Thursday, 12 May 2011

(9.30 am)

THE CHAIRMAN: Good morning. Yes, Ms Dunlop.

MS DUNLOP: We have Dr Frank Boulton.

THE CHAIRMAN: Good morning, Dr Boulton.

DR FRANK BOULTON (affirmed)

Questions by MS DUNLOP

MS DUNLOP: Good morning, Dr Boulton. We are going to begin, as we usually do, by looking at your curriculum vitae. You have actually submitted two documents. I think one is entitled a "biography" and one is entitled a "curriculum vitae". They are both very short. Could we have the first one, which is WIT0030293.

This tells us a bit about you, that you studied medicine in London. You did an MD on haemoglobin variants and you became a fellow of the Royal College of Physicians of Edinburgh in 1986. And then the positions you have held. I see you were at The London hospital. Were you there at the same time as Dr Colvin?

A. Yes, Brian Colvin followed me.

Q. I thought you must be. You then became a senior lecturer in haematology at the Royal Liverpool Hospital and Liverpool University and also the director of the Liverpool Haemophilia Centre between 1975 and 1980, and

then you came to Edinburgh. Consultant and honorary senior lecturer in haematology and blood transfusion in Edinburgh between 1980 and 1990, and you were also the deputy director of the Edinburgh and Southeast Scotland Blood Transfusion Service, I think, from 1982?

A. Correct.

Q. Then you went to Southampton and you retired from the NHS and blood service in 2006, but you remain a visiting lecturer in the faculty of medicine in Southampton.

Then we can see other positions you have occupied; including being the chair of the UK National Advisory Committee on the Care and Selection of Blood Donors for six years to 2006. And the chair of transfusion taskforce of the British Committee for Standards in Haematology, also in the early 2000s. You have some overseas' experience and I think, like many of our witnesses, a list of publications dealing with various topics, but you haven't given us a list of those and there is no problem with that.

A. It would be too boring to do so.

Q. Thank you.

Your other document is PEN0150506. Much the same information, although you have told us on this document a little bit more about your past as a haemophilia director.

A. Yes.

Q. We can see that there is some extra information with an asterisk in about the middle of the page.

Just to let everybody take a moment to read that.

(Pause)

Dr Boulton, a number of witnesses wear more than one hat and you are obviously here today having been a haemophilia centre director and also having worked in a Blood Transfusion Service, which is more unusual. I just wondered, you obviously moved across from haemophilia care into blood transfusion; why did that happen?

A. The situation in blood transfusion at that time, and to some extent still, differed very considerably from that in England. I think it would be fair to say that the history of the development of the Blood Transfusion Service in England was around a model whereby there was, originally, from the military regions in the Second World War, a regional basis of blood transfusion, blood donations, blood supply systems set up in a way that there was an organised system of collecting and testing the donations to be supplied to hospitals. For example, the 12 or 10 teaching hospitals in London were each supplied with blood from a region that would supply three or four of them. The model was that a regional

centre, with its specialist staff of collecting and testing and a few doctors to take the organisation, would be supplying the blood but the blood and its products would be used in a hospital by a team, initially of pathologists in the blood bank, supplying it to the clinicians, the surgeons and the doctors.

So there was a pretty clear split that developed throughout England of the regional model, whereby a centre, for example in Southampton, would be supplying a series of hospitals in the region, of perhaps 3 or 4 million people around it, where there would be between a dozen or two or three dozen hospitals. The hospitals having their clinicians using the blood but the blood actually coming from a centre in usually a university town somewhere in the middle of that supply chain.

In Scotland, and in particularly on the East side of Scotland, in Edinburgh, less so than on the West side in Glasgow, but on the east side of Scotland, Edinburgh, Dundee, Inverness, Aberdeen, the model was more that the transfusion service was developed within the settings of an active working teaching hospital, in Edinburgh's case in the Royal Infirmary. So that within the Royal Infirmary we had a transfusion centre that also had an very active clinical base. Whereas in England the blood bank -- that is the laboratory which tested the

donations, selecting them for specific patients -- was part of that hospital's responsibility, usually within a haematology department; in Edinburgh the testing of blood to be supplied to patients specifically was actually done within the remit of the transfusion centre, which is a contrast.

Obviously there were and are haematologists in the hospital and other clinicians in the hospital who would be using the blood, but the actual supply of blood and its products to patients was under the control, or at least under the responsibility of the regional transfusion centre, in those days, in the 1980s, in the Royal Infirmary at Lauriston Place.

Q. Thank you.

A. Therefore, what I should add is that the attraction to me of moving to Edinburgh from Liverpool was different from say, had I moved from Liverpool Hospital to Liverpool transfusion centre. I would have been less likely to have done that in those days because the nature of the work at the Liverpool transfusion centre was very different from the nature of the work at the Edinburgh transfusion centre. The Edinburgh transfusion centre was much closer to patients than the Liverpool --

Q. I was going to say, much more of a clinical content in the position in Edinburgh.

There were two things that were striking me as you were speaking, Dr Boulton, and the first was about London. So if you had drawn London as a very big circle or a very big oval, probably right to do, and then perhaps quartered it, is that an accurate mental picture --

A. Pretty well. The south is a bit blurred because Lewisham in the southeast was always fighting for its independence from Tooting in the south-west, but in the north you had a clear northeast that was interestingly centred in Brentford in 1950, and the story was, and I think it was true, that it was put out there in case an atom bomb fell on London and that there would be a surviving centre outside London that could supply blood. Whereas in the northwest, it was set at Colindale which was a little bit more central.

But, yes, the mental picture is right: that London was divided into four quarters and in each of the quarters there would be three or four teaching hospitals and a whole host of non-teaching hospitals who would be dependent on blood collected in that region.

Q. Right. It is interesting how often still one can trace developments back to the war.

A. Yes.

Q. We spoke earlier this week about Law Hospital.

A. Yes.
Q. About its having been built where it was so that it would be a safe distance from Glasgow, again for reasons connected with the threat of bombing.
A. That's right.
Q. That was the second point that struck me when you were speaking, that it has seemed as though the transfusion set-up in the West of Scotland was really slightly different --
A. The model in the West of Scotland was more like -- not totally like but more like the English.
Q. Yes. In the sense of having this geographically distant centre --
A. Geographically distant centre, the medical staff of which were less involved in direct patient care than the medical staff of the Edinburgh centre were with the care of patients in Edinburgh; both the Royal Infirmary and related hospitals and other hospitals in Southeast Scotland.
Q. Yes. Thank you.
Because of your involvement as a haemophilia director in the 1970s, it did occur to me to ask you if, for example, you remember the World in Action programme. You may know that we watched it. It was two programmes from December 1975 about the preparation of plasma

products in the United States. I just wondered if you remembered having seen that?

A. I certainly do remember, yes.

Q. Did you watch it when it was on or did you watch it afterwards?

A. I didn't see the programmes live but I was very shortly made aware of those programmes.

Actually there is a slight -- it is not a conflict of interest but I have a brother who was working with Granada on the World in Action team at that time and I can certainly remember me being actually slightly cross with him because at that time -- and in fact on reflection, I think my brother was right -- I felt that the World in Action programme had exaggerated the problems. But I was then quite a young and not very experienced doctor and not quite so aware of how things would work out.

So I suspect that that World in Action programme -- I certainly remember it very well and I remember conversations after it, and having read the transcript of it again very recently, it brings it back.

Q. We have all imagined it being the talk of the hospital, as it were. Is that how it was in your hospital?

A. Well, I think actually at the time the programme came out, I was not yet in Liverpool because I came to

Liverpool in October 1975, or if it was around then, I was right in the middle of moving.

Q. Yes, December.

A. It was December? That's right. This was December and my attention was quite honestly on other things like organising a family move up from London to Liverpool and I became aware of it, as I say, through my family connection with the production of the programme and also it clearly was discussed at the Liverpool centre. But by the time I really settled into my job in Liverpool in early 1976, it was already in the past.

Q. Right. But do you remember it having a continuing effect in relation to your attitude to products from the United States of America?

A. I might comment that back in London in 1973 or 1974, I had a haemophilic patient who needed Factor VIII over Christmas for a fairly major dental problem. He developed an abscess and it needed surgery. And although he was a mild haemophilic, we did not have enough Factor VIII cryoprecipitate or NHS Factor VIII in stock to safely cover his surgery in my opinion. This would be literally Christmas Eve in 1973.

So I ordered in a small amount of commercial Factor VIII, which was just becoming available at that time, and this mild haemophilic man in his 50s did

receive some commercial Factor VIII, as a result of which he got both Hepatitis B and non-A non-B. So that struck home to me very vividly. So I had a rather rude awakening into the dangers of hepatitis from commercial -- in this case it was American -- Factor VIII.

So one of the naive reactions that I had in Liverpool was when we bought commercial Factor VIII it was not American, it was European. It came from Austria. So clearly there had been a concern that American products were to be avoided. I think that was a legitimate, or at least an understandable reaction to my experience of treating and giving a patient -- and we didn't know at that time exactly the consequences of non-A non-B. It is very likely, if that man is still alive, and I remember him well, he would be in his mid 80s now. It is quite likely that he would have had quite a significant dose of hepatitis and liver disease.

Q. Where did Immuno get their plasma?

A. Austria.

Q. So it was Austrian plasma?

A. Yes.

Q. They didn't import --

A. Quite honestly, I did not at that time conduct a detailed enquiry into where all the donors came from,

and it is indeed quite possible that some of the plasma they procured and fractionated came from America. I would not know that but at the time I was clearly under the impression, and had been told by their own director, Norman Berry, that the material was Austrian in origin.

Q. Thank you.

A. But clearly from paid donors.

Q. I noticed that you had attended a meeting in 1977. Obviously because, having realised you had been a haemophilia centre director, I was looking for you and you are recorded as having been at the meeting of 24 January 1977. Could we just have a quick look at that? It's [SNB00017245].

A. Yes.

Q. There you are. Liverpool Royal Infirmary.

A. Yes.

Q. That was a meeting in Oxford?

A. Yes.

Q. I think, for our purposes, the most interesting part is page 6, if we could go to that, please.

Sorry, this is one of these documents where every second page is blank from the way it has been scanned or something. So when I say page 6, I'm meaning numbered page 6 but we may have to scroll through a few more to

find it. It's probably about page 11 or something. It is page 11.

It is just I notice that this is a meeting at which there had been a general discussion of the supply of Factor VIII in the United Kingdom.

A. Yes.

Q. Dr Boulton, it would be pretty amazing if you remembered this but I did just want to ask you: do you remember this meeting? Do you remember anything about these discussions?

A. Only very, very vaguely. I have no precise memory.

Q. Do you remember anything about this debate that we can see cropping up here, about whether English plasma could or should be sent to Scotland for fractionation?

A. No.

Q. We can see that Dr Prentice, whom we know to have been a haemophilia centre co-director in Glasgow, is saying that he thought there was still a shortage of Factor VIII in Scotland and he had to buy commercial Factor VIII to treat his patients.

A. I don't think I would have been particularly concerned about the Scottish situation at that stage in my life.

Q. Can we move then to your arrival in Edinburgh. I think it must have been at the beginning of 1980. Is that right?

A. Yes, January 1980 I think it was, the middle of January.
Q. We can see you in action in February 1980. Can we look at a letter, please, [SNB0072566]?

It looks, Dr Boulton, as though from very shortly after your arrival, you were in discussions with Dr Ludlam, who must have been a new arrival around that time too, about the question of home therapy. I'll just give you a minute to look at the letter. (Pause)

A. I have no specific memory of writing the letter, but I would think -- well, it clearly is authentic.
Q. Yes.
A. Actually it would fit the pattern in my mind, yes.
Q. Yes. I was going to ask you about that. Firstly, when you arrived in Edinburgh, did you become aware of what the then prevailing position was regarding haemophilia therapy?
A. Yes, I mean, this letter would indicate that I had had already, within the first couple of weeks of my arrival in Edinburgh, met and spoken to Christopher, who I remember from before, and he had made his position pretty clear and I felt at that time, and I think the feeling was right, that this was the right way ahead.
Q. Right. Had you known Dr Davies, who was Dr Ludlam's predecessor?
A. Only very slightly. I can't remember if I had met him

at one of the other HDO meetings but I did meet him afterwards. I did come to meet him and his wife was a practising consultant at the hospital at the same time. So there were occasions when I did meet Howard.

Q. Did you know anything about his views on concentrates?

A. Yes, he was a wise man and wiser in retrospect, perhaps, than seemed at the time.

Cryoprecipitate is very messy to deal with. My initial experience of dealing with cryoprecipitate was, believe it or not, as a houseman in Portsmouth in 1967, when the local haematologist was a man called Dr John O'Brien, who had been among the Oxford team that discovered Christmas Disease in 1952. And Dr O'Brien had at his beck and call The Royal Navy. And a severely haemophilic man developed bladder cancer, the first sign of which was heavy bleeding. Cryoprecipitate had been described only two years before and John O'Brien was able to procure fresh donations from the ships and the naval bases in Scotland, and make them into cryoprecipitate and I was the young man who had to deliver the cryoprecipitate into the haemophilic circulation as the houseman. I wasn't even aware that I was going to become interested in haemophilia later.

This man had very poor veins and I managed to catheterise a narrow vein on the back of his hand, which

was like gold dust to me, and I kept it going for a week and it had regular infusions of cryoprecipitate into it. Dr O'Brien was not pleased with me for using one vein for a week because he felt it was likely to cause thrombosis, interestingly, and I should have catheterised a new vein every day. I politely told him I thought he was wrong but that goes to show that my introduction to cryoprecipitate was early.

It is messy to deal with. In order to maximise its potency, one should wash out each bag with a bit of citrate, and it had this nasty property of gunking up and so it was not easy. So I had every sympathy with doctors whose job became a daily infusion of cryoprecipitate. Nevertheless, when I was in Liverpool as a consultant, I regularly did such stuff myself, partly to support the junior staff and partly to show them that it was actually a part of their duties.

Q. Would you sign up to a view that has been expressed by others that it really was not suitable for home therapy?

A. Very difficult for home therapy. It was not totally unsuitable. It could be used. But the patients, and if they were a young boy, the patient's family, the parents, would need quite careful and specific training and monitoring so to do. And so it was only really practical in families (a), who were relatively well

trained and (b), probably in fairly close proximity to the hospital in case things went wrong.

Q. Right. So just to go back to Dr Davies, what was your understanding of his views about different forms of therapy when you arrived?

A. I can't say that I was aware of those views within the timeframe of writing this letter, but as time went by, I did become aware of views that there were problems with fractionated product, even from NHS volunteer donors. But I think it was not unreasonable for the newer generation to advocate an increase in usage of Factor VIII.

The problem was that if one were to restrict the use to what, at that time, was felt on good grounds but not on established grounds, to be a safer product, ie a cryoprecipitate that was more difficult to use, less potent, the patients would not have so much protection from joint damage, whereas one would be able, with higher doses of smaller volume infusion lyophilised from the freeze-dried fractionated product, be able to embark on a programme of prophylactics for preventing the damage to joints, particularly in boys as they were approaching their teens.

Q. If that's the distinction between cryoprecipitate and concentrates, what did you discover to be the prevailing

view in Edinburgh about the difference between American concentrates and NHS concentrates; can you remember that?

A. We go back to the wonderful book, The Gift Relationship, by Richard Titmuss, which came out in 1970, which I still think -- I'm sure that many in this room will now have read that book and indeed its sequence, and indeed Richard's daughter, Ann Oakley, has also written on the same subject.

Although it is a rather ponderous social study type book, The Gift Relationship, it very clearly describes the risk of using blood from donors who are paid, that is the profit-making donor centres, and the blood from the non-profit-making donor centres, who used volunteer donors in America.

And indeed, there was a long drawn-out legal battle in America in which the for-profit companies were taking the not-for-profit companies to court for unfair practices; in other words, undercutting their commercial development by using donations that were not paid for.

The book very clearly established the greater risk from using blood -- this is not fractionated products but just straight blood -- from donors who are paid compared with donors who are not paid, and although there has been more than one magnitude of difference

drop in the risk of paid and non-paid blood donors, that debate is still going on to this day, as far as I know.

So by 1980 one would be very aware of the problems of using blood from donors who were paid and therefore, fractionating plasma from donors who were paid, and going back to the World in Action programme, that was certainly highlighted, and I think that one was certainly aware that there were risks associated with using commercially obtained plasma from companies who were bleeding their donors and paying them in America or indeed, on reflection, in Austria.

Q. So much so that Dr Davies, we have heard, didn't want to use the commercial products at all.

A. That, I think, would be fair comment.

Q. Yes. We also understand that Dr Ludlam continued that policy when he arrived in Edinburgh in 1980.

A. But the letter does indicate that Christopher was quite rightly anxious to increase the use of Factor VIII for the haemophilic patients, particularly the young ones, and that his preferred option was to use PFC-derived Factor VIII concentrate.

Q. Just to look at the response to the letter, can we look at [SNB0072568]. This is actually from Mr Watt back to you.

A. Yes.

Q. He makes a point in his letter about:

"... a bias in favour of Inverness where the geography of the region makes a more widespread utilisation of home therapy a rather necessary fact of life."

I haven't really come across very many references of that nature, Dr Boulton, but it is interesting to see it because in about 1973, when the commercial concentrates were coming in, at least some people seemed to think that perhaps they would be for people who lived a long way away from the haemophilia centre, but I think we understand that that wasn't really translated into practice.

A. There is a good reason why it wasn't necessarily translated into practice and I probably didn't make it clear enough to John Watt at the time. There is the magnetic effect of having a haemophilia centre, and this was particularly characterised historically in Oxford, where the centre there was developed under the great Dr MacFarlane, and Oxford became a magnet so that many haemophiliacs' families moved into the Oxford region so that their children could be treated.

It is quite possible, indeed probable, that some haemophiliacs' families in Scotland gravitated to Edinburgh and Glasgow, where they would be more likely

to get treatment more promptly. So although Inverness has the relative problem of geographic remoteness and the haemophilic living in the Western Isles actually was probably supplied by Aberdeen -- but nevertheless -- I think Aberdeen supplied the Orkneys and the Western Isles were supplied by Inverness. Although there was that very real geographical problem, it may have been more than countered -- although I wouldn't know this for certain by any means -- by, as I say, the magnetic effect of having a dedicated centre in a city like Edinburgh or Glasgow.

Q. Can we just look at the second page of the letter, please.

I think, in short, we can see that this letter was Mr Watt. We have to go on to page 3. We have another blank page here.

A. Yes.

Q. Mr Watt had come up with a sort of plan. I don't think we need to go into the details of it because it doesn't looks as though it actually was implemented, if we look at another letter, which is one that Dr Cash wrote. We can see this letter was copied to him, and then [SNB0072571], Dr Cash didn't seem to like the proposal.

Well, Dr Boulton, we know that one way or another, and perhaps with a few initial hiccups, more of a home

therapy programme did become established in Edinburgh using product from PFC, and you were obviously assisting Dr Ludlam in getting that up and running from 1980 onwards.

A. I think this correspondence, which I have seen recently, there is a slightly unfortunate assumption in there that John Watt felt that I could personally increase the amount of plasma that would go to PFC. Maybe that's unfair on John, and when he uses the word "you" in his letter to me, he wasn't referring to me personally but the Edinburgh centre.

What I can say is that at that time and shortly after, the amount of blood donated in the Edinburgh region was much higher, the number of donors that donated per year, the number of donations collected per year, was much higher than the national average, certainly in England, and it was actually accompanied by an almost conscious excess discard rate of red cells.

In other words, the blood donation emphasis became driven by the need for plasma so that a very significant proportion -- I'm not talking about 5 per cent but 15/20/25 per cent -- of the donations were collected and the red cells not used. So we were never short of red cells. But what we did do was to take off 200 mls of plasma from each donation to maximise the supply of

plasma within the bounds of the donor supply, the amount of plasma. And of course, when optimal additive became available in the early 1980s, that increased our yield. So steps were actually taken to increase the volume, the kilogrammes of plasma that were sent to PFC.

So although the specific proposals in this letter and its reply and John Cash's reaction to it were not specifically developed in the way that Christopher and I would have liked, there was still a marked increase in the amount of plasma that I think was sent to PFC and I guess that was also reflected from the other regions as well.

So we in Scotland were doing our very best to maximise the kilogrammes of plasma sent to PFC, and I think at that time I have no doubt we were way ahead of the situation in England.

Q. We have also had a impression from very detailed paper that Dr Foster has given us of efforts at PFC really to use every scrap.

