Monday, 19 July 2021

(10.00 am)

SIR BRIAN LANGSTAFF: Can I just say something first about today because it's likely to be very warm, we're told. If anyone feels at all uncomfortable and is currently wearing a jacket, please feel free to do without if you want to do so. Nobody will treat it as any form of disrespect to me -- I shall probably do the same myself -- nor to the witness nor to the Inquiry.

Today we have Dr Walford. Dr Walford, would you please take the oath.

DR DIANA MARION WALFORD (affirmed)

Questions by MS RICHARDS

MS RICHARDS: Sir, before we start I should say, with Dr Walford's permission, that Dr Walford has a health condition relating to her voice which might mean that we need to take more regular breaks than would otherwise be the case. We'll just see how it goes.

SIR BRIAN LANGSTAFF: Well, we critically depend upon your voice, so you let us know I think at any moment you want a break, and please do so sufficiently in advance. I would hate to think that you are soldiering on despite.

WITNESS: Thank you, sir.

MS RICHARDS: Sir, there's a lot of ground to cover in the course of Dr Walford's evidence and a lot of documents to look at, and so that both Dr Walford and those listening know, broadly speaking, the order in which issues are going to be covered, let me indicate what the plan is for today.

I'm going to start by asking Dr Walford a number of general questions about her employment history and also about the structure and organisation and systems for information sharing within the Department of Health and relationships between the Department of Health and organisations such as UKHCDO.

I'm then going to look at the question of knowledge of risk of hepatitis and the role of some of the committees or advisory groups on hepatitis, and then turn to look at what will be a big topic in terms of documents, which is questions of the redevelopment of BPL and issues relating to self-sufficiency.

I don't anticipate getting beyond that today.

Then, once that issue has been fully canvassed, I'll then turn, and this will be some time in the course of tomorrow, to issues relating to the emerging AIDS crisis, the Department's response and Dr Walford's role in that respect. Then there will be various other matters to pick up.

I hope that's helpful so that those listening as

well as Dr Walford understand the broad course of the evidence over the next two to three days.

Dr Walford, I want to start by just, as I say, going through your background, qualifications, early employment history. You've told us you qualified as a doctor, medical doctor, and in your witness statement you've said that you spent some ten or eleven months as a Senior House Officer in St Mary's Hospital?

A. Yes.

Q. And you rotated through four departments, one of which was haematology?

A. Yes.

Q. There was a haemophilia centre at St Mary's Hospital and you have described a memory of preparing cryoprecipitate?

A. Yes, yes.

Q. Now what you have described in your statement is a number of difficulties/disadvantages in relation to patients having to wait, patients coming to the hospital in the night in pain and so on, and you have said in your statement that you carried those memories with you when, some years later, you found yourself having responsibility for blood and blood products at the Department. Can I ask you to explain what you mean when you say you "carried those memories" with you.

A. Yes. It was really quite graphic. Essentially the process, getting up -- for myself -- in the middle of the night on-call, as an on-call doctor -- it usually was the middle of the night, actually. My recollection was patients coming in, usually often young boys, young children even. You knew that they had been at home in pain, that they were coming in by ambulance. How long had the ambulance taken? And they were waiting. I think that the -- I seem to recall that the patients at St Mary's who had haemophilia waited in a separate area from casualty, but they first came through casualty.

And then I would be called, hopefully in good time, get up, go across the road to the laboratory, make up the cryoprecipitate and that involved actually thawing, in an up to 37-degree water bath, some blocks. If you think about thawing a block of frozen soup, you know, at 37 degrees it takes some time and basically you're watching it and it's not thawing as fast as you would like and you know that the patient is out there waiting and in pain, almost certainly, waiting to have the cryoprecipitate.

So you thawed it, you made it up into bags for

infusion, brought it up to the doctors who were treating the patient at the time, and often you saw the patient in great distress. So that's my memory and you can't forget that sort of thing once you've seen it.

Q. We'll obviously come back at later stages of your evidence to questions of cryoprecipitate in more detail but did that memory mean you came to your role at the Department of Health with a view that cryoprecipitate was something that should be avoided, that it was a rudimentary treatment and somehow old hat by the time you were at the Department?

A. By the time I was at the Department I would say it was considered to be old hat, if you like. I mean, I saw the down sides of cryoprecipitate. There were obviously some advantages, for example, you really needed to use it in von Willebrand's disease or for small children, but the advantages of Factor VIII concentrate were, by then, very evident. I won't go into the disadvantages, you are going to take me through the disadvantages very soon, I'm sure, in relation to hepatitis and subsequently AIDS, but the advantages for patients with haemophilia, severe haemophilia, of Factor VIII concentrate were so manifold that it was hard to think that you would want

them to have the less effective, more difficult, treatment, which they couldn't use to improve their lives by having it at home.

Q. Just continuing with your employment history, from the beginning of 1972 you were part of the North West Thames haematology rotational training programme. That involved a rotation through various placements, including, I think, the North London Blood Transfusion Centre?

A. Yes.

Q. So you were six months at the North London Blood Transfusion Centre. We'll come on to issues about risks of viral transmission hepatitis in the course of the morning, but can you recall whether that was something that was part of your training or part of the discussions that took place at the transfusion centre?

A. Certainly at the transfusion centre, for example, I watched how cryoprecipitate was made. I mean, that was just part of the training. You watched actually -- didn't actually do it, but you watched the technologists making the cryoprecipitate, which was made in Regional Transfusion Centres at the time. So I certainly remember that.

Q. Do you remember anything specifically as part of your

work at the Blood Transfusion Centre, and I note it was only six months and a very long time ago, but can you recall whether part of the -- either the work you did there or the training you did there involved any discussion of the risks of hepatitis?

A. I don't remember that, no.

Q. Then from November 1975 to October 1976 you spent a year as a Medical Research Council research training fellow, undertaking research at the Clinical Research Centre in Harrow. Without going into very much detail, can you just tell us briefly what that research was about.

A. Well, that was -- I had found that patients of Gujarati origin that we were looking at at Northwick Park Hospital tended to have very small red blood cells, and the main reason why you would have very small red blood cells is because of a lack of iron, so iron deficiency anaemia, but these patients were not iron deficient. We decided that it should be explored and I got the training fellowship in order to look into the cause of these very small cells.

To do that, I needed to employ the technique of globin chain biosynthesis analysis, which was, in effect, a form of chromatography, a form of putting blood through a column and taking off samples at

different intervals.

What I was able to find, together with my colleague Rosemary Deacon, was that actually there was a defect in the synthesis of the alpha-globin chain of haemoglobin. So these patients had a form of alpha-thalassaemia, nothing like as severe, of course, as the beta-thalassaemia that we all know about, but it had never been actually described before.

So naturally I was very pleased to have actually been able to discover what the problem was. It really wasn't much of a clinical problem because -- but the problem was that people kept giving them iron, these women were getting far too much iron, for example -- weren't all women. So essentially it was just good to have been able to describe a new entity, hadn't been described before, and it was written up. I wrote it up in the British Journal of Haematology.

Q. You joined the Department of Health and Social Security, as it was then known, in November 1976, and we'll come on to that shortly, but as I understand it from your statement, part of the arrangement for working for the Department of Health as a doctor at that point in time was that you spent one day a week undertaking clinical work. So you were able to, as it were, keep your hand in clinically?

A. Absolutely.
Q. So you worked, is this right, four days a week for the Department of Health and one day a week as an honorary consultant haematologist at the Central Middlesex Hospital?
A. Yes, initially it should have been one day a week but, of course, the exigencies of work at the Department meant that it was usually half a day, but I did the sickle cell clinic, because there was a big population of patients with sickle cell disease in Central Middlesex.
Q. So you, I think, took out-patient sessions for patients with sickle cell disease. Did that work involve administering blood or blood products to patients?
A. Not at all.
Q. Before we look at the specific posts you then held within the Department of Health, you told us your witness statement broadly how the Department was organised at the time, and I just wanted to ask you about that in fairly general terms.

You have described two parallel hierarchies: an administrative hierarchy, the career civil servant who would report up the chain, ultimately to a Permanent Secretary, in the Department of Health and Social

Security; and then a medical and scientific hierarchy which reported to the Chief Medical Officer. Is that right?
A. That's right.
Q. You joined the latter, the medical hierarchy?
A. Yes.
Q. You have said in your statement that it was the administrative hierarchy that took the lead on policy development, financial matters and supporting ministers. What was the role then of the medical and scientific branch? In broad terms. We'll look at your specific jobs in a moment.
A. Well, in broad terms, the medically qualified and scientifically qualified staff actually provided the relevant advice (be it medical or the scientific) to the administrative colleagues, who took the lead, as you have described, precisely. And essentially we were there almost to act as a resource for the administrative side and also, very particularly, to act as a kind of interlocutor with the wider world, so that essentially we were not sitting there simply behind a desk, we were going forth and trying to find out from professionals in the relevant policy areas, if you like, what was the thinking going on in the professional side of things, in the wider outside

world.

So we attended various meetings of experts in their own field outside, and we brought back to the Department information that we had gleaned from that. So we were sort of intel, we were gathering intelligence for use by the people who were actually at the business end of doing the policy work or briefing ministers.
Q. Would it be fair to say, and again we will obviously look at some detailed examples of decision-making in the course of today and tomorrow, but would it be fair to say that the boundaries between the medical branch and the administrative branch and their respective roles were not always absolutely black and white? Policy on medical matters inevitably brought you and your colleagues and the Chief Medical Officer and the Deputy Chief Medical Officer into advising on from a medical perspective but advising on the merits of policy proposals.
A. Yes, absolutely, and I considered that to be an important part of my work. I think the problem sometimes was that, although I'd thought I put forward fairly cogent arguments in favour of something or against something else, it wasn't always the line that was adopted ultimately, but that was the way the

system was structured. But I definitely felt that, when I could, I should use my medical training to the best effect.
Q. In your statement at paragraph 2.2 5 you say that:

"This separation into parallel divisions of 'professionals' and 'administrators' ..."

Sorry, I will wait until you've got that.
A. Thank you. It's always the page that you can't just get to.
Q. I think it's page 27.
A. Thank you very much. Yes, I have it.
Q. It's just two sentences. I won't put them on the screen, I'm just going to read them out. You say:

"This separation into parallel divisions of 'professionals' and 'administrators', was the same arrangement that Lord Fulton, in his 1968 report on reforming the Civil Service, had recommended should be abolished. It was the system that had been described as 'the expert on tap, but not on top'."
A. Yes.
Q. Could you just elaborate upon that, please?
A. Yes, well, obviously, as I've been preparing this, I've been thinking back to the parallel hierarchy system and, about 20 years ago, I think, I wrote a small think piece for the Department because there

was going to be yet another review of our organisation and one of the things that I remember quoting in that review was something that I read in Peter Hennessey's wonderful book on Whitehall but it was about a Permanent Secretary around about the time of Fulton, I think it was Sir William Armstrong and he -- they did not accept the parallel -- that there should be a single, unified structure in the Department of Health or between what they call non-industrial civil servants.

That thing that he said that stuck in my mind, and I wrote it down at the time, was that it wouldn't do to have the likes of doctors and engineers and scientists on top because the traffic, he said, would be all one way; in other words, if you put the doctors and scientists and engineers on top, you were actually always going to have them at the top of the hierarchy and it wouldn't do.

Q. What do you think were the disadvantages of this parallel hierarchy?

A. Well, I think -- I mean, my own personal view was that we should have always been fully integrated. What was the point of having different reporting lines up a particular chain or up another chain and then, at the end of the day, you had to have the two people at

the top of the chain resolving things. There's an example in here where the Deputy Secretary, on one hand, and the Deputy Chief Medical Officer had to go head-to-head to resolve something. Why would you do that? It would be much better to have an integrated division.

Q. Sir, for your note and for the benefit of the Core Participants and legal representatives, relevant extracts from the 1968 report from Lord Fulton addressing this issue are on relativity. I'm not going to put it on screen but the reference is FLTN0000001.

What qualifications or knowledge was it necessary to have, in general, in order to become a medical officer within the medical hierarchy of the Department?

