yorkhill at that time?

A. Yes. At that era -- it is one of the many things I had to fight for -- we did not have a haemophilia centre as such. We had offices, a laboratory and a day care centre and a ward, which was obviously mainly for the leukaemia, bone marrow transplant and solid tumour patients. So the majority of the patients were seen in the day care area, which was not ideal for the purpose in that it was a mainly open area, although it was possible to have fairly discreet conversations. It was quiet at times.

I mean, that was the physical set-up. The day care area was used for day surgery, for splints and such like, and so we would sometimes be competing for space there or have limited space, and the nursing staff would be looking after a whole variety of different patients from throughout the hospital.

Q. So you didn't have a private room with a door that you could shut for appointments. Is that right?

A. Within that area there was -- my memory is vague on

this -- definitely one room where you could shut the door, which I think was mainly used for procedures. But you could use that as a room. Of course, I forgot to say, we had a clinic area where the rooms were completely private, where we did our clinics, where you could see patients if there was a clinic not in progress.

Q. Yes. So for the clinics you would have arranged beforehand for patients to come and see you. Is that right?

A. Yes, I would, yes.

Q. And --

A. But we could use those rooms ad hoc at times.

Q. Yes. Thank you.

In your answer in 1.1 you talk about a completely open approach. Could you explain a bit more how that operated?

A. Yes. I mean, basically, for many years in paediatrics, and certainly before this time, the old idea that you basically gave partial or unworrying information to people had almost entirely gone, and certainly had gone in this unit. So if people asked you about things, you answered them honestly. We had a problem, which wasn't entirely resolved, over what we could tell to children. The so-called Gillick competence was coming through and

we became more confident in that respect and then less confident with the pronouncements after Lord Scarman from Brazier and Donaldson and others.

So it was not easy actually to know exactly what you could say to the children, and especially young adolescents who did have a degree of competence. So far as the parents were concerned, we adopted several approaches which I put there. We had group meetings. We had clinics, both of which were new developments, which I had brought from London; and we spoke to the parents and we told them what we knew the best information that we had at the time.

This time, at the beginning of 1983, it was certainly unclear, and I would agree with Dr Forbes' evidence in this respect, that there was a great deal of doubt over whether this was going to be a real problem in the haemophilia field.

Q. Professor Hann, did you mention Brazier there? Who is Brazier?

A. I'm trying to remember. I'm not trying to be a lawyer here. I'm sorry, when it came to Gillick competence, we had Scarman's view and there were other views subsequently which made it much -- I need to be careful what I say about the law, but it made things more difficult for us as clinicians. The interpretation of

what you could say and not, for instance, tell parents to children, and this always came through usually because of contraception, but it also affected us in our area. What were you expected to tell children? What were you expected to tell children when the parents didn't necessarily want you to tell them, and so on and so forth, were all difficult areas.

Q. Yes, thank you. And when you say Gillick. Do you mean Gillick?

A. Gillick.

Q. Yes, thank you.

A. I presume this applies to Scotland as well.

Q. Thank you.

If I could just ask you to look down the page to paragraph 1.4. You are still answering question 1 and you say:

"When I took over, most of the patients had of course already been established on home therapy. Those few that were diagnosed anew had a full discussion of the disorder and its treatment."

Then you talk about Hepatitis C. Could you describe these full discussions of the disorder and its treatment?

A. Yes. Obviously, the main emphasis was on bleeding, avoiding bleeding, explaining what the factor deficiency

was and how that worked and how it came about. The genetic aspects were extremely important to families and were quite difficult to explain because there were different modes(?) of inheritance. All of that, plus a discussion of when treatment was required, what that treatment was, what the potential side effects of those treatments were and how to access the hospital social work disability allowances and so on; and of course, you can't do that in one interview.

One thing you learn as a paediatrician, when you bombard people who have just had their child diagnosed with a serious disorder, no matter how clever or scientific they are, they can only take in part of it. So what I was trying to say in this very wordy pre-amble I have put here is that in the view of a paediatrician, consent and the delivery of information is a process. It is not something you sort of hit them with and walk away.

Q. Yes, I understand. Could you turn over the page, please, to paragraph 1.5. There you say:

"There were many discussions with patients following the initial descriptions of HIV transmission risks and we would have explained what we knew at the time. We would never have knowingly exposed patients to increased risk."

When you talk about the initial descriptions of the HIV transmission risks, what time are you talking about?

A. Well, my memory is that this became a real issue during 1983. That's my memory. I can't remember exactly when and I want to avoid the sort of business of looking back at things saying, "Oh, yes, it was then", because I just simply don't remember.

I happen to have started on January 1. It definitely wasn't immediately obvious as a problem but as Dr Forbes said, it sort of hit us later that year that this was going to be a major issue.

Q. Yes. Could you describe these discussions at that time?

A. The discussions prior to knowing about the virus, et cetera, and knowing about virus positivity, would have been first of all to discuss the risk of non-A non-B hepatitis, which at that stage was thought to be not a major problem, and even the experts agree, probably a minor disorder, which turned out not to be the case sadly.

We would have said that there had been a few cases described of haemophilia. We didn't know if this was going to become a major problem. Even into 1984, when the European study had been done, the experts like Peter Jones were quoting one in 1200 risks, et cetera.

So we didn't have that type of information in 1983

but it appeared to be a rare risk. I hope and I believe that we weren't just reassuring, we were saying that this is a possibility. We know so little about it. We don't know the cause of it, et cetera, et cetera.

Q. Yes. Would you have given patients the option to take up a different therapy, for example to go back to cryoprecipitate?

A. Yes. To put it the other way, we would not have resisted that suggestion from them that it is for certain. From our point of view, for those patients who were receiving treatment at the early stages of their disorder, we offered cryoprecipitate treatment if it was possible logistically to give them it. If their veins were adequate, et cetera.

My memory is -- which may be incorrect -- that there were some patients, certainly into 1984, who may have reverted to cryoprecipitate treatment for a period of time. That is my memory. I certainly think that there were some guidelines coming through -- I can't remember exactly when they came out -- that very young children should be considered for cryoprecipitate treatment, and I do believe that we offered that as a possibility.

Q. Is that something that you would automatically offer as a possibility or would you wait to see if the parents would ask about that as a possibility?

A. I think we discussed all possible therapies, including DDAVP, et cetera, depending on, you know, the individual severity of the problem. I think it would be silly for us to expect parents to be very knowledgeable; some of them were of course as time went by. The whole idea was to make them experts of their disease. That was the whole plan of what we did.

So, yes, later on, we would certainly expect them to have detailed discussions with us about where we go from here, and so if they were newly diagnosed et cetera, and they were very young, then the use of cryoprecipitate would have been a real possibility that was offered to them and may even have been recommended as the first option in that difficult interim period.

Q. Yes, thank you.

If we could just pass down the page to question 3, because I think we have covered question 2. The question: when did Professor Hann start testing his patients for HTLV-III? You say in paragraph 3.1:

"We started testing for HTLV-III when a test became available and when its reliability had improved. I do not recall when that was but I think it was through SNBTS. There were several attempts at tests that were not satisfactory prior to that."

Doing the best you can, Professor Hann, could you

tell us how testing was carried out through SNBTS?

A. Yes, I'm not even sure it was SNBTS in retrospect. I see other people saying it is through virology and so on. That was my best recollection. What I would say is -- and I take full responsibility for this -- we did not do this as well as we should have done -- or I didn't. And we learned a great deal from this and by the time we got to Hepatitis C we did a great deal better. I wasn't complacent about that. We did studies straight afterwards to see the effects on families of what we had done.

As far as I remember, it may have been that this was actually instituted by the virologists themselves, or it may have been that we requested the virologists that they test samples that they had stored on our patients. For patients who had not been tested, or in whom samples were not available, which I think were quite a few, they would correlate with those where you don't have a negative test result. Then we would discuss it with the family and say we needed to do these tests and also we needed to do confirmatory tests if we did find a problem.

Q. Yes. The next question, which you have touched on:

"In what circumstances were blood tests carried out? When were blood samples taken from patients? Were the

blood samples taken with the intention of testing for HTLV-III? Who carried out these tests?"

You say at 4.1:

"I cannot recall the detail of testing. It was probably a mixture of look-back and actual testing in realtime."

When you say "look-back" are you meaning testing on stored blood samples?

A. Yes.

Q. Then actual testing would be a fresh test, getting the patient in and taking blood?

A. For one of two reasons. Either because there was no stored sample or because there was a positive test which needed to be verified.

Q. Yes. Thank you. We heard evidence from Dr Pettigrew yesterday that her recollection was that it was Dr Follett, I believe at the virology department, who did the testing. Does that ring any bells with you at all?

A. Yes, it does. And I may well be wrong when I said SNBTS. I did know Dr Follett and it was probably his laboratory.

Q. Right. Now that you have a chance to think about it, is that your best recollection of how these --

A. Yes.

Q. -- children came to be tested?
A. Yes, it is but I still can't remember if he initiated that testing or whether we requested it.
Q. Yes. Now that you have remembered about Dr Follett, can you remember receiving the results?
A. I can't remember specific incidents, I can remember that I received it but I don't remember. I noticed from Dr Pettigrew's evidence that there was a letter for us but I don't recall that incident.
Q. You have no recollection of a letter from Dr Follett?
A. I know that we got the results. I can't remember how.
Q. Okay.
A. Her recollection is, I'm sure, much better than mine.
Q. Yes. If it's correct that Dr Follett carried out tests on stored samples, do you think that permission was obtained from the parents before these tests were carried out?
A. The simple answer is that I can't remember. The more detailed answer is that I would hope that we were in regular contact with parents and were telling them this, and that the Haemophilia Society was doing the same. I would concur with what Dr Winter said on this. It was not the standard at the time -- quite wrongly -- for us to discuss these sort of things in great detail, and we sort of always assumed that the family, parents, would

want us to find out what the situation was. And I think I would be correct in saying that I did not go to the extent that I should have done, and I would have done, a few years later, having learned from this episode, in getting informed consent for that testing, and I regret that.

Q. Yes. Thank you. You remember that you received the results?

A. Yes.

Q. But can you remember what happened next? I mean, you must have communicated them to Dr Pettigrew?

A. Yes. We had discussions and had had discussions at national level, or either discussed them with colleagues in London, and I can't remember as to what. I think I knew Dr Tedder quite well, of the Middlesex. I was a trainee in London previously, and subsequently of course.

What did a test mean? That was the original question.

So we have to do several things. First of all we had to confirm that test with the gold standard, and the gold standard at the time was Western blotting. So we requested that that be done. That sometimes required a further sample, which we would definitely have discussed with the family why we were doing it. That

would not have been surreptitious. You know, there was no way we could have done that.

So we didn't immediately tell persons. Because there were definite false negatives, and I think Dr Ludlam and others had said maybe these patients are becoming negative. In fact, the test was a false positive usually and subsequent negativity was an extreme rarity.

So basically we went through a process. We confirmed the test, usually with Western blotting or maybe even a further test just to be certain. We just then took the next possible opportunity, within a few weeks certainly of discussing in full with the family of what the result was and what the meaning of the result was and what needed to be done.

Q. When you are talking about confirmatory testing, is that another test on a stored sample?

A. No -- yes, sorry. It could be if there was enough there, yes. Or it could be that we had to take another sample for a Western blot analysis. So we may well have had to take a further sample.

Q. I think what you are saying is that if you could do a confirmatory test on the stored sample, the parents would not be asked for their permission for a further test, but if the child had to come in and give a new

sample, the parents would be told about the test. Is that right?

A. Yes, to the best of my knowledge, yes.

Q. Could you have another look at question 5, please? Question 5.

A. I need to warn you that there is only two minutes of this video left. So I'll carry on.

Q. Yes, thank you.

Question 5, 5.4. You talk about the routine testing according to the standard UK guideline of the time. What are you referring to there, Professor Hann?

A. It is not a written guide. I probably should have said standard "practice" rather than "guideline". That was what we did. I had come from the Royal Free, which was particularly interested in viral infections, and so we were taking at least annual and probably more frequent tests, mainly to look for hepatitis.

Q. Yes.

A. And Factor VIII levels sometimes.

Q. Just finally, because it sounds like we don't have much more time, could you give us your best recollection of how the results were communicated to the parents?

A. Yes. They were communicated by Dr Pettigrew and myself. I was the consultant, so it's my responsibility. I was completely against the idea, which some have floated --

I can't remember who -- of sending people letters and saying, "Please, I need to see you in the clinic" or something, or phoning people up and saying the same thing. Basically we took the next opportunity. These people were visiting often, some of them weekly, some of them every few weeks, but certainly not monthly or very infrequently.

So I would be very surprised if there was a delay of more than a week or two or three. And that would be in the clinic or in the day care area, usually probably in the day care area. And using as private a way of doing it as possible.

Q. Why were you against writing a letter to the parents?

A. I think it would just cause extreme anxiety without actually providing information. It has been suggested that one send a letter. I could say I need to see you soon, full stop, or a letter saying, "Your son is positive and these are the consequences". I think it would be a horrendous way to deal with children and their parents.

