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(10.00 am)

THE CHAIRMAN: Good morning. One rather sad event that has happened since our last hearing is the death of GRO-A, who, among all the other causes to which she devoted her time, gave quite a lot of her time to the haemophilia community. We had hoped at one stage that she might come and give evidence to us, but I think by then her illness was taking over. But we do send our condolences to her family.

Professor Thomas, would you like to come to the microphone?

PROFESSOR HOWARD THOMAS

THE CHAIRMAN: Thank you for coming, Professor. I don't know how you prefer to proceed. Would you like to make your own presentation? We have seen your paper. If not, I am quite happy that we should ask you questions but it might be that you prefer to do it yourself.

A. I was asked to paint the picture of the natural history and what could be done for treatment, and that I tried to do in the paper, but I guess that is pretty given amongst the panel.

THE CHAIRMAN: It is unlikely to be controversial, I should think.

A. Exactly, so I think it is easier for me just to ask

questions.

THE CHAIRMAN: I think perhaps it should be said publicly, so we have it as evidence, if that is all right with you.

A. Should I make a synopsis of it?

THE CHAIRMAN: Yes.

MR MEHAN: Professor Thomas, could you introduce yourself as well?

A. Okay, well, I am currently Professor of Medicine at St Mary's, which is now part of Imperial College. Before 1987 I was Professor of Medicine at the Royal Free. I am a hepatologist, I work with a variety of different types of liver disease, and for the last ten years or so I have been Chair of the Advisory Group on Hepatitis at the Department of Health. I think you have noted those roles that I provide. We provide advice to the Executive of the Department of Health on these issues.

THE CHAIRMAN: Could you just tell us this, if we may interrupt: how long has that group been in existence in its present form? Are we talking about the last two or three years or does it go back to the 80s?

A. I think it goes back at least 20 years. I have been Chair of it for the last 10 years.

THE CHAIRMAN: We don't seem to have come across it in the

1970s.

A. No, I was a member of it before I was the Chairman of it for about five years before then. I certainly know it has been around since the end of the 1980s, 1990s.

DR JONES: Could I just interrupt on that? Who was chairman before you?

A. It was the Professor of Virology at St Thomas's. He was the immediate Chairman.

DR JONES: I thought I connected him somehow. I just wanted to check.

THE CHAIRMAN: Yes, please.

A. As I have stated in the document, there are five hepatitis viruses. Two of them are transmitted enterically, hepatitis A and E, and they really are not of concern to us in this context because they are not transmitted by blood.

Hepatitis B and C are the two that concern us. They are transmitted by blood. We have diagnostic tests for them. Of those infected with hepatitis B in adulthood, around 5 per cent will develop persistent infection and it is that group that develop the problems which stem from cirrhosis and the development of primary liver cell cancer.

As far as hepatatis C is concerned -- transmitted by blood obviously -- about a third will suffer an acute

episode and get better and there are no consequences of that, and then two thirds develop a persistent infection and about 20 per cent of those over a 20-year period will develop cirrhosis and 2 to 3 per cent of those with cirrhosis, but not those without cirrhosis, develop liver cell cancer each year. So the cumulative risk over 10 or 20 years is quite significant of development of the cancer.

THE CHAIRMAN: Yes. I gather that this type -- it was originally non-A non-B, wasn't it?

A. It was non-A, non-B and in 1982, 1985, that sort of period, there was a feeling that the natural history was different to what we know it to be now; in other words, we thought it was a fairly minor infection and --

THE CHAIRMAN: It takes some little time, I gather --

A. Exactly. It really takes 20 years before we start to get significant problems and in fact of the 20 per cent who have cirrhosis after 20 years, most of those are asymptomatic and it is over the following 20 years that they start to get -- progressively with problems, become seriously symptomatic.

THE CHAIRMAN: As opposed, for example, to hepatitis B, this was becoming recognised as a problem only probably in the late 70s, early 80s?

A. Yes, I think the transmission was known to occur, but,

in the absence of diagnostic tests, all we knew was that it was causing what was termed a post-transfusion hepatitis. Hepatitis obviously by definition infers inflammation of and damage to the liver, but there was a debate as to whether that was virus-related or whether it was relate to chemical contaminants of blood.

Also, there was a suggestion that there might be -- we know that the patients were immuno-compromised and it was thought that the Factor 8 concentrates contained a lot of H and A proteins and that that caused immunosuppression, and there was a suggestion that that might allow reactivation of the virus what was there all the time.

The reason I emphasised that is because in 1989, when the virus was discovered by Mike Harrington(?) and colleagues at Chiron(?), they of course filed patents and there was a large challenge to that from people who said it was obvious -- they challenged it on the basis of obviousness, and I was involved with Hart Varmars(?) and a series of other people in the High Court review of that patent.

In fact, the fact that it was not obvious at the time, people were thinking: well, you know, it probably is a virus, and then, because of the difficulties in cloning it and what have you, people are going to pull

back from that. And then these other possibilities of it being a chemical or an immunological suppression and the reactivation of an endogenous virus, all those came to the fore, and I think the judge found -- it was Lord Jeffries, I think --

THE CHAIRMAN: This was for patent purposes?

A. It was in patent purposes, and there is a nice transcript of all that, which went on for three or four weeks, which might be useful to you.

THE CHAIRMAN: It may.

A. I think they concluded it, by granting the patent, that it was not obvious that there were enough concerns about what was happening, that it was not clear that it was a virus until it was actually cloned.

THE CHAIRMAN: I see, thank you.

A. I have lost my theme now.

THE CHAIRMAN: My fault, I interrupted you.

A. So, yes, we knew about post-transfusion hepatitis and we didn't know that it was caused by hepatatis C until probably 1990/1991 when, retrospectively, the post-transfusion hepatitis series of specimens were tested and most of them turned out to have antibodies to hepatatis C.

THE CHAIRMAN: It was possible to test for a form of hepatitis, earlier than that?

A. Yes, what we tested for was evidence of hepatitis -- and by that I mean an elevation in something that we call the transaminases. Transaminases are normally within liver cells, and, when the liver is damaged, they leak out, so the level of transaminases in the blood goes up.

For instance, there was an MRC working party in the mid-1970s that looked at post-transfusion hepatitis and then there were several independent studies. One was done in Newcastle by Collins and Oliver James, and they concluded that in the UK about 2.5 per cent of people undergoing transfusions -- and the average amount of blood, units of blood that each person received, was about seven and of those receiving that average amount of blood, 2.5 per cent went on to develop hepatitis, this transaminases elevation I was telling you about.

THE CHAIRMAN: And we are talking at that stage, not hepatitis B but hepatatis C, are we?

A. We had excluded hepatitis B by that stage. That had been discovered about two decades earlier. We could screen for that and we knew about hepatitis A. This was the frequency of non-A, non-B, of post-transfusion hepatitis in the UK and it turned out that about 0.3 per cent of units of blood you could deduce caused that hepatitis, and, therefore, were infected.

That was about a quarter or a fifth of the frequency

at which post-transfusion hepatitis under the same criteria were seen in the United States.

THE CHAIRMAN: I yes.

A. That led to the suggestion that blood and blood products in the UK had a lower frequency of what we called non-A/non-B. That was almost 95 per cent found to be hepatatis C, once the diagnostic tests were available. So you can transfer those figures to the frequency of hepatitis C.

THE CHAIRMAN: It was not introduced from the United States in the first instance?

A. No, not as far as we know.

THE CHAIRMAN: One other thing, just before we -- I am sorry to keep interrupting.

A. That is fine.

THE CHAIRMAN: It will at least help to clarify in my mind: we have had evidence that some patients in the late 1970s certainly and early 1980s, who were diagnosed as having post-transfusion hepatitis, were told, "It is probably not very serious". Was that the general view at that time?

A. Yes, there were -- that was based on the fact that outside of the haemophilia population and a few studies actually amongst the haemophilia patients with non-A/non-B, liver biopsies were done, and the liver

biopsies showed what we call lobular hepatitis, which just means that the inflammation was spread throughout all parts of the liver lobule. There was very little fibrosis. Fibrosis is scarring, and, as the damage continues, then that scarring ultimately adds up to something which we now know as cirrhosis.

So there was this lobular hepatitis but very little fibrosis, and it was a chronic lobular hepatitis, so the transaminases would go up and down. We were not sure whether that was related to reactivation of an endogenous virus due to this immuno-comprised that you saw when you transfused large amounts of plasma proteins into patients, or whether it was each time you were introducing a virus and you got reactivation or renewal of a virus coming in.

But in the literature, in the 1982/1985 period, there are several statements that this was thought to be a mild disease. If you just did the biopsy, it looked just like an acute hepatitis, which, as I mentioned, comes and then gets completely better, but the fact that it goes -- you get repeated episodes, of course ultimately does result in scarring and cirrhosis.

THE CHAIRMAN: Yes, thank you. I am sorry, please go on.

A. So on the natural history, as I say, a fifth will get cirrhosis and 2 and 3 per cent get hepatocellular

carcinoma.

As we followed patients for longer -- and this has been really in migrant populations where infections occurred at an earlier age than in the UK, so, for instance, in South Asia, we see infection in the first years of life, so when we see them in their 40s and 50s, they are many years into infection. In the Bangladeshi community, for instance, in East London, it is clear that 30 and 40 years out into the infection, you get progressive cirrhosis; in other words, it is not 20 per cent and that is -- picked out a group that is going to get it, however long you study them, it goes on.

Similarly, amongst the cirrhotic group it is 2 to 3 per cent who develop liver cell cancer every year, and that has gone to cumulative incidence of about 20 per cent in the cohorts that have been studied.

THE CHAIRMAN: Then I suppose life expectation is fairly limited?

A. Yes of those with cirrhosis, about two thirds die of what we call decompensation. They develop liver failure and that group come forward for liver transplantation. About one third die of hepatocellular carcinoma and the treatment of choice for that, if we get it early -- and there are criteria for what constitutes early -- those

patients actually get a liver transplant. But afterwards, the transplanted liver gets reinfected on almost 100 per cent of occasions and that progresses more rapidly than it does, probably because of immunosuppression, than it did prior to the transplant, the first time around, if you like.

So a significant proportion of patients will have cirrhosis after five, six, seven years, whereas, as I mentioned, we don't usually see it until after 20 years in the non-complicated situation. That is of relevance, of course, in haemophilia, because where -- there you have got HIV infection as well, and I think in that group of course, with HCV and HIV, there is a more rapid progression analagous --

THE CHAIRMAN: Because the immunosuppression system is not working?

A. Exactly. As far as treatment is concerned, that has come on in leaps and bounds. The virus was found in 1989, we had the diagnostic tests and also tests for documenting the amount of virus in an individual's blood, which meant that we could then start to screen compounds for activity in an empirical way. Interferon was the first that was used. That only cured about 10 or 12 per cent and the first randomised controlled trials in the UK, we did at Royal Free, my group did

those, and similar studies were done in the US, and they were done in 1987 actually, before the virus had been discovered, and that, really, we thought, since interferon works against viruses, was confirmation that it was a virus.

But people relapsed almost immediately that we stopped treatment, and interferon was in limited supply, it was lymphoblastoid interferon. And then two or three years later -- 1989, something like that -- interferon was cloned and then large amounts of genetically-engineered interferon became available. That could then be given for longer periods of treatment, but, again, we only saw 10 or 20 per cent response rates.

It is really only gone on to be an acceptable form of treatment, in so much as large numbers of patients respond since we have had what we call pegylated interferon, which is a long-life interferon. Instead of being given thrice-weekly, which is what we used to have to do, pegylated interferon can be given once a week. It just has a longer half-life. In all other respects, it is the same as the native interferon.

We added a drug called ribavirin to it, which stops relapse. With that current so-called gold standard treatment, which is the treatment recommended by NICE as

of 2000 or so, depending on the genotype of the virus -- and you know there are several genotypes -- genotypes 1 and 4, we cure, and it is a cure. It is not like HIV, where, when you stop the treatment, it comes back.

But genotypes 1 and 4, when we give this treatment for a year, then about 40 per cent of people are cured. With genotypes 2 and 3, when we give this treatment -- and we only need six months in this context -- then we cure about 70/75/80 per cent.

THE CHAIRMAN: May I just ask what may be a obvious question: presumably this doesn't carry a risk of infection?

A. The interferon, you mean?

THE CHAIRMAN: Yes.

A. No, I mean, when interferons were first used -- it is the 50th anniversary of the discovery of interferon, so I have it quite clear in my mind because there was an anniversary meeting in Oxford just this last weekend. There was a guy called Kerry Cantel(?) in Finland who made interferon from the white blood cells obtained from blood donations. He stimulated those white blood cells with a virus and collected the interferon, and that of course then had to be sterilised, because he was adding a virus to stimulate the release of interferon, but that really was not used after about 1986 and that was

because lymphoblastoid interferon became favourable and that was made in a tissue culture with standardised conditions where there was not a concern about viruses carried through from the donors of white blood cells as there was with Kerry Cantel's material.

THE CHAIRMAN: I see. So until then, there was a possibility it might have been carried through?

A. There was a possibility, but, you know, you would have to be a really tough virus to get through what they did to it, because they spiked it have varies viruses and then showed that those viruses were killed in an experimental situation, and then looked to see if they could retrieve the virus in the tissue culture to make sure that the stringent conditions they were using then, which hopefully did not denature the interferon, destroy the interferon, but did destroy any viruses that would undoubtedly have been around.

That in the main, as far as I know, was a very safe preparation. But after 1986, and its widespread use, I don't think there has been any suggestion of carry over of viruses from either the cell line or the genetically-engineered material, which is of course totally free of those risks.

So I think that is where we are with current treatment really, and I think it is a good prospect

really. Overall, we cure about 55 per cent of all the genotypes that are out there.

THE CHAIRMAN: I am sorry, I interrupted you. Do you want to --

A. I think that is really is all I have to say on the natural history and the treatment. There is a lot of work going on to develop future treatment and perhaps I should make the point that, when people have cirrhosis, then the response to this gold standard treatment of pegylated interferon and ribavirin drops to about half of what you would otherwise see.

So, for genotype 1 and 4, it might go down to 20 per cent instead of 40 per cent in a non-cirrhotic patient, so there is a premium in identifying and treating people before they have cirrhosis.

THE CHAIRMAN: I think that is really it.

DR JONES: I would like to thank Professor Thomas very much for his submission, which was most helpful.

Just one point of detail relating to the submission: in view of the -- I will quote from paragraph 118 of your submission:

"All cases suffer recurrence of infection in the transplanted organ and usually the disease progresses more rapidly to cirrhosis than in the non-transplant situation."

In view of that factor, and the shortage of donor organs, does that actually reduce the chances of a haemophiliac being -- or a -- someone with hepatatis C rather, sorry, cirrhosis, being offered a transplant?

A. Yes, it does, because in order to be objective about who gets transplants -- I can't give you the historical background but I can tell you where we are with that at the moment: one thing that the NHS prides itself on is having equity of access and in an area where we have got only 600 or 700 organs and we probably have 2,000 or 3,000 people needing transplantation, we have come up -- when I say "we", I mean the medical community around this -- have come up with some criteria which would be that you would have a less than 50 per cent chance of surviving a year, were it not -- were you not to have the transplant, and you should have a greater than 50 per cent of surviving, I think, five years, if I have remembered the data correctly, but it is very prescriptive really.

Then there are algorithms developing for each disease, which tell you at each stage what the chances are of surviving a year. With hepatatis C, the real problem lies in the fact that, after transplantation, the survival rate is less than you would get with non-HCV related diseases. In fact it is one the worst

groups now in terms of survival after transplantation.

The auto-immune liver diseases, primary biliary cirrhosis and auto-immune chronic liver disease, I think they do best with transplantation. There may be 90 per cent, five years' survival.

Hepatatis B, we can prevent the graft getting reinfected and they do pretty well now. Alcohol-related liver disease, in people who are abstinent, they have given up taking alcohol and we transplant them, they have a better survival and the worst of the lot is hepatatis C.

I think, as an optimist, that will change, because at the moment the reason we have done so well in stopping a recurrence of hepatitis B after transplantation is because we have drugs that don't involve interferon. Interferon amplifies rejection. So we don't like to use that after a transplant, whereas the nucleoside analogues, which just inhibit the nuclear replication of the virus, the ability of the virus to replicated, those drugs we have for hepatitis B and we use them after the transplant along with antibodies to stop the virus getting to the graft, and we can almost stop it in all patients.

I think in the next five years we will have non-interferon treatment for hepatatis C. There are

about half a dozen drugs that are coming through and we will give those then in the run-up to transplantation and afterwards, and I would guess then hepatatis C will come forward in terms of results to the level that we have achieved with hepatitis B.

THE CHAIRMAN: Thank you very much.

DR JONES: Could I ask you one or two questions about some of your other roles really?

A. I should say -- when Professor Turnberg asked me to come along, I emphasised that I am coming along as an academic really, although obviously I do serve on these advisory committees. I have the same view, I think in both contexts, so I don't think you should be overly concerned about that, but I am representing myself, not any of these committees, is what I should say.

DR JONES: At one time you were a member of the UK Advisory Panel for healthcare workers affected by blood-borne viruses. Could you tell us something about the working of that panel and what it does?

A. The Advisory Group in Hepatitis is the group that I chair and their mandate is really to give advice to the executive, to the Department of Health on how to control infection, from the hepatitis viruses.

The advisory group for infected healthcare personnel really is a group really looking at individual cases.

So if somebody, for instance a surgeon, has transmitted hepatitis B or C to a patient, or HIV for that matter, then that would go to this advisory panel and they would look at what the individual was doing and could he or she continue, but taking out procedures that would transmit; in other words, could we make that individual safe.

So that was a more focused committee, looking at the issues around individuals, whereas the Advisory Group on Hepatitis, for instance -- we produced at the end of Banatvala's time as Chair and the beginning of mine -- we produced recommendations for how we should deal with hepatitis B, and then, in my Chairmanship of the committee, we also made recommendations on how we should deal with hepatatis C being transmitted by surgeons and other people doing what we call exposure-prone procedures, which are procedures where your hands are inside the patient's wound, where in that context, if you pricked yourself, there would be a chance of infection.

So the AGH came out with those recommendations and then the Advisory Group for Healthcare Workers would have to implement those and see if they could get a good result that was safe for the patients, but also meant that the individual continued contributing as a surgeon

or an obstetrician or whatever, but in a safe mode.

DR JONES: It was, though, essentially an advisory group? It didn't have many teeth? Or did it?

A. Well ...

THE CHAIRMAN: Was its advice usually taken?

A. The Advisory Group on hepatitis --

DR JONES: No, I meant the panel for --

A. For blood-borne viruses? The advice was delivered through the Department of Health, but I think in the main they did take the view of the committee. It was always made clear in these committees that they are advisory committees, but the Executive, I think, also takes the view that it is unwise not to take --

DR JONES: No point in having an advisory committee unless you listen?

A. The only thing I would say is that the Executive, of course, have to integrate issues other than the one that they are giving the advice on, so, for instance, they have an advisory group on HIV, as well as the one on hepatitis that I chair, and of course one of their functions, I think, is making sure we are doing comparable things with regard to those viruses so that there are not inconsistencies really.

I think where there have been issues, it is usually because of integration into a larger framework, a larger

perspective.

DR JONES: Thank you very much. You are also a member of the National Expert Panel on new emerging infections. Could you tell us something about the work of that panel? For instance, are you chiefly concerned with Prion diseases or what?

A. That panel was set up really because of the risk from SARS and Avian flu, and in order to get a wide -- at least, I believe this is why it was set up: in order to get a wide perspective, they wanted the Chairs of all the advisory groups, so that -- for instance, there is an advisory group on antibiotic resistants, there is an advisory group on hepatitis, HIV, what have you, there is a veterinary group, and it was a bringing together of all this expertise to try to undertake horizon scanning, really to anticipate problems before we actually got hit by things like SARS or HIV or what have you.

That is a difficult task, but I think they have a very good system now for risk assessment, where you can look at, you know, with any pathogen, what its probability would be of causing an epidemic and what the consequences of that would be and what the chances would be of intervening in a timely way that saved people's lives. So that committee functions in that area.

DR JONES: That presumably advises, again, the Department?