A. Well, all I know, because of course I never worked in personnel in the Department, but all I know is you didn't need to be an expert in your field or to be qualified in the particular field that you ended up in. I joined the Department and I joined in to the Medicines Division. Now, this was for the assessment of pharmaceutical drugs who were coming up for licensing and, subsequently, for biologicals. Now I had no relevant qualifications for that at all.

I mean, I think that it was understood that I had sufficient intellectual capacity to be able to analyse the material that was sent up by the pharmaceutical companies, but I had no pharmacological particular experience and I had no toxicological experience. So they actually appointed me to a job for which I couldn't actually necessarily see that I had any fundamental expertise.

Other doctors in that division might well be doctors who had left the pharmaceutical industry and had come in, so they knew and understood a lot more than I necessarily did.

Then when I moved to Med SEB, which was the medical division which dealt with blood and blood products and blood policy in general, again it happened that I was a haematologist. I didn't have to be a haematologist. In fact, as far as I'm aware, my predecessor and my successor neither were haematologists. So it was a happenstance, if you will.

Q. So if we turn then to your first period of employment with the Department, November 1976 to August 1979 you joined as a senior medical officer in the Medicines Division?

A. Yes.

Q. Can you just help us with an outline of what the function of the Medicines Division was?

A. Yes. Well, the Medicines Division actually acted on behalf of the licensing authority. The licensing authority was the Secretaries of State for England and for Scotland and for agriculture. So that was the overall licensing authority but, clearly, the ministers weren't doing this work themselves. Essentially, Medicines Division acted for them.

The way in which they acted was on the defendants of the Committee on Safety of Medicines and the Committee on Safety of Medicines itself had been set up under the Statutory Medicines Commission in 1968.

Q. So is it right to understand that the Medicines Division, as it were -- did it sit outside these two parallel hierarchies --

A. Yes.

Q. So it didn't report to the Chief Medical Officer?

A. Oh, it did. It did as well. Any doctor from the Department would be reporting to the Chief Medical Officer. But the Medicines Division was actually -- had a separate structure. It was quite different. I can subsequently, if you want, describe that -- I mean, not now, I can bring the description of the

Medicines Division. It had a slightly different structure.

The Committee on Safety of Medicines was the determining entity, not the Chief Medical Officer. So if the Committee on Safety of Medicines recommended or took a view on a drug, that was going to be accepted by ministers and the Chief Medical Officer would never intervene.

Q. Then I think you may, in effect, have already answered this but was the work of the Medicines Division -- did it cover Scotland, England, Wales, Northern Ireland or just England and Wales?

A. It covered Scotland because there was the -- no, did it? I'm just trying to remember now.

I would need to take --

Q. If you don't remember --

A. I don't actually remember. I can't see why because the licensing authority writ probably ran to all of the United Kingdom but I can't remember about -- I can't actually put it exactly in context, no.

Q. Then what was your specific role within the Medicines Division as a senior medical officer?

A. Well, initially -- excuse me, a moment.

Initially, my role was to assess new drugs, that is to say, new pharmaceutical entities and that was

from 1976 to 1977 and then, at some time in 1977, as I've described, I was asked to actually move from the new pharmaceutical entities to biological products. So my job then turned to the assessment of biological products such as blood, blood products and also, of course, vaccines.

When I say actually, it shouldn't even have included blood in that because blood was not covered by the licensing system because you can't standardise a unit of blood.

Q. The Inquiry will be looking at the licensing process in more detail in later hearings, but are you able just to give us a brief overview of what the process was. An application would be received by the Medicines Division, or by the licensing authority, for a licence for a new product. In very general terms, what would the process then entail?

A. For a new biological or a new -- for a new drug, say, huge volumes of data, which were actually provided by the pharmaceutical companies would come in, all of course paper-based and they would have to be analysed. Now, the role of the specialist pharmacologists and toxicologists in the division, the scientists, they would look at the toxicology, loads and loads of studies on mice, for example, and then the doctors

would look at any clinical data, especially clinical trial data and it would be our job to provide an analysis. There was a set format, as you can imagine, forms and format, a set format for us to do that and that went off to the Committee on Safety of Medicines.

Then when it came to that drug being discussed in the Committee on Safety of Medicines, one would be there as the medical assessor to be quizzed and questioned by the committee.

Q. In the period in which you were at the Medicines Division with responsibility for biologicals, including blood products, which I think was from roughly November 1977 onwards, can you recall whether you were involved in any assessment of any applications for licences for factor concentrates?

A. I don't remember at all, actually. It wouldn't surprise me if I were but I have no recollection of that.

Q. Again, I'm really just calling upon your memory in general terms in this regard. If you've got a product -- had a product that was already licensed, so it had already gone through a licensing process, but there were going to be -- there were changes, either changes in relation to the product itself and

how it was manufactured or increasing knowledge of the risks and clinical consequences of the product, was there a process then for looking again at the licence? How did changes get considered within the licensing process?

A. Well, essentially, I think, two ways. One is that the pharmaceutical company involved would actually ask the licensing authority to look at a changed formulation or some change that they wished the licensing authority to look at, because they wanted a variation to their licence. So they could be initiated by the pharmaceutical company applying for a licence, and it was a licence variation, if you like, and that was done really quite a lot.

If there had been concern generated from no matter where that there was a problem with a particular drug, it would be open to the Committee on Safety of Medicines to say well we want to look at this again, we want to consider the safety issues, and so on. Their role was entirely safety, quality and efficacy and they would be -- it would be their role to establish that the product was what it said it was but also that it was safe, of good quality and efficacious. So they could call in a pharmaceutical company and ask them to give more evidence.

Q. What, if any, role did the Medicines Division play in relation to the content of product information leaflets, the information that would accompany the blood product or the pharmaceutical product?

A. That was always looked at very carefully, and also it was a matter for the National Institute of Biological Standard and Control for Biological Products. They were involved in the so-called batch release system for biological products and they would take great care to see that what was said in the product information leaflet, if you like, for patients and for doctors actually was in conformity with what the licence required should be there.

Q. Now, you have described in your statement -- you recall at some point during this period visiting the manufacturing premises of a pharmaceutical company in the States that was producing Factor VIII concentrates. You can't, I think, recall which company it was. Can you recall anything about the purpose of the visit?

A. Yes, I can. The only thing I can remember about it, because I was really trying to think which one could it possibly have been. It was a very long haul flight it was about 13 plus hours, I know. I mean, I actually spent most of the inspection in a fog of,

you know, not being able to concentrate because of the long haul flight. But it was because the inspectorate wanted to inspect the manufacturing capabilities, the manufacturing capacity, and I went out, I think, with two inspectors and we -- I seem to recall that we looked at two different establishments or sites, I think, fairly close to each other, and made a report and the report was not a happy one for the manufacturers.

Q. Can you recall what your concerns were about the manufacturing?

A. Well, we were very unhappy, as I recall, about the facilities, more than anything else and, I mean, one thing that I remember, because ended up writing it up in the report, and I do remember this, was that the clean area -- the big clean area that was not a sterile area but a big clean area, and the toilets opened up into and off the clean area and people were just toing and froing and there was no changing of clothes, and so on, and that was not good practice, and we wrote it up, amongst other things.

Q. How common was it for those within the Medicines Division to do that, to go and inspect a pharmaceutical premises abroad?

A. I don't actually know. I think that it obviously

happened, from time to time. I mean, a lot of the manufacturing was in the UK and they would be going off to UK manufacturing facilities. I don't know how often others went. I just recall my own visit to an extent.

Q. We'll look at the medicines inspection of BPL and the consequences for that at a later stage today.

Did you have a role with the Medicines Inspectorate? Was it part of your work -- were you involved with the processes of medicines inspections generally?

A. Not generally. I mean, this was very -- for me, it was very unusual and, actually, quite an enjoyable thing to do. I don't remember doing that to any extent otherwise.

I was also trying to remember whether I went on any of the formal BPL inspections and I don't remember because I was always in and out of BPL quite a lot, so I don't remember whether I went on any of the formal inspections. I might have done; I just don't remember.

Q. You said in your statement that it was part of your role during the time when you were in the Medicines Division with responsibility for blood and blood products to liaise with BPL and you mentioned Dr Lane

in your statement. Was it initially with Dr Maycock or had Dr Lane taken over, do you think, by the time you took up that role?

A. No, Dr Lane had taken over. He had joined BPL to be the Deputy Director as for the year that Dr Maycock was about to retire, and then it was Dr Lane that I was liaising. I did meet Dr Maycock when I was in Medicines Division. I have some memories of meeting him when I was in Medicines Division. I can't remember, obviously it was to do with blood but I can't remember what, in particular, but I know that, really, all my liaison with BPL was with Dr Lane.

Q. Now I'd asked you for an overview in relation to the process of licensing pharmaceutical products, blood products. What role did the Medicines Division play in relation to manufacturing licences?

A. Oh, completely. That was -- it was manufacturing licences and product licences. That was their job.

Q. Then did the Medicines Division have any role in relation to clinical trial certificates or clinical trial exemption certificates?

A. Yes, same thing.

Q. Again, in broad terms, what was the nature of that role?

A. Well, it was Medicines Division. I mean, again, if

somebody applied to the Medicines Division or the licensing authority, as they actually were deemed, for a clinical trial certificate or a clinical trial exemption certificate that was to be considered. It fell to be considered by Medicines Division. Whether it needed to go entirely to a Committee on Safety of Medicines meeting I think might have depended on the product.

Q. Now, in September 1979 you moved from the Medicines Division to a division which I think you refer to as Med SEB, which was Scientific Services, Equipment and Building Division?

A. Yes.

Q. You were there from September 1979 to December 1983, with a period on maternity leave, April to October 1982.

A. Yes.

Q. Now, this division, Med SEB, was, I think you tell us in your statement, staffed by doctors and by bioscientists?

A. Yes.

Q. So it was part of the medical chain of command up to the Chief Medical Officer?

A. Yes.

Q. As I understand your statement, its role was to advise

and work with the health services branch.

A. Yes.

Q. So that was part of the administrative hierarchy within the Department of Health?

A. Yes.

Q. There were two divisions: HS1 and HS2?

A. Yes.

Q. They both reported to the Permanent Secretary?

A. They reported to the senior principal medical officer -- I beg your pardon, they reported to the grade 3 which was the undersecretary, who reported to the deputy secretary, who reported up the Permanent Secretary.

Q. The policy areas that fell within the health services division, HS1/HS2, included blood transfusion and blood products?

A. Yes.

Q. The Inquiry's seen reference in rather later documents from the Department of Health to something called to the blood policy unit. Was anything of that nature in existence at the time you were there?

A. I don't know what that was, actually.

Q. Now, you've identified in your statement a number of the civil servants with whom you worked -- and I'm not going to go through them by name, we will see the

names crop up in documents -- but you make a broader point that it was up to the civil servants within HS1/HS2, the policy division, to decide whether to seek medical or scientific advice and on what. Now, that tends to suggest that the role of Med SEB was reactive rather than proactive. Was that always the case or was it much more an exchange of ideas?

A. I think it's a sort of almost a blend of that. It depended how proactive one needed to be or wanted to be. Essentially the doctor in the Med SEB would have the services of a PA and that was it. The administrative hierarchy had a real hierarchy of staff working for them. So it was more difficult to be, you know, enormously involved in certain areas because you were only on your own, you didn't have anybody to support you, to go out and find more information or to research things.

So essentially you did really what you could, and basically I think -- I mean, I had a very good relationship with the people in HS. I did have no problem at all. But they were working hard on their areas and if they needed to call on me, they would do so, and sometimes I was able, particularly if I saw something developing that I felt I needed to comment on, I didn't need any permission to do that, I would

just do it.

So it's a blended thing. It's not black and white, absolutely, but there was no question that things would happen, submissions would be sent up, a briefing would be done, meetings would be held with ministers and I wouldn't necessarily be involved at all, even if it was maybe relevant to an area that I was working on.

But it shouldn't be considered to have been a massive obstacle to working. It just wasn't the most effective way of working.

Q. Now, in terms of your own line of reporting, I think you have told us in your statement you reported to a senior principal medical officer, that was Dr Oliver?