Q. So the strategy you adopted, the reason you adopted it was to avoid anxiety and distress to the parents. Is that right?

A. Especially as there was no immediate action that we could take. This wasn't an urgent clinical situation.

Say somebody developed a respiratory situation, then we would say, "Get him here now and we will discuss the implications".

Q. I know I'm pushing my luck a bit with the time but do you personally have any recollection of passing on this information to parents?

A. Yes, I do. Let me put it this way. I do recall it vaguely but I recall one thing only in detail and that was a contact with a parent who felt that we should not have told her that her son was positive. We worked through that and it's a reflection of the fact that there was not adequate independent counselling, which is what we learned about HIV. That's what you need. Dr Patricia Hewitt's [sic - Wilkie's] PhD research which followed immediately on from this and which will be supplied to you, or maybe already has, detailed that and we learned that. We didn't do it as well as we should and that was a reflection of it.

But of course we needed to know. We couldn't manage these patients blindfold.

Q. It seems that there were about ten children at this time who had been identified. Would you say that is correct?

A. That's my recollection, 10 or 11, yes.

Q. I'll just ask you again, Professor Hann: do you personally have any memory of passing on these results

to any of the parents of these ten children?
A. I can't remember a specific instance other than the general extreme reaction to this situation because of its -- the worst thing to deal with in paediatrics, if you are dealing with leukaemia, is uncertainly and it was that aspect that was so difficult.
Q. So is it --
A. I remember that, but I don't remember speaking to X, Y or Z.
Q. In that case, is it your recollection that Dr Pettigrew would have done most of that work, passing on that information?
A. Certainly on lot of the follow-up work, or almost all of the follow-up work, but not necessarily, I would have been seeing patients in the clinic which was held on a very regular basis, probably weekly or every other week. So I'm guessing it would be about half and half as far as personal information, but the follow-up was the social workers, eventually counselors, et cetera.
Q. Thank you. One final question, if I may --
THE CHAIRMAN: I'm not sure. If we are going to be cut off. You are not going to ask the final question and prevent a follow on.
A. I don't think we will be. It will be cut off at 12 o'clock.

MR GARDINER: You have told us a couple of times that things could been done better as far as communication of information, results and so on. Could you briefly tell us how you think it could have been done better?

A. Yes. I think you may have only received it recently or may not even have received it yet. Dr Patricia Hewitt [sic - Wilkie] did a research project, which was extremely good, along with the department of psychology -- psychiatry, funded by the Haemophilia Society and led by Dr Forbes.

Basically she showed what we learned at that time, which is that you need independent counselling, you need pre-test counselling and not just running off and doing the tests and expecting people to realise that that was essential. We were naive. This was the first time that this sort of thing had happened really. There was no looking at Dr Winter's evidence, you will see there was no real precedent for that.

So that's the first thing. And also we needed more counselling follow-up and stronger support for the families subsequently, although we did get that to an extent.

Q. Yes, thank you.

THE CHAIRMAN: Professor Hann, I'm terribly anxious that we are being limited by time and not getting the best from

you that you can give us, and probably want to give us. So what I'll do is discuss with counsel whether we ought to ask you to speak to us again.

You will appreciate that not only have you not probably been asked all the questions Mr Gardiner wants to ask you, but none of the other parties have had a chance to speak to you at all. So if I may thank you very much for your contribution so far and ask you, please, to accommodate us if we come back to you again.

A. Thank you very much.

THE CHAIRMAN: Thank you very much.

MR GARDINER: Thank you.

THE CHAIRMAN: I have said it but I think that it is quite clear that Professor Hann has got a very great deal to contribute to this Inquiry and I don't want his evidence to be limited by timetable in this way. I think that the other parties really must have the opportunity to speak to him. There are some questions I might have liked to have asked him myself. So I don't know how we handle it, Mr Gardiner, but it does seem that we have to try and get another slot and have a continuation of that. Perhaps it is Ms Dunlop I should be pressing on this and not you.

MS DUNLOP: Perhaps we can reflect on it and discuss it a bit, sir, rather than doing it at the moment.

THE CHAIRMAN: I'm merely raising it for you. I hope you will discuss it.

MS DUNLOP: Yes.

THE CHAIRMAN: But I hope that Mr Di Rollo and Mr Anderson and Mr Sheldon will be party to it.

MS DUNLOP: They have to have their chance, I can see that.

THE CHAIRMAN: I'm glad.

Where do we go from here?

MS DUNLOP: Perhaps we could have five minutes just to regroup before Dr McClelland comes on.

THE CHAIRMAN: That's a good idea.

(11.59 am)

(Short break)

(12.10 pm)

THE CHAIRMAN: Good morning, Dr McClelland. We are treating your evidence as continuing so we won't go through any preliminaries.

DR BRIAN MCCLELLAND (continued)

Questions by MS DUNLOP (continued)

MS DUNLOP: Dr McClelland, you are back I think for the third time and it is probably not going to be the last. Today we are going to look at a statement you have provided for us on our topic B2 and we should have that in front of us [PEN0150307].

Thank you. You were sent a schedule, which is

a standard schedule that we sent to a number of witnesses in this area, but in fact, since that schedule was drafted the topic has been expanded to look at the very early days of the introduction of concentrates, concerns in the 1970s, the television programmes and so on. You are nodding. I hope that's not surprising, that you knew that before you came.

A. Yes.

Q. You say, reading from line 3:

"The term 'AIDS' arose first at a meeting of leaders from the blood industry, haemophilia groups, the gay community organisations and representatives from the NIH and the FDA, on July 27th 1982."

Your reference for that is actually the Dr Evatt article, "The tragic history of AIDS in the haemophilia population". We have already looked at that, Dr McClelland.

We also, after you directed us to this article, also found the response that it provoked -- I think is the right word -- from Dr Aledort, and then the reply to that from Dr Evatt. You are presumably familiar with those two documents as well, are you?

A. I'm aware of their existence. I have to say, I haven't re-read them recently.

Q. In general terms, what is your view of Dr Evatt's

chronology as set out in the first article, the tragic history article?

A. I found it a very illuminating view and it certainly fitted quite closely to my own recollections, and the reason I actually included it as an appendix to my statement was because I felt, written many years ago, it gave a more sort of approximate view of somebody who was right at the inside of the very critical early stages of the discovery of this disease, and particularly of its association with blood products.

Q. Yes. I was just checking; it is actually published in 2007. So I suppose one of the attractions of it is that it is quite a recent piece of work?

A. I am aware of that but I assume that it drew on his probably fairly extensive documentation of that period.

Q. Yes. You refer us to the initial reporting of the virus discovered by Barre-Sinoussi and Montagnier in France and we discussed that in our preliminary report, I think, around paragraph 8.84 and the work of Dr Gallo in America. Then you say:

"The term 'HIV' was not assigned by the international committee on the taxonomy of viruses until May 1986."

I'm sure this doesn't matter very much at all but our reference suggests that it was proposed in 1986 but

it's actually quite difficult to find out when consensus was achieved. Is it something that just happened or was there some kind of specific acceptance of the term?

A. I clearly had misread that but I can imagine the taxonomy committee probably takes a very long time to come to a decision about anything.

Q. Right. You give your personal background. Say you were a first-year junior house doctor in 1969 and you actually worked for Dr Howard Davies. We have been talking about Dr Davies a bit this week in fact, Dr McClelland, and you maybe know that. I don't know if you have glanced at the transcript. You may have done. Have you seen the references to him?

A. I'm aware that he has been referred to.

Q. He was a physician who cared for patients with haemophilia. We have heard a bit about how people come into haemophilia care, that some are haematologists by training but Dr Davies' route in was as a physician. Do you want to explain any more about that?

A. I think Dr Davies, if my recollection is correct, his primary responsibilities in the Royal Infirmary were for the haematology department, as it then was, which was essentially a laboratory department. There were actually two other senior clinicians, both of whom had or attained professorial status, who considered

themselves to be haematologists, but the person who actually looked after the patients with haemophilia was Dr Davies.

For example, in the unit that I did my training, medical jobs in, Dr Davies didn't actually have beds assigned to him. He did not actually have admitting rights to that ward. But he just got on with it and cared for the patients. And with enormous care, attention and diligence. He was possibly one of the most conscientious clinical directors I have ever met, although his origin was primarily as a laboratory doctor.

Q. And you explain that he was a strong proponent of cryoprecipitate rather than Factor VIII concentrate, and that his rationale was the very pooling that we now understand, and in particular the pooling from other parts of the world. So it was a theory that was based on the concept of the potential for infection?

A. Absolutely. I should perhaps say, I mentioned this background history because haemophilia and the technicalities of Factor VIII have never been my specialist area. I was trying to single out one or two things that I remember with great clarity that I think would have had a bearing on the way I thought about issues in general at the time.

Q. It was very interesting that you had, Dr McClelland, because we had just been hearing about Dr Davies. So this fits what we have been hearing from Professor Ludlam. Can we move on to the second page, please?

You do make the point at the top of the page that as transfusion director in Edinburgh you didn't have clinical responsibility for the care of patients with haemophilia. Selection and use of blood products for patients with haemophilia is not an area in which you have ever been clinically involved.

As you have looked back on this period, Dr McClelland, and as you tell us about it today, you are telling us here, I think, that you weren't a principal actor. How should we see you? Were you a supporting actor? Were you a spectator? Were you behind the scenes but involved? How do you think it's best to see your role?

A. I think I was very clear about my role at the time and I'm still clear about it. My job was running the regional transfusion centre, part of the task of which was to provide blood components and blood products for all the patients in the Southeast of Scotland. A very important part of our efforts at that time was focused on providing what we hoped would be sufficient

quantities of Factor VIII but to do that we had to collect large quantities of plasma from donors.

So a large part of my work was related to the issue of obtaining the plasma from our blood donors and making sure that that found its way to the fractionation centre in appropriate quantities and in good appropriate condition.

My second engagement, if you like, with this group of patients was -- my department contained what was called the hospital blood bank, which had the storage facilities for blood products which, as biologicals, need proper storage conditions. So we were, if you like, one of the collectors within the SNBTS of the starting material from which the Factor VIII and Factor IX were prepared. We were also at the point of distribution of those, either to individual patients or to small subunits in the hospital, which themselves dealt with individual patients.

So, I'm not sure, I think you have to draw your own answer to the question from that. That was my position in the supply chain, if you like.

Q. Yes. I quite understand, Dr McClelland. I'm certainly not going to force you to adopt my analogy, but we have already looked, I think, when you were here the last time, at aspects of your role as a collector and how you

reacted to the emerging risk. I think today, perhaps later on, we will also look at the other part you have just mentioned, about being involved in storage and supply.

On the second page of your statement you have reproduced for us a very interesting poster -- well it's a leaflet really, I think, isn't it?

A. It was stuck on the window of the plasma centre with sellotape and I photographed it.

Q. Yes. You say it's an experience that coloured your thinking about the use of blood from commercial donors:

"Shortly after my appointment to the SNBTS in 1977 ..."

I'm reading from the middle of that paragraph:

"... I visited the Cutter company in San Francisco."

That's another one of the big pharmaceutical companies in America.

A. Cutter was at that time a major player in the plasma fractionation industry.

Q. We did already look actually in this topic at a section in Douglas Starr's book where he gives a little bit of a biography of these different companies. You visited the Oakland plasma centre and you asked why the centre was empty and you were told it was because it was the day when people picked up their social security cheques.

A. Their dole, yes.
Q. Because you say that the poster was obtained about 1982, we were interested in roughly when it was, and I think it has not really been possible for you to give us anything very specific on that?
A. Unfortunately I didn't keep my diaries for that period. As I said in my response early on, maybe I shouldn't have said shortly after my appointment. I honestly can't remember when it was.
THE CHAIRMAN: They seem to have been cutting the price at the time.
A. They were cutting the price to the donors, which was one of the things that intrigued me. This would have been very late 1970s or right at the beginning of the 1980s. I can't be more precise than that.
MS DUNLOP: Can we look at the next page, please? You say:
"This visit left me in no doubt that even in this relatively favoured part of the USA ..."
You will have to help us a little bit, Dr McClelland, those of us who have not been to California. Oakland, where is that? You're saying it's a relatively favoured part?
A. Well, it's on San Francisco Bay. It's actually not one of the better-off parts of the San Francisco area but, compared to many other parts of the world, I would say

at that time it probably was relatively prosperous.

Q. You say that it was clear to you at the time that plasma was being collected from individuals who might be dependent on the payments from the plasma centre and who would therefore have an incentive to conceal any aspects of their health that might make them unsuitable as donors.

When I look back at your CV, Dr McClelland, I saw that you had worked in Lieden, done some research in Lieden, at least partially into infectious diseases. Is that right?