A. It advises the Department, yes. I think it reports to the -- through the chief medical officer to the ministers.

DR JONES: I have one more question, but perhaps I have spoken enough.

THE CHAIRMAN: Please do, we are all right for time.

DR JONES: I just wonder, do you have any views on the present mechanisms for ensuring the safety of blood products? Do you think there are worrying deficiencies, or do you think on the whole it is pretty good now?

A. I think it is better than it has ever been really and I think what -- you can always make things better, but the bottom line really is how much it costs to do that.

I mean, for instance, if I give you the example of Prion disease, you know, there are who have been exposed, they have eaten beef and may have asymptomatic early stage Prion disease. Their leukocytes will contain the Prion in higher concentrations than serum, for instance, so blood is removed of white blood count cells now.

I can't recall precise figures, but I mean, to save -- prevent one case is hundreds of thousands, and just to give you an useful comparison, for instance, NICE argue that -- and this is an unofficial figure, so it can be moved either way -- that it is reasonable to

spend, as a community, up to £30,000 per quality adjusted life year gained, which is a measure of how much good it is doing. So again there is equity of access. So if you have coronary heart disease, or cancer, or hepatitis B or C -- and I have been involved with the NICE recommendations on B and C -- then you are not treating one group advantageously and the amount that is spent on preventing a death in a therapeutic sense compared to what is spent preventing transmission in a blood transfusion setting, it is chalk and cheese.

They are spending hundreds of thousands to prevent a case of Prion transmission and I think in terms of post-transfusion hepatitis B and C, you know, that is as rare as hen's teeth now, because we screen blood for hepatitis B and C. There are better and better screening tests. We can look for the DNA or the RNA of the virus rather than evidence of an antibody, but that will cost a lot more and it would perhaps --

DR JONES: It is not routinely done at the moment?

A. It is not routinely done, but that is a dialogue that is going on at the moment.

THE CHAIRMAN: Could I just ask two questions arising out of that? Clearly this network of advisory committees and panels was not available in the early 1970s, for example, was it? When did it begin to evolve? Can you

help us with a timeline?

A. I really can't actually, because I only know when I came into it --

THE CHAIRMAN: When was that?

A. I think I was on the Advisory Group for hepatitis for about three or four years before I became the Chairman, which was in 1999. So I was probably involved from about 1993, 1994, something like that. But Professor Banatvala, the Professor of Biology now, who has retired, was at St Thomas's. He could give you a picture of how long his tenure went back -- I tell you an easy way to get it, we can get it from the website, because all of these committees have a website and it will say, I guess, the history of it, I would think.

THE CHAIRMAN: That would be enormously helpful. The other thing that crossed my mind: I can't remember when NICE came into existence.

A. I can't remember either. I think it must be about 10 years ago, something like that. Something of that order.

THE CHAIRMAN: Prior to that, was there any committee which was required to take account of the cost of what it was recommending? Or was that the idea of NICE? It did, as you suggested; that it shared out the available pool of resources.

A. I think that of the whole idea of it. We wanted to have equity of access really across all the diseases, and I think to a large extent NICE has achieved that. You can look at -- look on it as a form of rationing, but I would ask -- you know, you need to come up with a better suggestion really, and I can't think of a better way of doing it than we have at the moment.

You could make it quicker by the way. I think after a drug is licensed, it sometimes take a year and a half for all the process to go through. But it is a very fair process, so, for instance, with the interferons, pegylated interferon is not better than thrice-weekly native interferon, but the evidence that came to NICE from the patient groups was that they preferred getting an injection once a week rather than three times a week, and NICE said, "Well, even though it costs another £5,000 to treat that patient, it is important that we do that."

So it is a very even-handed way of doing it, but it is pretty slow, and the Scots have a sort of quick and dirty system which I think often comes to the same conclusions.

DR JONES: Do you happen to know if Michael Rawlings was the first chairman?

A. I am pretty sure he was.

DR JONES: I rather think he was.

THE CHAIRMAN: We will be having, later today, I hope, some evidence on procurement of all this, but can you say, from when you entered, whether cost was ever a reason for not introducing something which clearly had a beneficial effect? The answer to that with NICE must be: yes, cost enters into this. But all the evidence we have had of the earlier committees dealing with this was, "We were not required to take account of cost. We just made the recommendations."

A. Yes, I think that is right. Advisory groups do deliver the advice but, I mean -- and there is a risk/benefit analysis that we are always invited to undertake, and the cost-effectiveness. This is in the Advisory Group on Hepatitis, so, you know, for instance, if we were to suggest that we screen all ante-natal mothers for hepatatis C, we would have to show that that is cost-effective, and that also there would follow from the identification of the case -- of hepatatis C, that we could we could do something about it, not only in the mother but also in preventing the child being infected.

We are engaging with a screening committee at the moment -- I think chaired by Sir Muir Grey -- to look at whether hepatatis C can be argued to be worthwhile to screen in the ante-natal setting. There is

a cost-effectiveness component, but I get the feeling that that has come in over the last decade more in a formal sense.

THE CHAIRMAN: That is rather the impression I was getting.

A. That is the impression that I have really, but until you shuffle up the system in academe and in these committees, you don't see this element of it. But I think that must have been an issue then.

The other thing is, I think, you know, the amount of Factor 8s that we had available to us, I think, in the early 1980s. I think, you know, if you look at the haemophilia directors, minutes of their meetings, I think in 1982 or something they argued that they had about a third of their Factor 8 concentrates from UK donor-derived material and two thirds from commercial, and there must have been a debate around that time that I have not been privy to.

THE CHAIRMAN: I think again we will be hearing a little about that later on today. Thank you. Judith?

JUDITH WILLETTS: Given the number of haemophilia patients who have been infected with both HIV and HCV, which you touched on briefly earlier on, clearly this is a major problem for a significant number of people within that community, can you say a little more about the complexities of the treatment and really perhaps what

the treatment options are for those individuals, and to what extent they are therefore limited and whether they are, therefore, a rather unpleasant position?

A. If I speak first of all about the non-haemophilia patient group, because the haemophilia patients have their care delivered through the haemophilia centres, and, as a hepatologist, I might get asked to see individual cases from time to time, but usually they deal with their complications of their patients. It is a comprehensive service, but outside the haemophilia population I think the prognosis has changed markedly. When you had hepatatis C and HIV and we had no treatment for HIV, then, as in the post-transplant setting, the progression of the disease was markedly accelerated.

However, if you -- my HIV colleagues at St Mary's tell me that now, with highly active retroviral therapy, the standard treatment for HIV, they can restore the immune system to virtually a normality and stop the decay that you would expect without treatment, and, under those circumstances, hepatatis C doesn't progress, which I think probably makes sense -- it does not progress more rapidly than it would in a non-HIV infected individual.

So I think there has been progress made there, but -- and there is a "but" coming in now -- liver

disease in HCV and HIV-infected individuals has become a problem now because of the side effects of the AIDS drugs; they cause fatty liver and all sorts of problems. So whilst we have probably solved the rapid progression of the hepatitis C by treating the immuno-compromise caused by HIV, the drugs themselves are causing problems and there are significant numbers of patients who are getting into problems with those issues.

If you then transpose it into haemophilia, the interferon treatment is given by injection and, initially, when I was at the Royal Free, and Peter Kernov used to invite me to see occasional patients, we were just using interferon there and we were looking at response rates of about 10 or 12 per cent and we were giving the intravenous injections along with the cryoprecipitate or the Factor 8 concentrates to treat those who already had non-A, non-B or hepatatis C by intravenous infusion, but then it became apparent that you could give it subcutaneously, usually at the appropriate time after the Factor 8 concentrates injections, and I think that has presumably moved on once the pegylated interferons became available. I say "presumably" because at the Royal Free, where I was at that time, up to 1987, had a haemophilia unit and a liver unit. St Mary's has

a liver unit, but not a haemophilia unit, so I don't take care of those patients since the introduction of pegylated interferon, but I imagine that is quite an advantage for them because it is one injection a week rather than three times a week, and that patient group then should be adequately managed with the same treatment as we use in the non-haemophilia group.

JUDITH WILLETTS: Thank you.

A. And you would have to treat the HIV as well, where that existed.

JUDITH WILLETTS: Perhaps we could find out a little bit more about that.

A. I think the haemophilia community could tell you really, but, as I say, I have not been involved since the better treatments became available.

JUDITH WILLETTS: Thank you.

MR MEHAN: Could I just ask: having hepatatis C, does that increase your risk of suffering from a haemorrhage?

A. Are you thinking about GRO-A ?

MR MEHAN: Indeed.

A. I have been watching that through the newspapers, so this is very soft data, but I think by the sounds of her symptoms I think she had a subarachnoid haemorrhage, which is usually a Berry aneurysm, it is a little outpouching of the blood vessels at the base of the

skull, which is usually there for decades before it actually bursts.

I think the interface with hepatatis C-induced liver disease would be that, whilst hopefully in you and I, if that happened, our clotting system might kick in and then you would get to hospital and the neurosurgeon would put a little coil in it and stop it bleeding, if you have clotting abnormalities due to cirrhosis -- and of course, that would be more of a problem in a haemophiliac with cirrhosis -- then you are going to bleed much more severely and there is less time then for the neurosurgeon to get in there and stop it.

So that is a lot of piecing together bits of information, but I think that would have had an impact.

JUDITH WILLETTS: Did she have cirrhosis? Did GRO-A have cirrhosis? She had cirrhosis, didn't she?

A. I don't know how much of that is privileged information.

THE CHAIRMAN: I don't know whether that was in the public domain.

JUDITH WILLETTS: I think it has been reported.

THE CHAIRMAN: I think it probably was in the press?

A. I don't think, were she around, she would mind one talking about it, because she espoused the area and was really trying it take it forward.

I think one of the things she tried to do was that

she tried to destigmatise hepatatis C. As you probably know, 90/95 per cent of people who get hepatatis C have acquired it through intravenous drug use -- and before you think that they are all down and outs, a good half of them are, dare I say, people like us who have dabbled in it at university. I am not speaking for myself now before anyone draws a conclusion, but there are a lot of people who have got it in that way.

But of course, there is a stigma attached to it and people won't comment, and that is one of the problems that those who have got it through blood and blood transfusions have. What she tried to do really was destigmatise that and she said that she was about to be seen in Cambridge for a liver transplant, which would mean that she would have cirrhosis.

THE CHAIRMAN: Thank you very much, Professor Thomas. That has been very helpful. May we come back to you from time to time as we follow up these things?

A. Do you mean by telephone or something?

THE CHAIRMAN: Yes, or whatever. Thank you.

MRS CAROL GRAYSON

THE CHAIRMAN: Thank you for coming back. The reason we suggested that you might want to come back and give further evidence was that you have sat through virtually the whole of the evidence we have heard, I think.

A. Yes.

THE CHAIRMAN: Presumably you have heard things which you would want to comment on, at least, or perhaps to question, so we want to give you that opportunity. Thank you for the second statement. Would you like to give us your own presentation?

A. I would. If I could read through, that would be quite helpful.

THE CHAIRMAN: Yes.

A. Thank you. My name IS Carol Grayson. I am the 47-year-old widow of Peter Longstaff, who is a haemophiliac. Both my husband and brother-in-law were haemophiliacs that died of HIV/HCV as a result of receiving contaminated factor concentrates. Peter died in 2005 and GRO-A in 1986. First of all, I just want to say thank you to the enquiry for allowing me to have a second submission and to Vijay for passing on evidence for me. If you have any questions, please just ask me as I read through it.

I have campaigned for many years and I formally set up my own campaign group, Haemophilia Action UK in 1994, running a "bad blood" campaign with the Newcastle Journal. The website for that is www.the-journal.co.uk, and if you search under my name, Carol Grayson. I also wrote an MA Dissertation entitled

"Blood Runs Not Just Through Our Veins But Through Our Minds: How Has The Global Politics Of Blood Impacted On The UK Haemophilia Community?"

This provided a critique of the Government Self-Sufficiency Report, which came out in 2006, and I used documents that the Government claim to have "inadvertently destroyed". I fought to have these documents released by the Government under the Freedom Of Information Act with help from Newcastle solicitors. My dissertation also investigated the impact of HIV/HCV infection on haemophiliacs and their families, exploring their attitudes to the national organisations and institutions that were set up to support them, and the National Haemophilia Society are kindly supporting the publication of the dissertation. It will go to the trustees shortly for a formal decision, and hopefully it should then be available to anyone who requests a copy.

I have basically divided my presentation into sections. The first one I have entitled "Undisputable Facts/Experimentation On Prisoners and Prisoners As Plasma Donors." This second submission has given me the opportunity to flag up certain issues, to tighten up my evidence and to challenge some statements brought to the Inquiry by previous witnesses.

The Inquiry is still considering the issue of UK self-sufficiency in blood products which was never achieved by the UK Government and why self-sufficiency was so important. I would like to start by reiterating the fact that my dissertation demonstrates, using evidence from many different sources which are all referenced, that it is an indisputable fact that imported factor concentrates were known to be manufactured from dangerous "high-risk" sources and transmitting hepatitis prior to the licensing of the first imported US products in 1973.

So I would ask once again: why was such a dangerous and unethical treatment, such as pooled factor concentrates, licensed not just for import, but licensed in any event prior to the manufacturers investing in finding a method of eliminating hepatitis viruses, which, I have to say, when HIV came along, they actually did fairly quickly. So --

THE CHAIRMAN: May I interrupt? You have probably grasped by now that one of the issues we will have to address is that, although it was known that the US products carried a risk of infection, products produced in this country were not sufficient to treat everybody. So the question was: do we refuse the treatment, or do we take the risk of the United States products?

A. Just to comment on that, that was because the Government failed to invest and -- there is a World in Action documentary, 1975, and William Maycock, who, at that time, was head of the Blood Transfusion Service, was actually quoted on that 75 programme saying that, had they invested in 1970, then the situation would have been very different. So basically, that was failure on behalf of the government, you know, from the evidence I have seen.

THE CHAIRMAN: Although, again -- may I put the opposite case to you so that you could comment on it?

What I think would be suggested is that the importance of self-sufficiency was not really grasped until at least the early 1970s. It was only when it became known that there were dangers of plasma which had been widely gathered that it became important to talk about self-sufficiency.

A. I would disagree, because that goes back to the 60s, from the evidence, and I have got quite a lot of research documents to show that pooled plasma was known to be dangerous in the 1960s, and if you look at America, they introduced factor concentrates before we did, so there was the experience from America.

If you have a look back to my dissertation, you will see there is some quite early references to that, and

that was why David Owen realised the importance of being self-sufficient. If you want, I can point you to those researches at a later stage.

THE CHAIRMAN: Yes, thank you. We have had them from you at an earlier stage, but we may have to come back on that.

A. What more do we know about the prison environment in which plasma was collected? I wish to elaborate on a specific issue briefly mentioned by Kelly Duda in his documentary, "Factor 8: The Arkansas Prison Plasma Scandal."

I wish to highlight that it is an indisputable fact that from the 1960s through to the 1970s US prisoners were used as guinea-pigs in a variety of unethical experiments which led to severe illness, death and a number of unmarked graves of inmates that did not survive this experimentation. I would like to draw particular attention to the link between the unethical experimentation on prisoners and the fact that prisoners also became plasma donors. Prison plasma was collected through a plasmapheresis programme, manufactured into factor concentrates, imported and injected directly into the veins of haemophiliacs in the UK.

I would like to draw the panel's attention to a British Medical Journal article by Allen M Hornblum called, "They Were Cheap and Available: Prisoners As

Research Subject in 20th Century America", which I have a copy of for you. It is an excellent article, but one key point is missing: there is no mention of the health issues of recipients of prisoners' plasma. The article informs us that, "Prisoners tested everything from tropical diseases and respiratory infections to infectious hepatitis", and then I have referenced the article.

It is an indisputable fact that what you had here was a captive group on which to experiment and a population of prisoners that were deliberately exposed to infectious hepatitis, amongst other things. From Kelly Duda's documentary we are made aware that it is an indisputable fact that prisoners admitted to having unprotected sex with other prisoners, shared needles to inject drugs, sold their blood and sometimes were moved between prisons, creating a reservoir of hepatitis infection throughout the penal system. This infection could be there as long as the prisoners were there and it is an indisputable fact that prisoners could still transfer hepatitis viruses to others years later, long after the viral experiments were stopped on ethical grounds.

It is also an indisputable fact that the UK Government and its licensing authorities sanctioned

treatment that came from unethical and highly dangerous sources. This was madness and went against all our own UK safety rules. I would like to submit two quotes regarding the experimentation, and this is related to the controversial career of Dr Austin Stough -- this is documented and quoted -- who worked on prison plasma programmes. Stough ran a business that 'claimed to have grossed close to $1 million a year. Stough -- and the pharmaceutical companies he worked for -- profited handsomely, while the inmates he used were made ill, and some even died, in an extended series of drug tests and blood plasma projects in Oklahoma, Arkansas and Alabama.

I have managed to trace some of my husband's treatment batch numbers, with the help of Kelly Duda, back to Arkansas State Penitentiary.

If I give you the second quote:

"Stough's high volume plasmapheresis programme attracted great commercial interest, but his poorly trained staff and shoddy operations resulted in inmate volunteers receiving the wrong blood type and as many as 30 inmates a month contracting viral hepatitis."

It is no surprise here that Dr Garrot Allen --

THE CHAIRMAN: Could you give us the references to those two quotes?

A. I have the article with me, so I will give everything to

Vijay. It is from the BMJ article.

THE CHAIRMAN: All right.

A. So it is no surprise here that Dr Garrott Allen -- and I have to say Dr Garrott Allen was ahead of his time. He had studied hepatitis since the 1950s and he was aware of the risks associated with prison plasma and he actually wrote to Sir William Maycock, who was, at that time, in 1975, head of our Blood Transfusion service, and warned the UK against importing factor concentrates -- that's in 75 -- and informed the UK of the "extraordinarily hazardous" non-A/non-B hepatitis risk with a risk level between 50 and 90 per cent infection rate from some products manufactured from prison blood with half of the cases proving fatal.

I have the letter in the back of my dissertation. He also noted that non-A/non-B hepatitis was a much more virulent strain of hepatitis more commonly found in prisoners.

Just to reinforce Garrot Allen's concerns about the very concept of factor concentrates as an ethical treatment, he was quoted as saying that drug companies had known all along that "no medical, economic or social reason could justify ever using pooled plasma and its concentrates. Large pools are highly profitable but medically bankrupt."

I would request that the panel -- if they would like to check back at some point to my first Inquiry submission, particularly the part "Safety Warnings to the UK".

I draw attention to the following quote from Dr Charles Rizza haematologist, reflecting on past knowledge of non-A, non-B hepatitis, and the quote from Rizza is:

"We recognised in the mid-70s and early 80s that all the concentrates were infected with non-A, non-B hepatitis. So why were patients not told this as part of the duty of care to inform patients of risk in order to make an informed choice regarding treatment?"

There is something else I would like to point out and that is when haematologist Dr Mark Winter gave his evidence here on behalf of the UKHCDO, he talked about non-A, non-B hepatitis being discovered in 1975. I have brought an article for you today, which is from "The Times", November 12th, 1974, and it is talking about the virus being discovered, so it is earlier than Dr Winter said. It says that:

"In the United States, up to 90 per cent of transfusion-associated illness is caused by this third non-A, non-B agent."

I would like to point out that in the US authorities

right up to the -- the director of the Centre for Disease Control were informed just how dangerous prison plasma was, as the July 1974 letter in my dissertation shows. I point out that this was never meant for publication, but it needs to be seen in the UK.

I would just like to give you this quote from this letter:

"Over a two-week period in February to March 1974, eleven clinical and six subclinical hepatitis cases were detected among inmates of the Kansas State Penitentiary. The majority were HBCAG-positive. Investigation revealed that 18 of these 19 cases were in plasma donors at the plasmapheresis centre; risk of hepatitis could not be definitely associated with the plasmapheresis programme."

What they were actually looking at, they were looking to see if things like reusing the equipment had caused the infection, but they would ruled that out, since:

"Intravenous drug abuse, including the sharing of needles was commonly practised by plasma donors."