A. That's right.

Q. What was his area of clinical expertise?

A. Do you know, I do not know. I simply didn't know about my fellow medics. We just got on with things. He had an overview of the whole of the division and would therefore, if he ever felt it appropriate -- we kept him very much informed and, if he ever felt it appropriate, he would join in any particular debate. But I really don't know what his specialty was.

Q. Then he reported, in turn, to Dr Harris?

A. That's right.
Q. Who was Deputy Chief Medical Officer. Do you know what his background was, no?

Then Dr Harris would report in turn to the Chief Medical Officer, who was Henry Yellowlees and then, I think from October '83, Donald Acheson?

A. That's right.
Q. To what extent did you have direct interactions with the Chief Medical Officer?
A. With Henry Yellowlees, very little. Very little. I don't actually recall having a single direct meeting with him during my time in Med SEB and of course he then left Med SEB and Donald Acheson took over, and I had far more interaction and in fact, in some cases, a lot of interaction with Donald Acheson, but initially not.

I mean, after Henry Yellowlees left, it was roughly the time that I moved from Med SEB to Medical Manpower, which had nothing to do with the business of this Inquiry, and there I would have had some interaction with Donald Acheson because Medical Manpower involved a lot of face-to-face working with the British Medical Association and other medical bodies. So that was something of interest to him.
Q. To what extent were there regular meetings within

Med SEB? Was there any kind of system of once a week or once a fortnight or once a month that the medical professionals would get together and discuss things, share information about things that had come to light?
A. From recollection, we did meet together. We were very small, a very small division. There were only a handful of doctors and a few scientists and one or two sort of administrative support at the secretarial level. So we -- and we were in the same corridor, so we would meet and talk.

We did have I think from time to time what you would call a divisional meeting but it wasn't -- I don't remember saying, "Well, every Monday morning we were having a meeting". We might have done but honestly I don't remember.
Q. You told us in your statement that the Chief Medical Officer was advised by various external doctors known as consultant advisers.
A. Hm-mm.
Q. I think that was across a range of different disciplines but one of the consultant advisers was in blood transfusion.
A. Yes.
Q. When you first joined, the consultant adviser was Dr Geoffrey Tovey.

A. Yes.
Q. Who was chair of the Regional Transfusion Director meetings at that time.
A. Yes.
Q. Can you just tell us a little how he, from your perspective, went about that role.
A. Yes. There were very few consultant advisers for the Chief Medical Officer. There were just a few disciplines, and I think cardiology may have been one of them, I don't recall, but very few. He had a handful of consultant advisers, and he had a consultant adviser in blood transfusion and he always had a consultant adviser in blood transfusion. Dr Tovey, who chaired the Regional Transfusion Centres Directors' meetings, was the consultant adviser when I joined Med SEB.

He met the Chief Medical Officer from time to time, I don't know how often those meetings took place, but they were always in private, and I never knew what was going on. He was obviously advising, that's what his role was, but he didn't feed back to me what he was saying and there was no way that I seemed to be able to understand what had gone on. There were no notes of those meetings as far as I'm aware.

Q. Did you ask perhaps not the Chief Medical Officer himself, if you rarely if ever met him, but did you ask those above you in the hierarchy if they could find out what was being discussed or else raised a concern about the fact that you were being kept, as it were, in the dark?
A. Well, I actually used to ask Dr Tovey what had gone on and I don't think that I found the answers terribly satisfactory. I think that's one of the issues.

If he spoke to anyone, he tended to speak to Dr Oliver, who was my boss, but he was only in post while I was there for about a year, I think it was, and then Dr Harold Gunson took over, who was entirely different. He did meet the CMO in private (it seems that the CMO liked these meetings to be private), but Dr Gunson always told me what had been discussed and I, broadly speaking, knew what was happening because he was somebody who would just communicate with me.
Q. Can you just assist with this: where physically was Med SEB located?
A. Hannibal House, I think. But, you know, I moved buildings quite often. I think it was Hannibal House.
Q. Was the HS division, branch, however it was termed, were they in the same building?
A. They may have been in Alexander Fleming House.

I mean, we had an estate -- that was one of the problems. Ron Oliver was in Russell Square. I mean, it was difficult. You had to navigate between different buildings as well as, actually, different hierarchies, if you will. I honestly can't remember about HS division but it should be at the bottom of some of these --

Q. I'm sure we can check.

Generally speaking, if HS wanted advice or input from you, what was the means by which they sought it? Would it be a telephone call or would they ask for a meeting or would it be a formal written request?

A. Almost everything was in writing in those days and one of the enormous difficulties of working then, and one even appreciated it then and I'm not saying this with any degree of hindsight, was that everything needed to go on an official file, and you really rarely knew from one moment to the next where the official file had ended up and in whose in-tray it was sitting festering, if I can put it that way, and not being acted upon.

Essentially, every document that you wrote should have gone on an official file, which was then sent forward to whoever it was intended to be the recipient of the file. So there could be quite large

intervals while secretaries searched for the official file.

Then, of course, we wrote everything out longhand. Then you sent it for typing. Then it came back from the typist with loads of corrections, so you sent it back for typing. Then ultimately, if you were satisfied, it went on the official file. This was not a swift way of conducting business.

Q. So there would be -- if people were located in different geographical locations, different buildings across the Department estate, would there then be files in different locations or did you have responsibility for maintaining your own file on a particular topic?

A. The official file would go via messenger to the recipient of an official file, and if it's HS division the messengers would take it to the relevant part of the Department.

Q. So if you were sending a minute to Mr Harley, it would go through the process you've described and then a messenger would literally take that physical document and deliver it to whatever building Mr Harley was located --

A. Would take the file and deliver it, yes.

Q. And you would retain a copy presumably?

A. Yes.

Q. Now, Med SEB was not, as I understand it, the division with responsibility for transfusion transmitted infections?

A. That's right.

Q. That was Med IMCD?

A. That's right.

Q. So whilst your division -- I say "your division", as in the division you worked for -- had responsibility for advice on blood and blood products --

A. Yes.

Q. -- the surveillance of infections, the surveillance of communicable diseases was the responsibility of Med IMCD?

A. Yes.

Q. Even where the infections were being transmitted by blood and blood products?

A. Exactly where they were.

Q. So data gathered through the Public Health Laboratory system and sent to CDSC would go to Med IMCD in the first instance?

A. That's right.

Q. And only then would they send it on to you then? If it was relevant to blood products?

A. Yes, yes. I mean, we relied on them to keep us

informed if something was coming up. It was their job to be informed by the Communicable Disease Surveillance Centre of the Public Health Laboratory Service. That intelligence would come through Med IMCD and Med IMCD would, as soon as practicable, let my division know.

Q. We'll look tomorrow, when we get on to the topic of AIDS, at the broad issue of how information was gathered in relation to that. But the MMWRs, which were obviously an important source of information, those, as I understand your statement, went to Med IMCD and would then be passed on to you if relevant to blood and blood products?

A. Yes.

Q. Where was Med IMCD located, can you recall?

A. I can't remember.

Q. Again, I'm sure we can check that out.

Now, that split division of responsibility, blood products sitting with Med SEB, infections/communicable diseases sitting with Med IMCD, that presumably meant that decision-making in relation to diseases transmitted by blood products was not the sole responsibility of one division. It was a shared responsibility effectively?

A. Well, that was right. I mean, the question of picking

up the problem, if you will, actually identifying that there was an issue here with regard to an infection in blood or a transmissible agent in blood, that was through the Communicable Disease Surveillance Centre, which was the GCHQ, if you like, of surveillance, came through to Med IMCD, and Med IMCD's role would have been to alert myself and Mr Harley or Mr Parker, whichever was the relevant person in relation to blood products, and obviously tell us what the position was. But that was the first port of call for that information.

Q. Did that, in your view -- looking back, was that problematic at all? Did stuff fall between two stools, as it were?

A. Well, I don't know that I was necessarily aware of that at the time except that I wasn't necessarily getting everything like the MMWRs as quickly as one might have wanted. I think, though, looking back at the papers that you have provided for me, there was an -- I had not appreciated the CDSC was actually surveilling for AIDS from, I suspect, July 1982. That hadn't been apparent to me. And I see that there is a document from Mary Sibellas, who was the senior medical officer in Med IMCD, talking about that?

A. Surveillance, and this was then coming very close,

about April 1983, and all that time I hadn't known that they were doing that surveillance. So that was obviously not optimal. It would have been good to know. Of course I was very pleased that they were doing it but I didn't know about it.

Q. Just in terms of how you yourself kept up-to-date with information, you've told us about MMWRs and information from CDSC. You said in your statement you would read the BMJ, the British Medical Journal, you would read The Lancet and occasionally the New England Journal of Medicine. How else, broadly, would you keep up-to-date?

A. Well, essentially, of course, one of the functions, my functions, was to go forth and talk to people who might know about blood and blood products, if you like. My two -- no, three main sources, I guess, would have been the blood transfusion directors, the Haemophilia Centre Directors -- the UKHCDO, the UK Haemophilia Centre Directors' [sic] Organisation as it was then was, directors' organisation -- and of course, ultimately, Dr Lane.

So those -- I would go out and speak to those specialist bodies and also bring that intelligence back in.

Q. You also refer to, in your statement, to some extent,

relying upon the lay press and what was being reported in the press?

A. Well, that really only happened around about the emergence of AIDS. I mean, basically I don't know that the lay press was of any particular assistance in earlier issues, for example, hepatitis, but it was only relying on the lay press when it came to, "Well, what on earth is going on? This disease in America, what's happening, what's happening here?"

That's where they were sometimes, apparently, ahead of the game, certainly producing high profile material in the press, which was actually very helpful because it meant that I could try and investigate and try and find out what was going on.

Q. Did you have any ability to access pre-publication medical research at all, as far as you can recall?

A. Well, the only -- I wouldn't normally have, no, not at all. The only pre-publication document that I found in the papers that you've given me is a letter that Dr Craske intended to send to the BMJ, I think it was, about non-A, non-B hepatitis. But normally speaking I wouldn't have any access to pre-publication work.

Q. Parts of your later career was involved in looking at various matters relating to medical education. I'm not asking about the detail of that but do you recall

whether your own medical training, or indeed any aspect of your Civil Service training, involved consideration of questions of ethics?

A. At that point no, not at all. I mean, I'm interested in your comment about Civil Service training.

Q. Was there any?

A. No. I mean, I didn't -- I found it very difficult because we were, as it were -- you came into the Department and you were by and large put into an area and expected to become very quickly reasonably expert, at least on paper, in that area. I did ultimately say to the Chief Medical Officer, Donald Acheson, "I'm not getting any training, I haven't been trained to do any of this, and I think I must leave the Department and try and get some more training outside, particularly in public health" to which he said, "Well, really, the discipline you want is epidemiology" -- he was, of course, a distinguished epidemiologist -- "I will release you for a year to go and do an MSC in epidemiology at the London School of Hygiene and Tropical Medicine", which was incredibly useful and informative, but I didn't have that training when I was in Med SEB.

Q. Then just to complete your career by way of overview, December 1983 you left Med SEB?

A. Mm-hm.
Q. And your role, I think, was taken on by Dr Alison Smithies?
A. I believe so.
Q. Then you moved to a different division, Med MME, have I got the acronym right?
A. Yes.
Q. As a senior principal medical officer and undersecretary, but there your areas of responsibility were medical manpower and post graduate medical education and you didn't have any dealings with the matters that the Inquiry is investigating?
A. None whatsoever.
Q. Then you remained in that post until 1986, when you took this year's sabbatical to study epidemiology at the London School of Hygiene and Tropical Medicine?
A. Yes.
Q. Did that sabbatical year involve studying matters of relevance to hepatitis or AIDS or was it more general?
A. No, it was not an infectious disease epidemiology course, it was actually chronic diseases. So no, it's not that we wouldn't have touched on infectious diseases. We did. I can remember an absolutely brilliant lecture on the epidemiology of measles, for example, the modelling, but certainly not particularly

hepatitis, not AIDS, no.
Q. You then returned in 1987 to the Department as a senior principal medical officer in Med IMCD, so the division that we were talking about which was responsible for infectious diseases.
A. Yes.
Q. You then had responsibility for the AIDS unit which had been created by that time.
A. Yes.
Q. You were in that post for I think a couple of years.
A. Yes.
Q. Then in 1989 you became Deputy Chief Medical Officer?
A. Yes.
Q. And Director of Healthcare for the NHS Management Executive?
A. Yes.
Q. You were one of three Deputy Chief Medical Officers, is that right?
A. That's right, yes.
Q. That was from '89 to '92. Again, very broadly, what did that job entail?
A. As Deputy Chief Medical Officer?
Q. As Deputy Chief Medical Officer.
A. Well, broadly speaking, of course, deputising for the CMO. He couldn't be everywhere. He had an incredibly

large brief, so you deputised for the Chief Medical Officer. I think I have put -- though I'd need to find it in the papers -- the exact areas of responsibility I had. It was quite schizoid, if you like, because I was not only part of the policy division, if you like, in the Department of Health but I was also a director of healthcare on the NHS Management Executive, which was based in Leeds, or moved to Leeds, and essentially I was doing two fairly separate things: policy on the one hand, with the Chief Medical Officer, and operations on the other hand, NHS operations, with the chief executive, Duncan Nichol.