A. Yes.

Q. Do you think that coloured your reaction to what you saw?

A. I was working in a very different area actually in Lieden. No, I don't think so.

Q. All right.

A. This wasn't a specialist observation, it was a sort of common sense observation. If people are dependent on their dole payments, you know, I felt, without needing to use any pejorative term -- because there was an awful lot of talk about skid row donors and all the rest of it. These might have been perfectly respectable people, but clearly the $16 or $20 that they could get twice a week for selling plasma would probably have been

a material part of their total disposable income. Naturally, there was a risk that they would not wish particularly to reveal features about their own health or behaviour that would lead them to lose that income.

Q. So not only was it not a specialist observation but perhaps a common sense observation even for non-medics?

A. I would have thought so.

Q. Then you go on to deal with our specific questions that we posed in the schedule. You were asked about your own experience at the time and you tell us that in August 1982 you and Dr Foster attended the Budapest joint meeting of -- and the abbreviations are --

A. The International Society of Blood Transfusions.

Q. Thank you.

A. The International Society of Haemostasis, I think.

Q. Right. Or haematology?

A. Or haematology. I'm not sure.

Q. Yes. And that was the meeting that was attended by Dr Aledort. He mentioned that there had been some recent problems in the treatment of haemophilia in the United States and that's the three cases that have been reported in the MMWR in July 1982. We know about that report.

Perhaps, because we haven't looked at it, we should just see what Dr Foster had in his report about that

intimation. Could we look, please, at [SNB0104452]. We described this in the preliminary report as being an incomplete version of Dr Foster's report, but actually it is a complete version. I think, at first we only had part of it but we eventually managed to get the whole thing. We really need just to look at the last page of the report, if we could, please. There it is:

"In discussion future problems in the treatment of haemophilia, Aledort reported that the most recent problem to surface in the USA has been three deaths from pulmonary infection."

Do you remember this being said?

A. I don't. If I heard it said at that time, it didn't hit me between the eyes until later.

Q. Then, if we could go back to the statement, please, you mention a meeting on 18 January 1983. That was the Regional Transfusion Directors Transfusion-associated Hepatitis Working Party. This is English regional transfusion directors working party?

A. That's correct.

Q. And Dr Craske was at that and reported that he would be studying the effects of American Factor VIII in UK recipients, and this is all on to the next page. Examining immunological markers.

This is what sometimes appears, sir, like one of the

few documents we don't have in our court book but it is, I think, perhaps not anything that is any different from the other material around this time.

It's simply saying, under a heading "AIDS":

"Dr Craske summarised the current situation and mentioned the involvement of homosexuals. (In the USA it is recommended that homosexuals with AIDS be deferred from donating blood or organs). Dr Craske will be studying the effects of American Factor VIII in UK recipients and will be examining immunological markers, though the field is currently very confused."

THE CHAIRMAN: It's a perfectly general reference to American products, rather than a specific reference to Hemofil at that stage.

MS DUNLOP: Yes.

A. I think, sir, though, it's fair to say that Dr Craske had a very particular interest in haemophilia treatment products. So I suspect that he, in his study, was primarily referring to Factor VIII.

MS DUNLOP: I suppose for Dr Craske, who had become interested in the problems of infectivity in the 1970s, when the commercial concentrates arrived, this must have been a wholly natural phenomenon to study?

A. Absolutely.

Q. Yes. It was completely within his territory when this

began to happen?
A. He was the natural person at that time in the UK to pick this up.
Q. In the next paragraph you deal with the letter, which again, sir, is something we don't have on our database, but on this occasion not for want of trying. A lot of research and a lot of effort has gone into trying to trace Dr Boulton's letter, but unfortunately without success. But --
THE CHAIRMAN: We can infer it was an attempt to be helpful.
MS DUNLOP: Yes, I suppose it is interesting to know that it happened.

We don't have it but we can see that it happened and we can make certain deductions as to the content of it from the response. But it does look as though Dr Boulton has written and expressed concern about the safety of Factor VIII from the United States.

You don't have a clear recollection of having seen it or, presumably, of Dr Boulton saying to you, "I'm thinking of writing," and what he was thinking of saying and in any sense asking whether you approved or agreed?
A. I don't, no. Because I realised this might be important, I have done my best to see if we had copies of it lying around in any odd places, also to recall the origin of it.

I have read Dr Bloom's reply quite carefully, though, and it is actually fairly clear from the reply what some of the points were that Frank Boulton was making in his letter. I think it is possible that he did not copy the letter to me, I don't know, but I think Dr Bloom's letter was copied to me. So it implies I probably did have a copy of Frank's original letter, but it has gone.

Q. Dr McClelland, it is actually my plan to ask Dr Boulton about it and he is probably our best hope, so I wouldn't intend to ask you any more about it at this stage.

A. Thank you.

Q. You say you had adjoining offices. This is in the old Royal Infirmary in Lauriston Place?

A. Yes.

Q. You said you were very close to Professor Ludlam -- or indeed "Dr Ludlam" then, I suppose. Can you just tell us a little bit about the layout?

A. Sure. The old Royal, as you probably recall, was what was called a Nightingale hospital, which was laid out with large bays projecting out from a big central spinal corridor. There were two hospitals in fact, one medical and one surgical, which tells you how simple things were in the 1850s or whenever it was built, and there were large spaces between these projecting spurs off that

corridor, which constituted the wards, and those spaces, over the years, got filled in with a variety of more or less ramshackle buildings, which included a substantial extension to the transfusion service building, which had been opened in 1960, I think, and then a haematology department, which was in various portacabins and things and then got enlarged at some point and virtually adjoined. In fact at one point we ceded some accommodation to the haematology department, so that there was a corridor that connected the two departments directly. They were extremely close together.

Q. So you, as the transfusion service, had your own building, and the haematology department was in portacabins, was it?

A. It was in an adjoining building, but these were both essentially temporary structures, slotted into spaces on the old campus. But they were clearly understood to be separate departments and, of course, the haematology department was a department of the hospital, whereas the BTS was part of the more or less national Scottish National Blood Transfusion Service.

Q. The next question you were asked -- and I think it is no doubt our fault that it wasn't very clearly expressed. But this question about why there was no discussion about the possible connection between AIDS and

commercial blood products was really meant to apply to the meeting of 21 January 1983, and I think we wrote and clarified that.

A. Yes.

Q. And actually you reconsidered your answer?

A. I had to reiterate that I actually had absolutely no recollection of what was discussed at that meeting and, as I recall, the minutes either were not available or did not inform or assist me in any way.

Q. Yes. Dr McClelland, I'm sorry to do this to you -- if things had gone differently this morning, I would have shown you this first, but I think we have your handwritten notes?

A. Okay.

Q. Could you look at [SNB0015227]? This looks like your writing but I may be wrong.

A. It does. It's suitably illegible. There you are, 21/1/83.

Q. Are they your notes on that meeting?

A. Yes, they are. Whether I can read them, let alone anybody else read them --

MS DUNLOP: That was going to be the next question, I'm afraid.

A. I'll do my best.

THE CHAIRMAN: There is a navigation problem first of all,

isn't there, before we get to reading.

MS DUNLOP: Sorry, sir, in terms of what?

THE CHAIRMAN: In trying to relate, yes, the various sections that are blocked off to the source material.

A. I think that's pretty relevant to the source material actually:

"We are still purchasing commercial Factor VIII because of 'uncertainties in supply for the forthcoming year'."

Which I imagine reflects something that I know Dr Ludlam was concerned about at the time, which was the degree of unpredictability in supplies from the BTS. So I have asked myself who is purchasing it. So that was Dr Ludlam.

Q. That has to be Dr Ludlam?

A. That's Dr Ludlam.

Q. Is this a note to self:

"Purchasing to stockpile"?

A. These are my scribbles from the meeting. Dr Bell, who was the Scottish Home and Health Department senior medical officer who attended these meetings said:

"Dr Cash, McClelland and Ludlam to sort this out. Is there any misunderstanding?"

Q. Then:

"Frank, what has been going on?"

I think it says.

A. That will be a note for me to ask Frank Boulton because Frank was at that time responsible for the blood bank part of our operation, and most of the dealings with Dr Ludlam, once Dr Ludlam was appointed, I think, were between Dr Boulton and Dr Ludlam because I felt they were the people who actually knew about the subject, in a way that I didn't.

So:

"Information: List all commercial purchases 1981, 1982, 1983.

"List total issues by month and year, PFC and commercial.

"Receipts from PFC.

"Receipts of PFC material from other centres ...

"Reporting adverse reactions."

I think this is moving on to a separate topic.

Q. Yes.

A. Well, that's just very interesting. I have absolutely no recollection of this discussion whatsoever.

THE CHAIRMAN: What's the relevance of the reference to Bruce Bennett.

A. Bruce Bennett was the medical consultant who was responsible for haemophilia patients in Dundee at that time and --

Q. Wasn't he in Aberdeen? He was in Aberdeen at one point.
A. Was he in Aberdeen? Sorry, I may have misremembered. Possibility Aberdeen.
Q. It is just that we have had correspondence from Dr Audrey Dawson and Dr Bruce Bennett, as if they go together.
A. That will be Aberdeen then, sorry.
THE CHAIRMAN: So you are extending beyond your own area here and collecting information from other centres?
A. I think so.
THE CHAIRMAN: Then, out to the right, the idea appears to be to put it all in a paper for Christopher Ludlam.
A. "Put on paper for Christopher and send to John D Cash," I think that means.

And "Oxford data". The reference to Oxford data is what is now called the Haemophilia Reference Centre Directors' database, which I know the Inquiry has had contact with. And I was obviously noting to myself to check whether we could actually get regional data at that time from the Oxford register, presumably to see if it concurred with the information that we were hoping to assemble. Unfortunately, I have absolutely no recollection of what I did following that meeting.

THE CHAIRMAN: It's an interesting use of language, isn't it:

"Can the Oxford data on the register be broken down to regularise --

A. Regionalise.

THE CHAIRMAN: Regionalise?

A. Yes.

MS DUNLOP: Then there is the reference at the bottom, Dr McClelland -- we can see there has been some discussion of AIDS and you have noted the reference to --

A. The Observer.

Q. -- The Observer.

A. Yes, I assume that, rather than meaning the Sunday Observer, which is a bit tautologous, it probably means last Sunday's Observer. We could easily check.

Q. We have it and we have looked at it and we are not going to look at it again. But just look at the formal minutes of the meeting, which is [SNB0015160]. We can obviously see the same topics in the minutes but it's perhaps interesting to note from the bottom of page 2 that Dr George McDonald, from Glasgow, is congratulating the SNBTS directors and PFC on the quantity and quality of Factor VIII concentrate being produced? But then, as we read on to the next page:

"Concern was again expressed about the amount of commercially produced Factor VIII which was still being

purchased."

Then there is a note:

"The meeting has noted that while purchases of commercial VIII had declined in Glasgow, purchases in Edinburgh had increased."

So the focus has obviously been on Dr Ludlam and that chimes with the handwritten notes?

A. Yes.

Q. Do you remember commercial purchases in Glasgow being an issue?

A. Not at all at that time but there is no particular reason why I would have been brought -- you know, would have --

Q. I was just meaning if you had been at meetings where that had been on the agenda and there had been questioning about it?

A. No, but clearly my recollection of this is fairly poor anyway, so that doesn't say anything. I do think, though, looking at this discussion -- I'm not sure whether I failed to read this document properly and whether there is any reference to AIDS, HIV or anything else.

Q. Yes, there is.

A. Right.

Q. Just --

A. What I was going to say, before you move on, is that my recollection of this time is that a great deal of my concern, possibly all of the concern, about the purchase of commercial Factor VIII, certainly from the Health Board's point of view, was that it was very expensive and there was a strong view that they were paying a lot of money to the BTS to collect all this plasma and make Factor VIII and the Health Department wasn't very happy about having to buy commercial products as well. So it may have been driven as much by concerns about the money as anything else at that level.

Q. If we move on to the next page, please, just perhaps to note at the moment the reference to heat-treated Factor VIII:

" ... concern was expressed about the commercial firms, who were anxious to capture the market for their own heat-treated product, and by offering supplies of their material for clinical trials might pre-empt the available suitable patients before the PFC product was ready for similar trials."

A. This was a bit optimistic. This, I think, probably refers to -- this was 1983, wasn't it?

Q. Yes, January 1983.

A. I think this is probably a reference to product that actually had been around for a while, which was

a heat-treated product produced by Behringwerke, I think, a German company, which had been intended specifically -- the treatment was intended to reduce hepatitis transmission.

Q. We certainly know, Dr McClelland, because we have paperwork about it, that there was a Hemofil heat-treated product coming through around this time and there is correspondence from Hyland about that. But --

A. But can you recall from that, was that heat treatment in relation to hepatitis or to HIV?

Q. It was hepatitis.

A. Hepatitis, yes, sorry, that was the point I was trying to ...

Q. And:

"Directors were made aware of the fierce competition facing the PFC from commercial concerns and were asked to bear in mind the stated policy for the Scottish Health Service to be self-supporting in blood products."

"Stated policy". Stated by whom? Do you remember?

A. I have absolutely no idea.

Q. And then:

"It was agreed that the working group..."

This is reading from the next page:

"... should keep these developments under review and

help to promote whatever collaboration was required to bring the PFC heat-treated Factor VIII most effectively into therapeutic practice."