A. Absolutely.

Q. Yes. To recover every scrap and to use every scrap.

A. I think I'm right in saying that they even used -- the plasma that the centres made into cryoprecipitate would result in a cryosupernatant, and I think that PFC even used cryosupernatant to get Factor VIII, because the

cryoprecipitate would have contained about 50 per cent of the original Factor VIII in the donation. That would be in 30 mls. The remaining 180/200 mls of cryosupernatant plasma still had Factor VIII in it. And although this would need to be confirmed from Dr Foster, I seem to remember that cryosupernatant was also put into the pot to make fractionated Factor VIII.

Q. I think that may have been an initiative that Dr Foster said in his paper was less successful because some of the batches were too "weak".

A. But it reflects the conscious need to maximise Factor VIII yields.

THE CHAIRMAN: I think there is a considerable history of development of supernatant Factor VIII but also considerable resistance from some directors to its use.

A. Yes.

THE CHAIRMAN: Especially from the West of Scotland. Or does that not square with your recollection?

A. I was not directly involved in discussions in the West of Scotland.

THE CHAIRMAN: We might hear a little from you about the insularity, otherwise called the autonomy, of different regions.

A. Yes.

MS DUNLOP: Just sticking, Dr Boulton, with a sort of

chronological progress at the moment and moving into 1981, I wanted to go back to another meeting, which is [SNB0017354]. The interest of this is really to note and come back to it later, about arrangements for obtaining, holding and distributing blood products. This is the minutes of a meeting of UKHCDO at the Royal Free on 9 October 1981. You were at that, by this time from the SNBTS in Edinburgh. If we go to page 9 of this document, please, I think this is going to be page 9.

We can see that this is a discussion of the question of purchasing, holding and distribution by blood transfusion centres of blood products; stocks of all types, including Factor VIII and Factor IX concentrate.

As I read this, Dr Boulton, it is really discussing a problem in England, I think. I'll let you take a minute to look at it. (Pause)

Perhaps we can scroll down to the bottom of the page, thank you. (Pause)

Perhaps we should look at the next page as well, please. (Pause)

It rather looks, putting it very crudely, Dr Boulton, as though the quid pro quo for retaining control over purchasing, holding and distribution of products was better furnishing of data about what was going on, to enable health authorities and transfusion

centres to carry out long-term planning. Do you remember this being a tussle in England about who had control over the purchase, holding and distribution of products?

A. I do have memories. They are rather vague. I think it should be realised -- and this is no aspersion to the English, who are ten times bigger than the Scots -- that the dozen or so regions and the relationship between the regional transfusion centre and the local clinicians, particularly the haemophilia doctors, was highly variable. In some there was a close relationship between the haemophilia director and the region, possibly helped by geography, and that was certainly the case at Liverpool and in others there would be a more remote relationship.

I remember in Liverpool I was given a budget of £40,000 to buy commercial Factor VIII and I was praised, amazingly, by the finance director, for keeping more or less within budget. But I also kept the transfusion centre, under Dermot Lehane in Liverpool at that time, aware of what was going on. So there was a sharing of information. We used whatever we could from Elstree. We used whatever we could from the transfusion centre in the way of cryoprecipitate, but we had to buy extra, and I'm pretty sure that we kept all parties informed. I'm

not sure that that pattern was duplicated across all the other centres in England.

Q. Right. I want to come back to that, having noted that that seems to have been the set-up in England. But now can we move to a slightly different theme by looking at a meeting of UKHCDO in September 1982. The meeting took place on 13 September and we have a number of different notes of that meeting, including one written by you.

A. Yes.

Q. Which is [SNB0017494]. I don't think this one is signed but --

A. This is me.

Q. It is you, yes?

A. Yes.

Q. There may be a signature on the last page but anyway, you are content that you wrote this?

A. Yes.

Q. We can see a number of points mentioned with which we are already familiar, but the particular matter to which I wanted to direct your attention is the reference to what was said about Acquired Immunodeficiency Syndrome in the United States.

Can we just move through, please, towards the end of Dr Boulton's note?

You see that note there, Dr Boulton:

"Acquired Immunodeficiency Syndrome."

A. Yes, I see the note.

Q. You perhaps know what I'm going to ask you, which is your record of the fact that three cases had occurred in haemophiliacs in the USA, possibly associated with parenteral drug abuse. You have also written there is a remote, underlined, possibility of transmission via commercial Factor VIII.

The reference to there being a remote possibility of a connection with blood products does feature in the main minutes of the meeting but not the idea that the cases in people with haemophilia in America might be associated with parenteral drug abuse. Just before I ask the question, can we compare what was said in the MMWR, which is [LIT0010559]. Look at this report.

A. Can we see the date of that?

Q. Yes, this is 16 July 1982. It is actually stated in the first paragraph that:

"All three were heterosexual males. None had a history of intravenous drug abuse."

If we look on to the second page, if we could, please, and I think we need to go down to the editorial note at the end of the second paragraph. It says:

"The occurrence among the three haemophiliac cases suggests the possible transmission of an agent through

blood products."

Dr Boulton?

A. Yes, yes.

Q. It is turning into a big question, but firstly you made a reference in your note to a possible connection with parenteral drug abuse and you also recorded that the possibility of a connection with blood products was only remote. I don't imagine that you made that up yourself. Do you remember what the source of that information in your note was?

A. It was the proceedings of a meeting. This was not a personal opinion about being remote. This was my record, taken by myself, with notes then transcribed a few days later, of the discussions at the meeting; and I think it is in the context of the hepatitis risk, which is the item immediately above there. So it was not a personal opinion; it was just what was said at the meeting.

Q. Yes. Indeed, but you don't remember who said it?

A. No, I didn't note that but, as I say, this comes in the context of the notes, immediately after the hepatitis risk.

Q. Yes.

A. So it would have been, in my recollection -- and if Christopher was there, he may remember better than me --

but my recollection is that this was not quite a throwaway but as a bit of an extra about the infectious risk, and the emphasis was on hepatitis. And I might comment that -- and I'm sure you will have observed as well -- there are two other reports in your files of the same meeting.

Q. Yes.

A. One of which I think came from PFC.

Q. One is Dr Perry and the other is from the Haemophilia Society.

A. That's right. And in neither case is a reference made to that particular item about AIDS, and so the only report in your files of the meeting that mentions the fact that AIDS was discussed at all was in my notes.

So I haven't actually seen recently the actual official minutes of that meeting. It would be interesting if they had a reference to it.

Q. Yes. The official minutes don't say that there might have been a connection with intravenous drug abuse. They do say that there was a remote possibility that blood products might be involved.

A. That's right.

Q. I think the only significance of it, Dr Boulton -- and at the end of the day it's only nuance.

A. Absolutely.

Q. But perhaps it could be thought there is a hint of, even at this stage, the risk being downplayed.

A. Sadly, I think that's true. I think there was a difference, certainly within Scotland, and the English haemophilia directors -- I wouldn't say this was the Scottish haemophilia directors -- but I think there was -- and I think they [sic - we] are coming to the Bloom letter soon. There was a distinct unease among the Scottish transfusion directors and consultants about the onset of this horrible disease, which by 1983 [sic - 1982] was becoming more and more apparent as indicated by that MMWR of June and of one that follows two weeks after this meeting in September.

So although it is only a recollection, and I don't think too much emphasis should be placed on it, there was unease among the Scottish. And I might comment that one of the reasons for the unease, particularly in Edinburgh, is that a year or so before I arrived in Edinburgh there had been a horrible outbreak of Hepatitis B in the renal unit among the patients and one of the fatal victims of that incident was a technician in the Blood Transfusion Service of Edinburgh, whose memory was, even though she had died a year or two before I arrived, still very strong among the scientific and technical staff of the centre.

So what I'm saying is that there was an awareness that blood transfusion could be dangerous in a special way in that setting, and on the other hand for entirely understandable reasons -- and this is most important to get this balance right -- families of boys who were being crippled by haemophilia, who had this cripple-saving and actually life-saving infusion available to them, were understandably anxious that their boys could grow up with healthy joints, pain-free, and were therefore in a dilemma between how dangerous was this stuff and how effective it was. And it's an entirely understandable, human reaction. When you see the immediate benefits -- a little child crying and then not crying within minutes of receiving an injection and the remote possibility of it going a bit yellow in a few weeks' time and HIV wasn't even thought of -- you can see that there was a lot of pressure dealing with the acute and not worrying so much about the remote possibilities.

Q. Yes. I quite appreciate that, Dr Boulton. In what you have said, you have mentioned the chance of having undamaged joints, and actually something did strike me, which I haven't asked any of the other doctors, so I'll just ask you: whether the availability of joint replacement made a difference in haemophilia care?

Presumably joint replacement began to be possible?

A. Well, total hip replacement was the first one that became available and slightly ironically it was realised that total hip replacement was frequently followed by thrombosis and so anticoagulants would be given to prevent the surgery causing thrombosis and pulmonary embolism. But it was confined to the middle aged and elderly.

Even to this day I don't think an orthopaedic surgeon would consider replacing the knee joint. Knees were often particularly badly affected in a young man of, say, 25, who had severe arthritis due to haemophilia. Joints have a habit of wearing out after 20 years or so and further surgery being required. You would have to ask an orthopaedic surgeon but I would very much doubt if joint replacement surgery would be certainly featuring in the 1980s.

Q. Thank you.

THE CHAIRMAN: Dr Boulton, why were you at the meeting in September 1982?

A. John Cash asked me to go.

THE CHAIRMAN: You were no longer a haemophilia director by then.

A. That's right. Harking back to my appointment at the Edinburgh centre and the reason why I went there: I have

explained that it had its great attractions because in contrast with English centres it had a real clinical link to the surgeons, the heart surgeons et cetera, et cetera.

I loved my haemophilic job in Liverpool. It was not one which I was wanting to run away from and I missed the patients when I left there. But I was encouraged to believe that I would still have contact with the haemophilia community, which I did, in Edinburgh.

Christopher had no problems about them getting to know me and I think I even addressed a meeting of the Haemophilia Society fairly shortly after I arrived. So the reason I went to Edinburgh was so that I could continue -- and particularly there were possibilities of research in the transfusion area, which was of interest to me.

But I was known to the haemophilia community in England. I knew Arthur Bloom personally, and it was thought not unreasonable that a representative from the SNBTS be present at those haemophilia directors' meetings in the early 1980s and I was very welcomed among them.

THE CHAIRMAN: Thank you very much.

MS DUNLOP: Another meeting you attended was the meeting at Heathrow Airport in January 1983 and you also prepared

a note of that, which we have. Can we look at that, please? That's [SNB0014033]. Do you remember this meeting?

A. Yes. Well, very vaguely, I'm sorry to say. Yes.

Q. It looks as though it might have been primarily, at least from Immuno's point of view, a promotional meeting. Would that be right?

A. I suspect so, yes.

Q. What Immuno was interested in talking about was their hepatitis-reduced Factor VIII and Factor IX concentrates. And it's interesting that in Immuno's notes of the meeting that is overwhelmingly the subject matter that's recorded, but in your note you have recorded that too but you have gone on to talk about a discussion which I think took place in the afternoon in relation to AIDS. That's page 3. So if we could go to that, please.

Dr Boulton, you were there. At that time, early 1983, was this going to be something that any gathering of haemophilia clinicians would want to talk about?

A. It is very difficult for me, 27 years on, to recall the chronology. Certainly at some stage around this time there was a heightened awareness of the distinct possibility that this awful disease would be transmitted in blood and there was an awareness that its

epidemiology was pretty close to that of Hepatitis B, which was well-known.

I think at this time, 1982/1983, there was still a reluctance by some haemophilia directors to -- and I think this is typified by my dear friend Peter Jones of Newcastle, who was really anxious to get the balance right, as I said earlier, between relieving the immediate problems of haemophilia bleeding against the remote -- I put that in inverted commas -- risk of some infectious disease later so. So I suspect at this time there was a spectrum of opinion among haemophilia directors about where the balance lay.

Q. You have underlined, I suppose -- I don't know if it's your underline. Someone has underlined that there was a 45 per cent mortality?

A. I don't think that's my underlining. I suspect it's Brian McClelland.

Q. Actually, on the first page, there are various hieroglyphics. It does looks as though you were preparing this note as a form of reporting?

A. Yes.

Q. I suppose you will certainly have wanted to show it to him?

A. Yes.

Q. Can we look on to the last page, please? There is

a paragraph there about the possible nature of the transmissible agents. It certainly looks as though the writer of this note -- that is you -- belonged to the school of thought that there was a transmissible agent. Is that right?

A. I think that's a fair assumption.

Q. Dr Boulton, you have mentioned --

THE CHAIRMAN: Are you leaving the note?

MS DUNLOP: Yes, I was going to.

THE CHAIRMAN: Can we go back to an answer which I think may need a little bit of unpackaging.

You were asked whether you could recall this meeting terribly well and you started by saying it was very difficult to recall it with clarity. At some stage around now, there was heightened awareness of the risk and of the common epidemiology between AIDS and hepatitis. Then you went on to say there was still a reluctance by some haemophilia directors, for example, your good friend Peter Jones, who were anxious to get the balance right. I think that you perhaps didn't explain to me clearly enough what the reluctance was about. I can see the point about getting the balance right but what was the underlying factor that explained the reluctance?

A. I would like to put this in the context of my

correspondence and telephone calls with Peter Jones, who I regarded as a leading haemophilia director in England and who I knew really quite well personally. Obviously it's important to get his own views on this, if possible. But at that time, 1982/1983, Peter, who was a paediatrician by training and largely dealing with boys with haemophilia in the Newcastle area, really wanted to test the thinking about the nature of this epidemic, or looming epidemic, that seemed to be focused in America, particularly the west coast, and how relevant that was to England. I think he was reluctant in drawing too much of a conclusion that would reduce significantly the amount of therapy he could give to his patients.

I think it's possibly, particularly because a large number of his patients were boys, growing up, for whom he felt a personal responsibility to give them a healthy adult life, which was dependent upon ever-increasing supplies of clotting factors. The British, particularly the English, could not meet the demands and so there was a need to go overseas, particularly to America, where there were products available, and although there were legitimate concerns about the safety of those products, Peter and many like him were reluctant to abandon the treatment; in other words, go back ten years or so to

the style of treatments usually only cryoprecipitate or small pooled products which would reduce the dosage that children could get and return them to a risk of getting permanent joint damage from their early years.

THE CHAIRMAN: Let me make my interest more clear: I can understand that a person concerned with the care of haemophilia patients would be very reluctant to give up a therapeutic product that had established itself as effective and indeed transformative in caring for the patient. That's one thing. But the basis on which the reluctance is maintained can be one or other of two things. It can either be a failure or refusal to accept the growing evidence of a competing risk, or it can involve the acceptance of that risk but preferring still to get the acute benefits and accept the long-term risk.

I'm anxious to know whether the haemophilia population, and the directors in particular, maintained a resistance to the growing evidence of a link, the transmissible agent theory, beyond the point at which that was reasonable and sensible as scientists. That's the focus.

A. I remember the Haemophilia Society at that time really quite well. I had very close links with the Haemophilia Society in my time in Liverpool. I helped found the local branch. One of the very first haemophilic

patients I ever met was a young man in those days, called John Prothero, GRO-A. He became a leading light in the Haemophilia Society. I remember him as a boy of 15. So what I say about the Haemophilia Society now has to be taken in the light that I knew them well at that time. And Reverend Tanner, I knew very well.

So we are going into Haemophilia Society history. Lovely people, very caring, very driving. Reverend Tanner was a lovely man but very focused on the care for haemophiliacs, GRO-A, and at that time, the early 1980s, I think it would be fair to say that the Haemophilia Society was very reluctant to accept the validity -- they wanted the risk of nasty things from their blood products to be really proved before they would agree to reducing the availability of material for their patients.

So there was a drive from the haemophilics themselves, including the Haemophilia Society, to maintain the amounts of therapeutic material available.

So there was, in other words, a feeling that the risk was probably acceptable.

THE CHAIRMAN: Of course, proof is a difficult concept unless one knows the standard against which the evidence has to be measured. What do you understand by proof at

this time?

A. The proof would have to be epidemiological. I mean, the ultimate proof would be the final demonstration of Koch's Postulates about infections, and that's why the chimpanzees in the Immuno report were so interesting. One of the problems that Immuno had was that there was a developing shortage of chimpanzees. In other words, could we get an infectious agent from person and put it into another person or animal and demonstrate the same disease? So that would be the proof.

So that's not epidemiological, that's just biological but you can then get an epidemiological indication that there was a proof. So there is a reasonable proof that Hepatitis B was transmittable by blood products. That risk was first identified in the Second World War and became more and more evident, particularly when the so-called Australia antigen was discovered. So when you find the organism, you can prove. Until you find the organism, proof has to be based on epidemiological grounds, which are always subject to some degree of contention.

THE CHAIRMAN: Yes. I think I heard on the radio this morning that American scientists think that they may at last have identified the HIV virus, but until that point --

A. The ancestral virus?
THE CHAIRMAN: Yes. But until that point, on this hypothesis Koch's postulate wouldn't be satisfied in the case of the connection between HIV and AIDS, would it?
A. I would have to be made familiar with the details. My understanding is that HIV or proto HIV was a virus that was transmitted among the higher primate world, was taken up by people who were in close contact, particularly hunters and eaters of the meat of the monkeys, and so particularly for HIV-2, I think, this is fairly likely but how it got into humankind... The other thing about HIV is of course its extraordinary propensity to evolve rapidly. So the viruses we have in the HIV group now may be really quite substantially different from the virus that was lurking in the 1950s.
THE CHAIRMAN: Thank you very much.
MS DUNLOP: Dr Boulton, I wanted to take you to one or two other events in 1983. We were looking at the discussion that was held at the meeting at Heathrow Airport on 24 January. You yourself mentioned a moment or two ago the Bloom letter, and actually there are two Bloom letters, I suppose, one we have and one we don't. The one I was going to ask you about is the one that we don't have, which is your letter to Professor Bloom. Is that what you were expecting when you referred to it?

A. I understood that this was likely to crop up.
Q. Yes. We should look, just to explain this issue, at the reply to your letter, which is [SNF0013711]. This is a letter to you from Professor Bloom, dated 23 May 1983. We can see that you have obviously written, he doesn't say when, but no doubt not that long before 23 May and you have made some suggestions. He is recording what he perceives as a consensus that it would be counter-productive to ban the importation of blood products at this moment. You must also, I think, have made some mention of deferral of home treatment.

Perhaps we could keep that letter and juxtapose Dr Boulton's supplementary statement, which deals with this issue. It is [PEN0150226].

It's the second, third and fourth paragraphs of this supplementary statement that deal with this topic, Dr Boulton.

I think it would be fair to say, sir, that a lot of people have looked for Dr Boulton's letter.

A. Including myself.
Q. Including you. But we haven't found it. So all you have been able to do really is to speculate as to what you might have said.

In a nutshell, Dr Boulton, I think what you are saying is that although you were writing from

Edinburgh -- and by that time you were working in Edinburgh -- you think the focus of your concerns may have been more to do with the treatment in England and Wales. Is that right?

A. Yes.

Q. Do you want to explain a little bit? I know you have set it out in your statement.

A. Also, at the same time, there is another document from this era, that you may have, which is my memo to Brian McClelland about a telephone conversation I had with Peter Jones on 24 May.

Q. I was going to go to that after we talked about the letter, if that's all right with you?

A. Yes, fine.

Q. Right.

A. It's impossible for me at this stage to say precisely what was in my mind and what made me write those letters. So anything that follows from me in this regard must be taken with a degree of, if not scepticism, at least realising the limitations of the value of my recollection.

And I find it very frustrating, just as you do, that I have no idea really what my wording was for my recommendations one and two. There were these two recommendations that I made to Arthur Bloom in my

letter, which was probably around about 20 May. As I say, it must be limited. But also his letter to me is marked "Strictly confidential", as I commented. And I'm not even sure that the letter I wrote to him, I would have copied to Brian McClelland. So consequently, although I would have kept Brian in touch with the gist of this conversation afterwards, it may not exist in the SNBTS files at all. If it exists anywhere, it will be in whatever remains of my personal files, which I left behind when I left Edinburgh in 1990.

But it may turn up one day, and the one thing I don't want to do is to say something now that is shown to be completely wrong if it turns up again. And anyway, I want to be totally honest, as I have got to be. I have affirmed so.

I think it is likely that my concern was directed towards the English more than in a way to the Scots. Arthur Bloom, the then director -- lovely man, very caring physician, really anxious to get things right, I would say actually little short of brilliance in terms of his intellect and his ability to see many sides of an issue -- was right in the middle of this dilemma about safety from the point of view of unintended horrible side effects and efficacy, the intended good effect.

All I can say is that in this increasing

awareness that fractionated blood products, particularly but not solely commercial fractionated products, were associated with a risk. Long-term -- remote therefore in the sense of long-term -- but not remote in terms of the actual risk to the patient, unintended, nasty side effects of producing a debilitating and potentially fatal disease.