Just something I picked up this morning when I was listening to Professor Thomas, and that is just to state that with haemophiliacs they would have been reinfected time and time again. I think that is perhaps what is

different with other patient groups and there has actually been some studies done on reinfection rates which I have somewhere in my documents.

I can't emphasise too strongly that this was the type of dangerous treatment licensed for import by UK authorities. The new wonder products that haematologists encouraged their patients, adult and children alike, to inject without informing them or the parents of the risks associated with these products.

THE CHAIRMAN: We have been told of course that patients found the new products preferable in many ways to the old ones because they could stay at home and didn't need to go to hospital and so on.

A. The advantages were that, with cryoprecipitate, you had to go to hospital, so obviously it took longer. And of course, if somebody is told, "We have this new wonder treatment and you can have it in your fridge at home and it takes less time", then people are going to want that treatment.

But of course, what they were not told was about the sourcing, where it was coming from and about the type of donors that were used.

THE CHAIRMAN: Your complaint is that individual doctors were not passing on to their patients the information which they had learned from the sources you have just

quoted?

A. Yes, because they were writing about it in their medical journals, but they were not passing on the information to the patients. So it could not be informed choice, because, informed choice, you have to know about the risks. Not small risks, but if you have high risk, which is medium to high risk, 50 to 90 per cent risk, then you have to inform your patients. And as Garrot Allen pointed out, the infection rate of some of these products was almost 90 per cent.

JUDITH WILLETTS: Is one the problems that it was not widely held back then that non-A non-B was particularly dangerous? Is that one of the issues --

A. I think it is one the issues, but I would have to say people like Garrot Allen were totally on the ball. So I think, because the majority hadn't picked it up -- there are always people that have the insight or do the studies that pick these things up. He had researched hepatitis from the 1950s in America, so he was in a perfect position to pick this up, and unfortunately people were so arrogant, I think, half the time that they were not prepared to listen, and obviously from the studies -- you know, we know from going back to the 60s -- the hepatitis rates were higher in America. So authorities here should have been listening to people

like Garrot Allen.

JUDITH WILLETTS: But wasn't he quite a -- not exactly a lone voice, but the -- kind of the perception of the danger of non-A/non-B, what seems -- from other evidence that we have heard was very different then, that it was not widely held to be a dangerous disease. Clearly, we know now that it is an incredibly dangerous disease but, although they may have been aware of the high risk of infection, it may possibly have been discounted or not deemed important enough to pass on to patients, if it were deemed that it were not a very dangerous disease.

I think there has been quite a lot of evidence that -- most of the evidence at the time is scientific and medical evidence -- was not actually pushing and demonstrating that this was such a dangerous disease, which may have been -- with this terrible ability to look back, the benefit of hindsight, we know very differently now, but at the time I don't think it was widely considered to be such a danger.

A. I would agree, in the sense that, obviously, as people were studying non-A/non-B, then they were starting to learn about the dangers and there were some early haemophilia studies in, I think it was, 1977 and -- '75 and '78, that were done by Crasse, so they were starting to be more aware. Certainly by '79 -- I mean

Diana Walford in the government was calling it a very dangerous disease by '79 in the government documents.

But what I would say -- yes, I agree with some of what you are saying, but what I would say was that before, you know -- obviously, before we had non-A/non-B, they should have been looking at hepatitis B, because, obviously, before there was a vaccine for hepatitis B, then these considerations should have been looked at with regard to plasma for hepatitis B infection, because, of course, what was happening was there was a higher risk of hepatitis B, of course, in the prisons and in America. So, had we taken better precautions for hepatitis B -- this has been one of the arguments over the years -- then we would not have used American plasma anyway, for that reason.

Doctors and scientists continually talk about the lower life expectancy of haemophiliacs in the past. Haemophiliacs did have a lower life expectancy before the introduction of cryoprecipitate -- that was significantly lower before then -- but it is important to remember that patients survived on cryoprecipitate for years before the concentrates were introduced. Some severe haemophiliacs were already well into their 30s before they ever used factor concentrates. My dissertation expresses the views of many haemophiliacs,

that their view, as they have since learned of the risks from treatment, is that the risks from factor concentrates far outweighed the benefits.

As I say, they could not make a decision at that time because they were not given information on the risks.

THE CHAIRMAN: In fairness, this is hindsight of course.

A. Yes, that is, but, as I say, there could have been a lot more information at that time. For example, hepatitis B was treated as if it was a mild dose of the flu, and it was not. I have done some work in prisons. If you go into prisons now, you see notices all over warning of the dangers of hepatitis B.

DR JONES: Could I just make one comment which is relevant to the point that you first made: I think going back to those times, when anyone talks about the incidence of hepatitis in a transfused population of any sort, that would have covered, in many ways, a multitude of sins because it would have covered people who were ill and a very sizeable number who were perfectly well but had abnormal liver function tests, and it was even in those days not uncommon to hear people refer to, almost laughingly, transaminitis. Do you remember that? Just relevant to what Judith was saying.

A. That is fine. I was working with people from about 1981

with hepatitis, so I remember -- obviously not as far back to the 70s, but -- thanks.

I would like to comment here that presumably the US plasma companies must surely have taken these risks into consideration when choosing prisons as a source of plasma. So I have asked the US lawyers -- and I spoke to one two evenings ago -- to try to obtain from the plasma companies their documentation on risk assessment regarding plasma collection in prisons.

For example, what documents do they hold on the deliberate infection of prisoners with infectious hepatitis, such as in Arkansas, and the deliberate exposure of prisoners to respiratory infections and tropical diseases? What information do they hold on prisoners who were sick or those who didn't survive the Auschwitz-like experiments, the ones who died and are buried in unmarked graves? What was the US plasma company's risk assessment regarding the dangers of collecting in prisons, given that, once prisoners were infected, these viruses could be there for decades and potentially in the plasma pool for years to come?

Could these American companies provide our lawyers with their risk assessment and can the UK Government explain why they considered such plasma sources to be safe, with regard to importing factor concentrates for

UK haemophiliacs?

THE CHAIRMAN: Again, in fairness, it doesn't follow that the committee who dealt with licensing, for example, thought that they were safe; they thought that the risk had to be measured against the risk of not treating haemophilia.

A. Yes, but, I mean, to use sources that they were deliberately infecting with hepatitis?

THE CHAIRMAN: I follow what you are saying, but in fairness what we were dealing with is balancing risks. Of course, we may well think at this stage that they got the balance wrong, but they didn't think, as you say here, that they were safe.

A. Not 100 per cent safe, obviously, but, yes, there is always a risk assessment. So I basically said, "Perhaps the Inquiry could take this issue to the Department of Health?" and I have asked my MP, Jim Cousins, to raise Parliamentary questions on this issue and also to remind Yvette Cooper that, when she was working in the Department of Health and met with a group of haemophiliacs and MPs, she promised that if we could approve that UK haemophiliacs had received US prison plasma that the UK Government would investigate this matter, and that is minuted.

We have proven this, but are now waiting for the

Department to act as promised. I would ask the panel to check out the US Department of Correction's document 1984, which I gave to Vijay in the past, which looks at both AIDS and hepatitis risk in prisons and the fact that there was a high risk in prisons -- and they actually say in their document that this would be an issue for haemophiliacs. Well, it would have been a huge issue for haemophiliacs in the UK, had they known the facts.

Then the names of the plasma companies contributing to this document and involved in using prison plasma are contained in that document.

I want to talk about paid donors now and current issues. I would like to come right up to date on the issue of paid plasma donors following on from what we have known for years about the dangers associated with paying donors in prisons, on Skid Row, et cetera, for their blood.

We currently import white cell plasma products from the US. There are some blood products where there is not a synthetic alternative, so some patients in the UK must still rely on human plasma. I want to draw attention to some current collection practices used by companies which supply the UK, and that is the use of paid plasma donors on the US Mexican border where

impoverished people cross over from Mexico to the US in order to sell their blood. Obviously, there are different safety levels, we know, in Mexico to the US.

There has long been a safety issue here regarding remunerated donors, and safety concerns and violations along this border were discussed in a documentary -- again, which I submitted to Vijay.

I have a further article here on this subject, a recent one, "Crossing the Border to Sell Blood", which is just a few months old, and there is a reference to it.

THE CHAIRMAN: We have the reference here.

A. I have a copy of it for you.

I cannot express enough the double standards in the UK by authorities that promote the safety standards of this country, such as the use of volunteer, unpaid donors and glossy publications and advertisements, yet turn a blind eye to importing plasma products from the US and companies that use paid donors. One of the companies named in this article supplied -- and I believe is still supplying -- UK hospitals. Certainly, my husband stopped taking treatment from this company around 2000 to raise objection to the use of paid donors. How can we go along with a practice that the World Health Organisation stated was dangerous and

should be stopped as far back as 1975? This is a practice that European Directives are supposed to have banned by April 2005.

In an article on the Euro Parliament blood donor ban, which is on the Irishhealth.com website, it states:

"Voluntary and non-remunerated blood donation was an important means of ensuring safe blood and reduced risks to both donor and patient. Experience has shown that the type of person who volunteered to give blood was difference from the type of person who might feel compelled to give blood for payment. Therefore, MEPs said blood and blood components should be collected from voluntary and non-remunerated donors only."

Yet Britain chooses to ignore its own safety standards not to use paid donors and import products from remunerated donors.

THE CHAIRMAN: Are you saying that we still import products from paid donors?

A. Yes, we do, that is exactly what I am saying.

MR MEHAN: Certainly to reduce the risk of VCJD, so we still import commercial products from the United States.

THE CHAIRMAN: Because we are still not self-sufficient. I follow that, but are you saying that those are produced from paid donors?

A. Yes, that is exactly what I am saying. There are some

voluntary donors but a lot of blood collection. We checked this out and this is documented in recent articles: come from paid donors.

THE CHAIRMAN: Do we have the article here?

A. Yes. I can't name it, but I can refer to you a particular company.

JUDITH WILLETTS: Do we not have more sophisticated screening methods now?

A. We do, but what happens when the next virus comes along?

JUDITH WILLETTS: You cannot screen for the unknown. I think the point of importing was that there was less likelihood of variant CJD from overseas than from UK plasma.

I suppose my point was: if that is the case and they can screen for the other viruses that we do know about, would it therefore not actually be a safe product?

A. I would like to answer that because I have a really good example for you and that is that my friend's son is at university -- was at university in America on a sports' degree and he used to go and sell his plasma quite recently to pay his -- to help him through college.

Now, the point of this is that he would not be allowed to donate in this country because we cannot collect white cell plasma from people in this country. This is what I am saying about paying donors. When

I explained the risks and that he might be putting other people at risk, he was quite shocked, and there is a documentary which I gave to Vijay as well, which showed a documentary team and they stepped off a plane, and they had come from France, and they went to one the collecting centres and they were accepted as donors to sell their blood.

THE CHAIRMAN: Were they questioned about their history or tested in any way?

A. I don't know, but they were accepted as donors, and certainly my friend's son --

THE CHAIRMAN: I can see your point about paying donors, but at least in fairness your friend's son has a rather different lifestyle from the lifestyle of some of those that we hear about who were donating blood in the 1970s.

A. Actually he was really honest with me and he wrote me a testimony and, you know -- I know this is not going to affect anybody but he had had a drink and he smoked dope before he went and he still got accepted. He took with him a friend of his from Peru. There is a rule in America that you are not allowed to collect outside, I think, a 50-kilometre radius, and one of the issues is that, if you are accepting donors that have come from different countries, there are different diseases, so there might be diseases in Peru that we don't have here.

So what I am saying is -- and he said at university all over there were notices, you know, "Come and sell your blood," "Bring somebody with you," "The more people you bring, the more we will pay you," "We will give you incentive money." This is my point about selling blood and this is why we should not go along with that. That is why we have our own volunteer system.

I just wanted to use an example -- and I think it might have been Mike that had brought this up at one point: if we look at the recent example -- it is a good example -- in the press of American toy manufacturer Mattel, where they imported toys from China which failed to reach the safety standards and the laws of America, sanctions were placed on the manufacturers and in some places bans put in place. This is a very recent issue.

What I am saying is that we should be giving a clear message to US manufacturers that still use paid donors for products exported to the UK that we will not buy their products unless they meet our safety regulations, and one of those regulations is a ban on the use of paid donors. And then I refer to another New Scientist article here.

THE CHAIRMAN: You would apply that test at the point of licensing in this country, would you? Someone has to say they cannot come in?

A. Yes, I think somebody has to check whether the donor is a volunteer or remunerated, and an interesting point, going back quite a lot of years now, was the plasma companies decided that they would not put on the plasma bottles whether the plasma came from paid or volunteer -- because one was possible litigation and the other was that people wouldn't want it.

THE CHAIRMAN: The question I was asking was, who do you suggest in this country should stop this happening? Presumably the licensing authorities?

A. Licensing, yes. It would have to be, I think, at that level. There should be checks. You know, is this blood coming from paid or volunteer donors? I think this double standard after 30 years is incredible. Surely we must ensure that overseas manufacturers reach our high standards of safety regulations if we are to import, not fall below our own safety standards.

I would ask the inquiry panel to recommend to government to place a ban on products that still use paid donors, as this practice remains a cause for safety concern and also an example of exploitative and unethical practice.

I would also ask that the UK Haemophilia Society review their current policy of accepting lower safety standards for haemophiliacs with imported products and

join me in fighting for the highest possible safety standards and not to compromise on this issue, as they have in the past. If they had fought to ban the use of import that used paid donors years ago, many more people might be alive today.

Companies have had many, many years to change their practice -- from 1975 -- and switch over to volunteer donors but, so long as Haemophilia Organisation and the World Federation of Haemophilia itself promote the use of paid donors, there is no incentive for international companies to improve their practice. Why should haemophiliacs in the UK not expect the same safety standards with blood and blood products as every other citizen in the UK.

I have recently written to the William Clinton AIDS Foundation to request that he both addresses the past issues of prison plasma, particularly the problems associated with the plasmapheresis programme at Arkansas when he was governor, and the global spread of HIV/HCV, and call for a global ban on remunerated donors in his fight to combat the spread of AIDS.

I think I may have sent you the article, but that is the article that I have had recently.

THE CHAIRMAN: Yes, you have.

A. That is an article by Mara Leveritt, which addresses

this issue.

There have been very recent global examples of countries using paid donors that have led to many more infections and deaths, China being one of them, which I visited last year.

Clinton's AIDS Foundation have replied to me and acknowledged my thoughts/insights on the global blood trade, but I am still waiting to hear how Bill Clinton will actually address this issue, and he will be sent a copy of the dissertation and a response will be requested.

HIV testing.

I read Dr Mark Winter's accounts of the early days of HIV testing on haemophiliacs and want to raise some questions on matters of concern and perhaps there are other witnesses here today that could help provide answers to the issues I raise. I would also like to point out that I too worked in the Health Service during the 1980s, when the test was first introduced. I was a nurse caring for some of the first AIDS patients in the UK that came through the psychiatric and addiction services. I felt rather disturbed when I read Dr Winter's account of haematologists' practice at that time and therefore feel I need to present another model of practice that was being carried out during the same

period, as I would be horrified that my former colleagues and I would be associated with the sort of practice to which he refers.

I would like to start with the following quote:

"In September 1985 the HTLV-3 test as it was then called was widely introduced. It was offered at GUM (Genito-Urinary Medicine) Clinics and certain other clinics, as arranged and publicised by the District Health Authority. Health authorities were asked to provide counselling services to people who tested positive, as well as their families and friends."

And that comes from a Department of Health and Social Services booklet, October 1985. I have with me my husband's first positive test result, which is dated 25th March 1985. The specimen of blood was collected on 13th March 1985. I would like to know whether haemophiliacs were used to evaluate these early tests, as I believe they were. This raises a number of ethical issues. My husband and his brother GRO-A were not blind tested here. The test forms have their names and details on them. Yet I hardly know of any haemophiliac that was asked if they consented to taking part in evaluating tests. I have with me a letter from the recently released government documents dated March 26th 1985 to a Middlesex hospital, talking about the

evaluation of anti-HTLV-3 kits, about the need to evaluate them and the need for a suitable protocol, as "There is not a suitable protocol". This is dated the day after my husband's test result.

A DHSS letter of May 31st 1985 reads:

"This is a follow-up to our conversation this morning about the importance that ministers and the department attach to completing the evaluation of the AIDS test as rapidly as possible and to have in hand the further steps that are needed when the widespread introduction of tests takes place. CMO and I will be reviewing with ministers on 7th June the position and I will be grateful if you could let us have a flowchart with dates as to when the evaluation studies will be completed and when the service will be geared up for the countrywide introduction of the test, with take-up facilities for confirmatory tests."

A further draft letter states that a report on some kits would be ready by June 85, again after my husband and his brother were tested.

I fully understand the need to evaluate test kits. I do not have a problem with that. But there are serious ethical implications that could have been addressed first with any study group. The early testing/evaluation of kits should not have compromised

patient care but it did.

DR JONES: Could I interrupt you? Could you just elaborate on that a little bit:

"The early testing/evaluation of kits should not have compromised patient care but it did."

A. I was just going on to say -- I will just read the next bit; it might make more sense: The Department of Health was very clear that counselling should be provided to patients with the introduction of widespread tests, as detailed in the circular of 3rd May 1985, and that trained counsellors must be put in place in preparation for the introduction of the test.

That is what I remember from my own experience as well. What I am saying is, when you are evaluating a test, you know, and you are not telling people you are testing them, you haven't got the back-up in place -- you know, they see in the news from 1983 that there is this deadly dangerous virus. The first thing they know -- and I will go on to explain. For a lot of people the first they knew of the situation is when they were told they were positive. They didn't even know they had been tested and they were just left.

DR JONES: So the compromising of patient care that you are referring to is the mental consequences?

A. Yes, and I will explain a little bit about that further

on.

THE CHAIRMAN: It is the consent point rather than the actual treatment?

A. Yes, because, as I say, things always have to be evaluated and as a nurse I do not have a problem with that. What I do have a problem with is the ethics. Once again haemophiliacs were treated as guinea pigs and appear to have been used as an early test group to evaluate kits before they were on the general market, without a thought as to how these patients and their families would deal with a positive test result (a) because their informed consent was not sought in the majority of cases; (b) they were in many cases being given a positive result without knowing they had been tested in the first place; and (c) the doctors delayed for some time, or in some cases completely failed, to put a system in place to provide counselling support and to deal with the terrible fallout.

As mentioned in my previous submission, the importance of informed consent and the ethical considerations around this were raised years before in the Nuremburg code following the terrible medical experiments of Auschwitz and other concentration camps.

In his testimony Dr Mark Winter quotes from Simon Garfield's "The Age of Innocence", page 55, which

is a book I am very familiar with. He refers to doctors at one hospital, one of the major AIDS treatment centres, not specifically working with haemophilia patients, and the quote read:

"We performed a large number of HTLV-3 tests without written consent. Blood was taken from patients with AIDS, patients with lymphadenopathy ... and controls."

Dr Winter argues that this was a pretty widespread practice, very different to now. He stated that the idea that you needed to explain at all times to a patient what blood tests you were doing was not held to be the case. I would agree with Dr Winter on certain points, and that is that many doctors were behaving in an unethical way and failing to obtain informed consent. They failed to follow government guidelines regarding informed consent and also to offer counselling.

I would just like to refer to --

THE CHAIRMAN: Just pausing there, Dr Winter was saying we are looking at the whole thing through rather different eyes now but this was the view being held in those days.

A. I was working with the first AIDS patients and we were -- before --

THE CHAIRMAN: I think he was agreeing with you, probably, was he not?

A. No, because what Dr Winter was saying -- he says in his

own submission -- was, people were being -- they were being tested and the blood was being taken and there was not informed consent. What I am saying was that, when I was working at that time, when we knew there was -- the HIV test was going to be introduced on the unit where I worked, then we sat down and we drew up guidelines for pre- and post-test counselling. I will go on a bit because I need to probably explain that a bit further.

I would just like to refer to advice from the Government's chief medical officer, Dr Donald Acheson, at that time. He advised against testing for AIDS "unless a specific request has been made." That was his quote.