Just look at that reference to AIDS, which is on page 7 of [SNB0015160]. We can see there Dr Cash appears to have drawn everybody's attention to recent articles in the United States and also to the one in the Observer. We do have the cutting from The Observer and we actually also have a memo from the Department of Health about it. So it's a reasonable deduction, I think, that it's that particular piece in The Observer that's being referred to?

A. Yes, having looked at this again, though, I think that my response to your question, as advised to this minute, is actually correct. I don't think there is any mention in here about the connection between HTLV-III, or whatever, or LAV1 and commercial blood products. There is clearly reference to commercial blood products, which I have suggested is possibly more likely related to concerns about the cost, and there is obviously concern about the possibility that heat-treated commercial products might make it impossible to trial PFC treated product, which may or may not be seen as a legitimate concern. But the connection between Factor VIII and AIDS is not apparent to me in this minute.

Q. Well --
A. Unless there is another bit which we haven't looked at yet.
Q. Perhaps, Dr McClelland, it would be a good idea just to look quickly at the Observer. It is [DHF0017108].
A. I think this is shortly after the first report in the Morbidity and Mortality Weekly Reports of the association of AIDS with Factor VIII and shortly before a publication, I think, in the Lancet, if I have got my years right.
Q. Yes. Just looking at it, Dr McClelland, it certainly seems to be making the point about the connection.
A. That would fit, yes. Well, this had already been raised, as we already heard, at the summer 1982 meeting in Budapest and it had by this date, if it was the first of -- what date was this again? Early 1983 anyway. This would have found its way into the MMWR by that time. So there was a source for it.

But I have to confess I hadn't looked up this cutting when I read at that minute and I wasn't aware of it.
Q. Please don't worry, Dr McClelland, it is just that, you know, we have looked at so much and we find things that seem to fit. But would it be reasonable if we drew the inference that, even though it is not specifically

minuted, the sentiment must have been at the meeting that this was an issue relevant to matters of blood transfusion and haemophilia treatment?

A. I think it is reasonable to draw that conclusion, although the lack of a specific reference to that connection in the minutes is surprising.

Q. Go back to your statement, please, [PEN0150307] at page 4. There is a question 2.1:

"Should Scottish representatives have been invited to the UKHCDO meeting on 1 May 1983?"

That question really has been superseded because we discovered that Dr Ludlam was there.

A. Yes.

Q. But there doesn't appear to have been anybody else from Scotland. You say in the next paragraph that you would be surprised at the reluctance to involve haemophilia clinicians from Scotland. This issue of whether Glasgow and Edinburgh were or were not formally designated as reference centres crops up quite a lot.

A. Yes. I hadn't realised just quite how much, but there clearly was a lot of politics in here, that I wasn't involved in at all. It is all new to me, this. There was a bit of status juggling going on, I think.

Q. Actually I think it is a set of your handwritten notes from 1981 which seems to make reference to a concern

that designation as reference centres might lead to two-tier care. Does that ring any bells?

A. I can see why I would have expressed that concern, put it that way.

Q. I'm not sure if it is your concern. It is just a note you've made about two-tiered care.

A. I don't recall that actually, I'm sorry.

Q. But in any event we haven't, I think, found any evidence that the lack of formal designation made any difference to people's attendance at meetings or people's awareness of what was going on.

A. I don't think so. It was a very, very small community of professionals.

Q. Yes. Then we asked you if there was any thinking along the lines of Dr Galbraith's letter to the DHSS in Scotland and you have said there was the letter that Dr Boulton obviously sent.

We asked you about knowledge in Scotland. You said you would be:

" ... surprised if Dr Galbraith's concerns had not been transmitted by the DHSS to the SHHD since this matter was important to the regulation of blood products and this was a UK matter."

But, as you go on to say later, when you talk about the meeting, that you were:

" ... under the impression that the meetings of the CSM were confidential. The business involved information that was commercially confidential."

Indeed, look at [DHF0014587]. This is a suggested agenda for the meeting on 13 July. In fact, if one reads through it, it has got some suggested conclusions as well, although they are expressed with question marks. But this is a document dated 28 June 1983. It is obviously something that has been prepared for the meeting that is coming up to look at Dr Galbraith's paper, but we can see that it's marked "in confidence". Indeed, the ultimate minutes of the meeting, which we have already looked at too but we don't need to go to, are headed up:

"Not for publication. Commercial in confidence."

So it does look as though not just the meetings of this body but the paperwork that was circulating in advance for the meeting was very much treated as confidential.

A. Since writing that statement it just occurred to me that I expect there would have been formal representation from the Scottish Home and Health Department at that meeting. That would, presumably, be evident from the minutes.

Q. Well, really the only person we have been able to

identify from Scotland as having definitely been there is Mr Watt.

A. He was a member of the CSM in his own right, as opposed to representing Scotland. So the confidentiality clauses possibly he would have seen as binding him from passing information on to the department. I don't know how that worked.

Q. Yes. It's difficult to know, Dr McClelland. We have two sets of minutes and they are both redacted in different ways but there isn't, I don't think, any specific mention of SHHD.

A. The reason I'm surprised at that was because my understanding was -- and others are more expert than I -- that this was clearly a pharmaceutical regulatory issue and the Scottish Home and Health Department, I think, had clear responsibilities in that general area. I would have thought there would have been a routine mechanism for communicating this sort of information between the two departments, as it then was.

Q. Before we leave that perhaps, to avoid going back to it, it is just perhaps worth noting that the suggested conclusions appear to be directed serially to Dr Galbraith's suggestions. Look particularly at the third page of [DHF0014587], numbered paragraph 4. Withdrawing concentrates cannot be recommended. We can

see what the reasoning behind that is. Withdrawing US preparations:

"Impracticable on grounds of supply."

Then:

"Use US blood products as sparingly as possible ... This possibility is largely a matter for physicians treating haemophilia, but it could in theory be decided to modify product licences ...

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

Then promoting self-sufficiency as a goal; trying to use only post March 1983 products; and viral inactivation as the sort of range of responses, and we know from the minutes of the meeting -- perhaps we should just look at them before we stop. [MIS0010291]. In particular, on the second page, where the conclusions are listed, they seem broadly to correspond to the suggested conclusions from the paper in June. Would that be right?

A. (Pause)

I'm sorry, I didn't realise you were addressing a question to me.

Q. I was just saying there seems to be an overlap between

the suggested conclusions and the actual conclusions?
A. Yes, absolutely.
Q. You didn't know about Dr Galbraith's letter, you tell us, until you started working for this Inquiry?
A. Peter Foster found it on the DHSS website a couple of years ago. That was the first time I was aware of it.
Q. Just before we stop, we asked you if you thought it was referred to in England and I think you say that if it is being described at a meeting of the transfusion directors in May, the reference is cryptic.
I absolutely see why you say that, Dr McClelland.
I don't think we really have any evidence that this suggestion was in any way being discussed outwith the forum of the Committee On the Safety of Medicines around about that time. So in fact it looks to have been very much kept confidential then and even those working in the area don't seem to have heard about it and you certainly didn't?
A. I certainly didn't.
Q. Sir, I think that's an appropriate moment at which we should stop for lunch.
THE CHAIRMAN: Thank you.
(1.03 pm)
(The short adjournment)
(2.00 pm)

MS DUNLOP: Dr McClelland, can we take up where we left off, please? Just looking at paragraph 2.4. I don't think there is anything particular in that that I need to ask you about.

You discuss in brief the report in 1983 of AIDS transmission by platelets. That's the article that was in the Lancet of 30 April 1983, which itself is the writing up of a case which had been described in the MMWR in December 1982.

A. That's correct.

Q. We have looked at that already.

You think that you were interested in it because you had invited, was it, Dr Diane Wara?

A. Yes, she was one of the authors of the paper.

Q. Yes. You are not sure whether you saw it in the MMWR when it was reported in the December?

A. I can't remember.

Q. Then the letter from Professor Bloom in June 1983 we now understand to have been a circular letter to all the haemophilia centre directors.

I just wondered, in connection with advice issued in Scotland around about that time, that is the middle of 1983, from what we have seen -- and we are obviously going to hear some evidence from Dr Foster next week and other people connected with SNBTS -- it does look as

though Scotland was much closer to self-sufficiency around that time than England, in 1983.

A. The proportion of the then demand that was met from indigenous sources was a lot higher in Scotland than it was in England. That's my understanding.

Q. Suppose there had been something of a direction to clinicians in Scotland that they were to use only Scottish product, what do you think would have happened?

A. I'm not quite sure what form of direction you have in mind. Something like a chief medical officer's letter --

Q. Yes, something like that.

A. My experience has been that that sort of very formal communication, if it's fairly unequivocal in what it's saying, it tends to be taken pretty seriously. More than that, I cannot speculate as to what a whole group of different clinicians with different attitudes would have responded to a direction.

There wasn't at that time a tradition of issuing instructions. So the strength of the direction would not have mandated every clinician to have to follow it.

Q. It is just that we have seen a lot of references, particularly in the minutes of meetings to the goal of self-sufficiency, and I just wondered when you had any recollection of that being set, as it were, from SHHD?

A. Well, I'm not aware -- or if I knew it, I have forgotten it -- of any explicit direction from SHHD that said Scotland is to be self-sufficient; you know, the various component parts of Scottish Health Service are instructed to achieve that.

What I am aware of was that substantial amounts of public funds had been put into the construction and operation of the fractionation centre, and as I said this morning, I think there was a concern that we shouldn't be paying twice for the treatment for this group of patients.

Q. Yes. Perhaps I could just ask you to look at the minutes of the meeting before the 1983 meeting, which is the 1981 meeting. That's at [SNB0015055].

We have looked at this before, Dr McClelland, so we are familiar with it to a degree, but the tone of the discussion about commercial purchases, which we can see starting at the bottom of the first page, seems to be that the increasing quantity of commercially produced Factor VIII is something to be examined. To put it mildly, it wouldn't be a welcome phenomenon.

A. That was my understanding, I think, at the time.

Q. I just noticed in these minutes, if we can go to the third page, paragraph 6, there is a discussion about the Council of Europe. We had some evidence at the Inquiry

about the Council of Europe, the recommendations in this area, and you yourself have drawn our attention to various papers emanating from WHO. I don't know whether you would want to take those two separately, but I just wondered what you thought was the attitude to pronouncements from bodies such as these within the profession.

A. Take the Council of Europe recommendation first. I mean, the group that, as I recall, produced that recommendation was then called SDS something or other. They all had amazing names, these committees. But it was very much a transfusion service-focused group. Certainly its successor group in more recent years, which I have been involved with, wasn't strongly representative of the treating clinicians. So I suspect that it was talking largely to the transfusion community and possibly perhaps many of the clinicians would not have even been aware of some of these recommendations, I suspect. I don't imagine it would have carried a huge amount of weight among haemophilia clinicians in the United Kingdom at that time.

Q. Right. We will ask you about WHO when we come to look at that later on.

A. Yes sure.

Q. I think that might be better.

THE CHAIRMAN: Ms Dunlop, could I see page 2, please, of this minute?

MS DUNLOP: Yes.

THE CHAIRMAN: I think we can see there that the factors creating demand were discussed fairly generally at this meeting. Yields are discussed, cryoprecipitate yields. I think then it goes over the page and begins to talk about the distribution of therapeutic products produced by PFC. This was in 1981 shortly before a major exercise in upgrading PFC was due to begin.

A. Hm-mm.

THE CHAIRMAN: Do you remember that context?

A. I remember the upgrading of PFC. Sorry, I'm not sure that I understood your question, sorry.

THE CHAIRMAN: Were there factors at that stage that were leading to restrictions in the supply of PFC products?

A. I think perhaps there were. There were a number of issues here that go beyond the simple matter of quantitative supply that influenced the treating clinicians' view of the desirability of the different products.

Although I'm not a haemophilia treater and I claim no expertise whatsoever in that area, it is fairly self-evident, I think, that many of these patients have a severe and obviously permanent illness and require to

be treated frequently and quite often intensively with this particular product.

So the practicality, the usability of the product is not a trivial issue for either the patients or their parents or the people who are trying to care for them.

That's the first issue, and I think there is no question that for reasons which I can touch on if you wish -- but Dr Foster is much better equipped probably to expand than me -- there are perfectly understandable reasons why in many cases the commercial products were easier to use because the volume required to produce a given dose would have been smaller, the dose content of the vial was essentially standard whereas the PFC vials were labelled individually. The dosage was clear but they were individually labelled and very often the commercial product was easier and quicker to dissolve from the freeze-dried state into the form which was suitable for injection.

Each of those things may individually seem rather trivial but if you are actually having to prepare 20 or 30 vials two or three times a day, these become very major issues for the patient.

The other issue --

THE CHAIRMAN: I don't want to get into Dr Foster's area too much. I was thinking of you, in the Blood Transfusion

Service, and how these things would impinge on your experience and understanding of what was going on.