So I honestly can't say more than that. It looks as if it was directed towards the English and I would agree that, but it was not irrelevant for the Scots, which is why I let Brian have a copy of Arthur's confidential letter to me.

Q. Yes. You have mentioned certain characteristics of Professor Bloom. It has been suggested to us that he didn't have a lot of clinical involvement directly in looking after patients. Is that your recollection or will you not have known about that?

A. I never worked in Cardiff, so I wouldn't be in a position to make that comment. But however directly concerned with patient care he was, he was an extremely caring man. There is no doubt that he was acutely conscious of his responsibility for the quality of life of the patients, the care of whom he was ultimately responsible for.

Q. The memo to which you have alluded, about your

conversation with Dr Jones, is in fact immediately preceding document in our database. It's [SNF0013710]. This is 30 May. We can see that, at least in part, the focus of the conversation that you had had with Dr Jones is to do with selection of donors, the possible deferral of donors, but you seem to have had a more wide-ranging discussion about the state of play as at May 1983.

A. Yes. And in fact, the third paragraph, the one that starts, "He went on ..." I think does throw a little bit of light on the letter to Arthur Bloom that I wrote, and his reply to me. Although I spoke to Peter on 24 May, I wrote this on 30 May, after which I had obviously received Arthur's letter.

It does rather look as if one of my points in the letter to Arthur indeed was about donor selection, a subject on which I became more and more expert as time went on. I do remember very clearly around this time in Edinburgh -- and I suspect it was around the time of the Edinburgh Festival in 1982 -- when we, that's the doctors in the transfusion centre in Edinburgh, were discussing how to cope with the influx of visitors, including Americans, who might want to give blood.

We were, in other words, sufficiently concerned at that stage that there was in America a virus that may be associated with a socio-economic group that was likely

to travel and go to exciting things like festivals and be so minded to donate while they were on site.

What could we legitimately do about minimising the risk that such people might be carrying a virus, which at that stage was totally unidentified? So admittedly it was hypothetical and I don't know that it ever had any tangible results, but what I'm saying is that in the summer of 1982, we were sufficiently concerned about the possibility of there being a causative virus or causative agent for this disease that might embarrass the quality of our donated blood. So that's just putting that in context.

So we were already facing up to -- and I know that Brian had good conversations, very productive conversations, with the gay community in Edinburgh, about how to get over the message to gay men that if they were minded to give blood, they should be aware that there was a potential problem.

Brian would be -- and probably has given you better testimony about that period, but what I'm really saying is that there was a real concern among the doctors in the transfusion centre in Edinburgh that this could be a problem.

So consequently, when it comes to being reluctant to talk about the sexuality of the potential donor in front

of you, I think we were somewhat ahead of the game than Peter Jones in May 1983.

Q. You are dating concern in the transfusion world in Edinburgh to the summer of 1982?

A. Yes.

Q. So you are sure about that? That's a year before really?

A. Yes.

Q. Before all this material?

A. Yes.

Q. Again, I said to another witness, there is not much point in asking you to say the same thing as you said in this memo in different words, but the comment at the end of the fifth paragraph, that you felt that Dr Jones was being somewhat less than cautious in his attitude:

"This is not unexpected given his interests ..."

Et cetera, and then the comments in the next paragraph as well:

"His ears being attuned to only part of the message which Anne Collins would have given him."

Just in passing, who was Anne Collins?

A. She was the transfusion director of Newcastle region.

Q. You can see there what you said, Dr Boulton. Is there anything that you want to amend or explain or should we just let the memo speak for itself?

A. I would rather the memo spoke for itself.
Q. Thank you. We should, I think, go back to your supplementary statement, just to say that you have also given us some input in it on this topic. That was [PEN0150226]. You cover this in the first paragraph and you return in the paragraph at the bottom of the page to the topic of the memo of 30 May, and we can read on to the next page as well, please.

You mention in your supplementary statement the meeting of October 1983 and I did want to have a brief look at that as well, more particularly your note of it, which is [SNB0017535]. This one is signed, Dr Boulton, so there was never any doubt that this was your note.

From page 2 on to page 3, there is a discussion of heat treatment and in fact on page 3 we can see a comment from Dr Jones:

"Any chance of reducing the risk of product should be taken."

Then a section, section 4:

"The current situation regarding AIDS."

When you said there was no evidence of AIDS entering the general population, do you think you will have been quoting from Dr Craske?

A. Yes.
Q. Right. In one sense, everyone is the general

population. It really depends on how you classify different groups of people.

A. Yes. How you select your population.

Q. Yes. Then can we look on to the next page, please? You have recorded that there was a previous discussion on the use of imported Factor VIII. You have commented in your supplementary statement that the passage saying that there was no logic in not using imported Factor VIII and also --

A. I apologise for the double negative.

Q. Yes, it is:

"The patients should be encouraged not to refuse imported Factor VIII."

You said you felt that was slightly tortuous phraseology but no doubt you didn't imagine it would be scrutinised all these years later.

THE CHAIRMAN: I think the next sentence worries me even more:

"In view of the AIDS incidence in haemophiliacs in the USA, it was felt that there was no logic in not using imported Factor VIII."

MS DUNLOP: I do have a question mark beside that as well, Dr Boulton. What do you think is the logical point that's being made?

A. Well, I wouldn't be surprised if actually, bearing in

mind this is 27 years ago, I added too many "nots" in there, but it would have been more clearly expressed -- and I think this would be a reasonable interpretation of what I was trying to say -- that, in spite of all the evidence that was accumulating -- and clearly there is a big difference in that one year -- my very brief comment in 1982, considerably expanded in 1983 -- there was still a reluctance by some haemophilia treaters to reduce or to stop -- or even just reduce the amount of Factor VIII of commercial origin for their patients.

That's really what it means, that although GRO-A -- I'm sorry, I also apologise for my bad spelling of "acumen". GRO-A was another man whom I knew very well and I actually can recall the conversation I had with GRO-A about his great concern for his case and that the local haemophiliacs had become very, very wary indeed of the use of commercial Factor VIII. So this is the haemophilic population around Bristol in 1983.

And nevertheless there were still, in other parts of the country, an anxiety to keep up the use of Factor VIII until the situation of the epidemiology, or even better, Koch's Postulates, could be clarified.

Q. In the official minutes of the meeting there is also reference to a point that was made by Dr Chisholm, who

was actually the director in Southampton, I think, at about that time. Was she your predecessor?

A. No. Dr Chisholm was one of the four clinical haematologists in Southampton General Hospital, and in fact she was on the panel that interviewed me for the appointment of director of the Southampton transfusion centre. So we were in the same town but employed by different bits of the NHS.

Q. She is minuted as having raised the question of patients reverting to cryoprecipitate, and in fact Dr Winter has explained to us since that that was more of an option for her because she had a lot of access to cryoprecipitate or access to a lot of cryoprecipitate.

A. The transfusion centre was right on her doorstep.

Q. Yes. But it doesn't seem that her suggestion was really enthusiastically accepted at the meeting.

THE CHAIRMAN: Dr Boulton, it's quite difficult to make sense of your own sentence, I think.

A. I agree.

THE CHAIRMAN: But one possibility that occurred to me was that it might be that there was no logic in discontinuing the use of imported Factor VIII because there was already a well established incidence of AIDS among haemophiliacs in the United States of America, which would suggest that it might have been too late.

Did that ever occur as a topic of conversation?

A. Yes, I would agree that that is a distinct possibility.

MS DUNLOP: Yes.

A. Could I just add that there was a feeling that the epidemic of this horrible condition in America was very likely to come to Europe but it might take a year or two.

MS DUNLOP: I suppose at that time too, Dr Boulton, the absolute numbers being described would be seen as very small in a country as large as the United States.

A. Yes.

Q. One more matter I wanted to look at. I don't know if we can carry on. It is coming up for ten past 11.

I just thought I should cover this with you, Dr Boulton, because you referred in your supplementary statement to 1983 being a peak year for commercial Factor VIII use in Scotland. I wonder if we could just have a look at the figures we have in the appendix to our preliminary report. [PEN0131433]. Was it these figures you were looking at when you made that comment? Could we go on to 1438, please?

Just having a very quick look at 1983. There is Aberdeen. An amount of FEIBA, and then 1441, 1983 in Dundee is shown. It looks to be entirely NHS product. And Edinburgh is on 1444. We can certainly see some

commercial product mentioned for Edinburgh but 1.75 million units of PFC product; far and away the largest there. 1446 is Yorkhill in Glasgow. By 1983 even Yorkhill, which we know had been a big user of commercial product earlier, it's 1.1 million units and then Glasgow Royal Infirmary, which is 1449, again some mention of commercial product, Armour Factorate, FEIBA, but 1.95 million units of PFC product. Then we should also look at Inverness, which is 1452. We can see there statistics for 1983. At least from these tables, it doesn't look to have been a particularly heavy usage in 1983. I just wondered if you had had those tables in front of you at the time?

A. I don't think I did and the tables are clearly much more likely to be reliable than my recollection. Could I just add, of course, that FEIBA, which was of commercial origin, would have been used specifically for haemophiliacs with inhibitors and would not have been given to the general haemophilic population, and would only have been given to haemophiliacs with inhibitors under rather dire circumstances, which I'm sure Christopher would explain in more detail than myself.

In other words, you can't really compare the use of FEIBA -- there was a sort of Scottish equivalent. I see it's used up there occasionally, of DEFIX or activated

DEFIX from the PFC, but FEIBA seemed to have -- and I think we now know the reason why, but it seemed to have a particular property of bypassing the inhibitor block that had developed in these tragically affected haemophiliacs. So you can't really compare FEIBA with straightforward PFC or indeed commercial straightforward Factor VIII usage.

Q. I understand. So for a patient with Haemophilia A, who had inhibitors, who needed treatment, there really was very little choice?

A. There was also a very significant demand of PFC Factor VIII because some responded to very high doses of straightforward Factor VIII and those sort of patients distorted, if you like, the general pattern of haemophilic usage. And I think there was one occasion when Christopher had two patients with inhibitors at the same time. I think it might have been 1984 or so. Which was a very considerable worry to himself and to us about how much we could sustain the supply, and I think that what has to be borne in mind is the specific problem of the Factor VIII deficient patient with strong inhibitors, and about 5 to 10 per cent of patients develop that complication.

Q. I see. Thank you, sir. That would be a good moment at which to break.

THE CHAIRMAN: I don't know how you want to use Dr Foster's data but his table 19, of course, gives information on the pattern of usage of commercial and if it is accepted, it might make a very acute picture but we will leave it until after the break.

MS DUNLOP: Thank you.

(11.13 am)

(Short break)

(11.37 am)

THE CHAIRMAN: Yes, Ms Dunlop?

MS DUNLOP: Thank you.

Dr Boulton, I wanted to ask you some questions about your involvement in supply of products for the treatment of patients with haemophilia in Edinburgh. First of all, I wanted to ask about the arrangements that there were for obtaining commercial product, if that was required. Can we look first at a document [PEN0150478]? This is a meeting at Lothian Health Board, I think, on 14 January 1981 and you were at that. As was Dr Ludlam and also Dr McClelland, and Dr Parker. He was another haematologist, as I understand it, from the Royal Infirmary.

THE CHAIRMAN: There are two Parkers.

MS DUNLOP: Sorry, Dr A C Parker, the "he". I can't remember his first name. Was it Anthony?

THE CHAIRMAN: Alistair.

MS DUNLOP: Thank you. Alistair Parker. We can see Dr Ludlam saying that:

"PFC were providing intermediate Factor VIII. The cost of this was met by the Blood Transfusion Service of the Common Services Agency."

So the health board wasn't having to fund the haemophiliac service, but that there would be cases where commercial Factor VIII had to be bought. There had been three cases in 1980. There is a discussion about supply of PFC products. That's paragraph 2. Dr Ludlam in paragraph 3 has provided an estimate of his requirement for the coming year. Then paragraph 4, please. We see that:

"With commercial Factor VIII, Dr Ludlam has pointed out the danger of liver disease, the cause of which [was] at present being investigated."

Then paragraph 5. Dr Cash and Mr Myers, presumably from the health board, had discussed the purchasing of commercial blood products in the past, and all commercial products were ordered through the regional transfusion service. Then can we go on to the next page, please.

So from this it would be correct, would it, to have an understanding that where a haemophilia clinician in

Edinburgh needed commercial product for a particular reason, it would have to be ordered by you, the regional transfusion centre. That seems to be the arrangement that obtained, indeed before this meeting, and that was to continue? Is that your recollection?

A. I regret to say I have no recollection of this whatsoever.

Q. Right. I suppose, if commercial material was needed for a particular patient and was then ordered in accordance with this procedure, it wouldn't really be much of a question of storage because it would be needed more or less immediately, but when it arrived, where would it go?

A. I have no recollection.

Q. Right. It looks as though -- and this is material that Professor Ludlam has provided us -- that arrangement then changed. Can we see [PEN0150480].

Part of the reason for looking at the minutes of the UKHCDO meeting earlier this morning, Dr Boulton, was to apprise ourselves of what the arrangements were in England, and we can see from this letter, which is Dr Ludlam to Dr Brough on 19 April 1983, that there was a change at that time. Do you remember any of this either, the change?

A. Although I'm quoted by Christopher in that letter, and

I'm sure quite justifiably, 28 years ago, I plead lack of recollection.

Q. Yes. Actually we have seen this before but we can note that Dr Ludlam was saying that the new arrangement would bring Edinburgh into line with arrangements that prevail in the rest of the United Kingdom. So that looks to be the position as far as commercial product was concerned.

As far as NHS product goes --

A. Can I just comment that whatever the details of who was ordering what, my recollection is that the Lothian Health Board actually carried the tab and not the SNBTS, but that may not be fully correct.

Q. Yes. Dr Ludlam is saying:

"As before, I shall still be accountable for the financial cost."

A. Which I think is consistent with what little bit I do recollect, but I have no recollection of the details of the meetings behind this correspondence.

Q. So in other words it would come from his budget, whatever his budget was, or his department's budget?

A. I think so, yes.

Q. Which would be health board money?

A. Yes.

Q. Yes. Can we look at some correspondence in relation to NHS product. The first letter is [SNB0015199].

This is a letter from you to Dr Ludlam of 10 May 1982 and you had in the transfusion centre a table of haemophilia home therapy patients and the amount of Factor VIII that had been issued in the first quarter of 1982. You are recording concern at the amount.

I think you are really recording that there is a gap between issue and usage. So you are saying that you are officially issued, in the first quarter of 1982, with 261,530 units, and the total for the first quarter that had been used on the home therapy programme was 206,800. And it has been necessary in fact to get some more from Inverness.

Then you go on to say that:

"The allocation is actually based on the amount of plasma we supply to PFC."

A calculation of that, you have said, would produce about 300,000 units, which is the amount you received back, plus some retained for stocks. Then you seem, on the second page, to be putting down, I suppose, some markers about what you thought needed to happen.

The first thing, Dr Boulton, is: do you remember there being a calculation of how much each region in Scotland was to receive by way of issue from PFC; that PFC would say, "You will be issued with ..." and there

would be a figure?

A. Quite honestly, I have no recollection really of writing this letter. I do recall the, I think very fruitful discussions I had with Christopher about the general problem of supply.

In answer to your specific question, I think I was too remote from the national scene in Scotland to be able to comment about the other centres in detail. Clearly, we clawed back some from Inverness, and presumably Inverness may have been reluctant to let us have it but were content to let us have that amount. That's as much as I can say about the regional distribution and reallocations. I can say no more detail than that.

Q. Do you remember the problems starting to emerge? Do you remember being anxious about meeting the demand?

A. Oh, yes. Yes, as a concern arising. And until I had seen these letters, I would not have been able to put a precise chronology to that but I think, whereas perhaps in the first year or so -- in other words, 1980 -- I was relatively reassured that the expanding programme for caring for haemophiliacs in Edinburgh could be met by the SNBTS, perhaps by this time we were getting anxious about the specific problem in Edinburgh. But I think then I was conscious of the thing I referred

to earlier today about the magnetic effect of having an effective haemophilia centre in one town drawing the customer.

Q. Right.

THE CHAIRMAN: No doubt there are lots of special factors that come into it.

A. Yes.

THE CHAIRMAN: I know, for example, that Inverness, for a considerable period had two very heavy users.

A. Yes.

THE CHAIRMAN: And if one of them happened to be attracted to Edinburgh for some reason or other, treatment or education, then, of course, there would be the point you make in paragraph 4, that perhaps they should come with their allocation in effect.

But leaving that aside, do you remember this regime in operation and do you remember it changing from time to time? For example, I know that at one stage allocation was on the basis of population. Do you remember --

A. I always struggled with the total heads of population because it already seemed to me to be much more sensible to do it per haemophilic, and I felt that all my life. All my life in haemophilia, I felt, even though there are considerably different demands of each haemophilic

depending upon their clinical status, it was better to do it -- and by this time we were getting quite a good idea of the total amount of at least severe haemophiliacs in the UK. So I always had been uneasy about it going on per total head of population. That's just a general comment. I can't at this stage recall detailed concerns.

THE CHAIRMAN: If we look at the regime you mention here, proportionate to the contributions of plasma, of course, many different factors could influence what a region was prepared to send.

A. Absolutely, yes.

THE CHAIRMAN: Such as?

A. Well, such as the nature of the other demand from the clinicians in the surgical units, in the heart units, in the emerging -- and interestingly, within the haematology camp -- the emerging far greater efficacy of leukaemia therapies, which required blood products.

So we had an increasing competition from platelet production from our donations, the same raw materials. So there are all sorts of other directions that blood was being used for. So if you had two or three big hospitals in a region like the West of Scotland, you could see that they had other patients than haemophilia to be concerned about, and that was also true, of

course, in east Scotland.

THE CHAIRMAN: I shouldn't look for a simple solution then, Dr Boulton?

A. Yes.

MS DUNLOP: Dr Boulton, I appreciate it's a very long time ago and I quite understand it is very difficult to recall the detail of any of this, but perhaps just for the record, to look at the next letter, which is [SNB0015205]. This is, I think, 10 August 1982, rather faint but we have other copies. You are apologising for repeating yourself but it looks as though you are really making the same points. In July -- I'm not sure, I think that's perhaps 350 bottles were used:

"Which is approximately 160 per cent of our monthly allocation."

It looks as though, as far as where the stock was, some of it will have been in or around the ward, and the Speywood material was in your deep freeze. But you were feeling a need to meet, which you did on 23 August -- we have a note of the meeting. That's [SNB0015207]. You began by noting the stock situation and, as recorded in the note, you were already in August eating into the September stock.

I wondered from paragraph 4 what was meant by the deduction at source effect. Do you remember?

A. 4(c)?
Q. Yes.
A. I can't recollect the details of this concept, and I'm having some difficulty in recollecting it right now, but I think that one of the problems that would be in people's mind -- depending upon whether they were a blood transfusion scientist, blood transfusion doctor, a haemophilia carer doctor -- is how much you could expect a kilogramme or 1,000 kilogrammes of plasma to yield. The deduction at source would have been the amount of Factor VIII that came out of a kilogramme of plasma. That was not used for direct treatment but was used for other purposes, such as quality assurance, to see how much Factor VIII there was in that particular batch, and other tests that might have been conducted which meant that there was an inevitable reduction of the final yield that reached the patient bank.
Q. Right.
A. I'm not certain but I suspect that that's what that means. So in other words, not every unit that was taken out of a gramme or kilogramme of plasma would have ended up in a patient. You wouldn't have expected it to because there were legitimate other uses on the way.
Q. Right. Then Dr Ludlam is setting out his position in section 5. On to the next page, please. It's obvious,

Dr Boulton, that from the time of you and Dr Ludlam arriving in 1980, usage, particularly for home therapy, has increased very considerably. Is that right?

A. It looks like it. I'm sure that's right, yes.

Q. Yes. Then [SNB0015213]. You obviously sent the minutes of the meeting to Dr Ludlam. I don't think we have had a letter but he wrote back.

A. Yes.

Q. 1 September. Then you replied on 3 September [SNB0015215]. I suppose you are really the middleman in both directions, Dr Boulton, aren't you? Because you are involved in how much plasma is going from collection in Edinburgh and the southeast to PFC, and then you are involved in trying to assist Dr Ludlam in getting the amount he needs with which to treat his patients. Is that right? Was that your role?

A. I think I felt at the time that the prior case was for the treatment of the patients, to give them as adequate an amount as we could. Therefore responding to Christopher's needs.