Acheson was in the position of chief medical officer from '83 to '91 and he was actually quick to realise the need for counselling and support to those requiring a test and proving positive. Then by '86 the "Don't Die of Ignorance" campaign followed, with health education advertisements on TV, and by '87 a leaflet on the same theme was delivered to every house in the country.

I know haemophiliacs have a bit of a negative view of that campaign because obviously there was a lot of prejudice because of the campaign, but, in terms of health education, it was probably one of the campaigns that people throughout the country can still remember.

The newspaper article tracking the virus by the blind route, by Philip Young, describes the ethical debate that was raging at the time of the introduction of the test between human rights activists for the gay community in the form of Terence Higgins Trust, which incidentally was formed as early as 1981, and other AIDS organisations and one north east haemophilia consultant.

Terence Higgins Trust were warning that:

"Telling unprepared patients they have HIV can have a devastating psychological effect."

And, as Philip young writes even totally anonymous testing presents problems. The very nature of AIDS means that random HIV screening could break World Health Organisation guidelines, and civil rights groups, among others, claim it is wrong to test a person's blood without their consent.

Viewing this situation through the eyes of a former psychiatric nursing sister, I really wish there could be some proper medical assessment of the psychological damage done to haemophilia patients as a result of unethical practice in a number of areas over the years.

Then, to continue, if I could quote Jo Dutton, spokesman for AIDS north at the time:

"I believe that medical investigation should only be taken for the benefit of the patient concerned."

Young states:

"His argument goes to the core of doctors' ethical dilemma."

There is further mention of the consequences of testing, psychological and financial, if a person is positive, and the responsibility to prevent the infection of others. I can give you a copy of this article.

I am not sure why Dr Winter and others were not aware of this debate. Certainly, the gay community were very much on the ball and active on this issue throughout the press from the very early days of AIDS.

As a practising nurse, this was very much an important issue at that time. Some of my closest friends, that were also my work colleagues at that time, were gay men, so I was fully aware of the issues that the gay community were putting forward to the media.

The consultant in the article mentioned advocated tracking the virus by blind testing. In the northeast, where this person practised, patients were tested around March 85 often without their knowledge and informed consent on a named patient basis. Patients often have their blood taken, for example for clotting levels, but that is very different to having an HIV test. This so-called "AIDS expert", as he was referred

to here, was the same person that made an official complaint to the Press Complaints Commission in 1983 against journalist Susan Douglas simply for highlighting "killer blood" sourced from "high risk" donors coming in from America -- that article was the Mail on Sunday, 1st May 1983 -- and putting haemophiliacs at risk of AIDS.

She identified the first haemophiliac sick with AIDS in the UK, actually before the authorities did. Dr Galbraith actually made reference to this article when he called for all US blood products manufactured after '78 to be withdrawn from use in May 1983. The complaint by this haematologist almost wrecked Susan Douglas's career. She had researched her subject well and was telling the truth. I am in contact with her now and she has never received an apology to this day. I find it very disturbing, when I see evidence in haemophiliacs' records, especially those that were mild, in one case with a 87 per cent clotting factor level, that they were given their first imported factor concentrates after May 1983.

I can tell you more about testing of haemophiliacs in the north-east of England. I have met with a number of patients and their memories are all very similar. Patients were given their results, most not knowing that

they had been tested and then some were subjected to an examination. Those that were told they were positive recall being asked to pull down their underpants and lie down and pull up their knees while their rectal area was examined. Some patients were told nothing; others were told that the consultant was looking to see if there was anal dilation.

At that time haemophiliacs and gay men were known to be in a high risk category, but the usual procedure, in my practice anyway, would have been to educate patients as far as possible about AIDS and explain about high risk groups, which would include asking a person whether they considered themselves to be in any other high risk group. I would not have expected any patient to be subjected to a rectal examination unless they themselves had identified the problem, an infection, pain, et cetera. One person examined at the time was 14 years old.

Dr Winter talks about the culture of the time and without doubt in many haemophilia units, though not necessarily on other units, there was a culture of paternalistic prescriptive care with little thought for the need to involve the patient in the decision-making process.

My dissertation explores how this extreme power

imbalance affected patient treatment. As mentioned, I worked as a nurse at the time. My unit had prepared guidelines for pre- and post-test counselling, as advised by government, prior to the tests being introduced. We obtained informed consent as part of the patient contract, which was also recorded in the medical nursing notes, and we provided the necessary ongoing support to our patients.

A patient contract meant that you sat down with a patient, explained the services on offer, discussed their expectations and devised a care plan acceptable to both care provider and patient. The patient then signed the contract, that they understood and agreed with their plan of care. This, to my mind, was just good practice.

It is important that the Inquiry is aware that there are alternative treatment models being practised at that time. I wish to point out that there is a principle in law called the Bolam principle, which is one of the rules used to determine the issue of professional negligence where the defendant has represented him- or herself as having more than average skills and abilities. One rule is that a doctor, nurse or other healthcare professional is not negligent if he or she acts in accordance with the practice accepted at the time as proper by a responsible body of medical opinion,

even though some other practitioners adopt a different practice.

I continually ask myself, where does the law stand if the majority of haemophilia doctors dealing with AIDS patients were adopting unethical practice in a number of areas, which went against government guidelines and duty of care to patients. Can there ever be circumstances in medical law where the majority get it wrong and must accept the consequences, or is it that just the fact of being in a majority protects certain people no matter how unethically they behave?

MR MEHAN: The issue is, the non-consent or information about the test doesn't create a harm or an injury as such. So that is why --

A. What if it's psychological?

MR MEHAN: It would have to be a recognised psychiatric condition. As a lawyer --

A. That is fine, Vijay. In our community there are recognised psychological conditions.

THE CHAIRMAN: Presumably, you are not asking about whether there might be compensation at law; the point here is whether they were doing something which in a court of law might have been designated as negligence?

MR MEHAN: That is right.

A. If it was documented in patient's notes -- and bearing

in mind I worked in psychiatry and I dealt with haemophiliacs that came in with psychiatric conditions when they found out they were positive. Would that be --

THE CHAIRMAN: I think what you are saying, Mrs Grayson, is that, although normally one test of whether someone is negligent is whether they acted in accordance with majority opinion among those who were qualified, you say, even if they did, it would not necessarily follow that they were right.

A. That is what I am saying, thank you.

Testing without informed consent, withholding of test results, continued long after HIV testing right through to hepatatis C testing. I wish to highlight the case of a haemophiliac that came to visit me recently with his medical records to confirm his case. He wishes to remain anonymous but I am sure he would speak to the panel in private if necessary providing his confidentiality was maintained.

He recalled how he only found out that he was HCV positive when his wife opened a letter in 1998 which was meant for the GP but went to the family home by mistake. When he confronted his consultant, he was told that his parents had been informed in '93. They insist that this was not the case and, even if it was, the person

concerned was 21 at that time, so the consultant actually had no right to tell his parents and not the infected patient. There was no informed consent to tests sought from the patient himself. HCV testing was introduced in 1991, so why did it take two years for this person to be tested, when a letter in his notes from 1982 refers to illness -- and he was quite jaundiced as a 10-year old boy -- due to an attack of non-A/non-B hepatitis, so he should have been a priority case for testing. He could also have unknowingly put his partner at risk of an infection and his child.

I ask myself, was this man another of the northeast patients to be originally tested in '91 but not told until years later, alongside my husband and others, that they were positive. What struck me as deeply saddening was that this person had until recently had the utmost faith in his doctors and is now left confused, bewildered and angry that those he so trusted let him down.

That is one of the points I am trying to say. Even now -- because a lot of information was not out there, people are still having reactions now. This man is really quite angry and upset at the moment.

The evidence of people tested without their informed consent and permission and results withheld for years

brings into question again the hepatitis legal waiver in 1991, particularly where doctors were assisting lawyers with patients' medical records for the HIV litigation and knew that many of their patients would be positive. In some cases there were actually positive test results in the notes.

I would also bring to mind a House of Lords ruling in 1984 that tightened up a patient's right to know of medium to high risks associated with their treatment, as these risks could impact on their lives. I believe, if haemophiliacs had been given the correct information from doctors and lawyers on the dangers of hepatatis C in 1991 and told that they were highly likely to be infected or had been proven already to be infected and could become seriously ill or die, as was actually written in the legal pleadings of the HIV case -- for hepatatis C -- or in some cases, as I say, given their positive test results, which were already in their records, they would never have signed the hepatitis waiver.

A number of patients throughout the country have put in an official complaint to the General Medical Council, but, despite all the evidence submitted, we could get nowhere, and, although the doctors could see every word of our complaints, we were not allowed to see one word

the doctors' reply in order to challenge their submissions.

This system is heavily weighted against the patient ever obtaining justice when things go wrong. Doctors have admitted in this room that they tested their patients for infectious diseases without informed consent, which is against General Medical Council guidelines and, as I say, came out of the Nuremburg Code and can supposedly be brought to a court of law, but haemophiliacs can do nothing.

I request, on behalf of the haemophilia community, that a copy of the Archer Inquiry's final report, whatever the outcome, be sent to the GMC so that they can be made aware once again of the issues raised in this Inquiry.

THE CHAIRMAN: I think that at least will be done.

A. Good.

Conflict of interest.

One thing haemophiliacs would like addressed is the relationship between the plasma companies and the doctors. What funding did doctors receive from plasma companies? Were any haematologists acting as paid advisers to companies or received incentives with regard to research funding or funding for lecture tours abroad, et cetera? Were there financial incentives for doctors,

as in other countries, where doctors received a type of commission the more treatment they prescribed? And one example of that is Germany, where -- doctors overprescribed in Germany.

Where would we be able to obtain this information in this country? I would like to establish more about the buying in of plasma products and why this was not regulated by a pharmacy. We have attempted over the years to get buying-in records but we have never had any luck and nobody has any record apparently of ever buying in plasma in 30 years.

I happened to be at a local trust meeting only a few years ago to raise the issue of recombinant for patients and noticed an item on the agenda. Basically, the pharmacy -- this is in the northeast, in Newcastle -- were annoyed that the haemophilia treatment had always bypassed their department and were calling for more control over treatment. I wonder if the UKHCDO can advise where the buying-in records are stored at each hospital? Did plasma go to a central regional depot or was it delivered direct from plasma companies? How were contracts set up? This is the sort of evidence we need to hear from doctors but is not forthcoming.

THE CHAIRMAN: We are hoping we may get a little information on that later on.

A. Recombinant and vCJD.

Haemophiliacs had hoped that lessons had been learnt after the infection of so many haemophiliacs with HIV and HCV. However, sadly, safety issues were once again ignored in relation to vCJD. My husband first wrote asking for recombinant in 1996 and I have submitted a letter where he was refused this treatment on 3rd April 1996. Once again the letter demonstrates how systems failed haemophiliacs. There was a breakdown in manufacture, which led to shortages, and despite all that haemophiliacs had been through, economy was once again placed over safety, as the letter shows.

It is worth noting that, if doctors had listened to their patients and granted their requests for recombinant, exposure to vCJD could have been prevented. My husband's first exposure to vCJD was in the autumn of 1996, which was several months after we had asked for recombinant. I would like to provide the panel with a copy of my husband's legal statement in his fight to access recombinant. He went on a high profile treatment strike to raise awareness of the safety issues surrounding human plasma and the future risks, including vCJD. As the virology experts say, it is not if a new virus comes along but when.

I will give you the witness statement in the legal

case between The Queen on the Application of Peter Longstaff and Newcastle Primary Care Trust, which was actually heard in the High Court. In a sense these are Peter's words from beyond the grave. He lost his case on the grounds that local trusts can choose how they wish to spend their budget. Recombinant treatment became a postcode lottery and despite all that my husband suffered as a result of his infection with HIV/HCV, this was never a consideration for the trust. Peter was deprived of synthetic treatment for many years, even during his last months in a hospice. The local trust showed no compassion towards him with regard to this issue. Recombinant was phased in and it was done on an age basis and Pete was in the last group to receive recombinant. He was finally eligible on 1st April 2005 and died on 16th April 2005 --

THE CHAIRMAN: Can I just put to you an issue that we may have to address? What you are suggesting is that the recombinant treatment should have been made available to him irrespective of whether the doctors who were looking after him wanted to administer it or not?

A. We tried to argue that -- obviously, he had been infected with HIV and hepatatis C. On psychological grounds alone, to have to keep taking human treatment where we knew that there was this risk of this new

Prion, CJD -- and that was a big, big issue for haemophiliacs at the time, and Pete went on treatment strike; quite a lot of other people said, "We have had enough."

THE CHAIRMAN: I doubt whether there would be much dispute that he should have been consulted about the treatment and become part of the decision, but to say that doctors must administer something whether they want to or not interferes, does it not, with clinical freedom?

A. I suppose it does but --

JUDITH WILLETTS: Was it not the decision of the local NHS trust? Were they not prioritising who received the treatment, rather than the individual doctors in this case?

A. Sorry, yes, I have not made myself clear. Yes, the Trust -- obviously they held the purse strings.

THE CHAIRMAN: Presumably, the Trust were saying, "We will not pay for this treatment" --

JUDITH WILLETTS: No, they are phasing it in according to the criteria that they have drawn up. He was therefore not eligible.

A. They only looked at phasing it in after the Haemophilia Society and a lot of the campaign groups had a very high profile campaign to get recombinant. We had to do that first. Basically, the attitude was, in the

early days, when there was a concern about vCJD: "It doesn't matter with these haemophiliacs that already have HIV and hepatitis C, they are infected anyway, so we can give them anything." That was actually the attitude.

At one point, when we looked at criteria, it was like, if you are infected with hepatitis and HIV, you were last. I can understand, and I totally agree, that children should be given recombinant first but it was as if they didn't care about the people who were already infected.

MR MEHAN: Did you know at the time in '96 that CJD was a potential problem?

A. Yes.

MR MEHAN: So is that the real call for widespread use -- or full use of recombinant --

A. Yes, because -- basically, my argument at the time was that, because of HIV and hepatatis C, they should err on the side of caution and, you know, get people on to recombinant as quickly as possible, and had they done that, had they acted more quickly -- what is really, really sad is there is quite a number of children being -- I mean, as I say, Pete was exposed to CJD in 1996 and so were quite a lot of children, and now the parents and the children have to live with that, and

that could have been avoided. Once again, it shows that lessons were not learnt and people are not quick on the uptake, and you have to go through these systems, go to the High Court, take legal cases, and it is all very exhausting for people that are sick and dying.

So lessons were not learned with regard to communicating information in relation to vCJD and haemophiliacs were only given the chance to learn of any exposure after myself and Pete leaked letters to the press, the Guardian, from the government and a plasma company advising doctors to withdraw treatment because of the vCJD risk but not to tell patients that they had been exposed. I am aware that it will probably not be too long before there is a test for vCJD, and after the disasters with HIV and HCV testing, I hope all appropriate ethical measures regarding testing and pre-and post test counselling are put in place in preparation for the future test.

I have just done a bit on education.

I would suggest that the past and present case of haemophilia treatment and the ethics surrounding care and treatment decisions is placed on the agenda of the medical schools in the UK and ethics departments at universities, as what better case to explore than ours, because there are so many ethical issues. Everything

that could go wrong did go wrong, and the tragic thing is so much could have been prevented.

I was just saying before, a member of staff at Leeds University has invited me to talk to the students on the history of our campaign and grass roots activism on their newly launched MA in activism and social change. I recall one haematologist referring to patients that campaigned as using low grade guerilla tactics. I think that, despite everything they have suffered, haemophiliacs and their families, although not afraid to be outspoken and challenge the system that caused them harm, have been remarkably dignified and restrained. My fellow campaigners should be proud of their activism and their contribution towards ensuring human rights are upheld and their fight for the best possible standards of ethics and care should be acknowledged. Let us face it, there are far more cases of doctors, haematologists and health officials being charged and convicted -- gaoled in some cases -- throughout the world for crimes against haemophiliacs than the other way round.

Just to get back to parity with Eire and Lord Warner, because I really want to clarify this situation again with regard to Lord Warner and his misrepresentation in the House of Lords and Hansard

regarding the situation with payments to haemophiliacs in Eire.

I first raised the issue immediately after I spotted that Lord Warner had got his facts completely wrong with regard to this issue. He claimed that the circumstances in Eire were somehow different to the UK but, as my letters from both the Eire government and Malcolmson Law solicitors proved, the Eire government paid recompense to haemophiliacs and their families at liability levels without accepting legal liability --

THE CHAIRMAN: Again I think we are clear on that. In fairness to Lord Warner, like any other minister he was relying on information he had received from the Department.

A. I would like to say that I did give him the benefit of the doubt because I wrote to him and said, "You have made a mistake; here is the evidence." I gave Lord Warner the benefit of the doubt, initially assuming he may have been misinformed by an adviser, and I provided him with the necessary paperwork. The haemophilia community did not receive an apology and the mistake was never rectified despite raising the issue with my MP and, I think, Lord Morris of Manchester -- I think at one point I raised it with him.

I then wrote to the Parliamentary Ombudsman to make

an official complaint and asked that they do something, but nothing happened here either. This causes me great concern as well, as I am aware that Lord David Owen has had his own problems with the Parliamentary ombudsperson, when he asked for the case of gross maladministration by the government to be investigated.

Could I request that attention should be brought to this serious matter of misinformation and it be flagged up in the final report of the Archer Inquiry, and both Lord Warner and the ombudsperson should receive a copy of the report.

As is so often the case with the haemophilia community, it seems that no matter what evidence we dredge up in support of our claims, we are unable to get justice. The decision of the UK Government not to provide recompense for haemophiliacs on a parity with Eire was based on the fact that the situation in Eire was different. This obstacle has now been removed. We can say with confidence that the situation in Eire is no different to the UK. We have now clarified this with evidence from Irish lawyers and the Eire Government, who know their own situation far better than Lord Warner and have backed us in our fight for parity and justice.

We also heard a supporting testimony at this Inquiry from Brian O'Mahoney regarding the situation in Eire.

The UK Government must now be made to formally address this issue and provide financial parity with Eire.

As we have heard, although the Macfarlane Trust and Skipton, do their best, they do not always deliver, and what people want is a reasonable settlement as our friends received in Eire, which would give haemophiliacs and their families financial independence, as opposed to relying on handouts in a system which can often seem humiliating.

I would just like to give one example about the system can fail haemophiliacs. One haemophiliac that had been infected with hepatitis C was turned down for the first payment on the grounds that he had cleared the virus, but not until years later, and after suffering a debilitating bout of jaundice as a 10-year-old child which had left him ill and weak.

As the hospital records had inadvertently been destroyed by a junior trying to put them on a computer -- a familiar story to many -- he was unable to prove his early illness. As it happened, I did help him go through some copies of some old records very recently that he had at home and found a reference to his illness, a non-A/non-B infection in 1982 when he was just a child.

He was finally found to have allegedly cleared the

virus many years later, but, interestingly, when he asked, no doctor would either put this in writing or state in writing that he could no longer infect another important. In fact, his consultant -- to be fair to her, his current consultant strongly supported this man in writing that he should receive the first payment and not be penalised because of his missing records, but he was turned down for payment.

I was able to establish the two other haemophiliacs that I know had been infected with hepatitis C, initially been ill in the same way as this young boy had and later cleared the virus, but they were paid the first settlement.

This shows how unfair this system is, and how, after everything this man has been through, as he is also HIV positive, he still cannot claim the payment that he deserves. We will be challenging this but this is an example of why a scheme such as parity with Eire is extremely important, as it provides a proper assessment, and I understand those assessing actually meet with the infected individuals to discuss their cases so any issues can be ironed out in a humane way.

Just finally, my dissertation highlighted many of the issues brought into this Inquiry. It was actually written in 2006 and submitted in January 2007, three

months before the Inquiry began. As stated, I used document and supporting evidence that were not at that time in the public domain.

While I was writing the dissertation, I was also fighting to get these documents released under the Freedom Of Information, with the help of a solicitor. The Government recalled all these documents, and, given the Government's appalling record for "inadvertently" destroying evidence, I cannot be entirely sure that all the documents are or will ever be released into the public domain, but I believe there is enough now to put the Government to shame.

The Government's Self-Sufficiency Report 2006 is a fairly worthless document, in that it excludes much of the important evidence regarding what happened to our community that has since been released. This also needs to be formally challenged, as this was supposed to appease us and be accepted as an accurate picture of the contamination tragedy.