A. That did impinge on my understanding quite a bit because we inevitably had very regular contact with the treaters and myself particularly with Dr Ludlam. So we were not immune from communication about these specific problems.

The second issue, which is slightly different from total, as it were, annualised supply, was that there were occasions, because the PFC was a very small operation compared to these large commercial suppliers, when supplies for a period would be restricted. And of course the third thing was that if one took the view that the PFC was the sole supplier, which was one of the concepts underlying self-sufficiency, then the PFC had to meet all those requirements. The commercial manufacturers could and often did say, "Sorry, we haven't got any; you have got to go to somebody else." So all of those factors were very relevant to the sort of perception of when it might be important to have access to a commercial product.

THE CHAIRMAN: I think if we go over the page, we see some of those factors mentioned at the top.

A. Yes.

THE CHAIRMAN: Yes. And going on to arguments about how to distribute it throughout Scotland, whether on

a population basis or on the amount of plasma supplied for processing and so on.

A. Yes, and that basis of distribution did change over time. I unfortunately cannot recall the precise date, but there was a period when I think, largely as an incentive to the transfusion centre, there was an attempt to distribute Factor VIII on the basis of plasma supplied to the PFC. That was abandoned at some point during the 1980s, the early 1980s, I think, and I cannot honestly remember what was the basis of distribution thereafter.

THE CHAIRMAN: Sorry. My interest was triggered by what I saw there, and of course the question whether there can be a direction to use only the domestic product becomes very much more complicated when one looks at the surrounding circumstances.

MS DUNLOP: Clinicians, you say, Dr McClelland, made their own clinical decisions about the choice of product, and for our assistance you have referred us to a section from the Lindsay tribunal. It's from the report of the Lindsay tribunal, rather than the transcript. We don't need to go to it but it is reproduced from page 15 of your statement, evidence of Dr Colvin, Dr Jones and Professor Christine Lee.

A. I think it's also, you know, relevant to your last

point. I mean, if we looked at the minute that we saw this morning from the CSM, the Committee on Safety of Medicines, it is very explicitly saying it is down to the clinicians to make the decision.

Q. Yes.

A. This is a recurring theme in many governmental-type communications.

Q. Yes. Can we go back to your statement, please, to page 7. You refer to this idea of whether large quantities of commercial Factor VIII were used at Yorkhill. You, in your answer, drew our attention to Dr Willoughby's book, and I think I have seen the whole book sitting here in this room. We don't have the whole book but we have some pages that you provided for us and I think we should have a look at them.

Can we have a look at [PEN0150066], please?

You provided us initially with a photocopy of the cover, which I think is a red cover, is it?

A. Yes, it is, a red and black hard book.

Q. A red and black book, which as I say, I have seen here. If we just look at the next page, please, you see Dr Willoughby's name appearing there. It seems to be 1977. You said 1976. Perhaps completed around 1976, that sort of era. Just to look a little bit at what

Dr Willoughby had to say in this book on paediatric haematology, can we see [PEN0161062], please?

I would like, if I may, to go to page 319, which I think should be the next page. Yes. He has been discussing hereditary coagulation disorders but on this page, if we look down a little bit on the right-hand side, we see him going on to discuss correction of the coagulation deficiency.

We see some information that we actually already have heard, cryoprecipitate in haemophilia and von Willebrand's disease but not in Christmas Disease:

"Appropriate concentrates of Factor VIII, Factor IX and the prothrombin complex have also become available in rent years and are of use in particular circumstances."

Perhaps not the next page but the page after that, I think, is talking about the use of the different products. This is a section on the use of cryoprecipitate. He explains about the pioneering work of Judith Pool and then goes on to give some more detail about how to use the material. He says, at the end of this section:

"Both plasma and cryoprecipitate have an advantage over human concentrates in carrying a low risk of transmitting serum hepatitis, since each bag is prepared

from a single donor rather than a pool."

So certainly shows, as one would expect, that he was aware of the risks. Then he goes on to talk in this section 3 about cost. He says:

"They are of course, expensive (for example, 10 pence per unit for Hemofil)."

Then we can see a section beginning in the right-hand column, "Management of specific problems." "Cuts and lacerations". Then on to the next page, "Soft tissue bleeding" on page 322. Haemarthrosis and then 323. Nose bleeds, haematuria, gastrointestinal bleeding, CNS bleeding, dental treatment. Then interestingly for our purposes, on to page 324, section 11 is on home transfusion, prophylactic treatment. So amply demonstrating what you say in your statement, Dr McClelland, that:

"His early interest in prophylactic therapy using concentrates is evident in his textbook."

We can see that for ourselves.

He talks, at the bottom of the right-hand column, about recent explorations into prophylaxis for selected severely affected patients with frequent haemorrhagic episodes. In to the next page. He has -- one assumes -- some reservations about prophylactic treatment. He says, and we can see it on the left:

"Prophylactic administration of Factor VIII or IX in severely affected patients has met with greater success but clearly this is reserved for patients with quite exceptionally severe and frequent haemorrhages."

He explains in the following paragraph that:

"The rationale for intermittent prophylactic replacement therapy is that spontaneous haemorrhage is only seen in patients with factor VIII levels below 1 to 2 per cent and infusions of concentrates at 36 to 48-hour intervals can keep the concentration above this level for most of the time ..."

Did you know Dr Willoughby?

A. I never met him. I know his book very well because it is an extremely good book. Although way out of date, it is one of those books that you still find the information that you want, when you want it. So I have always kept it.

Q. Thank you. Can we go back to your statement, please, and go on to the next page, page 8. Again, Dr McClelland, this is a bit of a trailer for the witnesses who are coming next week, but I just wanted to ask you if you could explain what you say at the top about the use of a particular technique, the thaw-siphon technique, to improve the yield of cryoprecipitate. By that do you mean that you would get more cryoprecipitate

from a given donation?

A. You would get more Factor VIII out of a given donation using this technique, which I think was originally developed or reported from Australia, and some of Dr Cash's colleagues did work on improving the technique. So it got more active product into the cryoprecipitate.

Q. Yes. Then can we move on to the next page, please. This is the WHO Geneva conference at the end of 1983, I think. We just discussed this in our preliminary report. You say:

"Dr John Watt presented a paper entitled 'Acquired Immune Deficiency: implications for blood and blood products'."

Just to show, sir, that we have this. Dr McClelland provided it to us and we have it in court book. It is [PEN0161076]. It appears to be, I suppose, a snapshot of a situation towards the end of 1983. Perhaps the comment that reveals a certain amount of resignation in the face of these problems is the one that's slightly more than half way down the page; so if we scroll down a little bit we can see:

"An unknown agent which transmits disease from donor to patient has been a feature of blood transfusion since the beginning with the exception of the period 1970 to

1981."

I don't understand that?

A. No, I don't understand that either.

Q. "The primary response of the transfusion community has been an updated version of the measures used against serum hepatitis until 1970."

I suppose he is meaning the introduction of screening for Hepatitis B, is he?

A. I'm not quite sure what he means.

Q. No. Then on the second page he refers to media coverage. The AIDS problem. Actually, Dr McClelland, I think we asked you about this the last time you were here. Certainly John Watt's view was that:

"Early dissemination to the public of media concern over the AIDS phenomenon was sensationalist in the extreme, rarely accurate and frequently a gross distortion of the truth."

Is that fair comment?

A. I'm not sure that it is a fair comment actually. I think, as very often, one would have to go through and analyse some of the articles of the time, but I think very often there were very dramatic headlines under which were quite reasonably factual pieces.

Q. It didn't look as though the paper was particularly contributing anything new to the debate; it was more

a sort of record of the way matters lay. Is that true?

A. I know nothing about the origin of the paper. It appeared in the copious documents for that meeting.

Q. Just to go back to your statement. You say:

"I submitted my report and recommendations from the Geneva conference to both the SNBTS and to Dr Bell."

And just put shortly, the references you make there are to the directors' meeting on 8 December, where you made a contribution on the conference, the draft report, which we mention in the preliminary report, working group on AIDS of November 1984 and a letter from Dr Boulton to Dr Bell. I think these seem to be the references, and you say you would have disseminated the information to colleagues with an interest in the topic.

We didn't have at the time of publishing the preliminary report but we do now have a final version of the report, rather than a draft, and just to note that too: [PEN0161079]. On the following page of your statement you have highlighted some of the recommendations from this report, if we can just look at it, and particularly page 14. That's [PEN0161079] at page 14.

The ones you have quoted, Dr McClelland, come from the section that begins "Sufficient information", and you have quoted as recommendations the fourth bullet:

"Informing persons with haemophilia and their physicians of the potential health hazard of Factor VIII or IX products, including the risks related to AIDS.

And the fifth:

"Considering the use of autotransfusion using frozen or conventionally stored blood for suitable patients."

Who are these recommendations aimed at? Are they meant to go straight to individual doctors or is that not really the thinking?

A. It's sometimes difficult to know what the thinking is with WHO but the normal -- I mean, WHO, like the rest of the United Nations institutions, consists of its member states, essentially it's a bureaucracy for its member states. So normally they would communicate, as would the Council of Europe, through the member state government representatives. So this would have gone to the Department of Health in the UK.

Q. Yes. In Scotland would it go to SHHD?

A. I don't think Scotland would have been recognised at that time by the WHO as a separate member state. So probably not. But I really don't know. I would be surprised if it had gone from Geneva to SHHD.

Q. Okay. Would you have expected it to go from Geneva to London and then from London to Edinburgh?

A. If anybody in London had read it, yes, I would expect

that to happen.

Q. Can we go back to your statement, please, at page 10. You say what you just said, that you can't say from personal knowledge whether or not a specific note was taken of these WHO recommendations by the haemophilia clinicians in Scotland. I suppose you were an ambassador, weren't you; if you have been there, you would come back and disseminate what the thinking was?

A. In some of the documents I have referred to, I tried to spell out my own thoughts as to what we should be doing, but that was the best I could do. I have just realised there is an error in my statement which is I have quoted two of those four recommendations and for some reason the first two, the most important ones, have got lost, actually in some cut and pasting exercise. I apologise for that. I have missed it. I had intended to quote the four recommendations relevant to blood.

Q. So you would have liked the quote to begin with the one that says:

"Persuading individuals with AIDS ..."

Et cetera?

A. Yes.

Q. Right. I think we can read your statement subject to that amendment.

A. Yes. That's an error, sorry.

THE CHAIRMAN: Professor James has his own take on these recommendations which it might be more politic not to read into the transcript.

MS DUNLOP: I don't want to ask you anything specific, Dr McClelland, about the question at 3.6, Scottish patients with AIDS. This is where you refer to Dr Evatt's article and you did include an extract from the paper, and as I have said, we were sufficiently interested in it to include it in its own right, together with responses to the aftermath, one might say, of the initial article.

Then on to the next page. This is moving back into the topic that we covered a month ago -- more than a month ago, in fact, two months ago -- that the meetings with Dr Sandy Macmillan and Mr Derek Ogg. You say that you have a definite recollection that by that time -- and this is, what, the first half of 1983?

A. Yes.

Q. "Dr Macmillan was aware that some of his male patients that were known to be gay were showing clinical features that suggested that they could be suffering from this new form of immune deficiency disorder."

I suppose, taken on its own, the fact that somebody had swollen glands wouldn't normally have struck a doctor as significant, or was this different?

A. I think what I was trying to get across here was that the question was a very difficult one to answer at the time, and it is a difficult one to answer now, because the early stages of what, in a given individual, would evolve into the syndrome which was taken at the time as defining AIDS, which was a combination of very specific things -- but the early features, like swollen glands or fevers, you know -- were highly non-specific. And we were really just saying there is something wrong with this patient, particularly if there was only one of those symptoms.

Fever is a very good example. If you look at any textbook of medicine, you know, there is usually pages and pages on the differential diagnosis of what's called PUO. Pyrexia of unknown origin. It is a symptom that something is wrong. So the early stages of a lot of these patients -- I think the shrewd clinicians had a sort of nagging certainty that something was going wrong with some of their patients and it wasn't quite like what they had seen before. But it was not possible to pin it down.

Q. I have heard it said, Dr McClelland, that context is everything and perhaps, is that the answer, that in other circumstances it might be viewed differently from how it was viewed when AIDS was very much on the agenda

and perhaps those who looked after men of homosexual orientation would be on the alert, as it were?

A. They most certainly would have been because obviously the epidemic originally in the United States was focused in that community and there was a great deal of communication about it. So there was a period when, you know, members of the gay community probably knew more about this syndrome than anybody else. They were the experts.

Q. Yes. You were involved in these discussions and we understand why and you have spoken about that the last time you were here, that you were already concerned about the donated blood in Scotland and blood donors but what about thinking further downstream, as it were and about the people who would be treating their patients with Scottish products. Do you think they were aware that there were these suspicions already in Scotland?

A. It's very difficult to answer. Obviously there will have been some in particular specialist areas but I mean, the most evident of those specialist areas for lots of reasons would be the haemophilia treaters because -- you already, I think, heard from Professor Hann and others -- their patients were expert. Their patients were the most intensively treated with blood products.