I fully understood Christopher's desire to maximise the treatment for his patients and I had a great deal of sympathy with that because, after all, we are in this world to make patients' lives as best as possible and haemophilia is a horrible disease, and it's not just the

patients that suffer but the families, it's their friends, and society has a big responsibility for the care of such people.

I'm very much on the side of maximising the opportunities for those people in whatever way you can. For that reason, it was therefore not unreasonable for the Blood Transfusion Service to maximise its own efforts.

So in a way I was the middleman and indeed I guess I was appointed to be so because I was the first actual haematologist, let alone a haemophilia doctor, to be appointed to the Edinburgh BTS consultant grade.

I guess, for their sins, that was the attraction for me to be appointed there. Furthermore, I was specifically put on the blood issue side. That was my job within the centre. To be the consultant in charge of the blood bank and all the things that were issued from it, which included, plasma, platelets and PFC Factor VIII.

So clearly I was involved deeply with Christopher in his work but at the same time I had a responsibility for maximising the use of donor materials as much as possible as well.

So yes, I was the middleman but I certainly recognised that there were limitations and Christopher

was very legitimately pushing us on that because that was his job, and it was my job to help him as much as possible but within the constraints that I was put under from the supply side.

Q. Just to follow the chain of events into December, can we have [SNB0015219].

You are reporting to Mr Watt. We can see that two other centres in Scotland have chipped in with offers. Do you have any memory, Dr Boulton, of what amount of stock you would have wanted to have at any given time? By that I'm thinking of a length of time. Would you have wanted to have a month's stock, six months' stock, a year's stock? What would have made you feel comfortable?

A. My recollection is it would be somewhere between one month and three months in stock. And it is only a recollection. I think it was nearer three months than one month, but that I think was likely, and maybe you are going to ask me this in a minute: I think there was a specific circumstance behind this, which is that Christopher had at least one if not two patients with inhibitors that were demanding a lot of material at that particular time, but they are not referred to in these particular letters by name.

Q. We can see that cryoprecipitate may be being used a bit

more. It's recorded in the second paragraph, notwithstanding its drawbacks, and we have heard quite a lot about that.

A. Yes.

Q. You wrote again on 29 December. That's [SNB0015221]. I think this may be the two patients to whom you were referring.

A. I think that's right, yes.

Q. There does come through from this correspondence, Dr Boulton, an underlying reluctance to have to resort to commercial material. Is that a sentiment --

A. Yes.

Q. -- both parties shared?

A. Yes, I think so.

Q. I don't think it's necessary to go to the minutes of this meeting but I think we know that there was a joint meeting on 21 January 1983 between the haemophilia directors and the SNBTS directors with government officials in attendance, and that this topic cropped up. That is purchase of commercial material in Edinburgh cropped up. We know from Dr McClelland's handwritten notes that he was thinking at the meeting it was something he was going to have to speak to you about. Do you remember all of that in the early part of 1983 or is that a bit of a blur?

A. I actually do remember that there were these concerns and when I saw this correspondence, the bell that went in my mind was fairly loud. Because I do recollect that Christopher and I were discussing in some detail the specific needs of the patients and how best we could meet them. So to be faced with this again was actually -- even though so long ago, I do remember. But that doesn't mean to say I can recollect the details.

Q. No. And it looks as though, after that meeting in January 1983, there was some sort of expectation that everyone was going to sit down and resolve matters around a table, but that probably didn't happen, if we read [SNB0015194]. This is Dr McClelland writing to Dr Cash.

In short, Dr Boulton, I think what comes across is that the home therapy programme has been expanding and that the haemophilia centre at the Royal Infirmary was a heavy user of NHS concentrate by this point. I don't think that can really be disputed and that obviously led to a bit of tension for you and --

A. It was not a problem for me.

Q. No.

A. But it was within one's professional duty to do one's best to meet the demand that was legitimate, but clearly there were wider implications for that demand.

Q. Dr Boulton, can you just explain to us, around about this time, 1982 and into 1983, what was your daily job? What were your tasks you had to do to make sure that everybody who needed material, whether blood or blood products, was supplied?

A. I was one of three, then four, consultants in the centre. My main work was to be the consultant in charge of -- and this is an interesting term -- of the blood bank. In other words, the blood bank, which distributed to -- not just the Royal Infirmary but other hospitals that were served by the labs of the Royal Infirmary; to supply them with all the blood products that came our way from the donors.

So it would be whole blood, it would be red cells, it would be platelets, it would be plasma and it would be cryoprecipitate, and sometimes even cryosupernatant, for the patients in the Royal Infirmary. There were four other hospitals in the southeast region, which included the Western General Hospital and Peel, Melrose, that had their own blood bank, to whom we just supplied the raw materials and they selected the patients.

But for about two thirds or 70 per cent of the southeast region's patients, the blood transfusion centres own laboratory selected the patients who were to receive that. That included, for example, the very

exciting development in the cardiac surgical unit about blood supply for heart surgery, which was at that time quite intensive. So I would go along to audit meetings in the cardiac departments, I would be very familiar with the use of blood for surgical purposes. I would be pretty familiar also with the use of blood for the leukaemics.

At the same time there was a small laboratory in the Edinburgh centre that conducted tests of coagulation on patients, not haemophiliacs. That was clearly Christopher's section. But in patients in intensive care unit, in the cardiac unit and elsewhere, who were in need of specialist advice concerning transfusion of appropriate products.

So we had a laboratory that did a clinical service and the same laboratory was also responsible for conducting quality control exercises on plasma and on other materials derived from PFC.

So it was actually quite a complicated set of responsibilities that I had. I did not have primary responsibility for donor selection and I did not have primary responsibility for the transplant immunology work that was going on in the centre at the same time. Although I was again familiar with those sort of problems.

Q. So much of what you are describing as the distribution part of your job?
A. Yes.
Q. What about the input into the centre in Edinburgh? Were you projecting on a daily or a weekly or a monthly basis what you were going to need and sourcing that, as far as blood products were concerned, from PFC? You would be reporting to PFC, "We need for June the following amounts"?
A. It wasn't as precise as that, and to some extent I think Brian was slightly more in that particular field because he would be part of the SNBTS directorate meetings at which John Watt would also be present. So I might get from Brian, the trend from PFC. Also I would be given notice of the periods when PFC had to be shut down, sometimes for two or three months, for refurbishment or upgrading or that sort of thing, and there would be a period in advance whereby there would be a stock piling process going on. So I would be involved but not necessarily at that close liaison level with PFC.
Q. Professor Ludlam described the van coming from PFC on a monthly basis. Does that ring a bell for you?
A. Yes, but not -- yes, yes.
Q. But sometimes not very regular or sometimes more than once a month?

A. To carry on that figurative analogy, it didn't ring very loudly outside my door.
Q. Right. When it came, did it just, as far as blood products are concerned, contain your allocation?
A. Of PFC-derived materials like Factor VIII and Factor IX, et cetera?
Q. Yes.
A. Yes, I think it probably would have done.
Q. Right. We have spoken about commercial products. So I suppose, if the allocation was running very low, if you were looking at your own stocks and you could see the allocation was running low or if there was a particular patient with a particular problem and you had to source some commercial material, would it be you or somebody in your department who would then actively take the steps to do that?
A. I don't recall being directly involved in the ordering of any commercial materials. So, although I would be aware, as indicated in some of these letters, of a surge in demand, and also to some extent aware of the reason for that surge in demand -- there would be one or two special patients or surgery had been planned or whatever -- I would be able to respond in terms of what the SNBTS could provide in the way, firstly of cryoprecipitate, second of PFC and thirdly perhaps the

Factor IX concentrates that might have been made available. And clearly from this letter, I was aware of materials like Speywood, FEIBA, et cetera. Speywood, as far as I recollect, was porcine Factor VIII. So those materials I would have been aware of but quite honestly I don't have any recollection of being involved specifically in the ordering pattern of those.

Q. Was there somebody who was your opposite number in the West of Scotland, who did the same job as you are describing for us but for the West of Scotland?

A. I think that was Bob Crawford, the late Bob Crawford.

Q. And he was based at Law, was he?

A. Yes.

THE CHAIRMAN: Was the structure exactly the same?

A. No, I don't think one can really compare the structure at Law very closely with that of Edinburgh because the only crossmatching activities that they would do would be for non-haemophilic patients, but for patients requiring blood cells that had funny antibodies. So they would be a sort of specialist laboratory for patient distribution.

MS DUNLOP: There has been reference to a daily order in fact, going to the centre at Law. And I think at one time also Dr Davidson may have been involved. He may have been --

A. I cannot answer for the practices that were going on in the West of Scotland.

THE CHAIRMAN: Was there a separate haematology department?

A. I think I may have described the --

Glasgow Royal Infirmary had two excellent haematologists in John Davidson and Isobel Walker, who were responsible for that part of my job analogous to the distribution of red cells, platelets and liquid plasma, frozen plasma.

But they were Glasgow, West of Scotland Health Board employees, so to speak. So they were in the hospital. I was a bit of a hybrid.

THE CHAIRMAN: So your function was really rather more distributed in the Glasgow area, with the Royal haematology department carrying some of your responsibilities and Law carrying others?

A. Yes. That situation is more like England. You can see the attraction for me as a relatively young man coming to a job with these diverse responsibilities. There were similar situations as far as I recall in Dundee and Aberdeen. They were more like Edinburgh than West of Scotland.

THE CHAIRMAN: Just before I forget, there was a question I wanted to ask you. Where was Dr Mitchell located?

A. West of Scotland, Law.

THE CHAIRMAN: At Law?

A. Yes.
THE CHAIRMAN: And Dr Wallace --
A. Dr Wallace preceded him at Law, yes.
THE CHAIRMAN: Yes.
MS DUNLOP: Dr Boulton, we should look at the statement that you provided as well, which is [PEN0150054]. I think there are really only two points that you cover in this statement that we haven't discussed this morning. Your answers are shown on this copy of the schedule, which was sent to you, and they are underlined.
A. Oh, I see, yes. Yes.
Q. I just wanted to ask you in the first place about your reference to self-sufficiency. You say:

"Scotland had become largely self-sufficient by the early 1980s but some commercial product was still being used in Edinburgh and possibly more so in Glasgow."

At the end of your answer you refer to "absolute self-sufficiency". I don't want to create the impression that we are hung up on self-sufficiency. We have asked a lot of people about it, but what do you mean by "absolute self-sufficiency"?
A. Something in which a community would be able to supply every single vestige of blood or blood products from within that own community, with no dependence upon outside agencies at all.

Q. We know that the Australians for example, in the early 1980s, banned the import of commercial blood products.

A. Yes.

Q. Would a country ever be able to achieve absolute self-sufficiency, as far as blood products are concerned, without a measure of that nature, without there being an actual ban on importation of commercial material?

A. Gosh. I think it would be cloud cuckoo land. What I have described as "absolute", it would be cloud cuckoo land. If we again go outside the world of haemophilia, there will be patients who require red cells of an extraordinarily special nature. There is a funny blood group called O-Bombay who appear to be blood group O. Who could therefore receive anything, but actually have a powerful antibody against practically everybody else in the world except for some people of their racial origin, which is India. That's why it's called O-Bombay. So if we in Scotland had a patient with O-Bombay, it would be very difficult to find a Scot who could give that blood.

So therefore, on those grounds alone, absolute self-sufficiency is not achievable.

In the world of blood transfusion, there is a need for communality. There is a pretty good WHO

organisation for blood transfusion. It's a little bit unrealistic in some ways but it tries very hard. Because obviously the world has to be self-sufficient. It has to come from humans somewhere -- or occasionally from dogs and cows and pigs, if you are talking about porcine Factor VIII -- but otherwise we have to be self-sufficient within the world.

Clearly now, with the development of recombinant technology, it is a lot different. I think the majority of haemophiliacs in this country who require factor VIII get it from recombinant sources, so they don't get any human sort at all. But in those days before it became available, they had to depend upon human-type material.

And of course we in Britain these days are dependent upon plasma and things like anti-D from overseas because of the ban as a result of the BSE tragedy. So self-sufficiency is a lovely ideal. It is one to which we should aspire at all times but we have to be balanced about it.

Q. The other answer I just wanted to perhaps just note in your statement on page 7, Dr Boulton. I'm not sure if my pagination is different. It is answer (vii). So I think we need to go back if we could. It is actually 2(vii). It's this mention you have made -- I wanted to note it -- of what I understand to have been a system of

dedicated patients to a batch, not a batch to a patient but patients to a batch?

A. This is a good idea of Christopher's, that in order to reduce the patient exposure to multiple donors, it would be sensible to batch the PFC materials that came to us.

This tragically was after it became established that PFC Factor VIII in the preheat treatment days could be contaminated with HIV. So consequently, with that established risk, in order to reduce it, if a patient required a treatment from a batch of PFC Factor VIII, until that batch ran out, that patient should only receive material from that batch. At the same time there may be another batch or two in stock and materials from that would be reserved for other patients.

So instead of the one patient arbitrarily, when treatment is required, getting a vials of Factor VIII from two or three of the batches in stock, it was a single batch that they were exposed to and that was a good idea in an attempt to reduce the amount of donors to whom they were exposed.

Q. In conclusion, Dr Boulton, I want to ask you one final point and it's more a reflective matter again.

Periodically in your testimony, you have spoken about people, particularly in the 1982/1983 period, haemophilia clinicians, who were anxious to maintain the

huge improvement in quality of life that had been achieved for patients with haemophilia, and you have also talked about how that sentiment persisted in the face of some of the reports that were coming, initially from America and then perhaps closer to Britain.

If you think of the people, the haemophilia clinicians who were at the very forefront of these developments, wanting to maximise home therapy and use American concentrates to do so, and perhaps telling their patients that boys with haemophilia would grow up normally, it has been suggested to us that such clinicians jumped the gun. Do you agree with that?

A. The onset of the AIDS tragedy, which really became apparent -- the first glimmerings came home, I guess, in early 1982 -- the danger is that one can sound terribly wise in retrospect. I think it would be fair to say that I referred earlier to Howard Davies being a wise man. So his concern was probably directed against the hepatitis risk but quite possibly he would have been concerned about the possibility of other viruses being present.

There is no doubt that the HIV tragedy, more than the Hepatitis B work of the 1970s, alerted -- it was a sea change in the community of blood transfusion throughout the world. It is easy for people like me in

retrospect to say in 1981 we should have been much, much more cautious and they were jumping the gun. It is easy for us to say that now. My recollection, a slightly guessed recollection, is that throughout this period of, say, 1982 to 1984 there was an increasing awareness among the haemophilia clinicians that actually the ice was getting thinner and that our patients were being more and more exposed to long-term risk.

I think actually it was not just the HIV possibility but also this mysterious non-A non-B hepatitis. When it became apparent that non-haemophiliacs who had been transfused and had an episode of jaundice a decade or two before now had severe liver disease. Their spleens were big and they had disordered liver enzymes. Then came the idea of looking at the livers of haemophiliacs. One big problem: they would bleed so you had to give them Factor VIII, rather ironically.

Nevertheless, people like Eric Preston in Sheffield did a study, and I think it was 1983, 1984, which showed that haemophiliacs, in spite of not being jaundiced and perhaps never having a history of an episode of jaundice, had severe cirrhosis and were impending for liver disease.

So it wasn't just HIV that stimulated this, although it was a major point, it was also the awareness of the

long-term effects of non-A non-B which eventually was characterised as Hepatitis C in 1989/1990, and which the transfusion service has been extraordinarily successful in virtually eliminating from risk.

So I don't like the phrase "jumping the gun". I think that it's a reflection of the period. Coming back, there was also an accusation -- and it was an accusation -- from one British transfusion director to another that by introducing a test for Hepatitis C before the rest of the country, that person was jumping the gun. So it wasn't just an accusation to haemophilia directors, the best way I can put it is: are we a team coordinated with a strategy that when a new test becomes available for a blood product -- as the HIV did in March 1985 from America, September 1985 for Great Britain -- are we a team in which we do all the preliminary work in planning that test introduction? Are we a team in which we are all coordinated throughout Britain? Or is each regional centre allowed to do its own thing?

Given human nature, among the 15 or so regional transfusion directors throughout the UK, there were one or two who broke rank, and there was some concerns.

On the other hand, why did they break rank? They didn't break rank because they wanted to have

a grandiose star for themselves. They did it for the sake, the concern of the patients who were going to get their production.

So breaking the ranks, jumping the gun is not done out of a sense of irresponsibility. If it is done at all, it is out of a sense of concern and, "Playing the team is all very well, but I'm so concerned that my patients are not going to benefit. And actually my patients will be put in danger unless we do this." We don't need to go into much more detail but we know that in other countries doctors have been sent to prison about the HIV status [sic - situation].

Many of us felt that there but for the grace of God, go I. We, people like myself, people like Christopher, have a real ache in our hearts, which is that 1,500 haemophiliacs have died; a very substantial proportion of the haemophilic population in Britain have died as a result of the material that we gave them.

So consequently you can see why jumping the gun was a very tempting thing to do, and although I personally don't think I did jump the gun, I can jolly well understand the feelings of those who did want to jump the gun. Because the greatest tragedy in my professional lifetime was what has happened to haemophiliacs. The variant CJD tragedy, which also

occurred during my lifetime, is awful in the same level of how it has affected individuals, but on a scale of numbers, where we have hundreds compared with thousands of haemophiliacs, you know, one's heart -- going back, John Prothero was a man I really liked and I still miss him at an individual level. So jumping the gun -- okay, but I think I have said enough.

Q. Thank you.

THE CHAIRMAN: I have heard the expression used that this was the worst tragedy, and I wouldn't in any circumstances want to understate it, but one does have to remember that there was thalidomide.

A. Absolutely.

THE CHAIRMAN: One does have to remember that there are other patient populations in the wider community who may feel that perhaps they are deserving of as much sympathy as the haemophiliac. For example, a very large group of people with compromised brain functions resulting from the circumstances in which they were born. Should one be a little cautious perhaps in emphasising --

A. I was quite careful to say that in my professional lifetime it was the biggest tragedy. I remember the thalidomide very well. In fact my mother-in-law took thalidomide from the middle trimester of her third pregnancy, fortunately too late to affect her younger

daughter.

Thalidomide was wonderful. It stopped women being sick, and it's horrible to be sick in the middle of your pregnancy but it caused phocomelia and other horrible things. Ironically it has come back into favour for treating certain conditions related to myeloma. But nevertheless it was a seminal experience in the relationship between the pharmaceutical industry and the clinicians and it considerably strengthened the regulatory system that has been so finely developed in the UK since. So I acknowledge the validity of your comment about other tragedies, absolutely.

I have seen other tragedies concerning organ donation. I have been through quite a lot in my lifetime that's observed directly. And we still see tragedies of wrong blood being transfused. I can guarantee that it still is happening in Britain. People who are group O receive a pint of group A and their lives are permanently affected thereafter.

It is happening all the time. So it is a question of developing the regulatory system and clinical awareness, education. I think the one really good thing that has happened in my lifetime in terms of the medical career is that we doctors are much more aware -- at least I like to think this -- of our role in society

that, we are members of a wider healthcare professional team and we should be listening to our colleagues who are presenting different view points and modifying our approach.

So I think there have been huge advances but there is still some way to go.

THE CHAIRMAN: Thank you very much.

Yes, Mr Di Rollo?

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

Questions by MR DAWSON

MR DAWSON: Thank you.

Dr Boulton, if we just have up on the screen one of the two admirably short CVs which you have provided to the Inquiry, that is PEN0150506. I'm particularly interested in asking you about the last paragraph in the section, "Employed posts", where you say that:

"At Liverpool and the London Hospital in pre-AIDS days, I worked with haemophiliacs on their comprehensive care and developed, especially for boys, prophylactic use of plasma-derived clotting factors. At Liverpool I helped to found the local branch of the Haemophilia Society and had an annual budget of £40,000 from the RHA for commercial blood products at about 10p per clotting factor unit."

Could you please explain what the reference to the

annual budget of £40,000 from the RHA means?

A. It means that after discussion with the treasurer of the RHA, I was allocated £40,000 to buy commercial Factor VIII.

Q. At that stage, I think you are suggesting that you had some involvement with the founding of the Haemophilia Society locally. Is that correct?

A. Yes, I did.

Q. What was your involvement with the Haemophilia Society at around that time?

A. Well, I knew the Haemophilia Society in London well. As I say, the Reverend Alan Tanner who was then the chairman, and John Prothero who was on the council were personal acquaintances and actually I would say friends of mine.

It was very simple. In the older Liverpool Royal Infirmary, which is a red brick late Victorian building, the labs were tucked away somewhat and people would wait in the corridor to have their blood taken, and on one occasion two women with their boys were sitting next to each other and they found that both the boys had haemophilia and blood was about to be taken for my technicians to analyse, and they got chatting and then they got chatting to me and I said, "Why don't we found a local branch of the Haemophilia Society", and

they said, "What a good idea", and went ahead and did it. And I gave them the address of the London contacts and from there it developed.