So I mean the areas of responsibility broadly mirrored each other but were not identical.
Q. Then, 1993, you took up a role as director of the Public Health Laboratory Service?
A. Yes.
Q. You remained in that role until 2002?
A. Yes.
Q. We'll come back to that, I think, a little later at the end of your evidence?
A. Right.
Q. I have been asked to ask you this, Dr Walford: in the course of the work that we've been talking about, were

you ever asked to sign the Official Secrets Act and, if so, did that or does that restrict the evidence you are able to give to the Inquiry?
A. I did sign the Official Secrets Act and, furthermore, when I was DCMO I had this special vetting, if that's the right word, very particular, every article of my financial, you know, matters, and so on, were taken apart, I was questioned for this particular extra vetting, to receive secret material, or whatever was the classification at the time, I can't remember. I don't actually remember ever having had the pleasure of seeing something that was particularly secret but I may have done.

It doesn't inhibit me at all in this Inquiry because I have been -- I am quite clear that I must tell the truth, the whole truth and nothing but the truth and so, if I inadvertently overstep the mark terms of the Official Secrets Act, I hope somebody will defend me.
Q. I want to turn to just now the relations between the Department and others bodies and look, first of all, at the Department and NHS bodies. You've said in your witness statement that the Department was fairly hands off in relation to day-to-day operation of the National Health Service and essentially it left

day-to-day operation running of hospitals, decisions on provision of services to the Regional Health Authorities; is that correct?

A. That is right.

Q. Why was that?

A. I suppose it depends when we're talking about but it was around about the time we're talking about that there was a Royal Commission on the NHS and that actually recommended that much more devolution to regions was the way to go, so that, so far from centralising power in the Department, if you will, devolution should occur to the regions.

So what seems to have happened, although I wasn't involved at all in the financial side of things, is that budgets were agreed for each Regional Health Authority (dependent on a whole host of factors and a terribly complicated formula) but, basically, every region was given its budget and was then told to work within it and the Department and whatever its priorities were, and if the Department wanted to impose a new priority the region's response would be "Well, give us some more money for that because we've set our priorities, that's what our budget is going on and you have agreed it, if you want us to do X, please can we have some more money?"

That was really the only lever that I am aware of, really, apart from some moral suasion which may have been possible from the Department to the regions, was that money had been given to them and if more work needed to be done of substantial difference from the work that they'd already signed up to do, basically they wanted more money.

Q. Now, might we infer from your statement that, in terms of this somewhat hands-off relationship between the Department and the Regional Health Authorities that there was -- the Department didn't consider, for example, the issuing of instructions or directions to Regional Health Authorities; is that right?

A. Well, it would have been extraordinarily rare and I can see in the papers that you provided to me there was one instance where there was a question of could we force regions to adopt the pro rata system of plasma supply to BPL in order to get a pro rata return of material, and the answer was that we couldn't instruct them but we could discuss, consult, exhort and hope that they would understand the rationale for that, which was that, ultimately, they would save money.

Q. Now, my next question's not designed to try and make you an expert on the legal framework governing the

National Health Service and the lawyers can look in due course at what powers were conferred by the National Health Service Act of 1977 but, as far as you can recall, then, was it the understanding within the Department that the Secretary of State couldn't issue instructions to Regional Health Authorities or was it more a matter of it wasn't seen as a good idea to issue instructions to Regional Health Authorities? Are you able to help with that?

A. I don't know if I've ever understood it in those terms. I mean, essentially the Secretary of State or the minister would meet with the chairs of Regional Health Authorities for an accountability review every year or every six months -- I forget exactly the frequency -- and, basically, I think that if a Minister or a Secretary of State said "really want you to do this", I think the chairs of the Health Authorities would really want to try and do it. So I think there was an element of "no, we're not giving you an absolute instruction but please listen to what it is that we would like you to do".

Q. Now, in relation then to clinical practice and what doctors did or didn't do, you've referred in your statement to the role of clinical freedom.

A. Yes.

Q. Essentially, you have said that those within the Department didn't seek to interfere with the practice of clinicians.

A. That's right.

Q. Why was that?

A. We were certainly not equipped to do it. We were not experts. We didn't have the wherewithal to do it. It was the role of the expert bodies, the Medical Royal Colleges, the specialist societies, to determine what was or was not good practice. For departmental doctors to have stepped into that breach, as I've said, we were not particularly qualified in any particular area -- didn't have to be -- would have been quite inappropriate and it didn't happen.

Q. Would it be right to understand then that there was, in effect -- I don't mean that there was something that was formally written down but there was, in effect, a policy of non-interference with matters of clinical practice?

A. With matters of clinical practice, that's right.

Q. Even if, hypothetically, patients were being treated in a way which exposed them to risks that might be avoidable?

A. I think if the Department decided that that's what was happening they would convene an expert group. The key

thing was to get the imprimatur of an expert group, a relevant group, a group that doctors in the field could see were obviously expert in the area, were more than their peers, if you will, and if you convened the expert group and the expert group made a recommendation, then the Department could follow up, letters from the CMO could go out. But you needed the imprimatur of the expertise of people who were practising in the field and not to rely on departmental expertise.

Q. Was that because the perception within the Department was that doctors wouldn't listen to departmental doctors then?

A. Well, I suspect there was an element of that and I'm very well aware from papers that I've seen that the expert groups didn't particularly welcome -- even when you attended to try to be helpful, didn't necessarily welcome your appearance at a particular meeting and what you might have to say. So I think they were probably right in thinking that if the Department or Departmental medical staff tried to lay down the law that would not be well received.

Q. You've used the phrase in your statement of clinicians jealously guarding their clinical freedom --

A. Yes.

Q. -- that was your perception?

A. Yes.

Q. What about the Chief Medical Officer, though? A consultant might not want to hear what Dr Walford or Dr Waiter or Dr Smithies or Dr Oliver had to say but wouldn't something going out with the imprimatur of the Chief Medical Officer be something that doctors would abide by or at least consider and be assisted by?

A. Of course, I'm having to think here for doctors that -- I wasn't a part of that cohort of people that I'm now thinking for, but the answer is, of course if the CMO chose to issue a document, then certainly account was taken of it and, hopefully, people actually listened and acted on it.

The thing was that the Chief Medical Officers traditionally had issued what you might call very broad public health advice. They did not issue specific clinical advice. They might do that if it was part of a recommendation of the standing medical advisory committee or of -- in terms, the hepatitis advisory group. If there was some recommendation that the whole body of external doctors and the Health Service needed to know about, then they would do it.

But in terms of just issuing statements based on

their own view of clinical matters, that didn't happen.

Q. We might come back later, probably tomorrow, to a couple of examples of "Dear Doctor" letters and I'll explore that a bit further.

What about the question of what information patients were receiving from their clinicians? Was that something which the Department or the Chief Medical Officer, as far as you can recall, ever involved itself in?

A. No, I think that's even more involving themselves in the clinical domain; in other words, the relationship between a doctor and his or her patient was sort of sacrosanct. It would be difficult to suppose that the CMO would come in on that sort of relationship. More general advice might be in relation to vaccines, for example. I'm sure you probably want to ask me about vaccines, which the Chief Medical Officer very often -- very often, wrote out about.

So that's different. That's applying a rule to the generality of patients but not intervening in terms of what a clinician says or advises his or her patient.

Q. I'm certainly not suggesting that the Chief Medical Officer would intervene between an individual

clinician and individual patient but, leaving aside the issue relating to vaccines, and, as I say, we'll look at one of the "Dear Doctor" letters on that and a "Dear Doctor" letter in relation to AIDS tomorrow but if there was a risk of something very serious indeed, would the Chief Medical Officer not regard it as part of his role or any of the medical divisions regard it as part of their role to ensure that patients as a cohort were informed about the risks of -- whether a communicable disease or the risks of an adverse reaction?

A. Well, in communicable disease, in general, yes, the Department would sometimes put out press releases or put out warnings, for example, if there was -- let me take an example. Largely, from Med IMCD, where mostly we were dealing with the national outbreaks of disease, of one sort or another. So supposing the whole of the water supply had got cryptosporidium in and you needed to boil water -- I remember that particular one -- everybody was told boil water. These were very significant major public health concerns.

In relation to what I suspect you're aiming for, if you will, is, let us say on the question of AIDS and what Haemophilia Centre Directors and haemophilia

treaters might have been saying to their patients, I think you'll see in one of the documents that Dr Gunson assured the CMO that patients were being informed. So the relevant group of doctors, the Haemophilia Centre Directors, did know about this potential problem. Obviously, none of us knew the extent but we knew that there was a hazard there, and so Haemophilia Centre Directors were well aware of that, and Dr Gunson said that they were informing their patients and he told the CMO that.

Q. We'll come back to that issue when we look at AIDS in more detail tomorrow and I know that you will be aware, Dr Walford, that the evidence the Inquiry has heard is very much to the contrary, in terms of patients being given that information, but I want to explore that in more detail when we look at AIDS in more detail.

Can I then just ask you just again, on quite a broad level, what the role of the Chief Medical Officer and of the Deputy Chief Medical Officer, there was a function in providing, obviously, advice to ministers and to the upper echelons of the administrative hierarchy. That was part of the CMO's role?

A. Yes.

Q. There was a role in providing advice to doctors to some extent, the "Dear Doctor" letters we'll come back to but there were some examples of the Chief Medical Officer providing advice to doctors. In terms of providing advice to patients and the public, is it then really only in those national examples that you are describing, the water supply is contaminated, that the Chief Medical Officer would become involved?

A. Largely, unless there had been -- an expert group had met very specifically to consider, maybe at the behest of the Chief Medical Officer, please will you look at this particular issue, it's worrying us in the Department, please look at it, their recommendations, those would be promulgated if necessary.

MS RICHARDS: Sir, I note the time. I'm still on the same broad themes but moving to a slightly different subtopic, so perhaps a good time for a break?

SIR BRIAN LANGSTAFF: Yes. We'll take a break then until 10 to 12.

Now, this is your first break. What I'm going to say applies to this break and any other break that there will be and there will be a number during the course of your evidence, as you may anticipate. You are giving evidence. What you may not do is discuss any answer you've given, anything you've been asked

about or anything you anticipate you're going to be asked about with anyone whether it's family, friend, lawyer, anyone. You can talk about anything else you like. I look forward to seeing you back at 11.50.

A. Thank you.

(11.15 am)

(A short break)

(11.50 am)

MS RICHARDS: Dr Walford, can I ask you to look at paragraph 47 of your statement. It's on page 128 and I'll put this on screen.

Soumik, it's WITN4461001. I think it's page 128.

A. Yes.

Q. So we'll see at paragraph 47.1 the issues that you were asked to describe the decision-making structures and processes in place, and with what oversight, during your time at the Department to ensure: comprehensive assessment of the risks; timely, co-ordinated and structured decision-making as to the nature and extent of risks; timely, co-ordinated and structured decision-making as to the steps that should be taken; and then adequate information sharing between officials and ministers.

I just want to pick up on a couple of issues

relating to that.

A. Yes.

Q. If we look at your next paragraph, you say this:

"Responsibility for the assessment of risks arising from blood and blood products did not rest with any one entity or organisation."

Then you listed a number of bodies with responsibility in relation to that matter, excluding the NHS itself, Regional Health Authorities and the like itself.