That's where I would -- that and possibly later on, maybe other people in haematology who were involved with the repeated use of blood products in patients; that's where awareness should have emerged first. The vast majority of doses of any product that the transfusion service provides are red cells, and most patients over a year will only get maybe two or three units of red cells and one episode, and so if it's the surgeons or the anaesthetists, they had no particular special reason to become concerned about that.

We started communicating what we knew about possible risks in blood quite early on. I haven't addressed that question in terms of saying precisely what we did and when but I'm pretty certain that we will have evidence of concluding -- I know we have evidence of concluding concerns about AIDS, if I can put it that way, in material that was intended for clinicians at quite an early stage.

THE CHAIRMAN: Dr McClelland, I wonder if we can get a little bit more specification, and I appreciate it's very difficult and it's a long time ago but that paragraph at the top of page 11 paints part of a picture and I wonder if we can take it a little bit further. Dr Sandy Macmillan clearly had very close contact with a number of patients who were members of the homosexual

community in Edinburgh and as such, would he have had really quite frequent association with complaints of swollen glands, other forms of infection in the genital areas and in the anus and so on, over a long period of time?

A. Oh, yes.

THE CHAIRMAN: This would not have been new to him if it had fitted that pattern?

A. If he was simply seeing patients with the conditions that we had habitually been seeing, obviously he would not have perceived something new going on. It would not have become evident to him, I'm sure -- I mean, he needs to speak for himself. I would guess he might find it quite difficult to define in retrospect but there will have been a point when he would have had an increasing awareness that, "There is something going on here that I haven't seen before". That's the way these things tend to work.

THE CHAIRMAN: Is that an important part of the background to this paragraph?

A. I think it is.

THE CHAIRMAN: These contacts are triggered by the appreciation that the Rubicon has been crossed in a sense.

A. Yes.

THE CHAIRMAN: Of course, another part of the background is that the emergence of features of this kind in previously healthy homosexual men was part of the picture painted in America from 1981/1982 onwards.

A. Yes.

THE CHAIRMAN: I would be very surprised if a person with the experience of Dr Macmillan, particularly working along with Derek Ogg, coming together with you, wouldn't have had these features in mind.

A. I think that's what I was trying to imply in my statement.

THE CHAIRMAN: Perhaps one just has to face up to it because you really have to know what the atmosphere at the time was, if at all possible. And I know it's not easy, but essentially, should one understand at this time, in the spring of 1983, there was a fairly clear understanding among people with an insight that there were features that suggested that the problem had arrived in Scotland?

A. I don't think I can actually say more than I have said because I think it would be important for the Inquiry to talk to one or two -- to hear from the clinicians who were seeing these patients day-to-day. All I can really say with confidence now is that looking at our actions at the time, I think I had come to the conclusion and Dr Anne Smith, who was working on this with me, that

this was something that was real enough that we were going to do something about it.

We were pretty convinced that this was real and that if it wasn't in Scotland today, it was going to be in Scotland tomorrow. And that we couldn't hang around. But as to what individual clinicians in relative specialities felt, I really think it is not something that I can comment on.

THE CHAIRMAN: It is not something that you can say. I appreciate one must be very, very careful to avoid hindsight here because living in Edinburgh, it is not possible to forget the reality for some people that some of us knew, but do you really think that it's up to Dr Macmillan to tell us what was in his mind?

A. I really do think so, sir.

THE CHAIRMAN: Sorry for interrupting but I was just trying to get as clear a picture as I could.

MS DUNLOP: I was interested, Dr McClelland, in your reference to material for clinicians. You referred a few answers ago to material that you prepared for distribution to clinicians.

A. Yes.

Q. Is that clinicians who would be using blood and red cells, all sorts of blood products?

A. I may have been answering the wrong question at that

point and I have not prepared specifically on this, but I was thinking of things like information that went out with PFC products which Peter Foster could comment on. I, at some point around -- we altered the labels on blood bags, we had text in things like The Transfusion Handbook and so on, which was modified to account for this. But I would have to assemble exactly the trail of how we did that and at what point we felt confident enough of what was going on that we could communicate it to users of the products that we were supplying.

Q. Yes. I think all I'm really getting at, Dr McClelland, is that we know that you were beginning your drafting of leaflets around about this time, the first half of 1983, and we know there are these discussions with Dr Macmillan and I don't want to put words in your mouth, so I think just using your own words, you say that AIDS, "if it is not here today will be here tomorrow".

But it then is rather striking that in a minute of a meeting in March 1983 it looks as though it is Dr Ludlam who is saying that there is concern that AIDS might appear in the UK. I was just wondering if there was enough interdisciplinary sharing of how close the risk might be.

A. I think the honest answer is probably there wasn't.

There probably was quite a lot of sharing, though, because it was already a pretty hot topic for a lot of people. I mean, I can't remember now whether Christopher Ludlam shared those concerns with me at the time or not. I really can't remember.

Q. Just moving on through your statement, Dr McClelland, you talk about, I think, really the detective work. It was detective work done by Dr Evatt, wasn't it?

A. Yes.

Q. About the requests for pentamidine?

A. Yes.

Q. It is a very special drug, is it?

A. It's a drug which has certain uses for which it's conventional, but its use for the treatment of pneumocystis pneumonia was a special off-licence indication and, for reasons which I probably never knew, the policy had been developed at some point in the United States that it was only available by contacting a particular office in the Centre for Disease Control in Atlanta, which allowed them to build a national epidemiological map of putative diagnoses of pneumocystis pneumonia on the basis that people would be requesting this drug for it.

Q. I see.

A. Their unique observation was that they saw in relatively

quick succession, I think, three cases of this drug being requested for that form of pneumonia in patients whose primary condition was haemophilia, whereas previously they would have seen it mainly in patients who had profound immuno-suppression, usually due to treatment with chemotherapy or something like that. So this was signalling to them a new form of immuno-suppression-related infection was occurring in the haemophilia population, and they had never seen that before.

Q. Move on to the following page. Making another reference to the WHO conference in Geneva in 1983. I think we appreciate the point you are making, that getting your case definition right is very important. I just wonder, if you say Dr Curran was emphasising the importance of creating a narrow case definition, does that have some disadvantages? Is it possible that your definition is too narrow, you are missing some of the people you should be looking at?

A. Yes, they were absolutely explicit that the tight definition would miss cases but the reason for using that definition was that they wished to be able to count a population that was all oranges and didn't include apples and grapefruit. They were in no sense ignoring the fact that, by doing that, they would exclude many

other individuals who probably did have the same condition but could not be reliably counted.

So this was a fairly typical CDC approach, and it had proved very successful in other investigations that they had done. They used a tried and tested approach on this occasion.

I really only raised it to try and, I suppose, emphasise the points that we have already discussed, that it would have been fairly easy for a clued-up clinician to see the combination of pneumocystis pneumonia, Kaposi's sarcoma and a couple of other things and say, "That's a case of AIDS." But the same doctor might be seeing four other people in the clinic who had one or two or three features which were strongly suggestive but wouldn't allow the diagnosis to be made.

Q. Just for the record, sir, that extract that Dr McClelland has quoted is on page 6 of the WHO report but I don't think we need to go to it.

A. Sorry, in the lower part of the quote, on the lower part of the screen there, it is explicit:

"This definition has been useful for monitoring trends and detecting patterns but may underestimate the extent of the problem."

Q. Then you make a response to a question about the purchase of commercial Factor VIII in 1984 and you say

it's really for clinical haemophilia specialists to comment on this.

Then, on to the next page, you explain the importance of collecting and processing enough plasma in Scotland because of the goal of self-sufficiency; there does seem to be an ever-increasing demand.

There does look to have been an ever-increasing demand, for reasons which we can understand. In a sense the more successful the treatment, the more product will be required?

A. Yes.

Q. Yes. Then you have furnished us with another document which I am afraid, because we only got it this week, we don't yet have in court book, but it's a paper which you have recently been involved in preparing for WHO about the definition of demand for blood products. You maybe have a hard copy with you, do you?

A. I don't but I think actually the relevant bit --

Q. Is all in the footnote?

A. Yes.

Q. There is some confusion about this reference --

A. An editorial problem on our part, for which I apologise.

Q. I think we didn't appreciate that the quote that you actually wanted to refer us to is in the footnote and so if we look at what is page 21 of your statement, if we

can scroll on to that -- I take it you are providing these extracts, Dr McClelland, because they help us to understand different concepts of self-sufficiency of demand and supply?

A. That was my intention. I'm not sure whether they do help but I was trying to find a way of pointing out I think self-sufficiency is in many ways a very unhelpful concept because it depends almost entirely on where you are looking at it from, and this was an issue when -- the purpose of this document was quite different. It was to try to develop a model that would allow individual countries to work out approximately how much blood their services should be trying to collect and that led us to have to explore the nature of the requirement.

Q. Right.

A. So it's a closely related issue.

Q. Yes. The paper for the record is entitled "Approaches to estimating the adequacy of blood supply for a population", and it's by Oliver Hassall, Rene van Hulst and you, and it was delivered, I think, was it, at a workshop in Oxford in October 2010?

A. It was actually written in Oxford in October 2010 and delivered to the WHO.

Q. I'm obliged. Right. Can you just talk us through

what's in footnote 11 that we can see?

A. Well, this, as I say, is only included in the context of thinking about self-sufficiency, and we identified three possible different view points, as it were, for the quantitative supply of blood to a population. One was the current use, which is, as it implies, exactly what is being done in the territory at a given time, usually a year, and is influenced by a whole raft of factors, including the availability of hospital facilities, the number of doctors, the prevalence of disease, the attitudes to treatment of both doctors and patients and so on.

Then there is demand, which we had, roughly speaking, defined as the amount which is requested of the supplier, whether or not that request is met. So we might supply 100 but 120 had been asked for.

Then the third question was need, which was to say in an idealised situation, where each patient was receiving the best treatment to what were considered to be the best available standards, what would be the actual quantitative requirement in that situation.

Obviously, the concept of self-sufficiency leads one inexorably towards the belief that we should be able to achieve the third situation, which is absolutely the best for everybody, and that, I think, as you have

already implied, is a recipe for almost infinitely rising demand, or use, or production, or whatever. The quantities going into the population will tend to increase under that situation.

THE CHAIRMAN: I have to confess that I was hoping for a rather more basic notion than that, since interest in Scotland appeared to focus on PFC's capacity to produce what was the demand for the NHS product and its capacity, had it been asked upon, to meet the current need -- in other words, there was a balance that was being met elsewhere -- and trying to work out factors of that kind, rather than perhaps take the very detailed approach you are suggesting. Would I be wrong to think in those terms?

A. Sir, I wasn't suggesting that we should have taken this particular approach in Scotland; I was merely using it to try and illustrate.

If I could just respond briefly to your last point, yes, I think that was my understanding, but the problem is that every attempt to project the quantity that was going to have to be produced to keep everybody happy, if I can keep the language extremely neutral, was that the quantity went up every time. So the expectation was continuously -- the target was moving and it was always moving upwards over this period.

MS DUNLOP: Yes.
A. And that only changed at the point when recombinant product, concerns about CJD, HIV and everything, began to have a counter force.
THE CHAIRMAN: That is merely a change of product rather than a change of need, is it not? You didn't need human plasma any more but --
A. Yes, that was a change of product. And I'm not privy to what has happened to the pattern of supply since we went to recombinant Factor VIII, but I would be surprised if it hasn't continued to rise fairly inexorably.
MS DUNLOP: Can we go back to page 13, please? You say:
"The SNBTS could never have been confident that it would guarantee to meet a demand that was essentially open-ended despite the concerns raised by Dr Boulton."
That's in the letter we have never found:
"I think it would not have been for the SNBTS as a supplier of product to propose the withdrawal of other suppliers' products, when this may have led to a shortage."
We know, Dr McClelland, that there was a lot of correspondence between Dr Boulton and Dr Ludlam about the supply of product for Dr Ludlam's patients and you will have been aware that there were some issues there, if I can put it like that. We saw your handwritten note

after the meeting in January 1983. You were going to speak to Frank and find out what had been going on. Is it reasonable for us to ask Dr Boulton about that?

A. I think entirely. I think there was unquestionably a degree of tension and I don't think that's necessarily particularly a bad or surprising thing; it was a difficult situation and we were, I think, all of us, trying to meet our different responsibilities as well as we could. Inevitably they clashed from time to time.

Q. Then you say, going on to the next page:

"I believe it was accepted by the SNBTS and the SHHD and considered as a factor of the professional independence of doctors that those responsible for care of the haemophilia patients should decide on the relative risks and benefits of continued use of commercial product versus reducing the total amount of treatment available in the event that supplies of indigenous product were less than the demand."

You were making these decisions in consultation with patients?

A. That's the way I thought haemophilia care had always worked and it's certainly the way it should work.

Q. Then finally heat-treated concentrates. You say:

"Heat-treated Factor VIII concentrates were licenced by the UK Medicines Control Agency in February 1985."

And you refer to heat-treated Hemofil T from Hyland being available from June 1983 in the Netherlands.