The reason always given in letters for refusing haemophiliacs a public Inquiry was that "all the information is already in the public domain". We now know this oft repeated statement was untrue. The Government should go some way now to addressing this situation by considering the future report and any

recommendations in the Archer Inquiry and offering an apology that is long overdue.

THE CHAIRMAN: Thank you very much. Thank you very much, Mrs Grayson. We may be asking you to give further evidence as other things emerge, but thank you for clarifying your views.

A. Actually, I have just remembered one thing from GRO-A here. He said just to point out that -- we were talking about quality of treatment. Less than 5 per cent of haemophiliacs have had a transplant. Where did you get your ...

UNKNOWN SPEAKER: (GRO-A). This is basically from the figures of the number of haemophiliacs who have died of HCV, and less than 50 haemophiliacs have been transplanted. So basically the rest have died. I am just one of very few lucky ones.

THE CHAIRMAN: Thank you very much. Shall we reconvene at 1 o'clock?

(12.05 pm)

(The short adjournment)

(1.00 pm)

MR GERALD HILARY and MRS JOAN HILARY

THE CHAIRMAN: Mr and Mrs Hilary, thank you very much for coming. Presumably you would prefer to make your presentation, and then you don't mind if we interrupt as

you go through it.

MR HILARY: Not at all.

THE CHAIRMAN: If you would like to do that.

MR MEHAN: Could I ask you just to bring the microphone closer to you?

MR HILARY: Can I apologise for the late entrance, as it were, the train from Manchester into London was late. So I do apologise.

MR MEHAN: That is okay.

THE CHAIRMAN: Something from which we all suffer.

MR HILARY: Shall I start? I am Gerald Hilary. This is my wife, Joan, we live at GRO-C, GRO-C. We were married in 1969, in July, and from that marriage we had three children. There was Dawn, who was born in GRO-C 1972; Gerald, who was born in GRO-C 1973, and Susannah, who was born in GRO-C 1974. Dawn and Susannah are alive and well today, but, however -- and that is why we are here today -- our son Gerald died on 15th November 1989 at 16 years of age, following a long illness.

When Gerald was 13 months old, we found out that he was a haemophiliac. He was in a hospital at the time, following an accident, and obviously there was a bleed and he was diagnosed with haemophilia. We were told then that he would require intravenous injections of

Factor 8, the blood-clotting factor, whenever he had a fall or a bump or an open cut, to stem the bleeding, and we were told at that time that the Factor 8 that he was to be given was imported from France and it was heat-treated and quite safe for use. Gerald --

THE CHAIRMAN: You were told that it was heat-treated?

MR HILARY: We were, yes. I think it was Sister Shaw at Pendlebury Hospital who actually said that this was heat-treated and free of all disease, because we wanted to know just exactly what was going to be injected into him.

He spent much of his early life in and out of Pendlebury Children's Hospital as a result of knocks and bumps that young children encounter, they get in their daily life, and in the late 1970s, early 1980s, we were taught how to inject Gerald intravenously with Factor 8 and the idea behind that was that we could catch the knock or the bump or the bleed very quickly and stem it then.

The alternative was to drive him from Stockport to Pendlebury Children's Hospital, which was not a great distance, but it was an hour, sometimes two hours, depending on traffic, and therefore we would treat the bleed quicker and hopefully stem it and stop it becoming more serious and being hospitalised.

Gerald's right knee was a particular problem. He had several falls on that knee and very quickly became susceptible to knocks and bumps where it would -- quite a heavy bleed in that particular knee, and in 1984 he got such a knock on that knee he was admitted to Pendlebury Children's Hospital.

At the time, the two consultants were discussing in front of ourselves as to the treatment that Gerald should have. One consultant was of a mind to bind the knee and hospitalise him for two months or whatever it may take for the bleed to be absorbed back into the knee, just purely a time factor thing. The other consultant was more of a mind to send him to Nuffield Orthopaedic Hospital in Oxford for what we were told was a synovectomy, which we were told was the opening of the knee and the scraping of the membrane or whatever inside to get rid of bleed and then resealing the knee, and hopefully that operation -- and his time in Oxford would be about three weeks.

Having spoken to the consultants it was our decision at the end of the day and we decided that perhaps the synovectomy was the right course of action and Gerald was then taken to Oxford.

We were told three weeks. However, there was a problem in so much as, following the operation --

I don't know how it occurred, whether there was a knock or a bump and I don't know if Joan can throw any light on that, but the stitches burst open and he required massive amounts of Factor 8 to stop the bleeding, and in actual fact he was there for three months.

Eventually, the knee became stable, we brought him home at the end of that period and he got full use of the knee again thereafter. We were told, or my wife was told -- I don't remember the particular conversation, but my wife stayed down there with him and I visited a couple of times a week, but one the occasions she was down there -- if you wish me to say what was said to Joan, was that one of the consultants down there said that he would need large amounts of Factor 8 prior to the operation, during and after, and of course, because of the burst stitches, he required extra again. But that would cost somewhere in the region of about £6,000 of Factor 8.

THE CHAIRMAN: This was said not by way of complaint presumably, just as information?

MR HILARY: Yes, just as information. It was just a conversation that took place whilst Joan was at the beside. He arrived home and he got full use of that knee again. Some time prior to Gerald's visit to Oxford we were told by staff at Pendlebury Hospital -- and

because of the passage of time, we are talking about 20-something years, I can't just say exactly who it was, whether it was a consultant, but that his Factor 8 was being changed and the reason -- when we asked why, the reason we were given was because it was becoming in great demand and it was expensive and they could -- when I say "they", be it the NHS or the Government, but we were told "they" -- we understood it was the Government because of what was said afterwards -- were now going to import it or buy it in from America.

THE CHAIRMAN: Which was cheaper.

MR HILARY: Which was cheaper and that was the main issue. A couple of things came to mind at the time and we asked -- because we had been told that the original he had from France was heat-treated -- would this be treated in the same manner, and we were assured by the staff at Pendlebury that that would be the case, that there was no danger to Gerald of any contaminated blood being injected into him. We were also told, about the same time --

THE CHAIRMAN: Forgive us, one of the things we try to keep in mind is a timeline. We are talking now about 1984, are we?

MR HILARY: It was 1984 when he went to Oxford and it was prior to 1984 when we were told that his Factor 8 was

being changed.

THE CHAIRMAN: Mid or early 1980s?

MR HILARY: I would think it was about 18 months before he went to Oxford. So we are talking about 82, possibly 83. We were told at the same time -- at more or less the same time that the Government were building a laboratory in the south of England where they were to produce their own Factor 8 so that the Government or the country could be self-sufficient in due course. We didn't know how far on that was or whether the initiative had started or not. That is the conversation that took place.

Some time after -- and I can't recall because of the time now whether it was after us being told in the 82/83 about it being imported from America or the change to the American product or whether it was after Gerald had been in Oxford in 84, but we heard and read -- there were media articles and there were conversations at the hospital, Pendlebury Children's Hospital, whereby lots of stories were that the American product was being supplied by drug addicts, prostitutes and prison inmates who were selling the blood for cash.

We also asked, that being the case, "I presume there is no danger to Gerald again, that it would be treated in such a manner that there would be no infection?"

I am a retired police officer and I was CID for most of my service and I recall problems about that time with drug addicts and contaminated needles and hepatitis and one thing or another. That was well within my knowledge and it was a question I asked to try to safeguard and get some assurance that Gerald was going to be all right.

I have an idea that that came to our knowledge prior to the 1984 visit to Oxford, but I can't be 100 per cent on that. As I say, we voiced our concerns about it following seeing these media articles and the conversations that had taken place. A lot of it may have been rumour mongering, but the hospital became quite concerned, I think, about it at the time, and we were asking certain questions, but we got the assurance that it was going to be all right and Gerald would be okay.

To our astonishment then --

DR JONES: Could I interrupt at that point? It is difficult at this distance in time, I realise. Can you remember who told you that?

MR HILARY: I think it was Dr Evans, the consultant at the hospital.

DR JONES: Did that hospital have a haemophilia centre.

MRS HILARY: They did.

MR HILARY: They were quite an established unit, the haemophilia unit. The two consultants were Dr Evans and Dr Stevens, who has since deceased himself.

To our astonishment, in 1985 we found out that Gerald had been contaminated with infected -- contaminated Factor 8 -- and that was by letter of all things -- and he was now HIV positive. Following that, in 1988 --

THE CHAIRMAN: Just pausing there, were you offered any counselling or --

MRS HILARY: No.

MR HILARY: No.

JUDITH WILLETTS: And you had no idea that he was being tested?

MRS HILARY: No.

MR HILARY: No.

THE CHAIRMAN: Please.

MR HILARY: He had an active life, still following that, for a couple of years, and we booked our first holiday abroad in 1988 with the children, all three children. We went to Portugal. However, Gerald had a -- he had had a broken leg, he had fallen and broken his leg and had been treated in hospital, but was at home at the time and was going back for a final check of the leg and his final discharge for that particular injury, the

broken leg.

Whilst there, we were talking to the consultants about our trip -- in 1988, we booked a holiday abroad. Gerald seemed well at the time, and, as I say, he went for this final check on his leg and discharge for his injury. Whilst we were there, we were talking to the consultants about our trip to Portugal and we were advised at that time not to take Gerald out of the country because his HIV had now become full-blown AIDS, and that was a conversation that originated with us talking about a holiday.

When and how they were going to tell us, I don't know. It was pre-empted with that conversation. Gerald's health deteriorated quite rapidly from the summer of -- from the summer of 1988, and at one stage he was diagnosed with pneumonia, but he came through that, but his periods of hospitalisation became more frequent and for longer periods.

On GRO-C 1989, Gerald was at home and looking forward to his 16th birthday, which was the following day. It is also his mum's birthday that day. It was quite a thing that he was becoming 16. On the morning of his birthday he had a massive fit and became unconscious. We rushed him to hospital where we were told that it was unlikely that Gerald would regain

consciousness and he would just slip away, or it was possible he might have another fit and not come out of it.

Gerald was a fighter and he did regain consciousness from that event of the 18th August, and a few days later he returned home.

The next time Gerald became ill and attended hospital was some weeks after his birthday. I think that was into the early September of 1989. However, on that occasion his antibiotics did not have any effect, which the doctors warned us would happen one day. We then made the decision to bring Gerald home and we nursed him until his death on 14th November 1989, and his death certificate shows that he died from an HIV-related illness.

THE CHAIRMAN: That is to say that the immune system was not functioning?

MR HILARY: The queries we had at the time and things that went through our minds was that, if the demand for Factor 8 imported from France had become so great, what was the reason for that and was it ever examined and did the powers that be think about prioritising the issue of Factor 8 from France?

We never got any information that anything like that ever took place. Many haemophiliac families are

families of haemophiliacs through no fault of their own. It was not a matter of them hoarding Factor 8. But they did hold, and we were one of those that held, supplies of Factor 8 at home.

THE CHAIRMAN: A deliberate policy so that it would be available if it was needed in fairly substantial quantities?

MR HILARY: That is right. In fact there was a time -- and I can't pinpoint the time. It was obviously well after Oxford and I point it around the 1988 time -- when we were told to give him injections daily whether he had had a bleed or not, and this was to pre-empt a bleed taking place, which is very nice and a luxury if you can afford that. I don't mean "afford" as monetary, but whether the people who supply it can allow that to happen, that people can store those amounts.

We were told to give him the daily injections to prevent a bleed occurring in the first place and thereby again perhaps preventing a hospitalisation in catching the bleed quickly.

As I said, earlier, if the demand for Factor 8 from France became so crucial, why wasn't the distribution regulated? And, if they did, we never had any information about that.

THE CHAIRMAN: We are hoping we may get some information

about that later today.

MR HILARY: We felt it could have been -- they could have continued to get it from France and issued -- given it on an essential needs basis.

We also believe, because of the time factor and how long it seemed to drag on in the papers and in the media about this contaminated blood -- and it was still coming from America -- that there was a possibility, and it is only a possibility, that if the Government had taken heed of these warnings, the concerns raised in the Factor 8 product, our son would perhaps still have been alive today.

Cost should not have been the primary reason for such decision-making to change from one product to another, particularly if that product was not of the same standard and safeguards were in place.

Just to finish, as I say, we were told by a letter that our son had been diagnosed HIV positive through being injected with contaminated blood. We were told that in a passing conversation about our holiday that it had changed to full-blown AIDS, but to date we have still not received any letter of apology for what we believe was the preventible death of Gerald.

THE CHAIRMAN: Thank you very much.

DR JONES: I don't think I have any questions.

JUDITH WILLETTS: May I just ask: were you given any indication of when he would have been infected?

MR HILARY: Yes, my wife, in fairness to Joan, can't remember the conversation, but following the period after we were told, several families obviously got together to sue -- not that that would bring their loved ones back, in fact -- you know, the problems with their children, and it was during that period of time -- and I think Gerald was still alive at the time -- that they traced the contaminated blood that Gerald was injected with to Oxford, whilst he was at Nuffield Orthopaedic, which was 1984.

JUDITH WILLETTS: So was the Factor 8 that he was receiving --

MR HILARY: That had been changed to this American --

JUDITH WILLETTS: So there is no possibility that it was the French Factor 8 --

MR HILARY: No, it had changed prior to that time.

MR MEHAN: Might I ask, would you have been eligible or did you receive anything from the Macfarlane Trust?

MRS HILARY: No.

MR MEHAN: You would not have been eligible, I assume because of Gerald's date of death?

THE CHAIRMAN: Thank you very much, Mr and Mrs Hilary. We have heard of the effects of this on many

families.

JUDITH WILLETTS: Many people were informed, perhaps by letter, and the lack of counselling and the somewhat arbitrary way of being informed seems to be quite common from the evidence that we have heard.

THE CHAIRMAN: I think that that practice has rather changed since. I think doctors realise now --

MRS HILARY: We were also advised not to tell anybody.

MR HILARY: We could understand that.

JUDITH WILLETTS: Because of the stigma attached?

THE CHAIRMAN: Of course, there was a social stigma about it then.

MR MEHAN: When you said that you were in the police force, can you tell us a little bit about how your career was affected by this?

MR HILARY: It was only affected in so much as I was a detective chief inspector in Manchester at the time and involved in quite serious operations. Forget the stress aspect, I was obviously having to support Joan and the girls. My children, the two girls, spent a long, long time of their childhood playing in the corridors of Pendlebury Children's Hospital, trying to do their homework there, having their evening meal there, sometimes until the early hours the morning when things were bad.

With regard to work, it has affected me in so much

as I could not give 100 per cent to work, obviously, with the time I was missing. It was a very bad period that we went through.

THE CHAIRMAN: Yes, we have heard evidence in other cases where there was an effect right the way through the family.

MR HILARY: The two girls really didn't have any life of their own, as such. It was school and hospital, or hospital missing school sometimes.

DR JONES: Has this tragedy had any long-lasting effect on them?

MR HILARY: My eldest daughter, who was very close, she still has -- after the incident and nothing to do with the hospital as such, but she did have some counselling as such, which was through our own GP.

DR JONES: The difference in age?

MR HILARY: There was only 13 months. It was my eldest girl, Dawn, in GRO-C 1972, it was Gerald in GRO-C 1973 and Susannah in GRO-C 1974, so they were very close together. My youngest daughter doesn't show it too much, but she keeps things to herself, but my eldest daughter has problems occasionally.

DR JONES: Changing the subject a little bit, presumably was it someone at the children's hospital, Pendlebury, who told you that the blood which is thought to have caused

the problem could be traced back to that given him at Oxford?

MR HILARY: From memory, I think it was the solicitor representing our case that had got that information by that time.

DR JONES: It came out at that stage, yes, I see.

MR HILARY: They said they had traced the bad batch to Nuffield Orthopaedic Centre.

DR JONES: Thank you.

THE CHAIRMAN: Thank you very much.

PROFESSOR GEOFFREY SAVIDGE

THE CHAIRMAN: Thank you very much for coming, Professor.

A. That is all right, my pleasure.

THE CHAIRMAN: You were Haemophilia Centre director -- I said "were".

A. Yes, I retired, thankfully. That is one of the joys of reaching the age of 65.

THE CHAIRMAN: Some of us feel we ought to have retired years ago.

DR JONES: I can't remember that.

THE CHAIRMAN: Could you tell us a little about haemophilia centres? I don't think we have had anything direct evidence about them.

A. I did finish off a statement, which I emailed to your good self at 2.30 this morning.

THE CHAIRMAN: I don't think that reached us.
A. Would you like to take a copy?
THE CHAIRMAN: Certainly, yes.
A. I can then expand on the virtues of HC74.
Haemophilia Centre, a national organisation really, was started up as a group of interested individuals during the 60s, mostly from Oxford, who had a lot of patients referred to them, some patients from Sheffield, from London and usually at the Hammersmith -- I think it started up there -- and they decided in the middle of the 60s, they would collect national data, so they could join together rather on an ad hoc basis, a bit like a gentleman's club.
THE CHAIRMAN: Could I just ask you, if I may interrupt, is this in your statement?
A. Well -- most of it is.
THE CHAIRMAN: I am just wondering how detailed a note.
A. Most of it is there. In the mid-60s they all got together and they managed to persuade the Department of Health to put together a health circular, which described a three-tier national haemophilia organisation. So you had the lowest tier, which was associate centres, which in essence were general haematology departments that looked after one, two, three, four patients. Then you moved up a little bit to

what we called haemophilia centres, that really managed -- and there were about -- of the smaller centres, the associate centres, there were about 100 at the time. Then you had your haemophilia centres which looked after about 20/30 patients, and they numbered some 10 to 15, and then you had the so-called reference centres, which was the top of the heap.

There essentially were two in London, the Royal Free and ourselves across the water, there was Sheffield, there was Manchester, there was Belfast, the two Scottish centres -- of course there have to be two in Scotland --

DR JONES: Not Oxford?

A. Oxford, very much so. The secretariat was based in Oxford, because at that time Oxford was very powerful in terms of the politics and treatment availability -- and Cardiff, so there were 10 in all and that is in my statement, which now appears. (Handed).

You will have to excuse some of the typos in it, but at 2.30 in the morning, I am not all that 20/20.

THE CHAIRMAN: I think we could find it in our hearts to forgive that.

A. Okay.

In terms of the organisation, you will see that on page 3, item 3, National Organisation of Haemophilia

Care through the UKHCDO. Late 60s, date, and "nationally on haemophilia patients including demography and blood product treatment". Obviously the idea behind HC76.4, which was the health circular which was published at the time, was to try to gain as much information as to what the problems were in relation to numbers, product usage, projections for usage and financial burden.

THE CHAIRMAN: Yes, I see. Just to clarify one point: your patients, were they referred to you by a hospital or by general practitioners or ...

A. Haemophilia patients are very inventive. They come from other hospitals, other haemophilia centres, GPs, they can even refer themselves.

THE CHAIRMAN: Sometimes they do it themselves?

A. Quite a lot of them at that stage used to come through the Haemophilia Society. They didn't like the treatment they had received and so they went along to the Society who said, "You can try A, B or C."

So you can get them from anywhere. We didn't have any holds barred because we were one the largest centres and the only problem we had was money, but then again most people had a problem with money at that time.

THE CHAIRMAN: You were funded by --

A. I started in 79 and I inherited, shall we say, a rather

low funding level.

THE CHAIRMAN: From where?

A. It was done through the usual mechanism, the Department of Health down to the Regional Health Authority. The Regional Health Authority say, "We have X number of districts, let us do a pro rata across the districts", and those districts then in turn referred monies across within the disciplines. So if cardiology, or most commonly, renal meds, if I remember correctly, were short of money, they had the first bite of the cherry. Okay?

DR JONES: I can't remember that.