So if we go over the page, we can see that you identify responsibility for risk assessment and monitoring of the safety of blood and blood components resting with the National Blood Transfusion Service and Regional Transfusion Directors.

Then, in relation to identifying blood-borne infections, that was with the Communicable Disease Surveillance Centre and then the Med IMCD division of the Department of Health.

You then refer to the role of the licensing authority in relation to biological products, dealt then with risks to healthcare staff. Then you have identified a range of committees -- this is paragraph 47.7 -- advising the Department on risks relating to blood and blood products. You name some

of them there.

Then, over the page, top of the next page, you have observed that:

"... there was no overarching advisory committee on blood safety, such as the Committee on the Virological Safety of Blood which was set up, some years later, to advise the Government on blood safety issues."

Just pausing there, you have recognised that there was no overarching body, and you've identified a number of different bodies, committees, working parties, organisations with a role in relation to this issue. Looking back, do you think it would have been a good idea to have a body such as the Committee on the Virological Safety of Blood at an earlier stage; in other words, one overarching body with responsibility for this issue?

A. Indubitably. Obviously it would have been a good thing.

Q. Was it something that you can recall ever being discussed during the period you were involved, so up to the end of '83?

A. Not at all.

Q. Then you say in the next paragraph this:

"Unless there were an identified hazard, with

risks to public health, which required a national response, the wider [Department] generally did not become involved in decision-making or risk mitigation, as this was best done by the responsible organisation, or through the Licensing Authority ... In the event that a hazard that identified with potential national or serious ramifications for the public health, the DHSS would become involved and would work with Regional and local public health officials and the PHLS to take the necessary action and offer guidance to the responsible bodies. In such circumstance, Ministers would be promptly informed, briefed, submissions provided and would be asked to take decisions as necessary."

Now, I don't know whether it's possible to answer what I'm going to ask you in the abstract or not but can you assist us with, really, when did something that was a matter of clinical practice or a concern about risks of treatment, when did that become a risk of such proportions that it became a public health matter in which the Department and Secretary of State would become involved?

A. Well, I suppose, strictly sticking with blood and blood products if I can, the area where I think appropriately the Chief Medical Officer would have

given advice was once the advisory group on testing for hepatitis B, surface antigen and its antibody, had recommended certain screening programmes to be undertaken and for hepatitis B, remember, all blood was potentially infectious, all blood would potentially transmit hepatitis B, and therefore it was a very wide public health significance.

Once there was a way of dealing with it, which was screening for hepatitis B surface antigen and its antibody in the blood system, then it would be perfectly appropriate for an alert to go out, advice to be given to the transfusion authorities, to people who were donating blood and so on, that actually here was a risk, here was what we were doing about it or what could be done about it and, of course, subsequently there was a hepatitis B vaccine.

So areas where actually there is some action people can take, something that you can do potentially to avoid actually finding infections that could have been avoided, then the Chief Medical Officer would put out appropriate guidance.

But, remember, I think that you will know, that this particular recommendation came from the third meeting of the advisory group on testing for hepatitis B and its antibody. So there had been three

meetings over a period from about 1973/74 or something until the date that the guidance was put out, and then firm recommendations put out as to the screening necessary for the blood products, blood and blood products.

Q. That suggests -- and this, again, is very much by way of inviting you to give general observations or general reflections, that suggests that potentially the Department was reactive rather than proactive in relation to assessing risk and taking action.

A. I don't -- I think, if I may say so, to characterise it as reactive is not appropriate. Essentially, the Department had to take advice. It didn't of itself have the capacity to formulate what needed to be done. It needed to rely on the committees that it established in order to do this.

So I don't think it's reactive to describe that a report is produced and the Department acts on it, and acts on it quickly, which it seems to me they did in that particular instance. I think that's the appropriate reaction, rather than saying it was somehow or other too slow or retrograde in some way.

Q. Going back to the question of assessment of the risks arising from blood and blood products, again, during the period you were there (so from '76 through to the

end of '83, and leaving aside what happened thereafter because you weren't then involved with blood or blood products for some years), in that period of time did the Department ever have available to it a comprehensive assessment of the risks from blood or blood products?

A. Comprehensive assessment seems to imply that all the information might have been brought together in a large and compendious document which contained all the possible risks, and the answer to that is, as far as I'm aware, no, it didn't.

Knowledge of risks obviously accumulated over time, and essentially, when we sort of start off this period, people were beginning to know about hepatitis B, and then of course gradually moving on to non-A, non-B, and then, alas, gradually moving on to AIDS. But those were not -- that was not knowledge that could have actually been there in a kind of compendium of what we know. There was a huge amount known about the fact that blood transfusion itself carried risks. There was no way, even today, that blood transfusion doesn't carry a risk, however small it may be now because of all the wonderful screening that can be done. But there is always a risk inherently in having foreign material from some other

person introduced into the body of another person. There is always a risk.

Q. What you described in that section of your statement could be said to be a somewhat fragmented system, multiple organisations, bodies --

A. Yes.

Q. -- involved in assessing different aspects and taking decisions or making recommendations on different aspects of risk and how to mitigate risk. Do you see disadvantages or down sides to that and if so what were they?

A. Well, there are disadvantages. If you are particularly looking at blood transfusion, I mean, what has evolved over time, apart from the Virological Safety of Blood Committee, which was something obviously would have been wonderful to have had it at the time that I was there, but we didn't -- but then there is the -- a really important system of what's called haemovigilance, which the National Blood Transfusion Service now operates, which is called SHOT -- the SHOT system, which is the serious hazards of transfusion, and that really monitors everything very, very closely. That's the sort of thing that we could have done with but we didn't have it.

Q. Then I just want to pick up again, as a matter for

general exploration at this stage, the role of ministers. First of all, I think the various ministers involved with blood, blood products in relation to the years that you were there were Dr Vaughan, Mr Finsberg, Lord Glenarthur, now Lord Clarke then Mr Clarke, and now Lord Fowler then Mr Fowler; is that right?

A. Yes.

Q. Can you recall whether you yourself had direct meetings with any of those ministers?

A. While I was in Med SEB, really very few. I was too junior, in effect, so I didn't -- I often provided material for briefing but I didn't have very many face-to-face meetings. I did accompany -- it's obvious from the papers, I accompanied Mr Finsberg, I think (and possibly Dr Vaughan as well; I don't recall), to BPL as part of an add-carrying contingent, but very rarely was I actually briefing ministers face-to-face.

Q. Who was it who would decide that a matter needed to go to the minister, a decision needed to be made, the minister needed to be either informed of something or asked to take a decision?

A. In general, it would be the administrative divisions.

Q. At what level would that kind of decision be taken?

A. Round about -- well, the decision would actually be sitting between the grade 5, who was called an assistant secretary in those days, and the grade 3, the undersecretary. So, taking some of the BPL material, it would be Mr Harley, as the grade 5, the assistant secretary, Mr Wormald, the grade 3, the undersecretary.

Q. Were you aware of any, as it were, yardstick or criteria by which those in the administrative division would decide this is a matter that has to go to the minister, this one doesn't?

A. No, no, it was a rather arcane art actually, from my perspective, because, as I mentioned, we didn't receive any training when we came into the -- I came into a policy division, if you like, the Med SEB, and I have no recollection of being trained in that or even understanding what a PQ was or -- all this I learned on the job, I didn't know, and it just seemed to me to be natural that, okay, they decided something was going to go.

Now, obviously there could be pressure from the Deputy Chief Medical Officer, for example, as there was on a number of occasions, because he was chairing some very important committees, but then that would be him saying to administrative colleagues,

"this needs to go up to ministers", but not -- by and large, not presenting it himself.

Q. Your statement I think is largely addressing decision-making affecting England and Wales.

A. Yes.

Q. Can you recall whether you had any interactions or any significant interactions with the Scottish office or the Scottish Home and Health Department?

A. Yes. I wouldn't call them significant interactions but I did interact on occasion. In fact, I went up to visit my counterpart in Scotland, Dr Bell, and he -- one remembers some of these things because they stand out and I remember that he gave me my first taste of haggis. So, yes, I remember that trip, and basically we exchanged information.

But I didn't often deal with Scotland -- in fact, very rarely -- except to receive information that they may want to convey. But essentially the Scottish Home and Health Department, through its Common Services Agency, ran their Scottish National Blood Transfusion Service, and they had their own protein fractionation laboratory at Liberton, and so they were pretty self-sufficient when it came to matters to do with blood and blood products.

Q. So decisions affecting Scotland on the areas in which

you were most closely involved were largely taken within Scotland, to your knowledge?

A. Yes, yes.

Q. Other than, as it were, you liaising with Dr Bell, for example, were there any more formal measures in place, either at your level or at a more senior level, to ensure that there was consistency of medical advice, for example, being provided both in Scotland and England and Wales?

A. Not that I am aware of. I don't know that I would necessarily have been aware of whether there was consistency or not because I might not have known what was going on in Scotland. The only area where I am sure that the same document went out was on the leaflet for donors which, having been developed in the English system, nevertheless based on one that had been worked on in Scotland, it was decided that that donor leaflet should be actually a UK leaflet, it should be used by both Scotland and, of course, England and Wales but that each part of the country would put out its own press release describing what was in the leaflet and that's what happened. But for anything else, I simply don't know.

Q. Then what about the position in relation to Northern Ireland? What we see in the documents is occasional

references to issues about plasma and arrangements being made between Northern Ireland and Liberton for fractionation of plasma collected in Northern Ireland, and so on. But, in terms of the areas of policy that you were feeding into and the decisions that were then being taken through the administrative branch in relation to blood and blood products, what role did Northern Ireland and the provision of products in Northern Ireland play?

A. I'm ashamed to say I probably never actually thought about Northern Ireland. It wasn't my area of responsibility. The only thing, looking back at the papers, that I find is that at some stage a decision was taken that Liberton should do the fractionation for Northern Ireland. So it was a Scottish decision and it was dealing with Northern Ireland. But, other than that, I was not involved at all.

Q. Did you have any of the equivalent interactions you have described with Dr Bell, did you have any interactions with the Northern Ireland office or any officials relating to Northern Ireland?

A. I'm not aware. I think they may have come to a joint meeting. There was one joint meeting where I think officials from Northern Ireland were there but I have no recollection of any interaction with them at that

meeting.

Q. Then, in relation to Wales, although, as I understand it, decisions that were being taken that you fed into largely affected England and Wales, we see, for example, Welsh Office representation again at some meetings. Do you recall any particular interactions with civil servants in the Welsh Office?

A. No.

Q. Can I turn then to the relationship between the Department and your own relationship with UKHCDO, as the next topic.

A. Yes.

Q. Before we look at a handful of documents, what was your understanding when you took up your post in Med SEB about the extent to which concentrates or cryoprecipitate were a regular part of the treatment of haemophiliacs in the UK?

A. Well, I think from my time in the Blood Transfusion Service and my time in the Medicines Division, where concentrates were obviously an issue, they were products which would have gone for licensing, and my time with the Medicines Inspectorate, and so on, I was well aware that both cryo and Factor VIII concentrates were used in the treatment of haemophilia.

Q. What about home treatment and prophylactic treatment,

did you have any understanding of the extent to which those were part and parcel of the clinical care of patients with bleeding disorders?

A. I'm just trying to think when I might have become aware of it in terms of the sort of dates because that gradually increased and I couldn't be certain exactly -- I can't identify exactly the time, but certainly by the time I was in Med SEB and talking to the UKHCDO, I was well aware that they were getting more and more into home therapy with concentrates and, as time went on, prophylactic therapy with concentrates -- not everywhere but that was available during my time in Med SEB.

Q. By the time you were in Med SEB and in that sort of four-year period, '79 to '83, would UKHCDO have been, or the Reference Centre Directors have been the primary source of your information about how haemophiliacs were treated?

A. Absolutely.

Q. Do you recall being aware of DDAVP or the extent to which that was being used?

A. Not the extent to which it was being used but I recall the various discussions in the UKHCDO meetings where it was always very -- once DDAVP was actually discovered, if you will, and its effect on releasing

Factor VIII from endothelial cells in the patient, it became definitely a part of the therapeutic armamentarium of directors or haemophilia treaters to use that for von Willebrand's disease, to use it for, mild haemophiliacs; in other words, to avoid using Factor VIII concentrate. But it really needed to be in a mild haemophiliac so that it can actually produce the Factor VIII level that you need to stop the bleeding. But it was definitely their policy, as far as I can recall, to use it as appropriate for such patients.