You supplied us with a short paper from the BMJ about a piece of work that was done, a study of 18 patients in the Netherlands who were treated with that product, and we don't yet have that in court book but we will. For those 18 patients it appeared that Hemofil T did not transmit HIV. That is the outcome of that study. Is that correct?

A. That's my understanding.

Q. Because you say you don't know to what extent this product was available in the UK, I think the whole situation can be seen by looking at what Kenneth Clarke said about the licensing of heat-treated products in the UK. If you look at [SNF0013323]. The first bit of this is the reference to the establishment of the Expert Advisory Group On AIDS, and we can see your name there. Then if we look on to the next page, Kenneth Clarke is making quite a long statement on what is being done as at that point, and he says -- and this has all been magnified for us on the right-hand side:

"Finally, imported heat-treated Factor VIII for haemophiliacs is already available for prescription by clinicians on a named-patient basis and we are considering urgently a number of abridged applications

for product licences."

So as at February 1985, heat-treated commercial product in Britain looks to have been available but on a named-patient basis. Do you see that, Dr McClelland?

A. Yes.

Q. We have had some evidence from Dr Winter about steps that he took, and I think also Professor Savidge took to get some heat-treated product for particular patients in 1984.

A. But it's just perhaps important to say that heat-treated Factor VIII, which was shown subsequently to not transmit HIV, was available in Scotland from the very end of 1984.

Q. Yes.

A. All the supplies for Scotland were.

Q. It was just really in light of your reference to the availability of Hemofil in the Netherlands in 1983. I just wanted to try and put that in context for the UK?

A. Thank you.

Q. Yes. Right. Thank you, Dr McClelland.

A. Thank you very much.

THE CHAIRMAN: Yes.

MR DAWSON: I do have some questions, sir, I wonder whether there is a requirement for a break at this stage.

(3.07 pm)

(Short break)

(3.21 pm)

Questions by MR DAWSON

MR DAWSON: Dr McClelland, from previous evidence to the Inquiry my understanding is that the position, certainly from the mid 1970s to the mid 1980s, which is really the period we are concerned with in this section, is that the SNBTS operated broadly on a regional basis. Is that correct?

A. Yes.

Q. And the idea was that each region would collect plasma for its own needs to the best of its ability. Is that broadly right?

A. Well, targets were set for each region. Yes, I think that's broadly right.

Q. Okay. Did you ever find in your period from 1979, as the regional director in the southeast, that you had a surplus of blood products?

A. We frequently had surplus of red cells because -- there is a very specific reason for that because the way that we obtained the plasma was by collecting whole blood and then after collection separating the plasma from the whole blood, which left us with the red cells in a pack by themselves. There was a period when the number of blood donations that we aimed to collect was driven by

the requirement for plasma, rather than the requirement for red cells. That meant that there was a surplus of red cells, which we, at periods, actually had an sort of non-commercial contract agreement with one of the London blood centres, which was always chronically short, so that we did everything we could to see that these red cells were not wasted.

Q. Does that period you have defined, the period during which the drive was for plasma, apply to the period that I have defined from the mid 1970s to the mid 1980s?

A. I think I would date the real drive for plasma from about 1975, at which time my predecessor, Dr John Cash, changed the operation of the Edinburgh centre so that it was almost exclusively -- sorry, let me say that again.

We were separating and collecting the plasma from almost all of the whole blood donations that were collected. The implication of that was that the surgeons and the people who were using red blood in bags were getting a concentrated red cell preparation from which most of the plasma had been removed, and that practical change -- it was a fairly fundamental change in the operation of the centre -- took place during 1975 long before I joined the service, and I think probably marked the start of a drive to increase plasma collection very substantially, which was linked

obviously to the commissioning of the new protein fractionation centre.

Q. Did you ever find over that period that you had a surplus of cryoprecipitate or factor concentrates?

A. No, I wouldn't say we ever had a surplus. Obviously, we never had a surplus of the plasma collected for fractionation because we shipped it all to the PFC, and they could use any amount that we could supply.

Cryoprecipitate. We maintained a relatively small stock of cryoprecipitate because, while it can be stored frozen, it's bulky and there is no point in having vast amounts of it in refrigerators. So we tended to produce cryoprecipitate, which is a labour-intensive thing to do, sufficient to maintain a comfortable buffer stock in the region, and we would not produce more than we needed because that made it non-available. Once we had processed a unit of plasma into cryoprecipitate, it was no longer suitable obviously to send to the fractionation centre to make Factor VIII.

You also mentioned surpluses of coagulation factor concentrate. The way that the blood bank worked, which, if you like, was the sort of retail distributor of the Factor VIII concentrate, it ordered periodically, regularly, from the fractionation centre and attempted to maintain again, a reasonable level of stock, we hoped

would be sufficient to meet the sort of surge in demand which could and were created by an individual patient who had had an injury or had to have surgery or something like this; because one patient could use a very large amount of material over a short period of time.

Q. Who was responsible for the management of that stock?

A. I think the routine sort of maintenance of blood bank stock levels and the calling off of further stocks from the fractionation centre was the responsibility of the manager of the blood bank, who would have been one of the technical staff. But we always had one of our medical consultants who had specifically delegated authority to supervise the blood bank. For much of the relevant period that was Dr Frank Boulton, who was himself a fully qualified haematologist and had been a consultant level haemophilia treater in Liverpool before coming to work with us.

Q. You mentioned in your earlier evidence that you had close contact with Dr Ludlam during your period as the regional director. I understand that Professor Ludlam arrived in 1980. Is that correct?

A. Yes. Professor Ludlam had trained in Edinburgh and I had known him in various other incarnations, as we were training, and I think he took up his consultant

post very shortly after I was made director in Edinburgh.

Q. Indeed, and before that, I think, as has been referred to, his predecessor was Dr Howard Davies, to whom you have made reference, as somebody you worked under, on the front page of your statement.

A. Yes.

Q. On the front page of your statement you give a description of Dr Davies' attitude towards the kind of product he thought should be used in haemophilia treatment. Would it be fair to summarise that as basically being that he preferred to use cryoprecipitate rather than Factor VIII concentrate?

A. Yes.

Q. That he preferred to use local products rather than imported product, and that the reason for that was that he thought that approach would be the best way to minimise the possibility of infection?

A. Yes, absolutely. I think his view was as a sort of matter of fairly elementary biology: the more, as it were, different donors' blood samples contributed to the dose that one received as a patient, arithmetically the risk of getting something nasty was increased, and the further afield the blood came from, there was a certainly incalculable but reasonable grounds to

expect that something new and different and unfamiliar to the indigenous population might be in that blood. So those were two separate and complementary arguments which led him to precisely the conclusion that you have stated.

Q. And the practical manifestation of that in the 1970s was that Dr Davies preferred to treat his patients with cryoprecipitate. Is that correct?

A. As I say, I had a rather brief -- I was a very junior doctor. It was my first job after graduation and of course, you know, as the junior dogsbody doctor you have to deal with all the consultants. But the reason I mention this in my statement is because it left at that time a strong impression with me of something that seemed to me then, and seems to me now from one perspective, to make a great deal of sense. From the perspective of a patient with haemophilia, it doesn't make a great deal of sense if you are plagued by repeated bleeds and you have to deal with this, probably have to come into hospital every time you need a dose.

It could be seen as a highly patient-focused view in one sense but in another sense, actually very difficult from a patient's point of view.

Q. I think, as I understand the timing, you became the director in 1979 and as I think you have said, Dr Ludlam

arrived as the haemophilia director shortly thereafter in 1980. Was there a change in philosophy at that time as regards the way in which patients in Edinburgh were to be treated?

A. I can't tell you about philosophy because I don't know.

Q. Was there a change in practice as regards the requirement for products?

A. There was certainly a change in practice, which is not surprising with a young consultant coming in who had done much of his training in another part of the country where there was an authority in haemophilia, Professor Bloom, who I'm sure Dr Ludlam had, you know, developed a lot of his thoughts about good patient treatment from that experience and was up-to-date, read all the literature and felt that the patient's requirement for better control of their bleeding disorder was something that he had a real responsibility to try and provide for them, and I think that was a very understandable view.

Q. So presumably --

A. That inevitably had a number of consequences. I believe initially Dr Ludlam was actually quite keen -- and this is maybe a misremembering on my part -- to continue Dr Davies' policy of working with cryoprecipitate, but fairly early on I think began to feel that he had to use

concentrate and from that point on, the requirement for use of concentrate for patients in Edinburgh did increase really quite rapidly.

Q. Did he communicate to you in some way, at the time of his arrival, what his attitude towards requirements for products would be likely to be?

A. I honestly can't remember. It is quite possible that he did but I have no recollection of that.

Q. The Inquiry has access to certain data showing the use of products in Edinburgh and I have focused on the period from 1980, at the time of Professor, Dr Ludlam then, his arrival. It certainly seems to be the case that that information reflects the impression that you had, that there was still a fairly large use of cryoprecipitate in the region of about 40 per cent in 1980, when he arrived, and that then there was a gradual decline in the amount of cryoprecipitate being used.

The question I have is: would it have been practically possible in 1980, given that in that year the amount of cryoprecipitate used of the total used in the treatment of Haemophilia A patients was 40 per cent, to maintain Dr Davies' commitment to the use of cryoprecipitate in a longer term sense, had that been Dr Ludlam's preference?

A. Would it have been possible to produce cryo for

100 per cent instead of --

Q. Well, to stick to a Dr Davies-type philosophy of using as much cryoprecipitate as possible?

A. It would have been possible but it probably would not have been possible -- in fact, I can confidently say it would not have been possible in the facilities that we had then. It was actually, I think, in retrospect, probably we shouldn't have been producing cryoprecipitate at all on the grounds of the safety of the staff, because the process involved a lot of alcohol fumes and all sorts of things that probably exposed our staff to unacceptable hazards. We would have had to have access, immediate access, to new premises were we to do that, but I don't think that it's a question that ever arose. Almost from the start of my appointment I was separately trying to find new premises, that was not the factor that was driving it, as I recall.

Q. So obviously my question is a hypothetical one because that wasn't Dr Ludlam's view in the longer term certainly, and there was a move towards factor concentrate use, but your position is that even if it had been his view, there would have been practical difficulties with maintaining a reliance on cryoprecipitate.

A. There would have been practical difficulties but if we

had been in a position, if the situation had been that we considered that it was a clinical necessity to do that, we would have done what we always did, which was to go and, you know, beat the drum with the department or the Common Services Agency or whatever, and do our level best to extract some money from somewhere to get the appropriate facilities.

So your first question was: would it have been possible? I think if we felt that the clinical need was sufficiently strong, it would have been possible. Not possibly immediately but in the time course of a year or something like that.

Q. Again, on my analysis of the figures provided by the UKHCDO, as I think you have said yourself, the dependence on cryoprecipitate declined in the first half of the 1980s to the point where we get to 1983 there is less than 15 per cent of the product being used in the treatment of Haemophilia A coming through cryoprecipitate. I think that's entirely consistent with what you have suggested. Would it have been possible by that point, had it been deemed clinically necessary to revert to cryoprecipitate as the main product in use for such treatment? That's in 1983, I should say.

A. It's really the same answer. It would be possible at

any time -- well, it wouldn't be possible now because of the restrictions on the use of plasma, but it would have been possible at any time to make a fairly modest investment into a bit of premises somewhere, equip it and make large quantities of cryoprecipitate.

Q. Thank you very much.

Could I just ask you a question about a phrase that you used in your evidence in response to questions from counsel to the Inquiry. This was in the context of describing the importance amongst haemophilia doctors of keeping abreast of developments in terms of infection, and you used the expression that their patients, being haemophilia patients, were experts. Could you just explain a little bit what you meant when you used that expression?

A. Well, it's very simple. Many patients with severe haemophilia -- all patients with severe haemophilia require regular treatment, not just with Factor VIII but the whole gamut of treatments that deal with the physical and often psychological problems that are associated with a very severe disabling chronic condition. They have -- many of them, almost constant -- very frequent contact with their providers of care in hospital and out of hospital and so on, and many of them take a great interest in their treatment

for very obvious and sensible reasons. And they acquire a great deal of information about it. In the early days it would be not infrequent, you know, when I was on-call for the BTS, we would occasionally have professional visitors who happened to be haemophiliacs, and these individuals would very often have a very specific -- their own specific, personal views about which product they had chosen to be treated with.

There were some individuals who would only accept to be treated with cryoprecipitate, even accepting all the inconvenience. There were some who would not accept treatment with imported Factor VIII. There are some who had a very strong preference for particular products and it would be quite wrong, I think, to say that these were idiosyncratic preferences. These patients almost certainly had extremely good reasons, which they could probably explain very articulately in many cases, why they chose a particular approach to their own treatment, and my recollection is that that was evident among some, not all, but some of the haemophilia patients early on in my career.

Q. Would it be fair to say that the expertise, which you've attributed to the patients, related to their perception of the effectiveness of the different products?