A. However -- so that was the way that the funding was distributed. The actual monies. But in reality, in terms of the product, of which 85 per cent of haemophilia costs rest with, one had product availability through two other sources: one was from the Blood Transfusion Organisation that supplied either fresh frozen plasma or cryoprecipitate, which is a sort of semi-enriched form of plasma, or the Blood Products Laboratory, which at that time was at Elstree and a little bit at Oxford and a little bit here and a little bit there, and what they did, they had an arrangement with the Blood Transfusion Service whereby the Blood Transfusion Service supplied them free of

charge -- notionally free of charge rather -- with plasma and cryoprecipitate, this semi-prepared thing, which in return was fractionated into a more purified form of Factor 8 and Factor 9 and albumen, and then returned back, notionally free, to the Blood Transfusion Service for distribution out to the individual district hospitals. So that was the bulk product which was notionally free.

However, because there was always a shortfall and that shortfall went down to perhaps as much as 60 per cent -- so you only had 40 per cent back on what was sent in, which, in effect, was not enough anyway -- there had to be a source of money to purchase blood products, usually from the United States. So that was where the money came on, through the Regional Health Authority, divided down to districts and any money that was loosely at district level went into purchasing that, should it be necessary.

And of course it never was enough because patients always wanted more and there was a general move at that time in the mid-70s to the 80s to actually increase the usage of patients' factor because --

THE CHAIRMAN: Just before you go on, looking back at the procurement, you say there was a shortfall, this was used to purchase --

A. The shortfall was the shortfall from the combination of product made available by BPL as a pro rata return on plasma.

THE CHAIRMAN: Was that procured by a direct relationship with the suppliers?

A. That had nothing to do with the suppliers at all. What happened was it was a relationship which existed between the blood transfusion directors and BPL itself.

THE CHAIRMAN: But you said -- there was a shortfall there?

A. There was a --

THE CHAIRMAN: And that was made up from foreign suppliers.

A. That was made up from suppliers from the United States in particular.

THE CHAIRMAN: That is what I really meant to ask you about. Was that done by a direct contract between the centre and the suppliers, or was there bulk purchase, or how was it done?

A. It well depended who felt they could possibly get the best deal out of the commercial companies. So you would perhaps have a rather cavalier pharmacist who would negotiate on behalf of the district hospital because it was district money.

THE CHAIRMAN: That is what I was wondering. So the direct contract was with the district.

A. The direct contract was with the district, not with

Elstree, not with RHL, not with Blood Transfusion. So if you had an adventurous pharmacist who wished to negotiate with his charming Americans, that was fine. If you had, on the other hand an entrepreneurial doctor -- God forbid -- you would find that he might do it, and they had to hand the numbers to make sure there was some form of cost-effectiveness. So one didn't buy in bulk enough for 10 years and realise that, after 6 months, it had all gone out of date.

The blood transfusion -- the local blood transfusion directors within the districts, sometimes would take responsibility for the purchase of it and store it within the hospitals. So it was very much something which was hit and miss, but invariably the people who actually did the negotiation were those who notionally took responsibility for the budget --

THE CHAIRMAN: I see. Yes, thank you.

A. -- and had to answer, of course, to the unit management teams or hospital teams when they were asking questions such as, "Why have you overspent?"

THE CHAIRMAN: Things haven't changed very much. Thank you, I interrupted you.

A. That is all right. So that was the way the funding at that stage was organised in 1979. There was a central purchasing facility, which I don't know very much about

because it was before my time, but I would have assumed that the Department of Health arranged to get all the companies together and say, "Right, this is how much money we have, this is our usage nationally, which" -- the figures were quite difficult because the data they were getting from the UKHCDO in general, was always two years out of date anyway, and with escalating demand for more product to treat patients at home, for example, or for preventative treatment in children, the figures were always wrong, but one anticipated that those figures should be doubled, and so usually in one's negotiations -- because I negotiated for St Thomas's over the road, I always estimated that it would probably be twice as much as needed.

THE CHAIRMAN: I see, but use of the central facility was optional.

A. I don't know because I never needed to use it, because by the time I arrived there, it had been abandoned because it was a bit of a catastrophe. So it was really left up to the individual districts to negotiate with their money, with the individual commercial companies for the amount of product they considered was necessary at a certain price.

THE CHAIRMAN: Yes.

A. Now, obviously, because there was never enough money,

one way of dealing with this, which certainly I pursued, was to go along to the Regional Health Authority and say, "It is a bit silly to do this on a district basis, why don't you top-slice regionally?" So you'd take your haemophilia money out of your starting pot and then distribute district-wise, in which case each district paid a proportion, because we were getting patients from all over the district, we were getting a proportion of those districts' monies being top-sliced and that meant that the renal physicians and the cardiologists could bathe in the money that they would have got, but didn't.

THE CHAIRMAN: Yes, thank you.

A. But there were very few centres, to my recollection, that actually addressed any financial issues locally to convert them into regional top-slicing.

THE CHAIRMAN: Yes. Would you like -- again, I interrupted you, would you like --

A. I have forgotten what I was on about.

MR MEHAN: Are you going through your statement?

A. I can go very quickly through the statement.

MR MEHAN: Even introduce yourself more formally. I don't know if that has already happened.

A. I think the majority, certainly the patients in this room, know me.

MR MEHAN: For the wider record.

A. I am or was, rather, Professor of Medicine at St Thomas's Hospital, as Guy's and Thomas's Trust but affiliated to King's College, London. Most of my training is as a physician and as a medical scientist, not as a conventional haematologist, which may explain why there are divergent opinions perhaps in the text.

I graduated from the University of Cambridge. I have specialist accreditation in medicine and chemistry, and I have, for my sins, spent a lot of time abroad training, and while I was abroad I worked in Stockholm, which is probably one of the most prestigious places in the field of blood clotting and coagulation, and I have my higher degrees from there.

I obtained the sources to prepare this for you from a number of things, obviously from the medical and scientific literature from 79 to 86. I didn't wander past 86 for fear that I would be accused of being wise after the event.

THE CHAIRMAN: That of course is an issue we have to grapple with, yes. But, going to the earlier stage, you said from 79?

A. I say from 79 because I feel that in terms of HIV, really, we have to start thinking initially from 79 through to 86 where there were problems, but I do in my statement make it pretty clear that before 1979 there

were problems with non-A/non-B hepatitis, subsequently called hepatitis C, and that those, coupled together with the whole of the European Community's self-sufficiency plans that they want to do, there is linkage throughout.

So you have a failure to implement self-sufficiency, which essentially was a mixture of safety and finance, to try to bring them together to make haemophilia care a little bit more cost-effective and safer, from a European perspective point of view for harmonisation. That failed in essence, and then it became pretty clear, towards the end of the 70s, that non-A/non-B hepatitis, as it was called then, was not merely just a biochemical abnormality that a few chemistry departments picked up. It did have clinical impact, but not in the short-term necessarily, in the longer term, and that all concentrates made from large donor pools had a similar rate of infectivity. That is 100 per cent on first exposure. So it is pretty straightforward.

THE CHAIRMAN: Can you give me any kind of date about when this became generally known?

A. You had two schools of thought. One school of thought was: this causes problems, and it was backed up by a lot of tissue work biopsies, liver biopsies, which showed progressive liver disease, and then you had another

group of individuals, who are quite happy to say that, you know: we just measure it with blood tests and the blood tests stay the same, so we just think it is a little bit of inflammation of blood tests from the liver. So-called transaminitis, which has no clinical connotation and which is merely a figment of a few people's imagination. So, by the time the histology data started coming through and by the time children started developing cirrhosis of the liver, perhaps it was a little bit more than inflammation of blood tests.

So I think the majority of responsible physicians and people treating these patients knew by the end of the 70s -- in fact pretty closely about 78 I think tipped it -- that large donor pool concentrates, whether it be for Factor 8 or Factor 9 were the cause of non-A/non-B hepatitis. Nobody knew what the agent was but they assumed it was an infective disorder; it came from an infection. And as time moved on, it became proven that was the case.

THE CHAIRMAN: And by that time, was it suspected that would be conveyed through blood, through large pool --

A. Very much so and that is the simple reason why 99.9 per cent of producers of commercial Factor 8 and Factor 9 in the world then started to invest money in their research and development departments to clean up

their blood products.

THE CHAIRMAN: By the end of the 70s?

A. At the end of the 70s, in fact the first product that was produced to go into patients was produced in Germany in 1978 and they treated, I think, about 34 patients with it over two years following all the parameters -- because the Germans are quite strict about these things -- following every known parameter and they demonstrated quite clearly that there was no biochemical evidence of transmission of non-A/non-B hepatitis using a pasteurised product, and they made representation over here to a number of my colleagues, I believe -- there was never really any report that came back about this -- and I would assume that they came here to explain their findings in greater depth because this was available to people who were attending conferences.

THE CHAIRMAN: But we have had quite a bit of evidence that there were people who were seriously troubled about this much earlier than this by the early or mid 70s.

A. Oh, yes, there were people who were very worried about the possibility of hepatitis much earlier on, but the big question was: was it clinically significant? It is very easy to take blood tests and say, "They go up and they go down. Isn't that wonderful? There may be something wrong here", but really you have to start

looking at the epidemiology of it, you have to really start looking at the clinical impact and relate what you find, particularly with histology, with the clinical findings and looking at mortality and morbidity. That takes at least five years to get valuable data, and when you have got conflicting thoughts and conflicting interests, it makes it even more exciting.

But I think by 78 the majority of responsible people were sold on the idea that there was a clinical problem associated with large donor pool products, as mirrored by all the blood banking agencies in the United States, as mirrored by all the authorities in terms of haemophilia management in the United States and in Europe and by the selfsame Council of Europe that recommended sufficient sufficiency.

JUDITH WILLETTS: May I just ask -- forgive my ignorance -- the German product, you said that they had actually demonstrated that non-A, non-B -- that it was safe from that being transmitted?

A. That is right. They started their trials in 78 and the Germans only trial out in Germany. So -- and they are very stringent about it and they -- one of the things you have to do is you have to follow blood tests every two weeks. So you more or less have to be German to volunteer for this, because you are backwards and

forwards to the hospital all the time and it would be painful, and some of the patients underwent some biopsies but mostly it was not needed. The patients felt fine, they reacted normally to the factor when put in, because one of the concerns, particularly raised over here against heat-treated products was the fact that it might damage the molecule and they'd produce antibodies.

But during the two years of trials in Germany at the end of the 70s, not one single patient developed an antibody. They all responded favourably to the amount of product that was put in them. There were no adverse events from that point of view. The only problem that was experienced was the fact that one patient, or possibly two, developed hepatitis B, and that was why the publication of this particular product was delayed until 1986 because there was co-infection with a virus, which is much more difficult to get rid of than non-A, non-B; namely, hepatitis B, and that was probably due to the fact they had not done adequate screening on the donors they used with third generation tests.

But that is another story. That delayed the publication but obviously did not delay the Department of Health in giving it a licence because it was the first heat-treated product to receive a full product

licence in accordance with the Medicines Act, not the Crown immunity thing.

THE CHAIRMAN: We have heard about that.

A. You have heard all about Crown immunity. Crown immunity was considered to be a bit of a joke at the time.

JUDITH WILLETTS: I think I am trying to understand whether non-A/non-B was in some way identifiable and could be tested/screened for back in the late 70s. That is what I am really trying to understand.

A. The definition of non-A/non-B hepatitis, which was invented in fact by an Italian, to complicate it even worse, was that you would follow certain liver function tests on a regular basis, usually every two weeks, and if those liver function tests exceeded 2.5 times the upper limit of normal, on two occasions, with a minimum of six weeks apart, after being exposed for the first time to a large donor pool product, by definition you had non-A/non-B hepatitis if you were negative to hepatitis B and hepatitis A and CNV, the other things that can cause problems.

JUDITH WILLETTS: Although hep C was not described until 89 and the test for it was, I think, in 91, you could identify non-A/non-B and test for it considerably earlier?

A. By exclusion, you did it by exclusion. And it was

pretty effective doing it by exclusion because you got rid of CNV and usually the type of patients we were talking about -- if you were treating children in the way that was recommended with low donor pools, they should not have problems -- at least until they reached 50 bags of cryoprecipitate, they should not have problems with non-A/non-B. Okay?

If it was a question of first time exposure in a patient newly diagnosed, who needed concentrate, you would follow that -- you know, we were involved with the first clinical trials of the -- where you had to stick to these protocols, otherwise you could not diagnose it.

So, really, it was a combination of biochemical diagnosis. If you were lucky but the patient was unlucky, they developed symptoms as well, but those symptoms were highly variable and there was a variable incubation period. So you could have something, shall we say, after two to four to six weeks, which resembled influenza, or, after three months, you could become extremely jaundiced and very sick. So very, very variable.

JUDITH WILLETTS: Did you say that the Blood Transfusion Service licensed product, even though it was known that it had hepatitis B?

A. No, what I am saying is hepatitis B -- any licensing in

this country was done on the basis of two principles. The first principle was based upon the Medicines Act of earlier on because of Thalidomide and everything else, but that was more directed towards pharmaceuticals, pills, from packets. You could check and double-check and everything else.

When you start dealing with blood, blood itself is an unlicensed thing. There is no licence for blood. There is no licence for what blood cells swim in, which is plasma. There was no licence for the cryoprecipitate which was an enriched form of Factor 8 which came from plasma and they were within the domain of the Blood Transfusion Service, which was part of the NHS. Okay?

The only way that any form of, shall we say, questions could be asked concerning problems associated with those things was by assessing each individual step if you were going to follow the legal approach.

THE CHAIRMAN: I think we have had some of this before, but the position then is this, is it: that, because there was Crown immunity, the question of a licence didn't arise.

A. It didn't arise because you didn't need it.

THE CHAIRMAN: There was no sanction if you used it without a licence.

A. And also the legality of it was entirely different,

because, if you were going to sue, shall we say, an American company that had a formal licence, you could pick out all those individual steps that had been quality assured by the regulatory authorities and you could attack each and every one of those, and you probably could win because you could identify some malpractice or some problem with one of those.

With Crown immunity, you could not do anything because nobody knew anything. So you were just sliding from one formulation to another with very little documentation and certainly no information passed out to the treating physicians who were taking primary responsibility for administering that product, as you do with a licensed product when you give it on a named patient basis, which one had to do with heat-treated products initially.

Does that help, or does it confuse it at a higher level?

JUDITH WILLETTS: That is helpful but I am also trying to understand -- obviously you are talking about there Crown immunity but when the product is being purchased, people are purchasing what they believe to be, for example, US licensed product.

A. You have to have a US licence to even talk to the people. If you have not got a full FTA licence, you are

not supposed to talk to them, not even on a research basis, unless you have something called an IND, investigation of a new drug. But that has to be approved through the FDA. You cannot even take those people into a room to talk to them about it because it breaches the ABPI Code of Practice.

THE CHAIRMAN: Just before you pass on, we have heard a great deal about the named patient basis. I am still not crystal clear in my mind how it operates. It is a question normally of doing it for research, is it?

A. You can do it for research but not usually. You don't usually do it for research. What you usually use named patient basis for is when a clinical situation arises that you know that there is a drug which is available but unlicensed for that clinical indication, that you feel could help the patient.

THE CHAIRMAN: So then, what is the procedure?

A. The procedure is the following: you have to take responsibility for lifting the telephone, you then have to speak to the company involved, usually the medical director and say, "This is my problem: I have patient X who has condition Y, everything else I have tried doesn't work. I think your drug, which isn't licensed for this indication, may help. I would like to purchase it on a named patient basis."

He will then scour through all the literature they have in the world and say, "Well, in Outer Mongolia they used it three times and it was successful, for somewhere else it was unsuccessful." They have to give you chapter and verse.

At that point, you have to then make the decision to use or not use. If you decide to use, then what you do is you say, "I would like to send you, by fax, the following information: name of patient, age of patient, consultant in charge, reason for requiring administration of this drug, for what condition, for how long, at what cost and a consultant's signature."

You fax it to them, they have a look at it and they send back to you what they have and they will then be expected to follow up on that. That is named patient use, formal style.

THE CHAIRMAN: Yes, I see. And it can't of course be used on any other patient?

A. If you use it on any other patient, you are in breach of the law.

THE CHAIRMAN: Yes, thank you.

DR JONES: Before we leave the German trials, can we just go back? There was a time, I believe, in the 80s certainly when the consumption of Factor 8 concentrates in Germany far exceeded that in any other European country.

A. Absolutely.

DR JONES: I am not quite clear in my mind.

A. Why.

DR JONES: I have read explanations why, but the relationship in time between the trials you referred to and that period of heavy use in Germany, were there trials before that?

A. No.

DR JONES: They overlapped?

A. They overlapped. You see the principle in Germany is entirely different because the Germans base it on third party insurance. So, first of all, the whole idea of compensation and finance, completely different. And they have worked it out quite well that, if you have got haemophilia, you save the cash, you have to.

The major centre in Germany, the centre in Bonn, was enormous, it treated 600 severely affected patients. So you can lump, shall we say, most of the UK for severely affected patients into the Bonn centre and still probably have a bit of room in the corridors. They did a lot of interventional surgery. They pursued a lot of home therapy programmes, a lot of prophylaxis. So they were using very much larger amounts of product per patient than, for example, in the UK. So if you work it out on an average how many Factor 8 units per head of

the general population, you could say that Germany was somewhere between 2 and 3 units per head of population per year, whereas the UK struggled to make a decimal point out of it, and that includes the notional, free-of-charge, Crown immune NHS product. Okay?

So patient expectation is higher, patient treatment more intense, particularly amongst children, to prevent the joint problems arising, when joint problems did arise, they were taken for surgery and not left hanging around for seven years on a waiting list which was pretty common at that time for haemophilia because nobody wanted to do surgery on haemophilia patients.

But the major contribution the Germans made -- and that started in 78 -- was they discovered a way of treating patients who had developed antibodies to the factor they received, the so-called Factor 8 inhibitors, and the principle is quite simple. What you do is you give them so much Factor 8 you turn them into a bottle of Factor 8. You give them 200 units per kilogramme, per day, and when you work that out roughly, for the number of inhibitor patients they had, which was probably about somewhere in the region of 15 to 20 per cent of all their severely affected patients, plus all the number of other patients that flooded in from the rest of Europe and the world to have treatment

there because they were the only people who could do it, you ended up with a cost for Factor 8 alone which equated to the cost of one American star fighter aeroplane per year.

DR JONES: I suppose another factor is that, of those 600 Bonn patients, a lot lived a long way from Bonn and their treatment was still controlled over the telephone often, and the only way you could get away with that was large home supplies.

A. Large home supplies, yes. Very good export business.

But I think it is very difficult to compare any other centre -- the Bonn centre particularly is an example of haemophilia management, because they had it down to a T. They had the right orthopaedic people, they had the right physicians in charge, they had the ideas, they had the biochemical back-up, they had the histology, they had the surgery, and on top of that the director of centre's uncle was the Minister of Finance.

THE CHAIRMAN: Would you like to continue?

A. Where do I start? Right. I was just going through where I got information:

"Proceedings, minutes of medical, scientific and strategic advisory (inaudible) relevant during the appropriate period, and the recommended, but not necessarily documented, clinical practice protocols used

to manage patients at the time."

I elaborate on this very much by talking about my impressions and feelings of the august body calling itself the UKHCDO, often confused by some patients into thinking it was a distinct animal called the "UCK-DO". However, I also produced documents because I was involved in the defence in the haemophilia class action which took place in the early 80s, that was run by Solicitors on behalf of the Department of Health.

Each and everybody who treated haemophilia had to go through and prepare a statement of what they did in terms of their defence. I had a problem, since I was the only one using heat-treated Factor 8 at the time. So they had to come back to me and I had two bites of the legal cherry at the time.

But obviously, there is a lot of information contained in those documents, which I have used. Similarly, for my sins, I acted on behalf of the claimants for the negligence actions in the High Court for HIV and hepatitis C. So there was a lot of information which had to be produced there, particularly generic reports for the judges. So I used those to get some of the information here, not all of it.

I first starting using heat-treated products in 82, after going through lots of discussions with the

Americans in 81. That was for the first trial, and the second trial was started about 84/85.

MR MEHAN: Was it vastly more expensive, the heat-treated product?

A. For trial purposes it cost absolutely as much as BPL's product; namely, zero. But, because it was quite clear that in some patients -- and it was meant to treat non-A/non-B hepatitis, to prevent it. So you had to use naive patients, patients who had not been exposed before, because the majority of the data that came out, shall we say, one year to one and a half years later, after the trial started, was very encouraging and it looked as if that particular combination of 38 degrees Celsius for 72 hours was enough.