Q. Would it be right to understand that the use of DDAVP was something which the Department itself did not become involved in; it was regarded as part of that clinical freedom that you have described?

A. Yes, because the Department, again, I would say, never became involved in what treatment was administered to what patient in any area, heart disease, gastrointestinals -- it didn't become involved.

Q. Would the same be true in relation to then the approach to treating children or the approach to the treating mild haemophiliacs more generally that would be regarded as something for haemophilia clinicians under the auspices of UKHCDO to formulate their own policies?

A. Yes.

Q. Now, in your capacity as principal medical officer at Med SEB, you sometimes attended the Annual General Meetings of UKHCDO?

A. Yes.

Q. I think, looking at the documents, you attended in November 1979, which would have been your first -- was that your first attendance probably?

A. It should have been, yes.

Q. Then you attended the next one a year later in September 1980. I want to look at that really just to get a flavour of UKHCDO meetings. So it's PRSE0003946 please, Soumik.

A. Do you, by any chance, have a number for my statement?

Q. It's not referred to in your statement. It's one of the additional documents that we were provided with, Dr Walford.

So we can see the date there. Glasgow, 30 September 1980. The chair is Professor Bloom. There's a list of apologies for attendance of those who are not present, so we won't look at that.

If we then go -- I really want to get a sense of how the meetings work from your perspective. That's the purpose of going to this section. If we go to page 4 please, Soumik. If we look at the bottom of

the page, there's a heading "Report on the 1979 Annual Returns from Haemophilia Centres". Then there's a reference to Dr Rizza presenting a report on the annual returns and then there's a long discussion about, essentially, what they show and issues about self-sufficiently and commercial concentrates, and so on.

You were there and present. We see you interjecting from time to time. Would you, as far as you can recall, get these reports on the annual returns in advance of these meetings?

A. Oh no, not in advance of the meeting. Whether we got them afterwards as part of the minutes, I don't know, but certainly not in advance.

Q. But you would get them at some point?

A. We might but it depends. Basically, if they were appended to the minutes, yes. If not, no.

Q. Then, if we just go over the page, there's a long discussion recorded about product usage and I just want to pick it up about six or seven lines down -- no, actually, I'll pick it up five lines down. It says:

"Dr Rizza said that there appeared to be total inconsistency between the usage in various regions. Professor Stewart said that there were difficulties

about getting any material at all. Regional Health Authorities were reluctant to pay for Commercial materials ..."

Then two or three lines further down, it says:

"Professor Stewart said he was worried about the increasing usage of Commercial factor VIII. He suggested that the Department of Health should look into the question of licensing a commercial firm or firms to make NHS material. Dr Diana Walford said that the Department of Health at the moment, was actively discussing this question" and then the discussion continues.

I'm not going to ask about the detail of the discussion, I just want to get a sense of how the meetings and the discussions worked from your perspective. These minutes record you actively contributing to the discussion. Was that generally how the meetings ran?

A. Well, I certainly spoke up if I ever felt I needed to. I mean, essentially it was their meetings but if I knew something that I felt they needed to know or they had raised an issue to which I knew the answer (as, for example, in this case), then I would say so. There was no bar to my speaking up, although I was an observer and it was their meeting. I wasn't

particularly slow in coming forward.

Q. Then if we just go on to page 9 please, Soumik, half way down the page, it says "Reports from Working Party Chairmen", and the first is a report from the Hepatitis Working Party chair, who was Dr Craske, and he refers to presenting a short written report and describing the findings of the Working Party and future plans. You've referred to Dr Craske and his reports being a valuable source of information for you. Would it be right to understand that those reports at least did find their way to you generally?

A. Yes, generally, and later, though. Basically, as far as I can see from the papers, I sometimes received the reports quite a few months after they had already been discussed. Obviously, if we were discussing or he was presenting the meeting, he often presented fact findings and so it would be up on a screen or whatever it was, well I would be looking at that but I wouldn't necessarily have the actual report.

Q. Then, if we go over the page, the bottom of the next page refers to the Home Treatment Working Party. It records Dr Jones giving a verbal report. So would this be, again, the kind of sort of information about the prevalence of home treatment that you would have?

A. Yes.

Q. Then if we turn to the last page, it may be a stretch to ask you to remember this because it's obviously over 40 years ago but we can see that this meeting took place in Glasgow and we can see its reference to -- there's a reference to the meeting closing and followed by a one and a half day symposium entitled "Unresolved Problems in Haemophilia", organised by Dr Forbes, the Royal College of Physicians and Surgeons of Glasgow and sponsored by Travenol. Do you recall whether you attended that symposium?

A. I was trying to remember because, obviously, I saw that that had happened and I've actually seen the -- I've seen a paper from the symposium. Unless you've got my name down as having attended then I don't know whether I attended or not.

Q. We don't have a list of attendees.

A. I'm sorry, I can't say.

Q. So you attended the Annual General Meeting in 1979, 1980. You attended the 1981 meeting, I'm not going to take you to that.

The 1982 Annual General Meeting took place when I think you were on maternity leave. Would you have expected someone to attend in your place from the Department? There's no sign from the minutes that they did.

A. I mean, possibly. It depended how my stand-in chose to operate. I don't know whether she did or she didn't or even whether she may have known about the meeting because if papers came through to my desk I'm not sure how she would necessarily have known. I hope somebody would have passed stuff to her but I can't be sure.

Q. You didn't attend the October 1983 annual meeting, although you did attend a Reference Centre Director meeting just before that, or a month before that. When you didn't attend, what was the kind of time-frame before which you will then get the minutes and copies of any reports?

A. Really long -- really long. It was just not a system that worked terribly efficiently. So it wasn't that we had the meeting and then a few days later along come the minutes. It took often, I think from recollection, I saw the minutes for the first time the draft minutes, if you will, at the next meeting. They obviously didn't consult the Department on what was going in the draft minutes. The chair of the meeting would have dealt with those.

Q. So we've seen correspondence from Dr Rizza often at this time sending out copies of the draft minutes and asking for comments. As far as you can recall, those

didn't get sent to you?
A. No.
Q. Then, is this right, you didn't routinely attend the Reference Centre Director meetings but you did attend some of them specifically either because you asked to or you were asked to?
A. Yes. It was not considered to be appropriate for departmental observers, if you will, to go to the Reference Centre Directors' meetings. Essentially, they were their private meetings and officials didn't go.
Q. So when you say "not considered appropriate", do you mean not considered appropriate by the Reference Centre Directors?
A. Yes.
Q. We will look, when we look at AIDS tomorrow, at a couple of the meetings in 1983 that you attended but one of which was a Reference Centre Director meeting on 19 September 1983. I don't want to look at those minutes now but I want to look at an exchange of correspondence between Dr Jones and Professor Bloom after that meeting, just to invite really your comment. So if we could have OXUH0000882, please.

This is a letter from Dr Peter Jones from the Royal Infirmary in Newcastle, the Newcastle

Haemophilia Centre, 13 October 1983, to Professor Bloom, and it refers in the first paragraph to the last meeting of Reference Centre Directors:

"... you asked us to write in with our views about centralised purchasing."

Just pausing there, the idea, as I understand it, and it was an idea that you brought up at the Reference Centre Directors' meeting was that, rather than haemophilia centres purchasing their own commercial products, it would all be done centrally.
A. Yes. This wasn't an idea of my own, this was something that had been brought up and had been in discussion in the various meetings on the national Blood Transfusion Centre service for a long time. I think it was first talked about in 1979 in one of their meetings, I noticed that. Essentially, there was a significant worry that material was being purchased and it was being purchased by individual haemophilia centres, and it was also being written up in prescriptions by general practitioners and it was also finding its way into hospitals that weren't haemophilia centres, not even associate haemophilia centres.

So there was a real sense that, well, actually where's it all going? We simply don't have a handle

on that. That didn't make sense to the National Blood Transfusion Service, who felt that the handle was necessary for safety reasons and so this idea kept emerging, if I can put it that way, and it was obviously, at that time, something that had bubbled up to the surface again.

In particular, of course, it turned out -- and I can't remember whether it was at this meeting or some other meeting -- must have been probably another meeting later on, I'm not sure what the date of this meeting was -- that it was discovered that some of the Factor VIII concentrate that had actually been used to treat the unfortunate man in Bristol who had succumbed unfortunately to -- he was the first case to succumb to AIDS, had actually found its way into other hospitals but nobody could trace it, and that seemed to be a major safety problem and that we really shouldn't -- that shouldn't happen and it could be avoided by making the NBTS responsible for keeping records of wherever the material went.

So that was the object.
Q. I think we'll see, if we look further down this letter, it certainly didn't go down very well with Dr Peter Jones. So if we see the third paragraph:

"However, if the new scheme means that firms are

going to be asked to tender for the market on a purely financial basis, then I am very frightened that this will lead to restrictions on our prescribing rights. There are two things to which I am totally opposed. Firstly, that my choice of product for prescription to any particular patient should be affected in any way regardless of cost. Secondly, that any Authority, be it the DHSS or the Blood Transfusion Service, should have any control over my clinical responsibility for my patients."

Is that what you are talking about when you talk about clinicians jealously guarding their clinical --
A. Yes, and what's more though that it was really horribly misguided because nobody was intending to interfere with anybody's prescription. People were free to prescribe, it was just keeping tabs on what was being prescribed, and I think the Inquiry has given me a paper where I looked at this rather ruefully, really, where I wrote a report, whether it was from this meeting or not I don't recall, but I wrote a report about how the concept of Regional Transfusion Centres holding the material and having it, as it were, controlled in that way, had been the subject of almost wilful misunderstanding by the Haemophilia Centre Directors. They would -- really

didn't want to accept that there was a genuine issue here, a safety issue. They wanted to be able -- they felt that we were going to, in some way, circumscribe their ability to prescribe and that was never the intention, and it was a sort of travesty of what we were trying to do.

Q. If we go to the second page, please, we can see Dr Jones says this:

"Although I have the greatest respect for her, I was very disturbed to find Diana Walford at the last Reference Centre Directors Meeting without prior consultation and hope that this will not happen again. Of course I would have no objection to her being invited for a specific topic, such as AIDS, but I do think that it is impossible to discuss matters of concern relating to our patients in front of outsiders, particularly when they represent 'authority'. From remarks passed at the meeting it would appear that the new proposals for centralised purchasing are dictated by financial concerns and are not in the best interests of our patients."

Leaving aside that last sentence for the moment for present purposes, this appears to characterise you and the Department of Health as an outsider representing authorities. Was that the sense you got

when you attended these meetings, that that was how you were perceived?

A. I don't think I saw it quite as starkly as this but, you know, if you turn up and say, "I'm from the ministry, I'm here to help", it's not usually particularly well received.

Essentially, I think our presence was tolerated. It was sometimes found helpful but other times I think people might have felt that it inhibited their free discussion, which might well have included criticism of the Department. But in general -- in general, I didn't feel as if I was going into the lion's den but I was conscious of the fact that I was an outsider and I was there, to a degree, on sufferance. These were private meetings.

Q. If we just look at the response from Professor Bloom it's OXUH0000892, we can see in the second paragraph Professor Bloom says:

"I take your point about Diana Walford but to be fair with her she did ask me beforehand if she could join our last meeting and in fact had she not been there we would not have had this prior warning of the possible intention of the health departments regarding factor VIII purchasing. It is also extremely useful that Diana is sympathetic to the

haemophilia organisations."

Now, that is Professor Bloom's comment but do you have any sense of what he meant by that?

A. Well, I don't know exactly what he meant but it's fair to say I had a really strong feeling of sympathy towards about haemophiliac population because I sort of knew stuff about what they were going through.

Q. Then it continues:

"Nevertheless I appreciate she's a shrewd cookie and perhaps it will be more circumspect in the future to invite her just for specific items on the agenda if indicated."

So it sounds as though the plan going forward, and you then moved to a different job, but the plan going forward was for you to only come to Reference Centre Director meetings for specific items rather than general attendance.