Q. Did you continue to have involvement with that local branch after the foundation?

A. Yes.

Q. What was your involvement?

A. Well, I was, if you like, the sort of consultant adviser to them about the realistic expectations that their sons, their affected sons, could have and how that should be improved over the course of the next decades.

Also, what was very striking to me is that the older haemophiliacs, those adults, who were lovely men, who had survived and were crippled, had a very different set of attitudes to the doctors who were caring for them. I mean, immense respect and rather almost embarrassing reverence, whereas these mothers and fathers of these haemophilics had much greater expectations from me, and I wanted to respond to that. And when they said to me things like, "Don't you think haemophilia is a bit like diabetes: we should get injections every day so that our boys can live normally lives?" I completely understood what those mums were talking about.

Q. This was --

A. 1976/1977.

Q. The late 1970s?
A. Yes.
Q. So that would be in the years after the World in Action DVD to give it a place in history?
A. Yes.
Q. Did the members of the local haemophilia branch seek your advice about the safety of products that were being used, blood products, at that time?
A. Oh, yes and I was quite upfront with them about the hepatitis risk, as far as I recollect.
Q. Would it be fair to say that members of the haemophilia community at that time and subsequently have generally a good understanding of haemophilia care and the products which are being used?
A. Around about that time, Peter Jones came out with his book, Living With Haemophilia, his first edition which I think was 1978 or 1979, which went down, as you will know, in the haemophilia world as a whirlwind. It was super, it was clearly illustrated, it was wonderful for the advice for the mums and the dads and the boys themselves, and it was highly successful and it did a lot to feed the understanding within the haemophilia community of the prospects of a bleed-free life.
Q. And the members of the Haemophilia Society with whom you were speaking, these were lay people?

A. Yes.
Q. At that time in the late 1970s there were difficulties and misunderstanding in the medical community about the safety of the product. Would that be fair to say?
A. In the 1970s --
Q. I'm thinking about the period post the World in Action DVD, which seems to suggest that that might be the case.
A. My recollection actually is that the vast majority of people felt Britain is not America, and it's an American problem and somehow or other the risk of American-derived Factor VIII would be attenuated by the time it got to Britain. And the only reason why that might have been understandable to the thinking was that the Americans were claiming greater and greater testing of their products, selection of their donors, to avoid the skid row component.

So I think, to some extent there was almost wishful thinking that this was a problem that would stay in America but wouldn't come over to Britain.
Q. How aware were you, as a haemophilia doctor at that time, as to how safe the American products actually were?
A. I have already intimated that when the opportunity came to buy in Factor VIII, I didn't go for the American. So in other words, American products to my mind, as a young

haemophilia doctor in the late 1970s, were to be avoided if possible.

Q. Presumably the members of the Haemophilia Society as lay people were reliant upon your advice about --

A. I think they felt that my advice was good.

Q. You made a distinction in your earlier evidence between weighing up the dangers of products against the effectiveness of products.

A. Yes.

Q. What I would like to ask you is: were the Haemophilia Society members reliant upon your advice about the dangers of the products?

A. Yes.

Q. I understand that you arrived in Edinburgh in 1980. Is that correct?

A. January 1980.

Q. And you became the deputy director in 1982?

A. Yes.

Q. So your arrival in Edinburgh coincided, I think, quite closely with the arrival of Dr Ludlam as the haemophilia director?

A. I think he was a month or so before me.

Q. So you were both around about the same time?

A. Yes.

Q. Could I just clarify something with you? In his

evidence about the way in which the BTS worked in Edinburgh, Dr McClelland suggested that there are really two parts to the operation and that one part was to do with collection of blood, so focusing on the donors, and the other part was to do with the storage and distribution. So to do with what one might call the blood bank. Is that an accurate representation of what your activities were?

A. My activities were with the blood bank. Yes, that's accurate.

Q. I meant in general, was that an accurate representation of what the blood transfusion service in your region was doing at that time?

A. There was a third component which was completely separate from haemophilia care, which was the selection for organ transplantation.

Q. I think Dr McClelland characterised the division of responsibilities as you being mainly responsible for the blood bank side whereas he was more responsible for the donor side. Is that correct?

A. Yes.

Q. I just wanted to ask one question about the main statement which you have given. Perhaps we could have up page PEN0150058, which is in the document that commences on [PEN0150054]. You have given us some

comments about this already. I wanted to ask about the section at the bottom and in particular what you say about the batch dedication or batch allocation system. Could I just read that out? You say that:

"I do remember at one stage in the Edinburgh centre, we attempted to reduce donor exposure to haemophiliacs by restricting batch numbers of PFC Factor VIII concentrate to specified patients. In other words, once a new batch of Factor VIII had been administered to one patient, further treatments came from the same batch until that batch was exhausted. This was Dr Ludlam's suggestion and was administered, as far as I can recall, reasonably well by the staff of the blood product issuing department of Edinburgh and Southeast Scotland BTS, based in the Royal Infirmary. I cannot date the start of this policy. I cannot comment on how much DDAVP was used ..."

Et cetera, et cetera. I'm just wondering whether, with the obvious exposure you have had to historic material prior to giving evidence today, you have any recollection as to when this system was actually introduced?

A. I'm sorry, I cannot be more precise. I suspect that Dr Ludlam would be better informed than me.

Q. Did this batch allocation system cause you, within the

BTS, administrative difficulties?

A. It simply meant that the staff day and night in the blood bank had to be aware of the problem, and also the doctors on-call in the haematology department for haemophilia care had to be aware of the system. I think there may have been occasions -- in fact I'm fairly sure there were occasions when the system failed, either because the lab staff member on-call at night was unaware of the system or was busy doing something else and breached the system or the registrar on-call for the haemophilia unit may have not been fully familiar with the system.

But that's the way it was designed and when I said it worked fairly well, to my recollection, I do acknowledge there may have been some breaches through human error.

Q. So when you say "some breaches", you mean that certain people, who should have been allocated to a particular batch, were exposed to blood product --

A. Yes, they got a vial in the middle of the night from another batch.

Q. Okay, thank you. Could I just return to something I asked you about a moment ago, which is to do with the administration within the Blood Transfusion Service and particularly the use of the blood bank. You have

answered some questions to the best of your recollection on this topic already but I have a few more I would like to put to you. The first is: did you ever at any time have a surplus of blood products within your region in the early 1980s?

A. Can I ask what you mean by "blood products"?

Q. Well, particularly factor concentrates.

A. Of PFC and cryoprecipitate, I very much doubt. Of the slightly specialised products, such as the Factor IX from PFC that would be reserved for inhibitor patients, there may have been batches that ran out. I'm not saying, however, that every single vial of PFC Factor VIII ended up in a patient. There may well have been occasions when some did expire, but we tried to minimise that.

Q. How long would a product be kept before expiry?

A. It would have had a date on it, which I think was two years or 18 months. Sorry -- but that sort of timescale. So, not unreasonably, the day after it expired clinicians would be reluctant to use it.

Q. To look at it from the other side of the equation, I think it's clear from the documentation we have looked at that there were times there were shortages of concentrates.

A. That's much more frequent, yes.

Q. In those circumstances what I'm interested to know about is whether it was possible, as some of the correspondence we have looked at seems to suggest, for you to make up the shortfall by looking in the stores of other regional blood transfusion services?
A. Well, that did happen, that's why we got some from Inverness on that occasion.
Q. I think we looked at a letter -- for the record, I think it was [SNB0015219], which was a letter of 7 December 1982, which suggested that you were able to get some product from both Inverness and Glasgow.
A. Yes.
Q. Is that, to the best of your recollection, accurate --
A. Yes.
Q. -- that you would have got some? How did that work administratively between the regions? Would you be responsible for that?
A. Not directly.
Q. Right.
A. There was a chief MLSO, a chief technician, in the blood bank, who was responsible for all aspects of, if you like, the mechanics of the delivery of blood and blood products to the relevant clinical departments. There is also, as we have heard earlier, an allusion to a van that the SNBTS had, a vehicle that could transport

safely and under proper conditions, ie refrigeration, materials that could be transferred between the regional centres, so that what was in store in Law or in Inverness could be driven down under proper conditions and placed in proper conditions in the Edinburgh blood bank, and the day-to-day running of that would have been through the chief MLSOs.

Q. Thank you. Was there a tendency for certain regions to have a shortfall of factor concentrates and other regions to have an abundance of this?

A. I can only answer for Edinburgh. Clearly, Edinburgh on the whole was short.

Q. You have suggested on a couple of occasions going to Inverness to make up the shortfall. I wonder whether perhaps that was one which you thought would be likely to have something, if you approached them.

A. I cannot recollect but I suspect that our wonderful chief MLSO phoned round the other centres, said, "How much have you got?" And they said either, "None," or, "A little bit," or, "Yes, we can do a bit." But I was not involved in those direct selection procedures.

Q. Thank you. I'm interested in exploring a little bit further the precise nature of your job because, as counsel to the Inquiry has pointed out, you are someone who is experienced as both a haemophilia doctor but also

within the transfusion service, which is very rare. I think you pointed out already that you were the first person to be appointed in the region who had that background. Is that accurate?

A. Yes, I think so, yes.

Q. I'm interested to know who was responsible within the Edinburgh and Southeast region for determining what products would be used in the treatment of haemophiliacs.

A. The primary person responsible for that would be the haemophilia director.

Q. And that at that time was Dr Ludlam?

You say the primary person responsible. Did you have any involvement in that process, given your background as a haemophilia doctor?

A. Christopher knew where I came from. We had a cordial relationship and I think you can see the evidence of particularly that 1982 period, where there were quite intensive meetings between us, that we actually came to a workable arrangement.

Q. Would you express your view as to the regimes for treatment that he was using from a haemophilia doctor point of view?

A. Well, I had the cheek to suggest that one patient might benefit from having no therapy at all. So the answer to

your question is yes.

Q. I'm aware of the reference that you are making and we may come to that in a moment. I think the word that you used was "impertinence" at the time.

A. Yes.

Q. What I'm interested in knowing is was that a regular concern. Did you regularly have conversations with Dr Ludlam about the way in which patients should be treated, either generally or specifically?

A. That's putting it too strongly. Not the way the patients should be treated, but we did have conversations about the problems or the various variations that might be available for patients. I think, although I can't be certain of this, that we were not always, but quite often, given notice of planned surgery for haemophiliacs. So if a haemophilic required a planned orthopaedic procedure which would be likely to require a lot of blood, we would be given advance notice.

Q. Could I ask you what the position was from a more general point of view? You have answered there in relation to specific patients undergoing operations, but the position, as I understand it, in around 1980 was that Dr Ludlam had expressed a desire to move away from the previous regime, which relied heavily under

Dr Davies on cryoprecipitate, but move towards more factor concentrate use, in particular with a view to putting more patients on home treatment. Is that accurate?

A. I'm sure that Christopher would give a better answer than me but that's what I recollect.

Q. I think that that is probably reflected in your letter, which we have looked at, to Mr Watt, dated 1 February 1980. Can we have that up, please? It's [SNB0072566]. That is a letter, as I say, we have looked at already but you are sending a letter to Mr Watt at the PFC. The title is "Factor VIII stocks for home therapy". You say in the second paragraph:

"Naturally, I'm anxious to support such a programme as much as possible and feel you ought to know that I see no reason to discourage Dr Ludlam from going ahead with this programme. I feel that he is very likely to expand his home therapy programme, certainly in the course of the next year, and this may well result in a significant difference in the pattern of our Factor VIII usage, ie less cryo, more concentrate, and this, of course, may mean that we should be prepared to ship you more fresh-frozen plasma for fractionation. Please let me know if you have any comments on these points.

It would be fair to say that this letter was written

as a result of a strategic planning conversation you had had with Dr Ludlam about his intention to increase home therapy?

A. That sounds rather grandiose but I suspect you are right. This was written two weeks after I had started my job.

Q. So by that time you had already had this conversation with Dr Ludlam, it would appear.

A. Yes.

Q. Did you have a view on the general proposal that there should be this move away from cryoprecipitate treatment towards the use of more Factor VIII from a haemophilia point of view?

A. My view was that Christopher was right. At that time we had no inkling of HIV/AIDS. We, of course, did know about hepatitis. But perhaps -- no. I was going to say "naively" but that would be unfair. We reckoned that the process of blood donor selection and testing for, on the whole, ever better hepatitis screenings would result in a quality of plasma sent for fractionation that would be as risk-free as possible and also a recognition that the process of fractionation, although the product that was infused into haemophiliacs had many more proteins in it than just Factor VIII and in technical terms was rather impure and was called actually "intermediate

purity", nevertheless that was as good a quality product as could be obtained anywhere in the world and on a par with commercial firms.

In some other correspondence you will have seen about how to package it and send it and the interesting point is that the commercial firms developed a very good marketing strategy. By that I mean the packaging, the water with which it came, and the literature -- lovely pictures of haemophilia boys riding bicycles -- which was beyond the budget of the PFC. So John Watt very naturally sometimes would say to me, "Frank, you are getting too enthusiastic about trying to beat the commercial boys at their own game, but we can supply you good quality material; it may not look as nice." So, in essence, that's the sort of thing that John Watt was saying.

So I supported Christopher's then desire to use more PFC Factor VIII for his patients. It was the right direction and to my mind was clearly so then and I think is entirely justifiable as an attitude even now.

Q. Did you have a view on his proposal that there should be this move away from cryo towards factor concentrates from the point of view of supply?

A. Well --

THE CHAIRMAN: I'm sorry, I don't think I quite understood.

A. I think what he is referring to is, Christopher's demand, was it realistic?

MR DAWSON: Indeed.

THE CHAIRMAN: We can come back to that after lunch, Mr Dawson.

(1.00 pm)

(The short adjournment)

(2.00 pm)

THE CHAIRMAN: Yes, Mr Dawson.

MR DAWSON: Thank you, sir. Dr Boulton, if could I ask you the question: in 1980 what was your view about whether it would be realistic to provide enough PFC Factor VIII concentrate to meet Dr Ludlam's plans for increased home therapy with PFC Factor VIII?

A. In early 1980, within a few weeks of me joining the service, I suppose that my feelings were that every effort should be made to meet the demands that were likely to occur over the next few years. I can't really be much more precise than that.

Q. Did you think it would be realistic to be able to meet those demands?

A. Well, I wouldn't have supported the proposal had I thought they were unrealistic. How realistic I thought they would be? I suppose I was still in a process of learning.

Q. What was the point then of your letter to Mr Watt that we looked at, dated 1 February 1980?
A. Could we refer back to that one?
Q. Absolutely. It's [SNB0072566]. You will recall that I read out the second paragraph of that. My question is: why did you consider it necessary to write that letter to Mr Watt at that time?
A. Well, one reason is to give John Watt some indication of the reason for a likely surge in demand:

"I feel that he [Dr Ludlam] is very likely to expand his home therapy programme considerably in the course of the next year."

So it was in a sense giving notice to the plasma fractionators that this demand was coming their way and therefore they should prepare accordingly or respond accordingly.

Q. Does this letter embody a concern that there might be difficulties of supply in the future if that home therapy programme were rolled out, as has been suggested?
A. I can't say. It is too far away for me to remember that.
Q. Can we roll on a bit in the timeline and can I ask you: did you experience problems with supply in the first half of the 1980s? Supply of Factor VIII concentrate

from PFC, I should say.
A. I think the records we have already looked at of the meetings I had with Dr Ludlam in 1982 go a along way to address that. But are you asking me if I thought in 1980 there would be problems in 1982?
Q. No, I'm just asking you whether in reality you did experience problems in supply?
A. The records of those meetings in 1982 with Christopher would indicate that there was an awareness of a challenge that we needed to address as much as possible. So there was a problem insofar as it required Christopher and I to jointly try to sort it out.
Q. But there was a problem of supply. Are you agreeing with that proposition?
A. There was a problem of trying to adjust the legitimate demand of the patients with what could conceivably be available. That's not quite the same as: was there a problem of supply? The supply and demand, in general, the equation has factors on both sides and both sides can be adjusted, and the important thing in this sort of situation is to devise a system whereby both sides can be satisfied but with some degree of compromise.
Q. Was there an increase in demand --
THE CHAIRMAN: Mr Dawson, can I remind you that you started off the section by asking about a problem in the first

half of the 1980s. It might be helpful to be more specific as to time.

MR DAWSON: Indeed. I apologise. I was actually just going to take Dr Boulton to a document that would pin it down to a particular timeframe, but before I do that, could I simply ask: by 1982 -- and we have looked at some documentation from that particular period -- was there increased demand?

A. Yes.

Q. And what was the cause of that increased demand at that time?

A. Principally, the desired switch from cryoprecipitate to PFC materials and a developing home therapy programme, as far as I'm aware.

Q. Could I just take you to that document, which we have looked at before, from the middle of 1982. It's [SNB0015199].

As I say, I think this is a letter to which you have been taken before. It's a letter which is dated 10 May 1982 from you to Dr Ludlam. You say in paragraph 2 of that letter that:

"My concern is the amount of Factor VIII that has been issued. The total for the first quarter was 206,800 units. This would be an annual consumption of 827,200 units. This means that for each of the 20

patient, the average annual consumption would be 41.360 units or 34,464 units, if you included all 24. These figures are obviously pretty close to the UK national average."

Then down to paragraph 4. You say:

"Hence, you will see that your home therapy programme alone has accounted for about 80 per cent of our allocation from PFC."

Would you like to make any comment about the reason why you were bringing to Dr Ludlam's attention at that time the statistics relating to the amount of PFC Factor VIII that was being used for what you describe as his home therapy programme?

A. I honestly don't think I can say any more. This is 27 years ago and I'm being asked to recall in detail the motivations I had for making these points. I honestly don't think I can satisfy you if that's the road you want me to go down, any more than is actually written down here. I don't refute any of these statements that I made in these letters. I think I just have to ask you to take them at the value you see them written. I can't add anything more at this stage.

Q. I understand that difficulty, Dr Boulton. If I could ask for the second page of this letter to be put up. Perhaps a third page. I think the third page of

the document is actually the second page of the letter. You say there:

"I think that the SNBTS as a whole can just about hold your requirements so long as the following points are borne in mind."

Then you have a list there of the kinds of things that you think might be able to keep the position as it is, which appears to be just about surviving. Is that correct?

A. It looks like it, yes.

Q. One of those is that no more patients are put on home therapy, number 2.

A. Yes.

Q. Can you tell me -- and of course you may have difficulties with your recollection -- as to whether you managed to adhere to these five propositions after that?

A. Well, it's not a question of me adhering. These are the requirements that would be on the clinicians supporting the haemophiliacs, and I was not a clinician supporting the haemophiliacs directly.

Q. Was Dr Ludlam able to adhere to these --

A. You would have to ask him. I don't know.

Q. Thank you. That's all I want to ask you about that particular document.

We heard some evidence -- I think you were aware --

from your former colleague, Dr McClelland, last week and he spoke about a number of these issues that we have been discussing with you. He was asked what the relationship between yourself and Professor Ludlam, the working relationship, was like and he said that:

"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."

Is that an accurate representation of the professional relationship or not?

A. If that impression is one that gives a negative picture, that is not correct. Tension can be productive and my recollection of those times, yes, there were tensions, but there was no animosity, and although occasionally frustrations may have been vented in the privacy of one's room, et cetera, et cetera, I think we are all adult enough to recognise that under these sort of circumstances tension can be used creatively, and I would like to think some years further on that the net result was a positive one.

Q. What was the cause of the tension?

A. We had different personalities. We have different training assumptions. Thank goodness there is diversity

in the nature of humankind. We are different people but we have a common outlook on many things, and whenever it comes -- it is like in many situations between colleagues or close friends, there are differences that had to be sorted out, and so long as we can sort it out in a civilised and positive manner, that's how progress is made.

Q. I think that in the same email Dr McClelland was making specific reference to the possibility of tension arising out of the fact that you were both experts in treating haemophilia patients. So was there any tension which arose as regards the way in which one might best treat haemophilia patients?

A. I did not want to be responsible for treating his haemophilia patients. I recognised that I had no direct role in patient care because that was his job and I had a different job. I might have had an insight into the nature of Christopher's job because of my previous work but I was not in the position and would never have wanted to be in the position of actually interfering with his work.

Q. I would like to ask you a few questions about a topic that we have touched on already, which is to do with your awareness of the increasing possibility of there being a risk of AIDS and the dangers for your patients

arising out of that.

Can we have up, please, to document [SNF0013710], which is again a document we have seen before.