My view was very much: well, that must be better, even if it costs something, than giving a patient what I know for sure that it is loaded in 100 per cent of cases with non-A/non-B hepatitis; namely, the BPL product. So although I never used any BPL products, it all went to the 26 smaller centres in the south-east because they had the first bite of it from the Blood Transfusion Service. I was always left with nothing at the end of the year. So I had to survive on money initially from the district and subsequently from top-slicing of the region. So I knew most of these

companies and it was quite easy to get involved, as the trial coordinator over here, to test out the first products which were heat-treated and available for research.

I couldn't get any of the German stuff, which I really wanted, for the simple reason that, after they came over here in discussion with some doctors and some people in 1981, they were scared away. They never decided to come back. So it was a bit difficult to get any product. I think they had such negative vibes here that they thought: well, let us stick to France, Belgium, Sweden, the United States and the rest of the world.

THE CHAIRMAN: There was not as much of a ground swell against the product?

A. No, no, no and that was probably because the -- there was a perception amongst quite a number of haemophilia treaters that the BPL product was safer, relatively safer -- I can't quantify it -- than the American commercial product because there were slightly fewer donors in the large donor pool.

But, if you are talking about 10 per cent less donors from a donor pool of 2,000, that is not really all that significant. But that was a perception which was maintained almost through to 1984/85. It even goes

through to the final recommendations in 85 that say, "Use heat-treated product but if you can't get any and you have not got any money, or you are too lazy to speak to the Americans, your second choice is BPL's product which "-- Crown immunity still existed and it was still 100 per cent loaded with non-A/non-B, and people were still using it, even after 85. "Getting rid of old stocks", I believe, was cited in the literature.

MR MEHAN: Sorry, I interrupted.

A. No. Now I am lost again. I talk about the UKHCDO in considerable depth, at page 3, item 3, about its composition, its function. Essentially, I compared it more or less with a club, rather than a formal organisation, because it really didn't have any affiliations with any of the learned societies or with the Royal Colleges, it was not part of NHS. It was not even funded by the NHS. It was there really as -- I tried to think of it as best I put in legal terms. So I came up with this concept of "Unincorporated Association of Interested Haemophilia Physicians", that was about the closest I could get because its legal status was plus/minus zero.

I think quite a lot of the information -- there was a lot of information that was fed back as and when required on an ad hoc basis on a number of instances.

Quite a lot of it went unheeded, particularly some of the projections, particularly some of the concerns with respect to what was going on with immune abnormalities in a lot of patients during 82/83. But there was this all-pervasive thought that, because there were fewer donors in the BPL product, it was intrinsically safer but not quantifiably safe.

MR MEHAN: Did you have a view on the status of voluntary donors being preferred, and not just interested in the sheer number making up the pool - over the commercial product, which used paid donors, such that it might have influenced the decision process.

A. I think it really relates to a number of things: first of all, how do you define remunerated and non-remunerated? There were some countries that said if you give them a cup of tea and a biscuit, they are remunerated. There is that problem. There is a thin line between what is payment and what is not.

Obviously, if you were going to pay them $40 a shot and you get these people coming back three times a week for plasmapheresis, which was, on occasion, the type of thing that happened in the US, you would collect a lot of plasma, and if you collect a lot of plasma, you make a lot of product. If you make a lot of product, you fill in a lot of holes in other countries where there

are deficiencies where they don't do it.

So on the one hand, if you want product, it may well be that you have to -- slightly modify your altruistic principles about biscuits and tea and perhaps cash.

Obviously, the Blood Transfusion people were very keen on this concept of altruism and voluntary donation, but one sees the knock-on effect of that now, when 10 per cent of blood donors fall off every year and don't come back. So you end up with a situation that is so altruistic that you have no viable business.

So I think probably altruism can go to the point of no return, whereas, of course, remunerated donors can go equally to a point of no return but in the opposite direction. So to strike this happy balance, I think that was originally the intention of the European Commission; to try to promote maximum self-sufficiency in the hope that a compromise would exist with more self-sufficiency and less dependence upon American commercialism. That, I think, was the fundamental principle, but it meant finding money to do it, which was a member state job.

MR MEHAN: You were talking about UKHCDO.

A. Yes.

As I say, there were really 10 main players and those players were those centres that were considered to

be the largest and the most influential. I am not necessarily talking about influential at a district level or even at a regional level, but mostly at a national level.

It was not, shall we say, very much sort of the type of meeting where one could discuss things. It was really information exchange. They set up their own working parties, they presented -- in fact I headed up a few working parties and one did bits and pieces, but, really, at the end of the day, it didn't make much of a contribution because it was very difficult to get anything published that had UKHCDO on it, because invariably it was going to be statistical, it was not really going to influence any form of general medical people. You would not find a renal physician really getting anything about haemophilia, you would not find that, and also the specialist journals thought it was too simplistic.

It was very much a sort of DIY job: let us keep the smaller haemophilia centres, which made up 80/90 per cent of the body, with information about what currently is being done nationally on a national basis.

In terms of the type of things relating to blood product safety, some concerns about that with the general people, but normally they followed what came

from the top. If BPL was considered to be safer than American stuff, it was safer than American stuff.

One saw this typically with some the blood transfusion meetings. One that I recall in 83, I think, in the West Midlands, where they had a surplus of cryoprecipitate but they didn't want to use that. They wanted to use the more user-friendly American concentrate because they didn't have to put it in the fridge, they didn't have to make it up, it was much more user-friendly, you could return the bottles when you wanted to, so there was no waste. This type of stuff.

In fact what you were doing was saying, "You pooled all this cryoprecipitate" -- and that was the time Elstree was going through a very bad patch, they were doing to 20 per cent reduction something like that. So you ended up with a situation where not just the doctors, but even also the patients, were saying, "It is much more convenient for me to use that stuff. It may be infected, but it is easier to stick the needle in and get it out and get rid of the bottle when it is finished." A lot of mixed messages.

That is why, certainly from my viewpoint, I think that there should have been far more stringent and dominant leadership from the doctor's side than had currently existed. It was very much, "Let us cobble

together some sort of compromise so everybody is happy", which was fine if you are not playing around with a lethal disease.

THE CHAIRMAN: We have heard some suggestions, almost to the reverse, that it was not really the -- this was not patient-led, the patients were simply listening to the doctors.

A. To some extent I can understand that, because patients' societies are usually advised by doctors, and, if you happen to be advised by a doctor who actually happens to have the wrong opinion, you end up with a problem.

So I really think that it is asking a little bit too much to put the responsibility on to the patients' backs and say that they insisted, because they were advised, or they should have been advised. I am sure there are people who decided to treat themselves in weird and wonderful ways, in fact I am sure there are a number in this very room that do it, but on the other hand, usually there is a component of so-called expert advice behind them.

THE CHAIRMAN: Yes.

A. We had very little feedback as a member of the UKHCDO from any other committees, particularly the more influential committees, because there was unofficially -- there was an arrangement of an

unofficial delegation whereby the chairman, who sat on all these committees and was so busy changing hats throughout the course of the day from one committee to another, he was really informally delegated to be a representative, to explain the feelings of the UKHCDO or his interpretation of the feelings of the UKHCDO, which we never found out about because we never saw any meetings back, and we had very few reports back about actually what he said, what they answered and what actions were taken. We had no idea.

So in fact we were functioning more in a sort of information-fed vacuum. And for my purpose, I have a problem with that. That is why I decided to do -- go the heat-treated way much earlier -- about two or three years earlier than anybody else, because I was not prepared to wait around for somebody to tell me that it would be better to use a Crown immune, approved product that I knew was contaminated in preference to a product that I knew had gone through formal FDA-type testing, looking at logs of virus -- model viruses and everything else to see -- and with prior clinical data to show it looked to be infinitely safer. So we swung into that much earlier, to the concern of lots of people.

JUDITH WILLETTS: So you were absolutely going against the flow completely with that?

A. Well, I don't think I was the only one who wanted it, but I was lucky because the Regional Health Authority showed an extreme level of generosity to my persuasiveness.

JUDITH WILLETTS: I am sure they did.

DR JONES: The German wasn't your uncle, was he?

THE CHAIRMAN: But was there a flow or -- was opinion divided down the middle or was there a preponderance?

A. I think what happened was -- and this is where certain -- what happened was that by 1983 there was enough scientific data there to state, (1), that HIV -- if we are just talking about HIV now -- HIV was caused by a virus, okay? It had an envelope which meant it was heat-sensitive. It produced a weird thing called a reverse transcriptor, which meant, further, that it was heat-sensitive.

It went along similar model viruses in the same way, with the same type of characteristics and it was derived from patients -- French patients, admittedly -- who had a pre-AIDS concern called PGL. So they had isolated it. They stuck it with a load of lymphocytes, and, within seven days, that virus ate up all the lymphocytes and ate up all the healthy lymphocytes around it, which is exactly what happens in HIV.

With that type of hard, scientific data, it is very

difficult to say, "I don't believe that it is safe or unsafe if there is 10 per cent less in the big donor pool". There is no comparison.

The other bit of information was the fact that there was a report in The Lancet of a child with a blood disorder that required transfusion. The child received the transfusion from an adult, who, 17 months later, died of AIDS, the child died of AIDS, one blood transfusion.

So you have got really basic scientific evidence to show that the epidemiology is there and also the basic scientific facts were there to show that it was some sort of virus which probably was heat-sensitive. So what is your choice? Do you carry on using a product you know is loaded with a virus?

And there were reports starting to come back late 82/early 83 that HIV was beginning to pick off patients in this country -- America was before us but they use a lot more, okay? Or does one say: okay, let us think the same way as the other scientists think and particularly the commercial people. The commercial people are not stupid, they are in it to make money, and if they are in it to make money, they know that the only way they can do it is by having a better product than someone else. They say: we think we have a product

which is effective against non-A/non-B hepatitis. What is stopping us saying, well, it probably, in terms of the scientific data, is equally effective or more effective against a lipid encoded virus that has reverse transcriptors; namely, HIV. Probably inactivate it better than non-A/non-B.

That to some extent was the after-effect of the first trial I was involved in. The first trial I was involved in, when they put the data together they found that one third still had non-A/non-B, and that was because, when they went back, they found that the donors had had a much higher level of liver function abnormalities than the rest. So there were constraints within that 68/72 level of treatment, okay?

But following up those same patients, and looking at the HIV test when it became available, all the ones that had had the heat-treated product were HIV antibody negative because they were all virally naive to start off with, so we had pre-tests and all these other things. And somehow or other the French got hold of a comparative group, age-matched, that had received the untreated product from the same manufacturer, the same batch, and they -- I think about 10 or 5 of 18 showed evidence of antibody production and developed AIDS. That was published in 85.

Similar publications came from other companies. So, for example, the German product, they published, I think about 85, the same thing before they actually had to publish on the hepatitis B thing. So there was information coming in that use of these products was superior to using other products in the sense that there was no development of antibody.

Lots of people tried to explain it on other bases but the most logical thing is the fact that you kill the virus, it is not there. So we felt perfectly justified in going out and completely disobeying the current ethical concepts and everything else, which I was accused -- I was accused of being a charlatan at one stage, which I thought was quite nice.

JUDITH WILLETTS: You took it as a compliment?

A. In this context, it definitely was a compliment coming from those people.

THE CHAIRMAN: Doctors do seem to be fairly passionate about these things.

MR MEHAN: Can we ask: we have heard a lot of evidence regarding the meeting, now, I suppose, infamous, of July 13th 1983, at the subcommittee of the Society of Medicines

A. I have never had access to any minutes or anything that happened with the Committee of Safety of Medicines. As

far as I am concerned, they hold their meetings in a little room in Fort Knox that is soundproof. I know nothing at all about what deliberations took place within the Committee of Safety of Medicines, so you will have to tell me, I am afraid.

MR MEHAN: I thought that at that particular meeting that I am referring you to you might have been in attendance, but it is a long time ago.

A. Absolutely not. The last place I would want to be would be in the Committee for the Safety of Medicines. Because you don't know what is really going to be on the agenda. You don't know what they are going to talk about and the chances are that the committee is going to be seeded with people who say that Crown immunity is wonderful, which it was not.

THE CHAIRMAN: But the general wisdom on a number of these committees seems to have been: all right, there is a risk, (a), of an infection, and (b), that if there was an infection, it could be quite serious, but as against that there is the risk of not being able to obtain the treatment at all.

That is what they were talking about, as far as I can see.

A. I think it was not quite that from some of the understanding I have had from other sources. It was

not that there would not be any treatment; it was that an absence of treatment would be detrimental, but that is implicit upon the fact that there is an absence of money.

THE CHAIRMAN: Otherwise, there were other sources of getting it?

A. Sure.

THE CHAIRMAN: I see what you mean.

A. You had the Germans producing it, you had the Japanese producing it. Admittedly, half of the executive board of the Japanese Green Cross committed hara kiri after they found out that they had been transmitting a disease.

THE CHAIRMAN: Is there anything else you want to say?

A. No, I have made a number of probably fairly controversial comments in this statement, which I hope you will enjoy.

THE CHAIRMAN: We are most grateful.

DR JONES: Can I ask one or two questions? You are not off the hook yet. But thanks very much. That is very helpful actually.

We have heard varying comments about the climate of opinion amongst the pool of haemophilia patients with the arrival of saturated concentrates. We have heard more than one description that it sort of transformed

the scene.

A. Absolutely.

DR JONES: We have heard another description that actually that was not quite the case. Can you remember what your impression of the impact on patient belief, patient thought was?

A. I can't really give any comment in this country because I was working in another country at the time and there it was standard practice that children received cryoprecipitate and none received concentrate because it was regulated. Okay?

There was availability of commercial concentrates, there was availability of national fractionation stuff which was semi-commercial at the time. Generally speaking, the patients accepted concentrates in a far more positive way, for the simple reason that the first Factor 8 concentrate was actually developed at the place where I studied, and so there was this loyalty component, one can say, to a certain extent. And so it is completely different. I would not like to comment on that.

DR JONES: Fair enough. Can I read you out something from evidence that was given to us by a haemophiliac:

"One thing haemophiliacs would like addressed is the relationship between plasma companies and the doctors.

What funding did doctors receive from plasma companies? Were any haematologists acting as paid advisers to companies or received incentives with regard to research funding or funding for lectures", et cetera, et cetera and more of that general ilk.

Have you any comment?

A. Okay. Generally speaking, if one had dealings with a commercial company -- and I have probably had more dealings with commercial companies than most -- the rules are very simple: they pay for everything to do with the research that they expect you to do. That includes patient travel, patient expenditure, how much it costs to photocopy the notes, et cetera, et cetera, what the lab costs cost, and they get a breakdown of each and every cost before you even embark upon signing anything.

One is expected, as part and parcel of being involved with the research project for a commercial company, to actually present one's data. You can't expect 6,000 people to travel halfway across the world and cram them in St Thomas's dining room. So you have to go where you are requested to go and give a presentation. You may be offered an honorarium or you may not, but that really covers the fact you are up until 2.30 doing a report or something similar and you

expect perhaps to at least have a few shekels to keep your eyes open. So I think it depends very much upon the individuals of what happens.

In my case, I had funds which existed within the hospital and within the trustees, and money was paid directly from those companies into those trust funds. So I actually never saw the money, although I did have the luxury of spending it, as I was the only signatory, but it had to be spent on something which related to the project, whether a staff member or the agents or anything else.

I am aware that there were many colleagues, at that time particularly, who were working as consultants for commercial companies and I suppose in a way there were some which were working not necessarily on a remunerative basis for companies such as BPL because BPL required advice, it may well be that perhaps such incentives could be recommendations for this or recommendations for that. I have no idea because I had no dealings with BPL.

So the answer to your question is: probably yes, depending upon the individual. How much? No idea. Because that is directly proportional to greed more than anything else, and really, you know, these things happen all the time in all walks of life without necessarily

being related to medicine or HIV or blood product.

DR JONES: Okay, thank you. Recently there has been quite a lot in the press about a problem that Abbott Laboratories are going through at the moment with the extent of their funding of consultants, advisers, et cetera, et cetera. I have not come across any such outcry about any of the companies involved in haemophilia products. Have you?

A. Not so much now, because it is all pretty tight. Certainly during the 70s and 80s, particularly during the 80s, there were a number of sort of small ructions which occurred. Bear in mind, when you think of haemophilia as a subject, it is very small, and the monies, although they may seem a lot, are very small. You know? You think of something like cholesterol testing, it doesn't seem much, but the amount of monies are ginormous and it is completely different. So that will attract the press much more because they are much bigger targets and that means a lot more mouths to feed. So there is a greater weakness to actually find out who has the biggest mouth.

DR JONES: Thank you very much.

JUDITH WILLETTS: Nothing else. That was very helpful.

THE CHAIRMAN: Thank you very much, Professor.

A. I enjoyed it as well.

MR MEHAN: Might we return to you if we have further questions?

A. I am sure, after reading this, you will have lots of further questions.

MR MEHAN: Thank you very much.

THE CHAIRMAN: Thank you, good bye.

(2.50 pm)

(Short break)

(2.55 pm)

PROFESSOR RICHARD TEDDER

THE CHAIRMAN: Professor Tedder, thank you for coming. You are Professor of Medical Virology at the Royal Free Hospital and at UCH?

A. It is the medical school which is joint between the Royal Free and University College.

THE CHAIRMAN: It is a joint medical school. I hadn't grasped that. I should have known that, as a fellow of UCH.

A. My affiliation is to the University College London, as an academic, and I was a clinical virologist at the Middlesex Hospital, in the old days, when all this happened and then subsequently it was amalgamated and changed and split.

THE CHAIRMAN: And you are now external consultant to the National Blood Service.

A. And have been for 20-odd years.

THE CHAIRMAN: 21, did you say, or round about that?

A. Well, David Dane retired in 1982 and he was the man who described the hepatitis B particle and it has his name attached to it. When he retired, I took over his mantra unofficially.

THE CHAIRMAN: This was mid-1980s?

A. 1982.

THE CHAIRMAN: I wonder whether you could help us first: we have heard a little today about the acquisition of blood products. We gather it was done very much on a basis of each Regional Health Authority producing its own products.

A. No, I think they would have secured their own products almost on -- and I don't mean this in a derogatory sense -- the international plasma spot market, which is basically, if you were purchasing, you would -- you probably remember -- you would purchase material in the manner which was most financially prudent at the time, and, particularly for commercial agents, this meant that you were working in the field of commercial blood products, and they have a problem, they always have had and I think always will do. It is not -- if I can just expand on that, as Professor Savidge said, it is not quite as he said. It is not the number of donors that

go into the pool, it is the number of infected donors which go into the pool, and you can have a tiny pool.

This happened in the Scottish Transfusion Service, the SNBTS, where one donor had a very high virus lode and in a very small pool was enough to cause devastation to the recipients of that pool, and that was a tiny pool.

Equally well, if that donor had not got into 20,000 or 30,000 UK blood donors, the UK blood donor pool material, if it hadn't been heated and activated, would still be relatively safe. I think we now know that the prevalence of blood-borne viruses is anything between 10 and 100 times higher in the commercial donor panel, even nowadays, than it is in the voluntary panel.

Two crucial things about blood products: what is the nature of the panel from whom the donations are taken? So that is: what is the safety of the donor panel, how well do you know your donor panel and how do you exclude? And the other crucial thing, which of course is relevant to the early 1980s, is whether you can terminally disinfect the blood product and still have a biological function, so that is heat or solvent or detergent treatment.

THE CHAIRMAN: That, of course, changed the whole nature of the game.

A. Very much. Providing of course that it is a virus which has an envelope and is sensitive to detergent and heat, and that was only known with some certainty, in spite of model infections, once the virus of HIV-related disease was formally characterised and accepted internationally, and that was actually not before the middle of 1984.

THE CHAIRMAN: I think we were given that date.

A. So it was a little bit later than when the initial discussions were taken on, what can be transmitted by blood products.

THE CHAIRMAN: I see. Could you just help us with this, it may be outside your expertise: when the Regional Health Authorities were acquiring whatever product they chose, their contract was directly with the supplier, was it, the blood company or whomever?