A. It looks like it would have been, I don't know whether it was the case, but my successor Dr Alison Smithies would have been invited if necessary for specific matters and not necessarily for the entirety of the meeting.

SIR BRIAN LANGSTAFF: Do you read the sense of the description of you as a "shrewd cookie" and perhaps it was more circumspect to invite you just for specific

items that this was a way of saying that you were a spy in the camp?

A. Yes, I suppose it does actually. I didn't mind being called a shrewd cookie actually, now that I've seen it.

SIR BRIAN LANGSTAFF: Well, no, I doubt people would, but the sense of it seems to be a spy in the camp.

A. I think that's right. Basically I think they were concerned that they would have a discussion which, inappropriately, I would bring back to the Department with my own interpretation of what the issue was and that that might not always be helpful.

MS RICHARDS: If you can just go back to your statement -- Soumik, it's WITN4461001, page 125, please. It's paragraph 44.4, Dr Walford. This is still in relation to UKHCDO.

A. Paragraph?

Q. 44.4.

A. Okay, yes.

Q. So you have said there that:

"The UKHCDO represented, for the DHSS, the group with relevant expertise in a rare disease which consumed a very significant resource in terms of the activities of the BPL and the NBTS, as well as of the budgets of RHAs in terms of the provision of hospital

and rehabilitation and other services for haemophiliacs and the need to purchase commercial concentrates."

I just want to focus on the first line or so there: UKHCDO represented the group with relevant expertise in haemophilia and related bleeding disorders. Again, really building on that and what you have said already, is it right to understand that, on questions of treatment, risks and benefits of different types of treatment, how to strike the balance in terms of risks, would the DHSS very much be guided by and defer to what UKHCDO's views were?

A. Completely.

Q. At the meetings which you attended, was there -- whether it's reference centre directors or the annual general meetings -- was there a dominant voice or voices?

A. At UKHCDO?

Q. Yes, in terms of individual clinicians.

A. Well, that should appear in the minutes. If it doesn't -- if you are asking me, possibly, whether Professor Bloom dominated the conversations, which I suspect you might be asking me, I think sometimes he did and sometimes he didn't. I think there was quite a free flow of information between the different

directors, as I recall.

Q. Professor Bloom was obviously chair of UKHCDO and, as we'll see as we look in more detail, perhaps later today, probably tomorrow, at some of the underlying documents, he was then involved in a multiplicity of other meetings, organisations, interactions with the Department of Health. Again, we'll see when we look at AIDS tomorrow, he's the person you write to or have telephone conversations with in early '83 as AIDS becomes a pressing issue.

Looking back, do you think the Department was too reliant upon the voice and views of what was ultimately one individual clinician; in other words, Professor Bloom?

A. He ought to have been able to represent to us the views, insofar as they were aggregatable, of the UK Haemophilia Centre Directors. He should have been able, and we had no reason to suppose he wasn't able, to take the temperature of any given meeting or to deal with a particular policy.

We did rely upon him, just as we would have relied upon the chair of the National Blood Transfusion -- the regional transfusion directors' meeting to represent the views of, if you like, the body of membership of their committees and essentially

we would have relied upon him to do that to the best of his ability and not to put a particular individual spin that wasn't held by other members of the UKHCDO.

Q. Would it be right to say that you'd have no way of knowing, either at the time or probably now, whether what he was doing was, as it were, conveying his own view or whether he was more broadly representing the views of others?

A. Well, only from the meetings I attended, and obviously I could hear what other people were saying. I don't recall particular dissent in those -- I mean, there were -- obviously some issues were picked up, there was various discussion, but it didn't seem as if these were very sort of vociferous meetings, it wasn't that people were disagreeing vehemently. On the whole I think they were vehemently agreeing.

Q. Did you or any of your colleagues in the Department, your medical colleagues, ever think of challenging or interrogating what was being said to you about the way haemophilia clinicians thought matters should be conducted?

A. Well, when I was in the meetings, I mean, there were breaks and I talked to people. I don't particularly remember any kind of what I would call a significant difference of view that I was putting across.

Obviously, yes, on organisational matters, that didn't go down well, but in terms of clinical matters, it would not have been (a) appropriate, (b) nor did I have the expertise and nor did I, as far as I can remember, actually intervene.

Q. Well, I may want to pick that up as a theme when we look at documents relating to AIDS again tomorrow.

Other than through your attendance at those meetings and then your attendance, and we'll look at some of the minutes at other meetings at which Professor Bloom might be present or sometimes Dr Craske was present --

A. Yes.

Q. -- were there other individual clinicians, either in relation to haemophilia care or virology or transfusion, that you had regular dealings with?

A. Regular dealings, no. I mean, obviously I saw in different fora different people. So Dr Arie Zuckerman -- Professor Arie Zuckerman, in terms of research, certainly I saw him on a number of occasions. You've referred me to a meeting which I had with Dr Tedder, a virologist, and Dr Mortimer, a virologist, whom I came to know very well when I was in the PHLS. But particularly -- I'm trying to think if there were any specific individuals to whom I would

turn. Of course Dr Gunson and then, needless to say, on BPL and so on and on fractionation it was Dr Lane.

Q. Can I ask you to look at a particular document. It's the minutes of a meeting of the Hepatitis Working Party. You weren't present but you are referred to. It's HCDO0000546.

So you'll see, Dr Walford, it's the minutes of the third meeting of UKHCDO's Hepatitis Working Party, November 7, and it's 1978, although that doesn't appear on that.

Could we go to the top of the second page. This is whilst you're still in the Medicines Division. Under the heading "Study of NHS Factor VIII", the first paragraph, top of the page, says:

"Dr Craske said that this would be assessed after 1 year. Dr Ellis said that he would like a more definite procedure for the investigation of cases of hepatitis, and a clearer definition of 'Factor VIII associated hepatitis'. Dr Craske agreed to discuss this with Dr Lane and Dr Walford of the Medicines Commission."

Then there's a discussion in the next paragraph about what would happen when a batch of Factor VIII was known to be contaminated with hepatitis B.

Are you able to assist us in understanding more

what the first paragraph is referring to, and why there Craske was envisaging he would have a discussion with you about this issue?

A. Well, I don't know -- by the way, I didn't attend the UKHCDO Hepatitis Working Party. I was not invited.

This was, of course, before I was in Med SEB. This is when I was in the Medicines Division. Now, my role in Medicines Division was the licensing of blood products, if you like, and essentially it sounds as if Dr Craske wanted to talk to me and Dr Lane about products which might be known to be associated with hepatitis.

This is probably going to be hepatitis B. Now, by then you could actually diagnose that. You could know that that product was associated, because you would have found the agent, if you like, in the product or maybe in recipients. But it's most likely at this point -- which must be, what, '78?

Q. November '78.

A. Then it's most likely to be hepatitis B.

Q. But you have no specific recollection --

A. None at all.

Q. -- of discussing this?

A. No.

Q. Then if we go to the next page, top of the next page

this doesn't refer to you by name but under the heading "Supra-regional Directors Meeting", it says, in the second line:

"The DHSS Small Grants Committee had requested that the Directors consider whether patients might be kept on one batch or a single product for some time, as this might reduce the incidence of transfusion hepatitis."

Then it goes on to set out what the directors' opinion was.

First of all, can you assist us with what the Department's Small Grants Committee was?

A. As far as I can recall, it was a committee set up to administer some small, and it was small, grants to people wanting to do particular research.

It is possible -- I don't know for sure -- that Dr Craske's surveillance of hepatitis, the Hepatitis Working Party surveillance, which he chaired, was funded from the Small Grants Committee. I don't know but it -- that sounds as if it could have been.

Q. We see there reference to a possible approach of patients being kept on a single product or a single batch. The Inquiry has heard evidence that come clinicians adopted that approach for safety reasons and some clinicians, the vast majority of clinicians

did not. Do you recall that ever coming up in discussions within the Department of Health, that kind of approach?

A. No, I don't remember.

Q. Then just again, on the Small Grants Committee, it might just help join the pieces, help join the dots, if we go to DHSC0001121. This is a minute authored by you and we can see your name at the bottom of the page, and then a handwritten date "December 1980". We can see you are now in Med SEB. Then, if we go to the top of the page, it's entitled:

"Studies of the epidemiology and chronic sequelae of [Factor]VIII and IX associated hepatitis in the United Kingdom".

A. Mm-hm.

Q. Then you refer to not having -- you refer to a project number, to not having inherited a file on the project from Dr Waiter, who was your predecessor. You refer to talks being delivered by Dr Craske and it records there:

"... it is generally acknowledged that Dr Craske et al are performing a valuable and necessary study."

Then it says:

"The study has 1 more year to run and I would have no hesitation in supporting it. I see that

Dr Craske is proposing to make an application to the Small Grants Committee to study whether patients with mild coagulation defects with minimal previous exposure to blood products, should be treated with special coagulation concentrates made from a small pool of donors to minimise the risk of hepatitis in this susceptible group. I would certainly endorse such a project."

Then you talk in the next paragraph about a valuable spin-off from Dr Craske's research was:

"... documentation on the type, quantity and source of [Factor]VIII administered to haemophiliacs is now much more accurately known."

So if we just stay with that first paragraph that's on the screen and the reference to the application to the Small Grants Committee, do you know whether the application there described was made and, if so, what the outcome was?

A. No, I don't know -- well, I don't know whether it was made. This seems to be maybe simply a continuation for another year of Dr Craske's funding by the Department to do -- because although it was an HCDO working party, the Department actually was providing for as a research fund grant, if you will. Certainly his continued surveillance went on for another year.

Whether he actually did this particular bit of research, which would have been extremely valuable had he done it, I don't know. I don't know if the Inquiry has any information on this.

Q. Not that I'm presently aware of.

It might be said that patients with mild coagulation defects with minimal previous exposure to blood products shouldn't be being treated with concentrates at all, even if they are concentrates made from a smaller pool than the commercial concentrates or, indeed, the standard Elstree concentrate. What do you say to that?

A. As a matter of general practice, I would say yes, they should -- they could actually have cryo or DDAVP as necessary. But if you had a serious operation needed, if there was likely to be a lot of blood loss, if there was trauma, for whatever reason, then although mild haemophiliacs did not actually bleed spontaneously or, in general, did not, faced with a significant trauma or assault, if you like, on the body then they could. So if you needed to use concentrate then it would be far more convenient to use a freeze-dried product because it's given in so much smaller a volume but also, if you make it from a small pool of donors, then, essentially, you're

getting to the same point which you might be getting to with cryoprecipitate because if you have to use 20 bags of cryoprecipitate, that's 20 donors, if you like, you could have a small pool, if this research showed that you could do it, a small donor pool which would be another way of administering a relatively low-risk product.

Q. We can take that down, thank you, Soumik.

More broadly, and leaving aside those couple of examples about the DHSS's Small Grants Committee, are you able to assist us with what role the Department played in directing or monitoring or funding medical research or observational medical studies relevant to blood and blood products?

A. Well, the Department did fund a small number of projects. It depended how fundamental the research was. There was a sort of concordat between the Medical Research Council and the Department, so the more fundamental the research, the more likely the medical research council would be to be the funder. For more operational work, such as Dr Craske's committee, his working group, that would fall more likely into our camp.

Q. Now, I want to ask you next about your own knowledge of risks of hepatitis and then, more broadly, what you

think the understanding or awareness might have been within the Department.

You have said in your statement that, as a haematologist trained in blood transfusion, risks of infection was something that was a fundamental part of your training.

A. That's right.

Q. But you pointed us to two publications that you authored as being an illustration of the state of your knowledge at the time they were written, and so I just wanted to look at those because we haven't looked at them yet in Inquiry hearings.

The first is WITN4461002, and we can see the *extract that you've provided to us, it's been printed from Meyler's Side Effects of Drugs*, *Ninth Edition*, a Google search suggests that this was published at the beginning of 1980 --

A. I think that's right, yes.

Q. Can you just assist us, first of all, what's the purpose of this publication?

A. Well, when I was still in the Medicines Division, I was approached by the publishers Excerpta Medica, and asked -- I was never quite sure why I had been fingered for this task but I was asked if I would be prepared to review a series of papers on blood and

blood products, including risks from hepatitis, for *Meyler's Side Effects of Drugs*, the Ninth Edition. This was a reference work which was in medical libraries, it was placed in medical libraries.