Just to put it in context, Dr Boulton, this was the memo that was sent from you to Dr McClelland on 30 May 1983, in which you had made reference to your telephone conversation with Peter Jones on 24 May. Can I ask you first of all why it was that you had made that telephone call to Peter Jones?

A. The second sentence, I think, might give an indication. I was basically following what he was claimed to have said on a nationwide programme the previous week about non-rejection of gay donors. I have no memory of why I phoned Peter Jones other than what's in here, but it does look as if what I was a little bit concerned about was the issue of the appropriateness of men who have had sex with other men giving blood.

Q. So was that an issue, as far as you can remember, within your Blood Transfusion Service at that time?

A. Oh, yes.

Q. What was the issue?

A. By May 1983 we were well aware of the epidemiology of this strange disease, coming from the States, that heavily associated it with men who had had sex with other men.

Q. So would it be accurate to say at this stage that there were discussions going on between yourself and Dr McClelland about whether you could and whether it would be a good idea to try and screen donors who had a history of homosexual contact with other men on the basis that it might pose a risk?

A. The question, I think, that is highlighted in this memo is how appropriate would it be to ask men if they had had sex with other men somewhere along the line between them attending and giving blood.

1983, very different times from now, when there is much greater acceptance within society as a whole of the validity of the homosexual lifestyle. Much less judgmental these days than those days and we were sensitive to social stigma that would be associated with men who admitted that they had sex.

So, given the fact that donor sessions, although meant to be totally confidential, are nevertheless conducted sometimes in a more open way, given the fact that the general public was aware that some people did not give blood or were not allowed or were not expected to give blood because of their sexual history, given the fact that donors sometimes turned up in bunches to encourage each other to give blood, given the fact that any one of those who was turned away was a cause of

suspicion, given all these social circumstances around the blood donation procedure, there was great concern about the right way of, as you say, screening, which isn't quite the word I would have used, but of selecting donors according to their sexual history, a very delicate subject, particularly in those times.

So whereas Peter Jones was of the opinion that we should not ask them verbally at the session about their lifestyle but leave literature around explaining it, most of us on our side -- and I'm pretty sure that I was on this side -- were of the opinion that that would not be adequate, that in fact a person who had already screwed up enough encourage to come and give blood was unlikely to be deterred by a slightly strangely worded, incomprehensible document when it needed to be explained to them in words by a friendly, non-judgmental person, who would be able to explain to them in some sort of way at the interview session.

So why -- where I go on later saying that -- is it in this one, where I say Peter Jones was less than cautious? Yes, I felt he was being somewhat less than cautious in his attitude, et cetera, my feeling is -- and I might say that until I saw this again a few months ago, I didn't remember this whole thing. So you are asking me to recreate from the back of my brain a set of

concepts that I can't guarantee the total accuracy of. But in reconstruction it does rather look as if we felt that you needed to do more in donor selection than just leave a document hoping that they would read it.

Q. Thank you for that.

I think that just to put it in a bit of context and maybe just to refresh your memory, I can refer very briefly to paragraph 8.33 of the preliminary report which gives some background to what is going on at this time, and it says there in the last couple of sentences:

"In June 1983, Edinburgh and Southeast Scotland produced a leaflet, "AIDS and Blood Transfusion". The leaflet asked those in certain high risk groups not to give blood until there was a suitable screening test. It appears to have commenced circulation around 15 June 1983."

So that appears to suggest that the leaflet route was what was decided upon after this. Do you recall that leaflet coming out, Dr Boulton?

A. Sorry, can we have --

Q. I can put the document up if it's of assistance to you. It's the original page 196 of the preliminary report. Sorry to jump about between documents. Paragraph 8.33.

A. Is it going to come up on the screen?

Q. It's going to come up on the screen, yes.

You see there under the heading "Summer 1983", this is in a chapter of the preliminary report where we are discussing HIV and AIDS. In this paragraph we are talking about the particular time period, summer 1983, action taken in the United Kingdom. What I have read is four lines from the bottom of the first paragraph, starting:

"In June 1983, Edinburgh and Southeast Scotland produced a leaflet, "AIDS and Blood Transfusion". The leaflet asked those in certain high risk groups not to give blood until there was a suitable screening test. It appears to have commenced circulation around 15 June 1983."

I think you made reference earlier to a leaflet. This is presumably the leaflet you were talking about a moment ago?

A. I certainly recollect a leaflet being prepared with this theme. I could not possibly date it.

Q. Right. There is a reference there to high risk groups. Would that include the gay donors that are referred to in the opening paragraph of your memo to --

A. Yes, however, I think it fair to comment that probably around about that time, or maybe a little before that time, there was a lot of concern, as I'm sure you are aware, in Edinburgh of injecting drug users being

a particular risk group category. So in some ways I think we were as concerned about the injecting drug users as we would have been about homosexual men.

Q. Would there not have been, at that time, some other method of excluding injecting drug users from giving blood?

A. Well, the lesson of the epidemiology of Hepatitis C is clearly no; we can say that now, no. Whether I was able to say that in 1983 is a bit more dubious, but may I remind you that when we found that there were people, after 1991, when we introduced the Hepatitis C test, who were Hepatitis C-positive and who admitted to, on reflection, one or two parenteral drug using episodes a decade or so before, we realised that even one parenteral injection of a drug under such circumstances could infect with Hepatitis C with all the dire consequences that could result. We were not aware of that in 1981. But nevertheless we were aware and the other thing is that Edinburgh seemed at that time to be a hotspot of parenteral drug use.

Q. Was there a concern at the time of these documents, in the middle really of 1983, that the HIV virus had entered the UK blood donor population then?

A. It's very difficult for me at this stage to identify the degree of that concern but I think it's likely that

there was a concern about the possibility, either already there or about to come.

Q. Right. The concern was great enough to give rise to these attempts to exclude groups -- gay donors or intravenous drug users -- that you think might be at a higher risk of HIV than other people. Is that correct?

A. Yes, I imagine so.

Q. Could we return to the document we were looking at before, [SNF0013710]. It will come up on your screen again, Dr Boulton.

This is just us back to the memo between yourself and Dr McClelland relating to your conversation with Peter Jones and you referred already to the second last paragraph, could I just read that out. It says:

"He [which is a reference to Dr Jones] also claimed there is a lot of doubt about the diagnosis of all the AIDS cases in the UK, and in particular the haemophilics."

You then say:

"I felt he was still being somewhat less than cautious in his attitude but this is not unexpected given his interests ..."

Et cetera. Could you tell me first of all why it was that you thought Dr Jones was being somewhat less

than cautious in his attitude at that time?

A. I think this goes back, although I say repeatedly, I think that this goes back to a suggestion that we don't ask donors at the session but just leave leaflets, ask them to read a leaflet, and that, I think, could arguably be said to be less than cautious enough.

Q. Why did you think that the fact he was being somewhat less than cautious in his attitudes was not unexpected given his interests?

A. This may seem a little unfair but one possibility could be that he was anxious, particularly with the earlier paragraph about the diagnosis of -- sorry, I have lost it somewhere:

"He also claimed that there is lot of doubt about the diagnosis of all the AIDS cases in the UK."

So one possible reason for his interests being implicated in this is that asking men if they had had sex with other men would not be a very effective way of screening out such donors because AIDS in the UK might have had different diagnostic and clinical characteristics than AIDS in the US, but I'm being speculative here.

But Peter's interests were in maximising Factor VIII availability for his patients. He was aware that there is a problem or potential problem in supply in relation

to an infection but at that time there was still some doubt about the impact of the infection and I think one's views on those impacts could be, understandably, although possibly not legitimately, but understandably influenced by one's own practices. So that if you are responsible for stopping little boys from having a distressing bleed, that will head you in one direction. If you are cautious about giving little boys a disease that might haunt them in 20 years' time but only might and might not -- and the might not is more than the might -- then you have a slightly different emphasis.

So if you like, it's a tension between the clinical insights of the one side or the other.

Q. So it's a balancing exercise, if I understand you correctly, between his practice of giving treatment in a certain way, balanced against the risks?

A. At that time the risks were incredibly ill-defined in quantitative terms. There was an understanding about what the risks were qualitatively, but what was AIDS? How infectious was it? Was it likely to be a permanent illness? Could it have been transmitted by other means than blood? Those were questions that were still in the air. And until the actual virus was identified and its epidemiology addressed, clearly in the Koch's Postulates

way, there were all these sorts of questions beforehand.

So there was an area of uncertainly. So the balance was very difficult to achieve because you didn't know how much the weight on that side of the seesaw was.

Q. Were you aware of Dr Jones' attitude towards the use of commercial product?

A. Well, I think Peter was very aware of the availability of commercial Factor VIII, not least because the commercial manufacturers were very active in marketing it in the UK.

Q. Were you aware that he had a relationship with an American pharmaceutical company as a paid consultant?

A. I was not aware specifically. There were certain statements to that effect.

Q. Right. Could that relationship or those statements as regards that relationship be what you mean by his "interests"?

A. Well, no. I don't think I meant in his interests that he had an interest in a commercial company. I think the interests he was referring to would be to his clinical concerns for the benefits of his patients. I don't think -- I'm pretty sure -- again, you are asking me to recollect, and it's a good question but I honestly don't think that I meant by his interests that he had some sort of commercial/financial/shareholding, or whatever

interest, in those commercial companies. I think it's a clinical interest.

Q. Okay, thank you. Could I just ask you about the final paragraph there. I don't think we have actually read this bit out:

"He also seems to have picked up a somewhat different picture of the Cambridge Travenol meeting than that which you gave to us. I think it is probably a question of his ears being attuned to only part of the message which Anne Collins would have given him. However, I think it has been useful that we, as transfusionists, do interact with the haemophilia treating doctors, and certainly I think Arthur's letter is not unreasonable."

Could you just, to the best of your ability, tell me what you were talking about when you referred to the Cambridge Travenol?

A. I am afraid I can't. I can't recollect now what that Cambridge Travenol meeting was, and anyway I wasn't there. I think it was Brian who was there and then Brian would have transmitted his impressions of that back to us, which apparently differed from the message I had from Peter.

Q. It certainly suggests from the words "that which you gave to us", that Brian was there because he had given

you a certain impression of what had gone on. But there might have been a different impression conveyed to Peter Jones. Is that right?

A. I think that's right. It looks to me as if Brian was there, gave us a resume of his understanding of what had proceeded, and it didn't quite tally with the resume that Peter Jones had given of the same meeting.

Q. Could I ask you just a couple of very general questions to finish off.

Did you, in your time in Edinburgh, speak regularly with haemophilia centre directors about your views on matters of the day, including issues relating to the possible infectivity or infection which could be transmitted through blood products?

A. I think my only contact with the UK haemophilia directors were at that three or four meetings of the UK centre directors in that period of time, and that one telephone call with Peter. There would have been meetings of the British Society for Haematology, at which I also may have met them, but it was not on anything like a regular basis.

Q. What about with Dr Ludlam? Would you regularly discuss issues about risks of infection with him at this time?

A. "Regularly" implies that there was a predictable date at which we would meet. I think our relationship was often

less formal than that. So --

Q. I didn't mean to suggest any formality. I was wanting to know how often --

A. We saw each other perhaps three or four times a week but we probably didn't actually talk about the haemophilic problems as frequently as that. Christopher was in the department next door. We didn't often need to actually have a specific date but there were these occasions in 1982 in particular when we were addressing the situation about the right balance of supply, which were specifically recorded. We had more meetings than that that probably were not often recorded, of which there is no extant record. It wasn't just those meetings. They were on a more frequent basis. How regular they were and how long they went on for, I can't remember.

Q. I understand. What was your opinion about the risk of HIV transmission through blood and blood products in the spring of 1983?

A. Spring of 1980 ...?

Q. 3.

A. 3.

Q. Roughly about the time that you wrote the memorandum we were just looking at to Dr McClelland.

A. My opinion was not mine, it was one that was as a result of discussion with other transfusion doctors and with

Brian and with whoever else, other clinicians around. My recollection is that I felt there was sufficient grounds to be concerned about the possibility of transmission of whatever causative agent was.

Q. Can I just put one quotation from the evidence we had from Dr Mark Winter whom you will no doubt know.

A. Thank you, yes.

Q. Just to get your reaction as to whether you agree with this proposition or not. This is just for the record from his evidence on day 16 of the hearings.
It's page 34 at line 8 under a reference to a document dated March 1983. He said:

"I think by that stage, all haemophilia clinicians were signed up to the infectious theory because of the evidence of the San Francisco child. There was no other construction you could put on that evidence. So I think these minutes are just reflecting -- they are setting out the other theories and discounting them because of the new haemophilia data."

A. Sorry, I did read Mark Winter's -- it is not on the screen.

Q. His proposition, I think if I can summarise it, was that in March 1983, all haemophilia clinicians had signed up to the theory that HIV was a virus and that it was transmissible through blood. Would you agree with that

proposition? I know that at that time you might not be described as a haemophilia clinician but obviously you had been, and would you include yourself within that category at that time?

A. The answer to that is yes. What I cannot say is how valid the word "all" is.

Q. But you would have associated yourself --

A. Yes, I would have been of that opinion, yes.

Q. Thank you, sir.

Thank you, Dr Boulton.

THE CHAIRMAN: Mr Anderson?

Questions by MR ANDERSON

MR ANDERSON: Yes, thank you.

Dr Boulton, good afternoon to you. You will be relieved to hear I only have one or two questions for you.

A. Thank you.

Q. Dr Boulton, the chairman used the phrase:

"'insularity', otherwise called autonomy of different regions."

If -- and it may be a very big if -- insularity suggests that one region didn't know what the other was doing or wasn't cooperating with another region, would that be an apt description, do you think?

A. We didn't always know what was going on in other

regions, yes.

Q. But was there any failure to cooperate if cooperation was required?

A. Well, thankfully I was not the director of the Southeast Scotland region. I was just one of the consultants. So to some extent I was protected from the negotiations or whatever or the relationships that were being exercised at a higher level.

So I'm not really very competent at making any observations. But let's face it, we are all aware that in any greater society there will be pockets of local loyalty that result in occasional rivalries or even differences. So it would not be surprising that in each of the five regions, that were of very disparate sizes in Scotland, there would be a difference of emphasis, a difference of attitude.

If I can come specifically to Glasgow. Glasgow did have a very interesting practice of freeze-drying their own cryoprecipitate, and I think this practice extended until the early 1980s, and when that plant was closed down on the grounds of the Medicines Inspectorate's opinion, I think that was a blow to the Glasgow pride. So I think in the context of what one region could do and what other regions could do, there was always a tension.

Q. I was thinking more of the ability of one region perhaps to help another region out. We have seen an example this morning already of Inverness, for example, sending supplies to Edinburgh?
A. I have no doubt that if one region approached another region for help and gave a sound reason for that request, the help would be forthcoming with very little difficulty.
Q. Thank you, Dr Boulton.
I think you have talked about one of your officers phoning round various regions. Do you know if that happened often or is that a relatively isolated incident?
A. I don't think it happened very often but that phoning around story that I gave earlier is one that I can recollect in that it happened, but in terms of frequency, I can't say. Again, to a large extent I wouldn't necessarily have been involved in that.
Q. On a separate matter, Dr Boulton, counsel to the Inquiry took you through some correspondence, not long after your arrival in Edinburgh. Can we look at one document that you weren't referred to, please? It's [SNB0073264]. You are not a party to this letter. It is a letter, I think, from Dr Cash to John Watt. Have you seen this letter before? Take time to read it.

(Pause)

It appears, you will see in the second paragraph, to make reference to the pro rata meeting. Do you recall if you were at that meeting?

A. No, I can't recall.

Q. Can you help us with what "pro rata meeting" means with reference to the final paragraph on that page, the question of reintroducing pro rata.

A. I would imagine that it means that if we gave 4,000 litres to PFC, if the Edinburgh and Southeast regional centre gave 4,000 litres of plasma to PFC, the Edinburgh haemophilia centre would get 4,000 litres' worth of Factor VIII.

Q. You will see in the final paragraph it says:

"What I would like to explore with you is whether we should reconsider the matter of reintroducing pro rata as soon as possible, rather than sitting on a stock which could prevent certain patients in the SE being exposed to commercial concentrate."

Again, one gets a flavour of the preference, I think, for NHS product. Is that right?

A. I would imagine so. I was relatively remote from this particular level of discussion, I think.

Q. All right. Pro rata has nothing to do, does it, with allocation being based on head of population? Or do you

not recall?
A. I think the pro rata was on plasma but I may be wrong.
THE CHAIRMAN: It is quite difficult, I think, on the documents to sort out exactly where one was at any one time, but I have seen population as a reference. I have seen contributions of FFP and I have seen variations on it. It's not easy to be sure.
MR ANDERSON: I think, conveniently, we are going to have the author tomorrow. So we can ask him.
THE CHAIRMAN: If that is as hopeful as you suggest, I would be delighted.
MR ANDERSON: Very well, thank you very much, Dr Boulton.
A. I would like to know the answer to that question, as well.
THE CHAIRMAN: Mr Sheldon?
MR SHELDON: I have no questions for Dr Boulton. Thank you, sir.
THE CHAIRMAN: I can't undertake to make sure that you will get to know but perhaps Professor Ludlam will tell you if he hears it.
MS PATRICK: I think we are continuing with the B2 topic tomorrow and we are moving on to the C1 topic just now.
THE CHAIRMAN: Yes.
MR MACKENZIE: Sir, good afternoon.
We return to the topic of C1. Dr Dow has returned

to hopefully finish his evidence on this topic today. So could I ask for Dr Dow to come to the stand.

DR BRIAN DOW (continued)

Questions by MR MACKENZIE (continued)

MR MACKENZIE: Dr Dow, welcome back. Sorry to keep you waiting. We are returning to your evidence on the topic C1, being the acceptance of blood from higher risk donors; in particular (a), prisoners and (b), those with a history of jaundice.

We had largely completed your evidence on the question of prisoners. I would like to just deal with one or two things before we move on. Firstly, there were two matters you wished to clarify firstly, from your own evidence on 18 March this year. So if we could please have the transcript for your evidence on 18 March at page 118.

We see in line 24 and 25, on page 118, we then went to a document [SGF0012836]. Go on to the next page of the transcript, please. There is a letter from Dr Wallace, dated 26 June 1976. It was a letter from Dr Wallace to Dr McIntyre in the SHHD. I don't think we need to bring the letter back up but in short, I think Dr Wallace was providing Dr McIntyre with the results of his comparison between the RIA test and the RPHA test to make the case for funding to continue testing by RIA.

Is that correct, doctor?

A. Yes, what happened prior to this, they had been testing with CIEP for five years and on August 1975, they had started using RIA and this was nine months into that period of using RIA. They then asked for more money to continue testing with RIA.

Q. We covered all of that last time. So we don't have to go back to that. If we can scroll down through the transcript, please, and stop there and look at the sixth line down from the figures you had seen on screen. When you gave your evidence you gave an answer that:

"Using these figures, [you] would have to actually say that the IEOP technique was roughly about 35 to 40 per cent sensitive as opposed to the 60 per cent I had estimated."

I think you explained to me today that you had since had a chance to read the whole letter and look at all of the numbers.

A. Yes.

Q. And you had wished to clarify your answer from lines 6 to 8. What's the clarification you would like to make?

A. Well, the clarification is that the data in the letter is skewed and all you could look at is the new donors within that data to do a comparison of the various tests. Because obviously, five years' use of

counterimmunoelectropheresis, we were obviously missing samples that would have been detected by RIA, and these regular donors kept coming back and were detected by RIA within the first nine months.

So you can only look at the new donors there. And the new donors, 13 were detected out of the 22 by counterimmunoelectropheresis, and that's roughly equivalent to about 60 per cent. So really I can't actually agree with -- the way the data was presented to me, obviously it appeared that there was 35 to 40 per cent but the data is skewed and it should really be 60 per cent.

Q. So having had a chance to read the whole letter, your evidence is that the sensitivity of the IEOP technique based on the figures in that letter would be about 60 per cent?

A. Yes.

Q. I'm grateful.

The second matter for clarification, Dr Dow, I think you wished to make arose from the evidence of Dr McClelland, given on 22 March of this year at page 69. And if we could go to line 7, please, I asked Dr McClelland a question about the English findings of the higher incidence of Hepatitis B among prisoners and in line 11, Dr McClelland said:

"It is possibly just worth mentioning that one contributory reason for that is almost certainly the fact that almost all the donors in prisons will be first time donors. As opposed to donors from the community."

Et cetera. I think you wished to clarify something in that regard in respect of the west coast of Scotland?

A. Yes, I can't obviously comment on Dr McClelland's experience in Southeast Scotland but certainly in the West of Scotland the number of new donors in prisons would be round about 20 per cent.