A. In the broad sense -- well, it depends how you define

"effectiveness". Strictly speaking, I would define clinical effectiveness as essentially describing the balance of benefit and disbenefit. So safety is actually, in that sense, part of effectiveness, but it may be easier to separate them out and say were they concerned about the safety, which, if you think might be: what will this do to me in the long-term? Will I get something nasty in two, five, ten years' time? As opposed to: will this stop my bleed and control my pain now, better than other products?

And of course, the third factor that to some patients mattered a lot, is inconvenience. Will it take me an hour fiddling around with syringes and needles and jars of salt water and other things to get my dose, or can I go to the fridge take it out, stick a syringe in and that's it? All those factors and many others would have influenced their choices.

Q. How do you imagine patients would have become experts as regards matters of safety in the products?

A. I think the patients fairly early on had -- in my impression, and this is only, to a large extent, second-hand or anecdotal impressions because I have never, as I have emphasised, had a personal clinical involvement with treating these folks.

I mean, I think you may have seen the other day the

1 television programmes World in Action. Those were
2 filmed, I think, in the north, in Newcastle or
3 somewhere. I'm not exactly sure when, but I was very
4 impressed watching those, with the common sense
5 knowledge that a lot of the patients and some of the
6 parents expressed about the infection risks, and both
7 safety infection and effectiveness of the products.
8 I think they probably learned in a whole variety of
9 ways. They all learned from discussion with the people
10 who were sort of caring for them clinically. They will
11 have learned from the Haemophilia Society, which very
12 actively communicated with its members, from press in
13 pre-Internet days. I suspect not many of them would
14 have had access to medical journals but they had
15 a number of ways of acquiring information, not
16 necessarily systematically but quite a lot of it.
17 Q. Is the reality not that that expertise as regards safety
18 came exclusively from doctors upon whom they were
19 relying for the purpose of giving them information as to
20 how safe the products were?
21 A. I honestly don't think I can answer that. I think
22 possibly directly or indirectly, that might be the case.
23 The Haemophilia Society, for example, which I have
24 already mentioned, I think there is quite a lot of
25 archived material, which I am sure the Inquiry has,

about their communications with the patients, and they were clearly attempting to filter out the best advice from whatever sources they could get it.

It may be that most of the sources of advice that they used were doctors, I can't really answer that. But I think there were probably nurses involved in haemophilia care fairly early on who may have had a view. I mean, yes, it would primarily have been from the medical care system, I would think, in one way or another.

Q. Okay, thank you.

Could I ask you a few questions about the use of commercial concentrates. Firstly just a few practical questions. Obviously, as I have demonstrated, there was use of commercial products in Edinburgh in, say, the early 1980s, even although there was generally an attempt, it would appear from your evidence, to try and use domestic products where possible. Who would be responsible for ordering commercial products in your region?

A. Well, I would have to try and cudgel my brains a bit to remember the very start of this. I think the best I can dredge up, and there is a little factual information around this that I have seen, the Inquiry, I hope has more -- I think I inherited a system which had been

negotiated by my predecessor, probably with the Scottish Home and Health Department, that where commercial blood product -- this I should say, was in the run-up to the full commissioning of the PFC, where there was, I think, an attempt being made to sort of begin to change clinical behaviour towards the use of blood products.

What I remember with clarity was that in the blood bank in the Royal Infirmary -- my blood bank, if you like -- the first couple of years I worked there, we held stocks of albumin, which was definitely made by a commercial supplier, and I remember the reason for that was because the PFC had not yet reached full production and couldn't meet the requirement that had been created slightly prematurely in the expectation of the PFC coming through.

We, secondly, held stocks of a product called FEIBA, Factor VIII inhibitor bypassing activity. Which is a plasma product made by a German company specifically for the haemophilia patients with inhibitors and has never been made, as far as I know, by any other company. Certainly was never made by SNBTS or the BPL. It appears that we also had some commercial Factor VIII at that period, that was presumably part of the same original -- whether it was a written agreement or an informal agreement, I don't know -- between

Professor Cash and the department -- and it was reflected in the meeting that counsel to the Inquiry took me through this morning; there clearly was a concern -- presumably it was a concern on my part but I really can't remember -- that there was perhaps more commercial Factor VIII being purchased than there should be or than we had realised.

Your specific question was: who was ordering it? It's clear that the material which had to be stored in a cold room was being held in the BTS, in the blood bank, and I'm certain that if it was held there, its actual mechanical issue to individual patients will have been recorded by the blood bank. The critical thing is probably who decided what product was to be ordered --

Q. I think the critical thing is who decides what product --

A. I can't answer that but I'm jolly sure it wasn't ever me because whether Dr Boulton had an involvement in that, I really don't know. He would have been competent as a haemophilia treater to make a choice. I would never have felt competent to choose a product but I have no recollection -- it is also quite possible that the orders were actually created or the instructions to order a particular product could have been created by Dr Ludlam and passed to the BTS who then converted it

into, you know, an actual order document. But I'm sorry, I don't have those mechanics available to me.

Q. You were asked earlier about a series of correspondence between Dr Ludlam and Dr Boulton, which, as I understand it, illustrated perhaps a slight tension between the two of them. As I understand, the nature of that tension -- and please correct me if I am wrong about this -- is because Dr Ludlam is obviously asking for there to be more and more product for his needs, and Dr Boulton is saying that it might be difficult to meet that demand. Is that an accurate representation of the correspondence as you understand it?

A. I actually can't answer that without reviewing the correspondence.

Q. Would it be fair to say that there was a tension of that nature between the haemophilia department and your department at the time when you were there?

A. I would think it would be fair to say I would be quite surprised if there wasn't because it was a difficult situation and it is also possible -- and this is something that Dr Boulton may or may not wish to comment on, but it is also possible that there may have been some sort of medical professional tension between them, because they were both experts in treating haemophilia patients and experts frequently don't agree about

things. But Dr Ludlam had the authority for treatment at that time and Dr Boulton clearly did not.

Q. Was it the case that commercial concentrates were kept in stock, if you like, to meet any shortfall there might be in domestic product?

A. I really can't answer that. I really don't know.

Q. Right. Could I just ask you about a comment that you make on page 13, and perhaps it would be good to have this up. It is [PEN0150307]. This is page 13 of your main report on this topic. I'm looking at the second last paragraph at line 4 and this is in the context of the matter that you discussed earlier with counsel to the Inquiry about the definition of the word "demand". You say there in line 4 that:

"The decision to administer larger or smaller amounts of Factor VIII is, in most cases, not a life and death decision but a choice about levels of quality of life."

Could you explain a little bit about what that means?

A. Yes, sure, and if there was a haemophilia doctor present among us, he might strongly disagree with my statement. I think actually it probably should have said "in many cases" rather than "most cases" because, as written, I think on reflection it gives a slightly wrong

implication.

If a patient with haemophilia had a intracranial bleed, the patient will probably die or be gravely and permanently disabled if they don't get the most intensive and rapid treatment. If they have to have orthopaedic surgery, it is absolutely essential to maintain the amount of Factor VIII going round in the patient's blood at a level that will guarantee effective blood clotting for the period until that surgery has completed and the joint has healed. Failure to give a big enough dose in those situations can either be life-threatening or limb-threatening or have very profound and irreversible medical consequences.

Where I think the situation, in my limited understanding of haemophilia treatment, becomes where there is more room for manoeuvre, more room for balancing priorities, is in the questions of prophylactic treatment or the provision of, as it were, home therapy; where the patients actually have the material in their own refrigerator and can treat themselves when they feel they need it. And that, I believe, leaves the situation open for patients to make their own judgments about the clinical signals or other signals that will lead them to decide to give themselves another dose of therapy.

For example, if you are the parent of a child with haemophilia and the child wants to go and play football and you know there is a risk therefore of them injuring their knee joints, there is a choice. You can say to the child, "No, I don't want you to go and play football," which is limiting the child's quality of life but also will mean that that particular dose of Factor VIII may not be necessary. Nothing clever. That's all I was trying to say.

Q. Does it follow from the view you have expressed in that sentence that in many cases one could reduce the amount of Factor VIII a patient would require if the patient were prepared to make adjustments to the way in which he lived his life?

A. That's my understanding as a non-haemophilia treater.

Q. Thank you.

A. But I stress, as a non-haemophilia treater.

Q. While we are on that page, I would just like to ask you about one other comment there. This is actually going slightly back. This is in response to question 4.1. We don't need to flick back a page for this:

"Why was it necessary to buy commercial Factor VIII in early 1984?"

So you are being asked there about the necessity for the purchase of commercial products at that time. In

the paragraph above the paragraph we have just been looking at you say:

"The quantities of Factor VIII being used were increasingly due to increased patient demand combined with clinical enthusiasm for more intensive treatment and there would also have been the influence of active marketing by the commercial suppliers of Factor VIII concentrate."

What I wanted to ask you particularly was what you meant by your reference in early 1984 to the influence of active marketing by the commercial suppliers of Factor VIII concentrate.

A. Perhaps I didn't phrase my response terribly well. That's the factor that is ever present. Nothing special about 1984.

Q. Right. To whom was that marketing directed?

A. Like all pharmaceutical marketing, directed at everybody who is potentially susceptible. So patients, clinicians, doctors, nurses, administrators, public health directors, policy-makers; you name it. It is hugely pervasive. And to single out any one group of recipients would underestimate the scale of the situation.

Q. I just wanted to ask you a little bit about NHS concentrates. I think you have touched on this already

so just have a couple of questions.

It has been mentioned by a number of witnesses who have given evidence in this section so far, that there might have been concerns in the early 1980s amongst haemophilia clinicians about the quality of the NHS Factor VIII concentrate product. In particular, there has been suggestion -- and I think you have maybe touched on this already but I would just like to get more of an explanation from you about your view on it -- that, as opposed to the position with commercial products, the NHS concentrates may have been difficult to use on the basis that one could not rely on how much active Factor VIII protein was within them. Do you accept that proposition as at the early 1980s?

A. Not quite as you have expressed it. And again I would sort of defer in advance to my colleague, Dr Peter Foster. But my understanding is that the individual vials of Factor VIII were labelled with their content of Factor VIII, expressed in international units. So it's not correct to say that nobody knew how much was in them. But you did have to read the label, which is something that people find quite difficult.

But that was an inconvenience factor, and not a trivial inconvenience factor, because it meant that if you were giving guidance to the patient or the parent

was giving guidance to their child, instead of having some sort of rule of thumb that, "If you have a big bleed in your knee, in a clinical situation you should take ten vials," which, if the vial content was standardised at 250 units, that meant you were getting 2,500 units in ten vials. If the vial contents varied between, say, 200 and 260 or something like that, then you actually had to do a little bit of arithmetic and get the right dose from that number of vials or alternatively just ignore the labelled dose and accept that the dose would be around about 2,500 units, but because you hadn't actually checked the individual doses it could be a bit more or a bit less. There is a reason for that labelling difference, which I can go into if you want to, but I think it is probably better left to Dr Foster because he can explain it with more authority.

THE CHAIRMAN: Mr Dawson, I wonder if you would bear in mind the time. I understand that those who have to travel do prefer to get away about now.

MR DAWSON: I really only have a couple more questions, one on this topic and one on other topic if that's permissible.

THE CHAIRMAN: I don't know if it is. It may be preferable to bring Dr McClelland back because there are other people to ask questions.

MR DAWSON: I would perhaps anticipate that Dr McClelland may be coming back at another time during the Inquiry anyway and I would be happy to address my questions to him then.

THE CHAIRMAN: I'm not happy to break the topics. What's the position?

MS DUNLOP: Dr McClelland is not in block 3, sir, but I think he will be coming back in the autumn, yes.

THE CHAIRMAN: That's not satisfactory. But I don't think that we can really keep going and make it difficult for the stenographer and the others to get the transcript right.

Could you come back --

MS DUNLOP: I'm wrong, he is in block 3. We can probably organise something in block 3.

THE CHAIRMAN: I am much more anxious to get your evidence fully than to push into short periods.

MS DUNLOP: It is obviously depending on what Dr McClelland's plans are. There wouldn't be anything wrong in just doing it on Tuesday morning. It is usually better to kind of finish before you start someone else.

THE CHAIRMAN: That is so.

MS DUNLOP: If that were possible, we can do that and just start Dr Foster an hour later or something like that.

THE CHAIRMAN: If it's an hour, then we certainly have to make changes.

MS DUNLOP: I'm guessing.

THE CHAIRMAN: Can you come next Tuesday.

A. I can't.

THE CHAIRMAN: When --

A. I'm due to go to Switzerland to do a course and I have to get a plane.

THE CHAIRMAN: You didn't refer to a horse there, a course?

A. I wish.

THE CHAIRMAN: I don't know what to do for the best but I think that getting the transcript right is extremely important and if we don't complete that exercise now, then, of course, it becomes more difficult to make corrections. I think we simply have to interrupt at that point and fit you in as best we can, as soon as possible.

MS DUNLOP: Yes.

THE CHAIRMAN: Right. Tuesday.

(4.04 pm)

(The Inquiry adjourned until 9.30 am on Tuesday, 10 May 2011)

I N D E X