A. I am sure it would have been, because one of the ways of securing a reasonable price would have been to commit yourself to purchasing from a supplier, and it has never been different with a monopoly purchaser, that you can pressurise companies into giving you good deals, whether it is diagnostics, whether it is surgical swabs or whether it is in this case blood products.

So depending on who and where, and what the nature of the relationship between the purchasing group, the haematology, haematologists, haemophiliac doctor group

and the producers would have been, it would have been a patchy representation of some producers with one health authority and some producers with another health authority.

THE CHAIRMAN: Was there ever discussion in this country of bulk purchase, the department heading it or something of that kind?

A. I was not involved with the Department of Health at that time, so I don't know. Clearly, the captive producer would be BPL and there might have been discussions about trying to become self-sufficient in that instance.

THE CHAIRMAN: It just seems that on the face of it they would be in a stronger position to negotiate prices, apart from anything else, if you were purchasing in bulk.

A. I think that is true. I suppose the only problem is when you are purchasing in bulk with a reagent or a blood component which is not fully characterised and is not quite certain of its efficacy -- whether the side effects -- its safety, and probably in the early days there was a lot of reluctance to believe that -- it was not called AIDS in those days, GRIDS and so on, the acronyms that were around, was actually due to a virus. I was in Washington in early 83 and heard people saying it was nothing to do with an infection, it was just

antigen overload, or it was poppers, or it was drug addiction, lots of other reasons.

So there was a small caucus of people who were clinical virologists, and particularly those who had been involved in the hepatitis B field in the 1970s and early 80s who said, "Look, this sounds just like a virus infection, viruses hunt in packs, there must be an infective agent there", and we were slightly sort of out on a limb at some of those meetings.

THE CHAIRMAN: Yes, I see.

A. So there really was real uncertainty in retrospect.

THE CHAIRMAN: Could we come -- you may be able to help us substantially on this, on the self-sufficiency drive in the mid-1970s.

A. Well, I think one of the -- this probably sets me apart from a number of people, but I think the question of blood products and blood safety, one of the most important mantras I still believe, even in this day and age, is "know your donor". Know your donor and know the infection risks in your donor.

If I can just step sideways from your question for a moment and give you a current example, we have good British donors who go abroad and they go to some area of the world where there is something else out there that we don't know of, for example, malaria, dengue, which is

a virus infection, not terribly nice, rabies, we have had transmissions of rabies in Europe and other virus infections. We now have concern of this strange virus which The Times tells me is a feature of global warming, chicken gunya, coming into Italy.

These sorts of issues show that you need to know your donor and you need to know the environment in which your donor is, where they come from, where they are travelling. Obviously, it is not xenophobic, we restrict people who have been in areas of the world where these microbial infections are common. That becomes an extension of the concept to be self-sufficient.

Self-sufficiency was driven, not so much -- in my experience, was not driven by the financial requirements or ease of manufacture or trying to protect a home market, it was just merely a principle that it is much better to take your blood and tissues and organs from donors whom you know where they have been, they are in your country and they will not harbour something which is not enzootic, endemic, whatever, whether it is in animals or humans, in this country, and they will not bring something in. That is the principle of self-sufficiency.

THE CHAIRMAN: That, presumably, was becoming accepted, even

if people hadn't thought of it much earlier, by the early 1970s.

A. Yes, there were publications by the WHO, putting forward the concept of self-sufficiency as a central plank. That was in the late 70s, that I know of.

THE CHAIRMAN: Late 70s?

A. If someone has a date, I would immediately bow to that. I was aware of that in the mid to late 70s, as I say, working with David Dane and already being interested in blood transfusion and transmissible agents.

THE CHAIRMAN: We have heard that David Owen at the Department was talking about the drive for self-sufficiency by 1974 at least.

A. That would fit.

THE CHAIRMAN: What has been suggested is, when the time came, there seemed to be two limiting factors. One was that there was not sufficient blood supply available in this country, and I gather -- I think it was half a million pounds was put into a drive to increase it.

A. That would be plasma procurement.

THE CHAIRMAN: Yes. And the other thing was being able to process it, and Elstree and Oxford simply hadn't the capacity to do that.

A. I would not disagree with that, and I think the third issue was that there was insufficient investment in the

late 70s/early 80s, looking at processing and making the products virus-reduced. I don't like the term "virus safe", I don't believe there is anything which is -- I naturally worry about life and I don't think anything is "virus safe", it is a virus less dangerous.

THE CHAIRMAN: At least obviously reducing the risks.

A. Yes.

THE CHAIRMAN: And your view was that this was not taken seriously enough and there was not enough --

A. The retrospective scope, as we say in medicine, is a remarkably fine and acute instrument. It is very easy to say there was not enough effort put into it.

I think the continued use of cryoprecipitate somewhat blunted -- you know, to have a facility to access that, which would very seriously and markedly decrease your donor exposure. Think of the concept of donor exposure: how many people go into this bottle with which I am going to inject myself? Is it 10,000, 50,000?

Obviously, if you are a low level factorate user and you are only mildly phenotypically affected, the continued use of cryoprecipitate was relatively safe because the donor exposure was very small. It would not be safe entirely. With non-A/non-B, the prevalence of course of non-A/non-B in the UK donor population was

significantly high to really not be a suitable argument to compare that per se as a risk analysis with HIV or HW3B, as it was then, because the prevalences were orders of magnitude different.

What the non-A/non-B did tell you was that if you put material into a pool and you made products from it, you will carry through an agent. We only knew what the agent was for non-A/non-B in 1989, so, again, that was very much post hoc, but as a marker of potential infectivity, both hepatitis B, non-A/non-B were very good biological markers.

THE CHAIRMAN: Could you go back to 1973? When the time came that it was actually announced by the Government that there would be this drive for self-sufficiency, I think the target date was 1979.

A. That would be --

THE CHAIRMAN: I think hoped to be self-sufficient by -- 1980, was it?

A. Yes.

THE CHAIRMAN: The fact is that by then, first of all there had been an underestimate of the amount which would be required apparently, because it was increasing exponentially.

A. And ease of administration, I think. One mustn't forget that -- I mean, I can remember rolling up 30 packs of

cryoprecipitate. It would take a very long time. I don't think I contaminated it, but I was always slightly worried. It was a very, very messy procedure and to do that two or three times a night kept the duty pathologist up and out of doing anything else for the evening and the following morning.

THE CHAIRMAN: What you are really saying is it should not have surprised anyone that there was an increase in the requirement for it?

A. I think that is a logical argument, yes, because it is easier to give and it is very effective and you can err on the side of overprescription rather than having to limit yourself and knowing the underprescription is limiting the access to blood.

THE CHAIRMAN: We are told that the facilities for processing (inaudible) in this country were simply -- I will not say "nowhere near adequate", but were inadequate.

A. They certainly were, in retrospect.

THE CHAIRMAN: If there had been anything like an accurate assessment of the requirement ...

A. I am sure if one had sat down then, knowing what we know now, yes, it would have been very easy to say, "We are undershooting."

Certainly the fact that there was great interest by

the pharma industry or the fractionators industry in getting pool blood fractions into the UK market must have alerted people to there being an undersupply.

THE CHAIRMAN: I think we are very conscious of the dangers of hindsight, but what has been suggested is that it was a little late, by 1974, to think about upgrading the facilities for processing this. Elstree, for example, was a long way behind what its capacity could have been if there had been timely investment.

A. I think that is probably fair. I think the -- if one blames anybody, it is the financial structures in this country which sometimes don't put money into health service emergencies, and certainly one didn't recognise this as an emergency until much, much later, or it became an emergency because of a failure to invest.

THE CHAIRMAN: Of course the time to provide for something is before it becomes an emergency.

A. Indeed, yes.

THE CHAIRMAN: The other thing about Elstree seems to be that it was then discovered that what one might call the hygiene of the thing was somewhat lacking. It was just closed down, wasn't it, whilst these things were sorted out?

A. I don't know that. When was the closure?

MR MEHAN: 81 or 82?

THE CHAIRMAN: I thought it was -- the inspection was 1981 and this followed in 1982.

A. Didn't that coincide, though, with redevelopment of the site?

MR MEHAN: Yes, there was a budget of some millions and then it reopened in 1987.

A. Surely it cannot have been closed down for that length of time? Because they would have been fractionating in the meantime. Where did our plasma go for fractionation up until then? Because we were collecting plasma in the UK.

THE CHAIRMAN: It went to Elstree. It was only then that it was realised that it was: (a), inadequate in volume; and (b), that it was unhygienic.

A. Yes. What does one mean by "unhygienic"? The obvious thing is that you give something to somebody and they suffer a bacterial or virus infection. I don't think it was based on that. It was probably a combination of shoestring investment and trying to provide a service which was not in line with the developing international guidelines.

Certainly, if you go -- fractionators -- everything is stainless steel, nothing is reused without strict decontamination. Those sort of attitudes were very much post hoc. At the time -- I don't think it was

criminally behind the guidelines that were in place, but clearly it was lagging behind and that is what the reinvestment was and the refurbishment of the fractionation unit.

But I am looking from outside. My concerns were very much different from that.

THE CHAIRMAN: I appreciate that. It is perhaps not fair to press this with you.

A. You can ask, but I can only give you a personal opinion.

THE CHAIRMAN: Although you can see that it may have been open to some criticism that -- what the need was for foreseeing, you would not say it was of a horrific nature?

A. It was a missed opportunity.

THE CHAIRMAN: A missed opportunity. I mustn't monopolise this.

DR JONES: Can I take you back to a talk you gave to a haemophiliac meeting in Cardiff in September 84.

A. You can, but only because I have it in front of me.

DR JONES: You look as if you have a wonderful memory.

The first question really frankly shows my ignorance, but at a time when there was still a debate about the nature of AIDS and its cause and you were saying that there was sufficient evidence from epidemiology, particularly that this was caused by

a virus which you described as "friable". Now, does that characteristic relate to the envelope that Professor Savidge referred to, and susceptibility to heat treatment?

A. Yes. Can I put this in context? This was 1984 and the first descriptions, which really received very scant publicity were from Francois Clavel and Montaigne(?) in 1983. In May 1984, the two papers came out in "Science, back-to-back", which was the Montaigne Group and Gallo(?). We had been offered the 83 virus, but it had died in transit through Liverpool Street Station, and that is very interesting, to look back on what happened.

DR JONES: Not a unique experience, I believe.

A. Yes. By 1984 we had the virus with Robin Weiss, and, because of previous collaboration with him on the leukaemia retroviruses, it was very easy for us to develop an assay and we were probably the first laboratory in the UK to be running the assay diagnostic thing, and the figures that Dr Evert(?) has taken out here came from the September paper, putting the prevalence of what we then called HDLB3B infections measured by antibodies in the populations as shown in the table, showing that really it was in the so-called -- I don't like the term, but the "risk groups", there was a high prevalence of infection.

I extrapolated from this being clearly because it was in fractionated blood -- that is not a blood component, which is sort of wet giblets, but it is blood which has been purified and the proteins have been extracted. The fact that it was present in there tells you that it has to be present in the donor as a plasma viraemia.

That is a small point, but it means that there is virus in the blood away from the cells, which puts it at a different position from the first two viruses which we -- in this discussion, at the time that we are talking about, HDLB1 and 2(?) so the data which was already evolving from America and our own data says that that has to be a plasma-borne virus that is present in there.

If it is like any other retrovirus that we know about because we obviously knew and worked with both Gallo and Montaigne, it has to be a virus which is enveloped. Okay? It has a lipid membrane around the outside of it. I used to use the analogy of a good, hot British cup of tea about 60-65 degrees Centigrade; you cannot catch AIDS by sharing a teacup. It is going to be very sensitive to detergents, sensitive to solvents and probably sensitive to heat. That is why I called it friable.

DR JONES: In the same paper later on, it is alleged that you made the comment that:

"In veterinary medicine, products from one country would not get through incoming customs from another country in the way that concentrates have come into the human market for haemophiliacs in the UK."

Would you like to elaborate?

A. Oh, yes. These things do come back to haunt one. I think it is true, because we tried -- we, at the time, were dealing with making monoclonal antibodies, which you raise in mice and you make a culture, and trying to get these across European country boundaries and global boundaries proved to be really quite tricky because they were mouse-derived, and the paperwork and hoops which you had to jump through to take a biologically active agent, which is zoonotic and it goes in animals, across a country boundary was really quite considerable, and that was not taking it across to put it in another mouse, it was just to take it across and use it in the laboratory.

MAFF in those days, as it was, and the international equivalents of MAFF, were very, very concerned about transmittal of infectious agents between one group of animals and another group of animals. You only have to see what has happened recently with foot and mouth.

THE CHAIRMAN: I think what we are more concerned with is the other side of the comparison.

A. I think the way to get to the other side of the comparison is to walk through the animal thicket first and then say -- I have always found -- and this is coming back to the question of self-sufficiency. I have always found it very strange that the pharmaceutical industry making blood products can show safety in trials, or claim safety in trials, and this material then can cross boundaries.

It is the same discomfort I have with kidney transplant holidays, with haemodialysis abroad, with blood products in the spot plasma market; it does not make sense. It doesn't matter what you do, it is who you do it with, and in this particular case, who you do it with is irrelevant, it is where the material has come from, that you give a patient or -- for all the altruistic reasons you are giving materials to patients, it is the history of where it has been and where it has come from, and then, of course, how it has been treated.

THE CHAIRMAN: And licensing could not be a complete control over this, when it gets here?

A. The problem is licensing would only have reduced the inflow into this country of a material which was commercially required. There was not a sufficient

material in this country and it had to come from somewhere. And as so often with these biological products, they are produced and they fill a niche and then you have to say, "If we cannot buy it from there, what do we do? Do we let the patient languish without treatment or do we do what we think is best? We may get it wrong, but do we do what we think at the time is best and say we will let this in, we will use it?"

Perhaps it is the altruistic aspect of being doctors and saying, "We are going to do this, we think it is best", that enables one to import material in the way which MAFF, or DEFRA nowadays, would have absolute hysterics about.

You could not begin to think of bringing in bovine plasma to protect Bovidae in this country. It might not be financially viable, but, if you wanted to, you would be hung, strung and quartered. It comes back to: this is why self-sufficiency is such a laudable concept, even if it was not pursued to the extent that it should have been.

DR JONES: Related, but more pertinent and up-to-date, you will be glad to hear, you are now:

"An external consultant to the National Blood Service with particular responsibility for aspects of transfusion microbiology in the safety of blood and

blood components."

Do you feel able to tell us your honest views about the present situation with regard to ensuring the safety of blood and blood products?

A. This is slightly --

DR JONES: Are the procedures in place at present superb?

A. In the UK?

DR JONES: Yes.

A. I think they are as good as anybody else. I think on the whole transfusion microbiology flourished extremely well over 15 years up until about 10 years ago and now I think we have been caught up by others. We were probably the first country -- historically, if you look back to the early 90s, we were one the first countries to develop PCR testing; that is genome detection for hepatitis C. I am not sure it is financially viable, but we can do that.

We have committee structures which spend a lot of time doing what I call "navel gazing". We have a protocol for looking for risks, and if we identify a risk, we undertake a risk assessment. It can be something as trivial as, "What do we do about chicken gunya?" -- this is the new virus that is present in Italy, "What do we do about malaria?" What do we do about chagas?" "What do we do about BSE, Variant CJD?"

So we now have in place mechanisms which are rather uncomfortable because we sit down and say, "What happens if ... can we justify doing nothing? Can we justify doing everything? Where are we going to find the balance in between?"

Much of this anxiety, navel gazing, has come out of the retrospective analysis of what happened with HIV. Was the Blood Transfusion Service correct in how it dealt with it? Then Lord Justice Butler's comments on the hepatitis C, non-A/non-B, has all taught us that, even if what you are doing is right, you have to say to people what you are doing and why you think it is right.

It is not so much that I think the Transfusion Service has ever been wrong, we might just not have been able to exteriorise our reasoning to say why we did what we did and why we do what we do. So we are worried about that. We have standing committees which meet four times a year, and at any time the Chair of the standing committee who reports to the Microbiological Safety of Blood Tissues and Organs, or what used to be MSBTO, can ask for advice on this, that and the other, and we have people who read PubMed each week and look for the next little outbreak of some infection.

It might be absolutely trivial, but: can it be transmitted by blood? If it is going to be transmitted

by blood, then what do we do about donors? Do we screen, do we quarantine, do we remove donors? It is an ongoing process in a much more aggressive and an objective way than it ever used to be.

DR JONES: I have the impression that on the whole you think the present structure is as good as we can think of at the moment.

A. We are under-resourced, overworked, we have too many things to do, but, yes, it works and I think it is very foolish to say that we will not be caught out, but we will be as quick as anybody else working with our colleagues in Europe. We have networks now.

You must realise that the worldwide web, whether we like it or hate it, in terms of information transfer -- for example, four years ago when SARS came out, within three or four weeks we ourselves were working with the genome, we had tests set up. We could never have done that without the web, and the opportunity for monitoring, WHO monitoring, is very much better than it was 10/20 years ago.

If this had happened 10 or 20 years ago, people would have been screening very, very, very quickly. The information flow would have been so much quicker.

JUDITH WILLETTS: I know you have to leave, but very briefly --

A. I would like to get back to hear Simon Wayne-Hobson late from the Pasteur talking about viruses, but ...

JUDITH WILLETTS: You mentioned earlier about people who were only suffering from a mild form of haemophilia and it was clearly preferential that they were receiving cryoprecipitate.

A. Can I turn that round: it was obligatory that they did not receive concentrate. It was the other way round; people had small requirements for Factor 8 replacement. Certainly in our hospital, under the late Jimmy Stewart, who was the consultant haematologist, he maintained, with the agreement and support of David Dane, on the one side, and John Crasse, on the other, both of whom you will have heard of, that the policy should be that unless you had to give a concentrate -- this was in the late 70s and early 80s -- don't give a concentrate unless you absolutely had to, maintain people on cryoprecipitate.

JUDITH WILLETTS: Was that nationwide?

A. It was nation known, but not a nationwide policy because of the way that haemophiliacs -- directors decided to run their own centres.

JUDITH WILLETTS: Because we have heard evidence of people, who suffer only from a very mild form of haemophilia, who were given concentrates.

A. I know, I lost a great friend of mine through exactly that procedure; an elective surgical operation which we had expected to be covered under cryo was covered under one dose of Factor 8 concentrate, and it was an American product, one of the well-known companies, and two weeks later he had glandular fever syndrome and that was it.

JUDITH WILLETTS: So there was no Department of Health Directive or policy or advice or ruling?

A. Well, Spence Galbraith, who was then head of CDSC, took this up in the very early 80s with the Department of Health. The trouble is he put it -- he overstated the case to try to find a median point of view and actually destroyed his own argument. He said nobody should be using Factor 8 concentrate, it is a lethal material, remove it off your shelf.

And you couldn't do that generally because -- you could do it generally, but specifically there would be people whose whole life depended on a very high level replacement, either for surgical purposes or because of bleeds, or for other reasons, and you couldn't have removed it completely because you could not have sustained a requirement for Factor 8 replacement.

But that was, I suppose, Spencer's email -- it wasn't email -- Spencer's letter which went round the fax that went round, it must have been 1982, because

David Dane was still my mentor at the time and he retired at the end of 82, so that would have been in summer 82, and that was as a result of hearing what was going on from America where there seemed to be concerns about what was happening in the haemophiliac populations.

MR MEHAN: Is there any alternative treatment for mild haemophilia as opposed to Factor 8 or cryoprecipitate or any other ...

A. There is a drug, DDAVP, which is supportive. Plasma used to be the old-fashioned thing, fresh plasma. Those are the only two options that I know. It is a very -- it is a devastating deficiency if you have it.

JUDITH WILLETTS: Thank you.

THE CHAIRMAN: Thank you very much, Professor, I am most grateful. I hope we have not caused you to miss --

A. I am sorry, I didn't want to be peremptory. If there is anything else, please feel you can get back to me.

THE CHAIRMAN: Thank you. You may care to know that there will be further evidential hearings, but we are not in the position to announce when they are, at the moment. Vijay assures me that we will publish another date soon.

(3.30 pm)

(The Inquiry adjourned)