Q. How are you aware of that, Dr Dow?

A. I'm aware of that because I did a trawl of all the prison donations between 1982 and 1984 and in that period there was 5,700 donations taken in West of Scotland prisons, and in a similar period from 1970 to 1980 there were about 10,000 new donors only from institutions, which is prisons. So taking these figures, 5,700, total donations in two years, multiplies up to something like 25/26,000 in ten years, and taking the figures for new donors, which is already published, at being roughly 10,000 you are talking about roughly 20 per cent.

Q. Is that an exercise you have carried out recently or carried out a number of years back?

A. Well, the trawl one, the donors between 1982 and 1984

was done probably about 18 months ago. The data on 1970 to 1980 was already published within one of the publications from the West of Scotland.

Q. I understand. I think those were the only two matters you wished to clarify, Dr Dow. Is that correct?

A. Yes, really a point about these new donors I found was that when we look at the higher risk in institutionalised donors, which we have been going on about, five times the normal level, that's based on new donors. Obviously when you take prison donors as a whole, the risk is a lot less than what we were obviously going on about. It's not five times.

Q. Yes. No doubt, when we come back to read these reports again, we can bear all these points in mind.

A. Yes, thanks.

Q. Thank you. Moving on, please.

THE CHAIRMAN: I'm not quite sure I follow the explanation. I think that I had noticed that so far as new donors were concerned, it was five times.

A. Yes.

THE CHAIRMAN: But the point you make here, that if you take the totality of prison donors into account, the risk is a lot less than 5 times, I'm not quite sure I understand why that should be.

A. Because the regular donors in prisons have already been

screened for Hepatitis B on a regular basis.
THE CHAIRMAN: Right.
A. So really they could have given outside prison and then gone into prison to give their next donation.
THE CHAIRMAN: But one way or another, so far as return donors are concerned, in or out of prison, there is a prior screening test.
A. That's right. The return donors are obviously cleaner than new donors.
THE CHAIRMAN: I think that satisfies me.
MR MACKENZIE: I'm grateful, sir. Certainly, as ever, when we read the literature again, we have to compare like with like.
THE CHAIRMAN: So far as Dr McClelland's qualification is concerned, it rather assumes that people only go into prison once and give a donation early on, whereas you probably have a different experience.
A. I don't know what sort it is: whether they go in there and don't come out.
THE CHAIRMAN: You have got a lot of return donors for different reasons.
A. Yes.
MR MACKENZIE: Dr Dow, moving on, you had referred --
THE CHAIRMAN: Sorry, yes. Just trying to make sure that Professor James and I are on the same wavelength about

this.

MR MACKENZIE: Dr Dow, moving on, you had mentioned last time around of becoming aware in March 1984 of the problem of drug use in prisons through reading a newspaper article. That was referenced in your PhD thesis and I think we have managed to track that down. Could we have, please, document [PEN0160456]. It may be this hasn't found its way to court book yet but that's not a problem, we can put it in, but perhaps I can read it out to you to see if it sounds familiar. It is headed, "Drug Boom in Prisons", and it's present in the Sunday Post. It states:

"Scotland's prisons are fast becoming the country's largest drug centres. In the last ten years, there has been a 30-fold increase in the number of addicts becoming inmates. In 1973 only six people were diagnosed as dependent on drugs on admission to prison. The total for last year is expected to pass the 300 mark. That's about 6 per cent of the prison population."

Et cetera. I appreciate you are at the disadvantage of not having a copy of the text in front of you. In fact I can just hand you a copy. That may short circuit things. (Handed)

THE CHAIRMAN: Mr Di Rollo, the Control of Drugs Act was

1972, was it?

MR DI ROLLO: My recollection was it was 1971, I have to say. Misuse of Drugs Act.

THE CHAIRMAN: 1971. I think we have to be conscious that drug testing might not have had a long history before the early 1970s.

A. I don't think that's quite the same one as I remember but ...

MR MACKENZIE: Unless, doctor, the Sunday Post carried two articles on that topic on that date which seems unlikely. In fact, the article actually appeared on the same page beside a photograph of a couple on their wedding day. We have actually cut that photograph out so it doesn't appear in the public court book. But if I give you the whole page of surrounding people it might help.

THE CHAIRMAN: We are carrying sensitivity very far at the moment it seems to me. (Handed)

A. That doesn't tally with my recollection of what was in the Sunday Post.

Q. What was your recollection then, doctor?

A. It was probably the same thing, it's just the style of this, it doesn't look like the Sunday Post. It looks more like a Dundee paper.

THE CHAIRMAN: Is that not the Sunday Post?

A. Not the Sunday Post, even The Telegraph or something like that, but probably the same story regardless, and I would agree with what's actually carried within it. It was certainly news to me at the time.
Q. That was the date, March 1984?
A. Yes, it was a Sunday, obviously.
Q. Yes. Moving on to a separate paper again. This is [PEN0020582]. This would be a familiar paper to you, doctor, I think you were a co-author, "The prevalence and epidemiological characteristics of Hepatitis C in Scottish blood donors". I think in short, once testing for Hepatitis C of blood donors was introduced in, I think, September 1991, this paper reports on the results of the first six months of testing. Is that right?
A. That's correct, yes.
Q. I think we can see from this summary in the second paragraph commencing:

"In the period under study between September 1991 and February 1992, 180,658 blood donors attended. The prevalence of HCV infection was 0.088 per cent ..."

Which is roughly 1 in 1,000.
A. Yes.
Q. The paper is also perhaps interesting, if we go over the page, please, looking at the risk factors of those

positive donors, at page 122 under "Results". In the second paragraph we can see that 159 donors were found to be infected with HCV. Do you see that? Sorry, it's the left-hand column under "Results", the second paragraph.

A. Yes.

Q. "151, which is 95 per cent of these donors responded to the invitation to attend for further counselling and follow-up. 101, 68 per cent, were male and the analysis of risk behaviours that might have been relevant to transmission of HCV infection is shown in table 1."

If we then go to table 1 at the top of the right-hand column, we can see the risk factors as follows: "intravenous drug use," 39 per cent; "transfusion," 15.2 per cent. Then it's "other parenteral exposure," 11.2 per cent. If we go down to just under the table, two lines down, we see what is meant by "other parenteral exposure" includes "tattoos, ear piercing and needlestick injuries." Do you see that?

A. Yes.

Q. Going back to the table just to complete it: "heterosexual contact," 8.6 per cent; "history of jaundice," 5.9 per cent; "non-UK origin," 1.9 per cent. Then down to "unexplained," 29.1 per cent. We can see

just below the table it's stated that some donors reported more than one risk factor?

A. That's correct, yes.

Q. I think, doctor, at this stage, given the time, I will then, I think, move on to the second part of this topic, which is the consideration of accepting donors with a history of jaundice. So if I could please have your statement on screen, which is [WIT0030094].

Sir, what I propose doing here, Dr Dow has set out in his statement quite fully various literature on this point, together with the main conclusions, and rather than have Dr Dow read or I read each paragraph, what I would intend to do, or seek to do, is simply take these paragraphs as read, provide all of the court book references, so people can cross-check the various literature and perhaps just choose two of the literature, which appear to me to, I think, provide a good summary of where things were at particular dates in terms of research into this subject. I think that may be a way of shortening things to make sure that there is an opportunity for cross-examination, while still getting the main points over.

THE CHAIRMAN: Well, we will try that. But Dr Dow, you ought to be very certain of your ability to come in if it doesn't look as if you are getting your full story

over.

A. Okay.

THE CHAIRMAN: We can easily mistake where we are in documents and it's your evidence I want at the end of the day. So we will stop briefly now to give the stenographer a chance to have a break.

Have you shared any of this with Dr Dow?

MR MACKENZIE: Any?

THE CHAIRMAN: Your approach?

MR MACKENZIE: No, I thought of it as the clock was ticking by and I was waiting.

THE CHAIRMAN: Perhaps you could have a word with him and tell him roughly what you are going to do and that might help us get ahead.

(3.17 pm)

(Short break)

(3.28 pm)

THE CHAIRMAN: Before we start, gentlemen. Tainted Blood have sent a CD containing what they describe as two files with quite a lot of material on facts and figures. I don't want to view this first myself. What I'll do is make it available to parties with a short note on the contents and ask you for your advice after you have read it as to how I ought to handle the material. I don't want to reject any material without at least having had

it seen and thought about by the interested parties. So we will make this available to you in the first place and you will let me know at some convenient time whether you have any advice for me. Yes?

MR MACKENZIE: Thank you, sir. I have discussed my proposed approach with Dr Dow who I think is happy to proceed as I intend.

So we had Dr Dow's statement on topic C1, [WIT0030094]. The subject of the history of jaundice is dealt with in paragraph 20 through to the end of the statement. What I propose doing, sir, is going through each paragraph, taking it as read but providing the court book reference for it so those reading the transcript can identify the article being referred to, and for my part, accurately summarised by Dr Dow in his statement.

So in paragraph 20, the corresponding article is [PEN0020821]. Then the next reference is in paragraph 23; our reference for that article is [PEN0020850]. Then paragraph 24. Our reference for that article is [LIT0012155]. That is one of the articles I will come back to shortly with Dr Dow.

Then paragraph 26. Our reference is [LIT0010430]. Then paragraph 27, which I will come back to with Dr Dow. Our reference is [PEN0140067].

Over the page, paragraph 28, there is a reference to Dr Dow's PhD study. That runs to over 260 pages, unsurprisingly, and our reference is [LIT0013300]. That completes, sir, the reference to the articles.

So if I may now take Dr Dow to three documents, which I think capture the thinking of the Blood Transfusion Service at the time, and Dr Dow can no doubt disagree with me if that's wrong.

The first article is [LIT0012155]. From the top of the left-hand column we can see this is a letter in the Lancet of 21 July 1979, headed "Blood Donors with History of Jaundice". If we scroll, please, to the bottom of the left-hand column, we can see the authors were Dr Crawford and also yourself, Dr Dow, as well, as a co-author.

A. Yes, correct.

Q. Can you summarise for us, doctor, what was involved in this study?

A. Really it was a look at the Hepatitis B surface antigen status of ordinary donors against donors with a history of jaundice. It really was a comparison of the two groups. It really just showed that there was really no difference between the two, which is what John Wallace actually said a few years earlier in another publication.

Q. If we go to the final paragraph, please, we can see it's stated:

"We conclude from these results that a history of jaundice does not materially increase the prevalence of Hepatitis B surface antigen among blood donors and is likely to imply previous infection with Hepatitis A virus rather than with Hepatitis B virus."

You can put that to one side, please.

THE CHAIRMAN: Just before you go, there is no reference here, is there, to NANB hepatitis?

A. No, not at that time.

THE CHAIRMAN: So that would be another factor, if you were doing it retrospectively et cetera, that you might be looking at now?

A. Now, yes.

THE CHAIRMAN: Yes.

A. But at that time, non-A non-B was just coming to my mind at that particular time.

THE CHAIRMAN: The point of the last paragraph is that HAV is likely to have gone or what?

A. Say again?

THE CHAIRMAN: There has been a transient jaundice experience at some time and then --

A. Well, Hepatitis A is not really that important so far as post-transfusion hepatitis goes because the Hepatitis A

carriage doesn't happen. It's an acute infection.

THE CHAIRMAN: Yes.

MR MACKENZIE: Thank you, sir.

On the question of non-A non-B, doctor, it may also be useful, given the point has arisen, to look, please, at [LIT0010429].

We can see from the top of the right-hand column this is a letter in the Lancet of 15 March 1980. Again, it's on the topic of blood donors with a history of jaundice. This is from the Edinburgh transfusionists, in particular Dr Hopkins and colleagues. Is that right?

A. That's correct, yes.

Q. I think this reports a similar study. We can see from the start of the letter:

"Sir, -- The former policy of the Scottish Blood Transfusion Service was to reject as donors all persons admitting a history of jaundice. Lately this policy has been modified to exclude only would be donors with a history of jaundice within the previous 12 months: Donations are now accepted from most persons with a history of jaundice, provided they are HBsAg negative upon routine testing."

A little further down in the left-hand column:

"HBsAg was detected in 12 new blood donors -- one out of the 792 with a history of jaundice plus 18 out of

the 8467 with no such history. The single HBsAg positive donor among those with a history of jaundice was a drug addict ... Of the 36 donors who were followed up, 16 gave a history strongly suggestive of viral hepatitis, but in only six was it possible to obtain the results of HBsAg testing at the time of illness: all were negative. These findings show that in this community, a history of jaundice does not define a group with a high prevalence of HBsAg carriage."

Then the right-hand column, please, to the conclusion. The authors state:

"We conclude that in the donor population of Southeast Scotland, a history of jaundice is not associated with an increased risk of HBsAg carriage. This is in agreement with findings in the West of Scotland reported by Dr Follett and colleagues. The prevalence of antibody to Hepatitis A in our region is similar in donors with and without a history of jaundice."

Then the last sentence:

"This suggests that the viruses of non-A non-B hepatitis may be a significant cause of jaundice in this population."

Doctor, do you have any comments on that final sentence?

A. Yes, well, there are a few comments throughout that little letter -- that I couldn't actually get to grips with the mathematics in the second paragraph, I think it was.

Just scroll down a bit. The third paragraph:

"HBsAg was detected in 12 new donors. One out of the 792 with a history of jaundice, plus 18 out of 8467 ..."

I don't know what's wrong there but that should either be 11 or the 12 new donors -- the 12 might be 19, I don't know.

THE CHAIRMAN: I wondered if it was just bad punctuation.

A. Certainly the figures don't fit.

THE CHAIRMAN: They don't fit.

A. Then going back to the Hepatitis A prevalence in the history of jaundice donors and normal donors that came out roughly the same within this particular study, but there is a study also by Dr Follett, Barr, Crawford and Mitchell, which is [LIT0010430], the one after this one, which actually gave the history of jaundice and normal donor Hepatitis A levels for the West of Scotland, and they were dramatically different.

MR MACKENZIE: What I'm interested in is the final sentence:

"This suggests that the viruses of non-A non-B hepatitis may be a significant cause of jaundice in this

population."

A. That was based on that Hep A prevalence being similar in history of jaundice donors and normal donors, 84 and 78 per cent. What I'm saying is, the West of Scotland data on Hepatitis A prevalence in these two groups show a lot higher level in those with a history of jaundice.

Q. From looking at the report of the study in this letter, do you consider the authors had a sufficient evidential basis for what they state in the last sentence?

A. I don't know how many they actually tested. They just have:

"The prevalence of antibody to Hepatitis A ... is similar in donors with and without ..."

We need to actually know the figures. I know that Bob Hopkins at one point used to write papers based on 100, whereas the West of Scotland, we tried to have significant numbers like 1,000 or 2,000.

Q. In terms of looking at the Edinburgh data, as reported in this letter, do you consider the Edinburgh data supports or establishes what is said in the final sentence or do you consider the final sentence as more in the way of speculation, albeit perhaps informed speculation?

A. Purely speculation. Again, because we have contrary evidence in the West about the Hepatitis A prevalence.

Q. Did you read this letter at the time, do you remember?
A. I remember reading it at the time and obviously dismissed it because our data did not fit.
Q. It depends which data one looks at.
A. I'm blinkered.
Q. Even putting the West of Scotland data to one side and only looking at the Edinburgh data, as reported in this letter, does that data establish or prove what is stated in the final sentence?
A. I think it indicates that potentially non-A non-B hepatitis could explain what they found. By having only 84 per cent of those with a history of jaundice having Hepatitis A antibody and 78 per cent of normal donors.
Q. To be fair to the authors, they do say:

"This suggests that the viruses of non-A non-B hepatitis may ..."

So they don't, I think, present it as the data having establish that, they simply offer that --
A. They offer that as a possible explanation.
Q. In any event, you would say one has to have regard to all of the data not just that from one study?
A. Yes. You don't believe one set of data from one group of individuals. You continued to look around and have an independent corroboration of that data before you consider it as read.

Q. Yes. Thank you.

The next paper, doctor, is [PEN0140067]. Again, I'm sticking with the consideration given in the Blood Transfusion Service to the question of blood donors with a history of jaundice, and we can see this from the top of the page, a letter in the British Medical Journal of 23 October 1982. Again, we can see the title of the letter if we scroll down a little, "Blood Donors: the History of Jaundice", and if we go to the far right-hand column, please, we can see the authors come again from Glasgow, Dr Barr and others including yourself, Dr Dow.

A. Correct.

Q. Then going back, please, to the start of the letter, I think it is worth reading all of this letter to give a flavour for the work, a consideration on this topic at the time. This letter states:

"The leading article from Dr P M Jones ..."

Who was Dr Jones?

A. I think he was Newcastle but I'm not very sure. He certainly was south of the border.

Q. Involved in transfusion, perhaps?

A. Yes.

Q. "... reopens the question --"

THE CHAIRMAN: Is this possibly Peter Jones?

A. Yes.

MR MACKENZIE: It might be sir, yes. Yes, I'm grateful:

" ... reopens the question of whether blood from donors with a stated history of jaundice is safe for transfusion."

I suppose we would have to see the content of the letter from Dr Jones, but it may be of interest in itself that at this time, October 1982, Dr Jones had written an article about the question of donors with a history of jaundice.

Reverting to the letter:

"In an earlier study from the West of Scotland, we found that these donors were much more likely to have had an infection with Hepatitis A virus than with Hepatitis B virus. In addition, we found that a history of jaundice was no more common among carriers of Hepatitis B surface antigen and hence was of little use as a marker of Hepatitis B infectivity. A history of jaundice is obtained from 2.8 per cent of blood donors in the West of Scotland."

Then the letter goes on to report on the current study:

"We have now studied a group of donors according to the age at which the jaundice occurred. Almost all the episodes of jaundice occurring before the age of 13 years were due to Hepatitis A but about 20 per cent

of those with jaundice in adolescence or later had no markers for Hepatitis A or B. Other viruses can cause jaundice ..."

They are set out:

"... and many other agents can cause liver problems. We cannot therefore equate unexplained jaundice with infection by the elusive non-A non-B viruses."

Is that perhaps, to pause, doctor, a rejoinder or response to the last sentence of the letter by the Edinburgh authors we looked at shortly previously?

A. No, I think it was a response to Dr Jones' letter at the time. That was really what this was about.

Q. Yes, but could that equally be a response to the Edinburgh letter we looked at shortly?

A. I think the Edinburgh letter was in the Lancet, whereas this is in the British Medical Journal. So you are responding to whatever is in a particular journal.

Q. Yes, I understand. Reverting to this letter:

"We cannot therefore equated unexplained jaundice with infection by the elusive non-A non-B viruses. Indeed, it is uncertain whether sporadic non-A non-B hepatitis is caused by the same agent as the form of the disease transmitted by transfusion, and it is not known how often a carrier state follows sporadic infection. Furthermore, it is possible that as with Hepatitis B,

clinical jaundice may be an indicator of elimination of virus rather than carriage."

It goes on in the middle, half way through the middle column:

"In the last three years, this region has transfused nearly 400,000 donations of blood and their derivatives. Only 12 cases of overt post-transfusion hepatitis possibly attributable to non-A non-B agents have been identified and of these, four were haemophiliacs who had been receiving imported blood products in addition to Scottish large pool factor concentrate. None of the donors involved in the eight cases associated with red cell transfusion had given a history of jaundice and these cases could not have been prevented by the policy proposed by Dr Jones."

Then the right-hand column:

"As the sensitivity and specificity of serological tests for non-A non-B carriers have yet to be proved, we could find ourselves excluding 2.8 per cent of donors because of a history of jaundice ... the present British policy appears to be correct and any change could cause a serious loss of blood products when some regions are still struggling to make 80 per cent of the blood plasma they collect available for Factor VIII production."

In short, doctor, do you consider the case had been

made out on scientific grounds at that time for excluding blood donors with a history of jaundice?

A. I felt there was no case to actually exclude these individuals at that time, based on the data we actually showed there: that the history of jaundice was mainly due to Hepatitis A. I took then those whose history of jaundice was before the age of 12.

Q. Yes. What consideration was given to non-A non-B hepatitis, and in particular whether or how many, if any, donors carrying non-A non-B hepatitis could be excluded if all donors with a history of jaundice were excluded?

A. If we excluded all the donors with a history of jaundice, I don't think we would have excluded many with Hepatitis C. They were a very small number.

Q. Why do you say that?

A. Again, because Hepatitis C, as we knew later on, tended to have only moderately high levels of ALT. Most of them didn't actually become jaundiced as such. They would have high levels of ALT but it didn't become icteric, as was the case of people with Hepatitis A or Hepatitis B. Indeed, the likes of cytomegalovirus and Epstein Barr virus that was mentioned in that letter, we did a trawl of the SCIEH database at that time and they actually showed the various symptoms for these viruses,

and 5 per cent roughly of people that were found to have infection with Epstein Barr virus or cytomegalovirus presented with jaundice.

Q. One final document I would like to take you to, please, doctor, is [SNF0011109]. We can see, doctor, this document is headed, "Surrogate tests for non-A non-B hepatitis: a special report to regional transfusion directors", by yourself, dated May 1986. Do you remember writing this report, doctor?

A. Yes, I was prompted to write it by Dr Mitchell. I didn't actually attend the meeting when it was discussed. It was just a report I had to furnish for discussion purposes.

Q. Do you remember why you were prompted to write it?

A. I think it was topical at the time and it needed to be discussed, all the things within it.

Q. I think you had just completed a PhD --

A. Yes.

Q. On the question of surrogate testing for non-A non-B hepatitis.

A. That's correct.

Q. I think in this report, if we look about half way down we can see history of jaundice in the USA:

"Individuals with a history of prior jaundice are excluded because of the possibility of their jaundice

episode being due to non-A non-B and subsequently becoming chronic carriers of non-A non-B agent or agents. Exclusion of such individuals in the West of Scotland population would incur a loss of around 2 to 3 per cent of blood donors."

Over the page, please, to page 2. I think you had considered in your study essentially three possible surrogate markers for non-A non-B hepatitis. One was donors with a history of jaundice, secondly, elevated ALT levels and thirdly the presence of anti-Hepatitis B core antigen?

A. Yes.

Q. Then if we look at the second paragraph:

"The effect of these strategies in identifying implicated donors involved in NANB PTH cases."

I think when you speak of these strategies, you refer to all three surrogate markers we have just mentioned, and you say in the report:

"The acid test for either of these three means of identifying potential non-A non-B carrier donors is to examine the effect, if any, they would have in identifying such donors amongst those implicated in reported cases of NANB PTH. Of the 65 donors implicated in 18 NANB PTH cases, only two had histories of jaundice and both were involved in the cases in which the

jaundice may have been caused by the effects of drugs rather than transfused blood."

A. Yes, correct.

Q. So did that essentially provide further support for the view that it would not be a materially effective strategy to exclude donors with a history of jaundice from donating blood?

A. That's right.

Q. Over the page, please, the final page. The conclusion states:

"The present UK policy of accepting donors with raised ALT levels (ie not routinely ALT testing), anti-HBc or histories of jaundice would appear to be correct. It would appear from the study that the introduction of such surrogate screening procedures would have little impact on reducing the already low level of NANB PTH cases at present reported within the West of Scotland region."

I think you have explained that this report was put before a meeting of the SNBTS directors perhaps, and we certainly know that at no point in the 1980s, for example, was the policy introduced of excluding donors with a history of jaundice.

A. No, but the thing was that ALT and anti-core was thought of being introduced in the United States at that time.

As a measure of producing non-A non-B, and we did actually make noises about anti-core testing ourselves in 1991, I think it is, or 1992, as a means of reducing the number of Hepatitis B post-transfusion hepatitis cases.

Q. But we will come back to that, I think, after the summer. In short, doctor, if we could perhaps just conclude by --

THE CHAIRMAN: Could we go back to the previous page just for a moment before you reach your conclusion?

MR MACKENZIE: Yes.

THE CHAIRMAN: Dr Dow, on the page before this, you have the paragraph right in the middle:

"Of the 65 donors implicated, in 18 NANB PTH cases, only two ..."

What test were you using to determine NANB hepatitis at that point?

A. These were cases of post-transfusion hepatitis, notified either to ourselves or through the hepatitis reference lab at the regional virus lab in Ruchill, where there was no evidence of Hepatitis B and there was not any evidence of Hepatitis A through IgM Hepatitis A testing. Some of these individuals -- there were paracetamol overdoses as well included because they had had transfusions. So unfortunately they were included

because they had had a transfusion.

THE CHAIRMAN: As Professor James said, it is heterogeneous.

A. Yes.

MR MACKENZIE: Thank you, sir.

So finishing, doctor, with your statement, please, which is [WIT0030094], paragraph 30, over the page, please, at the bottom. You state:

"In conclusion, exclusion of donors admitting to a history of prior jaundice would have excluded almost 3 per cent of the donor pool at a time when SNBTS was attempting to be self-sufficient. The data linking HBV with a history of jaundice was not scientifically proven and thus attempting to link non-A non-B hepatitis with a prior history of jaundice would even now seem implausible, especially when it is recognised that non-A non-B hepatitis has milder ALT elevations than either HAV or HBV."

Doctor, what I have sought to do to conclude is, looking at your evidence on this topic and also those of previous witnesses, sought to draw certain propositions together, which I would like to put to you to see if you agree or disagree or wish to revise or reformulate them. The first proposition is this, that from the evidence I derive that excluding donors in the 1970s and 1980s with a history of jaundice is unlikely to have

materially reduced the incidence of transfusion-associated Hepatitis C?

A. I would agree with that.

Q. Secondly, if we look at why that is, only approximately 3 per cent of donors gave a history of jaundice and of those donors, that episode of jaundice may have been caused by a number of factors. Is that correct?

A. Correct, yes.

Q. In particular, including Hepatitis A.

A. Mainly Hepatitis A, yes.

Q. So mainly Hepatitis A, which we know is not blood-borne?

A. No, it can be blood-borne. It's very rare, though. There is only about a handful of cases in 30 or 40 years.

Q. Yes. An episode of jaundice could also be caused by Hepatitis B.

A. Correct.

Q. For which we know there was screening introduced from the early 1970s.

A. That's right.

Q. An episode of jaundice could also be caused by non-hepatitis virus.

A. That's correct.

Q. For example CMV or EBV.

A. Yes.

Q. Thirdly, an episode of jaundice could in fact be caused by a non-viral cause.
A. Correct.
Q. For example, alcoholic liver disease, gallstones, reaction to medication and other causes.
A. That's right.
Q. The second one, I am afraid was quite long. The third one is short and it is this: most people who contract Hepatitis C do not develop jaundice.
A. The ones that are known about -- one or two obviously do but the vast majority, I think, do not actually have clinical jaundice at the time they come down with infection.
Q. So these propositions I have set out represent a reasonable summary of at least your evidence on this matter?
A. I would agree with that, yes.
Q. Sir, I have no further questions for Dr Dow.
THE CHAIRMAN: Mr Di Rollo?

Questions by MR DI ROLLO

MR DI ROLLO: Yes, thank you.

Dr Dow, there are just two points I want to take up with you. I think it would probably be best to get the transcript. It's at page 77 and page 78 of the transcript of your evidence.

It's the foot of page 77 and the top of page 78. I don't know whether that's the same passage that I have actually. No, it's not. I don't know what has gone wrong there. It is perhaps the page numbering.

The passage in your evidence is along the following lines, you said at a fairly early stage in your evidence that you realised the likes of prison donations were needed, actually to keep your stocks up. Without them obviously you would run into difficulties of supply. That's what you said.

A. That was my understanding at the time, yes.

Q. Right. What was that understanding based upon?

A. I would walk into the blood bank and see how much blood was there. There was a lot more there then than what there is now.

Q. There is no evidence that when any of the regions stopped taking blood from prisons, there was any difficulty in making up any shortfall. We have heard of no evidence of that kind.

A. You may well have heard no evidence but I have heard anecdotal evidence where we had to supply blood from the west through elsewhere in Scotland at times of critical need, as in the likes of Christmas, et cetera.

Q. Yes. I understand that. A decision was taken in Glasgow at some point to stop taking blood from

prisoners, and do you know if at that stage there was any difficulty in making up any shortfall from elsewhere?

A. I wasn't involved in supplying units of blood to hospitals, et cetera. I was really there to do testing.

Q. It doesn't seem to be -- and I'm just challenging the proposition really -- that prison donations were in fact required in any sense to keep stocks up. It may have been an impression that you had but I'm suggesting to you that the reality was that prison donations were not required for that purpose.

A. I can't answer that. I wasn't in the, you know, the supply of blood to the hospitals.

Q. I understand, all right.

The other thing I should suggest to you is that in this particular area we have had evidence from Professor Ludlam that a letter was sent to him by Dr Mitchell indicating that there was a surplus of factor concentrate in Glasgow, that he didn't need any more.

A. I have heard of that as well.

Q. Sorry, a letter was sent to Mr Watt, it was Professor Ludlam that gave that evidence. You have heard that?

A. I have heard that obviously through the Inquiry.

Q. That would tend to suggest that if there was a surplus, there wasn't a shortage of blood that needed to be made up by prison donations.
A. You are talking about two different things here. I'm talking about blood on the shelf, which is red cells or the remains of red cells, because the plasma has already gone through to the Protein Fractionation Centre, and what you are talking about is Factor VIII, the little bottles of Factor VIII that we made. The two things are completely separate.
Q. I can understand that but we have heard some suggestion that, in order to pursue self-sufficiency in Scotland, it was needed to take blood from prisoners, and the self-sufficiency of blood supply would also be going into making factor concentrates as well as blood on the shelf, as you put it?
A. We were plasma driven way back in the 1970s and 1980s. We were striving to get that 80 per cent target of plasma to send through to PFC to make the Factor VIII which was needed to become self-sufficient in Scotland. We were plasma driven.
Q. Can I just deal with another point then. You started your evidence this afternoon and indicated that you wanted to challenge the suggestion that in general terms, prison donors would be more likely to be new

donors as opposed to being repeat donors. Is that right?

A. No. I said the entire opposite to that.

Prison donors, if you went along to the session in the West, the number of new donors amongst them would be only 20 per cent.

Q. Yes. That's right. I'm sorry, I am not making myself very clear. I think the suggestion had been made by another witness, I think, in passing, that prison donors would be more likely to be donors for the first time. You are saying that that's not correct, that they would be repeat donors generally in the west. Is that right?

A. Certainly in the west.

Q. It does come as a surprise to me, I have to say, that the statistics that you have given us result in the idea that only 20 per cent of prison donors would be giving blood for the first time in Glasgow. So that means that 80 per cent of prison donations would have been repeat donations, I assume.

A. Correct.

Q. That does, I have to say, come as a surprise to me, hearing that as I say, for the first time this afternoon.

But you have arrived at that by extrapolating, I think, not from the 5,000 or so donations that were

taken between 1982 and 1984, but by making certain assumptions about donations taken between 1970 and 1980. Is that right?

A. Yes. I have looked at the data we have on file between 1970 and 1980, which amounted to only 10,000 new donations from prisons.

Q. Are those new donations from prisons or new donations -- you said from institutions. Are "institutions" and "prisons" synonymous?

A. They were synonymous, yes. We use the word "institutions" to mean prisons.

Q. You didn't go to any other places other than prisons?

A. Such as?

Q. I don't know.

A. I don't know either.

Q. Right. So they may not be prisons that you are referring to between 1970 and 1980?

A. Of course they were prisons.

THE CHAIRMAN: We are not having trouble over young offenders' institutions?

A. I would include them as prisons.

MR DI ROLLO: You are assuming that the 10,000 new donors is reflected equally in the period between 1982 and 1984, that you can extrapolate from those two periods to the other.

A. From 1982 to 1984 there were 5,700 donations taken in that period I looked at, which was between something like April 1982 to March 1984.
Q. Right.
A. Probably in the March 1984 we were actually at the stage of stopping at that point.
Q. And do you know how many donations in total were taken between 1970 and 1980?
A. I can't because the 1970 to 1980, the total number of prison donations in that time, I certainly don't have at hand. I did try to do an exercise to try and go through all that but certainly it seemed to be roughly 2,000 to 3,000 donations a year were taken from prisons in that period in the West of Scotland.
Q. Without knowing exactly what we're dealing with there, it is quite difficult to extrapolate from one period to the other?
A. Well, as I said, my extrapolation is more accurate than what was written down by other -- in the transcript book.
Q. I think the general point you are making is that one should not assume, I suppose, that a prison donation is a new donation. One can't make that assumption. So that --
A. What I'm trying to say is that you can't say that all

the prison donations were from new donors.
Q. I think that's probably about as best we can do?
A. When you look at the prison donations as a whole, only 20 per cent, I'm saying, were from new donors.
Q. It is the 20 per cent I'm perhaps taking issue with.
A. The rest were from donors who had already gone through a Hepatitis B screen at some previous point.
THE CHAIRMAN: Perhaps, Mr Di Rollo, if you told Dr Dow why you are surprised, he might be able to comment.
A. We went back to these sessions on a regular basis. We were going to Barlinnie twice a year, and the same with quite a lot of the other institutions; it was on a regular basis we were going to them, and usually at holiday periods, to cover, obviously, when we had got shortfalls because our other donors didn't want to give blood.
MR DI ROLLO: I suppose it just seems surprising that there should be that amount of repeat business.
A. Our normal sessions at that time were roughly 10 per cent new donors. That's the sessions outside prison.
THE CHAIRMAN: Some people would be in Barlinnie for quite significant periods of time.
A. They could have donated prior to going in there and, obviously, once they are in there, they go along and

give blood again.
THE CHAIRMAN: It might be good for your appearance before the Parole Board if you've got a good record of giving blood. You wouldn't know that sort of thing, Dr Dow, I suppose.
A. And some of them, obviously, once they come out of prison, they give blood again.
THE CHAIRMAN: Of course there are environmental and other factors within prison that can give rise to infection --
A. That's true.
THE CHAIRMAN: -- during the course of -- but what you have done is given us your best estimate?
A. It's the best estimate, yes.
THE CHAIRMAN: I doubt if we can go beyond that, Mr Di Rollo.
MR DI ROLLO: I quite agree, I follow that.
THE CHAIRMAN: Mr Anderson?
MR ANDERSON: No, thank you, sir.
THE CHAIRMAN: Mr Sheldon?
MR SHELDON: No questions, thank you.
THE CHAIRMAN: Dr Dow, thank you for coming back.
A. Thank you.
THE CHAIRMAN: I will read everything, even though we have only had little bits of it so far. Thank you very much.

Presentation of outstanding matters on topic C1

MR MACKENZIE: Sir, there are no further witnesses today. I have got about ten minutes' worth of miscellaneous matters to largely finish this topic but it need not be done now. We can easily come back at a time which is convenient to do that. It is entirely a matter for you, sir.

THE CHAIRMAN: If you are going to complete the topic in ten minutes, I'm sure that we should do that now.

MR MACKENZIE: I can complete the topic subject to one outstanding line, which relates to reports by the Secretary of State for Scotland on prisons and also reports by Her Majesty's Inspectorate of Prisons as well. That's the one outstanding matter.

THE CHAIRMAN: That's may be a self-contained chapter.

MR MACKENZIE: I think it is.

THE CHAIRMAN: I think we should go on with the miscellaneous points other than that.

MR MACKENZIE: I'm grateful.

Sir, the first thing was you had asked for a note on the various guidance documents on the selection of donors and the use of blood. That has now been done, sir. It has only very recently gone into court book. The reference is [PEN0120347] and this has been sent to the SNBTS, who have agreed it as being factually

correct, so I won't go through it. I think this does explain, I hope, all of the mysteries actually, including the different red and orange books. I think I need say no more about that at this stage, but clearly if any party has any further queries on that, we can seek to address that.

THE CHAIRMAN: Thank you very much. We will have to come back to the detail of it but that seems to provide a lot of information.

MR MACKENZIE: Thank you, sir.

Another point. Dr McClelland, on 22 March -- we don't have to go to this but on 22 March, at page 71/72, he referred to having seen a textbook by Professor Garrott Allen from 1972. In short, Dr McClelland said he couldn't remember having seen the 1975 letter by Professor Garrott Allen to Dr Maycock but he had read Garrot Allen's book and we have provided now in court book an extract from that textbook, which is at [PEN0120164]. We don't have to go to any of these documents now but, in short, it's to provide the reference which Dr McClelland spoke to. I think one will see that it really fits in very nicely with Dr McClelland's evidence on that.

Another loose end in that regard, sir. Professor Cash spoke to, in the United States of

America, the FDA not recommending cessation of the practice of collecting blood from prisons until 1995, and again we found a reference for that. It's [PEN0120173], which is a recommendation from the US FDA, dated 8 June 1995, and in particular recommendation 1. Again we don't have to go to that. It's really for completeness that's provided.

Sir, you may recall a reference to the letter dated 1 May 1975 by Dr Yellowlees, the chief medical officer the England and Wales, on the question of continuing to collect blood from prisons. I think one can see the genesis for that letter if one goes to [SGH0030259]. Again we don't have to go to that but, in short, this is a February 1975 draft of the second Maycock report, and if one goes to the first appendix of that earlier draft, one will see in relation to prisons pretty much the same text. That appears in Dr Yellowlees's letter of 1 May 1975. By way of contrast, if one were to go to the final version of the second Maycock report in September 1975, which is [SGH0030079], one would see that appendix 1 no longer appears in the final version. Again, I think that will all be self-explanatory if one then looks at the documents in due course.

THE CHAIRMAN: So what one should understand is that the second Maycock report had material of this kind in it in

appendix 1. Then Dr Yellowlees writes as CMO and Maycock takes it out?

MR MACKENZIE: Yes, sir.

THE CHAIRMAN: Do we know anything more about the circulation of the Yellowlees letter in Scotland?

MR MACKENZIE: There was evidence at the time, sir, that it certainly went to the SHHD, who sent it to Major General Jeffrey. Certainly, I covered that at the time, sir.

THE CHAIRMAN: Yes, but is there anything that takes it from the General outwards to medical officers in the areas?

MR MACKENZIE: No, sir. As far as we can take it is that I think it was considered at a SNBTS directors meeting at the time but we have no evidence that it went beyond that.

There are three additional papers, sir, which I haven't put to any witness. They really, I think, are part of the general background, as opposed to being very much in the forefront, and that's because they all post-date events. I think it is worth the parties and you, sir, at least being aware of the papers.

The first one is reference [LIT0013258]. It might be worth just briefly going to that, simply to see the heading, the authors and the subject matter. In short, this was a study of the incidence of Hepatitis C

infection in five Scottish prisons between 1994 to 1996. Obviously, that way post-dates the events we are concerned with but I think it is of some background interest. In short, sir, this study found a prevalence of Hepatitis C infection among prisoners of about 20 per cent. The parties can no doubt read that paper for themselves in due course.

The second slightly similar paper relates to an English study. It's [LIT0013266]. Again we can perhaps just see the paper to see the title and authors. In short, sir, this was an English study carried out in eight prisons in England and Wales between 1997 and 1998 and this found a prevalence of antibody to Hepatitis C of 7 per cent. It's really quite a different finding from the Scottish figure: different tests used and detecting slightly different things. That's provided for what it is worth.

Then lastly, on a slightly similar vein, sir, is a paper looking at the background prevalence of Hepatitis C in England and Wales, which I think was touched on with the previous witness, and that's [PEN0020822]. Given the time, I'm not going to go into this paper in detail, sir, but essentially it gives an estimated prevalence of Hepatitis C among the population in England and Wales of between 0.55 per cent and

1.07 per cent.

The one other thing of interest, I think, in this paper, is if we can, please, go to page 225, which is 0828. Go on to page 225, please, and the bottom of the left-hand column, the paragraph commencing:

"Most of the HCV infections in the population ..."

It gives an interesting narrative about the drug abuse epidemic in England and Wales. To what extent that applies in Scotland isn't a matter we have heard evidence on but it is there and is of some background interest, I think. It has to be treated with some caution and I think it doesn't really go beyond what it says.

THE CHAIRMAN: Up to the top of the right-hand column, please? Yes.

Yes, thank you.

MR MACKENZIE: Two final matters. The second last matter: we had hoped that Dr McIntyre, a former medical officer of the SHHD, would be able to give evidence on this topic. Unfortunately, Dr McIntyre is unable to attend the hearings, so we will have to rest on his statement, which is [WIT0030013].

Finally, sir, the only, I think, outstanding matter under topic C1 is that we had promised to look at what reports there were on prisons, and in particular the

health of prisoners, including drug use. We have identified a number of, I think, quite helpful reports, which are presently going into court book and we will shortly be seeking to identify a witness via the assistance of the Scottish Government to certainly provide a statement and possibly, depending on the statement, come along to the hearing, sir.

THE CHAIRMAN: Thank you very much indeed. Is there any other business today? No?

So what's tomorrow?

MR MACKENZIE: We revert to B2 tomorrow, sir.

THE CHAIRMAN: And in human terms that means?

MR MACKENZIE: I knew you would ask me that, sir.

THE CHAIRMAN: Professor Cash?

MR DI ROLLO: And Dr Perry.

THE CHAIRMAN: And Dr Perry.

(4.25 pm)

(The Inquiry adjourned until 9.30 am the following day)

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