They, at the same time, asked me if I would also write an article or rather a review piece in the Side Effects of Drugs Annual, number 4, I think, for that year. So I thought it would be a good idea, actually, to do that, a good exercise for me, and not unhelpful to my CV, I thought at the time, to do this work. So I did, and basically they provided me with a significant tranche of publications and they gave me the hard copies to review, and they only wanted me to focus on what was in the papers that they gave me to review, and I duly did.

Q. Was this publication *Meyler's Side Effects of Drugs*, you said it would be in medical libraries, so it was for clinicians or for clinical investigators?

A. Everybody really, medical libraries. Essentially, it was deemed to be a reference document. As far as I know, it's ongoing. It's just one of those publications which is used as a reference work for people who are studying a particular subject.

Q. If we go to the third page, please, Soumik, we can see the chapter, which your name and co-author's name

appears at the top "Blood and blood products" and then the first paragraph says:

"The transfusion of whole blood or blood products into man may be associated with a variety of adverse reactions. The presentation adopted in this chapter classifies these effects according to the blood component involved ..." and you give examples.

So it encompasses a number of different adverse reactions but if we go to what is of interest to the Inquiry, which I think is probably page 16, electronically, Soumik, that's it. So bottom right-hand corner, "Transmission of disease by blood products":

"Many viral, bacterial and protozoal diseases can be transferred from the donor to the recipient with transfused blood or blood products. Some of these complications will be discussed below."

Then you have a heading "Hepatitis":

"Post-transfusion hepatitis may result from the transmission of several viruses namely, hepatitis A ... hepatitis B ... non-A, non-B virus(es), cytomegalovirus and the Epstein Barr virus."

Then if we go to the next page, we can then see, I'm going to skate over hepatitis A, but there's then a discussion about hepatitis B. It talks about how:

"Prior to the introduction of sensitive methods for the detection of [the hepatitis B antigen], about 30 per cent of cases of post-transfusion hepatitis were caused by [hepatitis B virus]."

Then there's a discussion -- I'm not going to go through it in detail -- about how that figure has been reduced and the value of the screening test.

If we go to the next column, so the same page but the right-hand column, pick it up just a little higher than that, please. So about six lines down, it says:

"Despite the introduction of systematic screening ... the risk obvious post-transfusion [hepatitis B virus] infection remains greater for certain pooled plasma derivatives than for single donations. Plasma fractions such as fibrinogen, antihaemophilic factor and the prothrombin-complex concentrates are associated with a high risk of HBV infection ..."

You then go on to say:

"Partly this high infectivity may be explained by the fact that these fractions are often prepared from paid-donor plasma in which the incidence of ... positivity is 10 times that in plasma from a non-commercial source ..."

Then, again I'm not going to go through the detail of the rest of what you say about hepatitis B, but you discuss the hepatitis B. Go over the page. We have a heading "Non-A, non-B hepatitis:

"In the USA at present, some 60 to 90 per cent of the post-transfusion hepatitis is unrelated to either hepatitis A or hepatitis B ... Neither cytomegalovirus nor the Epstein Barr virus have been implicated in such cases ... at least one additional human hepatitis virus is suspected. Recently, three studies have provided convincing evidence for a transmissible agent of non-A, non-B hepatitis."

Then you refer to three studies, one of volunteers who developed non-A, non-B after inoculation of stored sera from donors, and then the other two studies, non-A, non-B hepatitis was transmitted from infected human sera to chimpanzees, and then it goes on to say:

"The latter studies also confirmed the existence of a chronic carrier state in humans ..."

Then a couple of lines further down:

"Further confirmation oh chronic carrier state has come from a follow-up of 44 patients with proven non-A, non-B hepatitis ..."

Then if we just look at the paragraph below

that, picking it up halfway down, you refer to Knodell's series. You refer then to a striking difference in the frequency of chronic liver disease in relation to patients who had received prophylactic immunoglobulin.

So just pausing there, I've looked at that, not really because I necessarily have a specific question for you about it, Dr Walford, but because we haven't looked at it before but, as you say in your statement, this can fairly be said to represent part at least of your knowledge at the point in time at which you wrote this, which is before you moved to Med SEB?

A. Yes. I think there's even more in the Side Effects Annual.

Q. So if we go to that second publication, WITN4461003 and we go to the third page, I think, Soumik, if we zoom, thank you. So you say in the first paragraph:

"As refinements with techniques of serology, blood banking and plasma fractionation have widened the scope and scale of therapy with blood and blood products, so attention has been focused increasingly on the problem of post-transfusion hepatitis and its possible progression to chronic liver disease."

Then you refer to data from the United States, 20 to 30,000 cases of post-transfusion hepatitis and

a death rate from this cause alone of 3,000 per annum. If we then go back to the full page, there's then -- under the heading "Hepatitis", you say:

"This year's literature has had two main themes ..."

Just pausing there, again, do we understand you have been asked to review specific pieces of literature for the purpose of producing this?

A. Yes.

Q. We can see the two themes are:

"... additional screening tests for hepatitis B infectivity ... and the severity of non-A, non-B hepatitis and its progression to chronic liver disease."

It's just the latter theme I want to look at for present purposes.

So if we go to the next page please, Soumik, the one after, we can see, halfway down the page, left-hand column, there's a heading:

"Severity of non-A, non-B hepatitis and progression to chronic liver disease ..."

You say:

"Hitherto, direct evidence for the transmission of non-A, non-B hepatitis by blood products has been lacking."

Then you refer to a paper by Wyke et al demonstrating:

"... the transmission to chimpanzees of an agent responsible for two fatal cases and one non-fatal case of non-A, non-B hepatitis in patients with liver disease who received the same broach of commercial prothrombin-complex concentrate prior to liver biopsy. A further death apparently from non-A, non-B hepatitis occurred in their series of 17 patients with liver disease who received four different batches of concentrate."

Then you say:

"These well-documented cases underline the potential severity of this form of hepatitis in patients with pre-existing liver disease ..."

Then you deal specifically with the question of using prothrombin-complex concentrates. Then very bottom of the page you say:

"The need to limit the non-essential exposure to coagulation factor concentrates is reinforced by reports that non-A, non-B hepatitis may progress to chronic liver disease. In one of these reports, histologically verified non-A, non-B hepatitis was shown to progress, both histologically and clinically, to chronic active hepatitis within a two-year period."

Now, I'm not proposing to go to the detail of the reports but you footnoted in this chapter, we see, the various different studies and reports?

A. Yes.

Q. So you would have read all of those at that time for the purpose of producing this?

A. Yes.

Q. So would it be right to say then that throughout the period of time that you were at Med SEB, so from the end of 1979 through the end of 1983, you would have known, you knew that the transmission of non-A, non-B hepatitis was through blood products and blood was a significant problem?

A. Yes.

Q. And you knew also that non-A, non-B hepatitis had at least the potential to have serious consequences in terms of chronic liver disease?

A. Yes.

MS RICHARDS: Thank you.

Sir, I note the time. I think the next document I want to look at might take a little time so it might be a good point at which to break.

SIR BRIAN LANGSTAFF: Yes. Just one question I would like to ask, if I may. One of the earlier papers which is mentioned in Meyler's book, by you, one of the --

presumably coming from the study you'd reviewed, talks about hepatitis B having represented 30 per cent of post-transfusion hepatitis. Now, plainly, until hepatitis B was identified, the only means of saying that a disease was hepatitis B was clinical in some way?

A. Yes.

SIR BRIAN LANGSTAFF: What did you understand the 30 per cent figure to be based upon? A sort of retrospective analysis? And if so, what was the other 70 per cent and when was the other 70 per cent, the missing 70 per cent which wasn't B, first known? Do you know? Can you help?

A. Well, obviously, I can't say, but basically the figures that I was quoting were quoted from the literature. I mean, there were more causes of hepatitis than hepatitis B known at the time. I've mentioned a few of them. Actually some of them gave mild hepatitis so you might have cytomegalovirus, you might have Epstein-Barr virus, and of course everything was, to a degree, complicated by whether there was any pre-existing liver disease in individuals which might be simply for reasons of alcohol ingestion and so on.

So I can't actually tell you now -- I might have

been able to tell you earlier on, when I wrote this -- but basically I cannot say what the other 70 per cent were, and I think it's quite likely it's because nobody really knew. A very significant proportion of them might well have been hepatitis B but they weren't measuring, they weren't able to assess, they weren't able to do the analysis.

SIR BRIAN LANGSTAFF: That's what surprised me when I saw that 30 per cent figure. Plainly it was related to post-transfusion hepatitis and so alcohol wouldn't be a cause of that. It may no doubt bring to life something which was created by the post transfusion.

A. Absolutely.

SIR BRIAN LANGSTAFF: But there was an attribution to the transfusion in this?

A. Exactly and, of course, what one did find with all of this is if there was any element of pre-existing liver disease, then a further insult, if you like, a further onslaught caused by infection might well make overt hepatitis more likely.

But I suspect -- I don't know -- that the 30 per cent was demonstrably known to be hepatitis B because there was a way of determining the fact that it was hepatitis B, and the other 70 per cent, significant proportion, might well have been

hepatitis B, but it was not detected or detectable.

SIR BRIAN LANGSTAFF: The article was going on to say, well, now we've reduced it perhaps to about 10 per cent, leaving 90 per cent for something or something else --

A. Something else and it was, I think, beginning to be considered that the something or something else, the virus or viruses, which couldn't be characterised as hepatitis A and they couldn't be characterised B, were this something also, which was non-A, non-B.

SIR BRIAN LANGSTAFF: Yes, thank you very much. We will come back at, looking at the time, at 2.05.

MS RICHARDS: Thank you, sir.

(1.03 pm)

(Luncheon Adjournment)

(2.05 pm)

MS RICHARDS: Dr Walford, we were looking at the issue of hepatitis, knowledge of risks of hepatitis. In terms of relative risks of commercial products and NHS products, you've said in your statement there was a general view, which you shared, that UK plasma from voluntary donors carried less risk than US plasma from paid donors. That was the broad understanding.

A. In terms of plasma, absolutely -- not necessarily in terms of large pool concentrates though.

Q. I think what you also say in your statement, but please correct me if I'm wrong, is there was a general understanding of which you too were part that the larger the pool size, the greater the risk?

A. Yes.

Q. What you then said in your statement is you don't think it was appreciated, at least by you, until a slightly later point in time, and you have referred to the publication by Fletcher, that there came a point in time when the pool size was such that the risk of infection with hepatitis was near inevitable?

A. Yes, I don't know that I knew that early on but it obviously became apparent that pretty well all concentrates, from whatever provenance, UK donors or commercial donors, because of the pool size they were going to transmit non-A, non-B.

Q. Now, we've looked at your own knowledge as a haematologist and, having authored the publications that we looked at before lunch and therefore read the various papers, I just wanted to explore with you a little what the wider knowledge within the Department might have been. I appreciate there's a limit to the extent you can speak to the knowledge of others or speak to something nebulous such as the knowledge of the Department, but what you say in your

statement is you think within the Department the risk of hepatitis B through transfusion was pretty well known and understood.

A. Yes.

Q. You have said you think that there was -- non-A, non-B hepatitis was a problem known to the Department, known within the Department, but you think there was a less of an appreciation of the risks of serious liver disease from non-A, non-B hepatitis.

A. Yes. Of course, I'm not in a position to know for sure but I think it was the case that everybody knew about non-A, non-B. They were not necessarily aware or conscious of the fact that it potentially could give rise to severe chronic disease. I mean, they knew that it would give rise to hepatitis, and maybe they knew that sometimes it was asymptomatic and sometimes it was overt, the hepatitis, but I don't think at this remove -- and I'm trying to not to overlay it with thoughts that I have now rather than thoughts that I had then -- I don't think they appreciated that it was potentially more severe than they might have thought it was. And that was one of the reasons why I spoke about it really quite forcibly in my minute through to Mr Harley, 15 September 1980.

Q. And I'm going to to look at that with you in just

a moment. Before I do that, am I right in understanding that, amongst the papers you reviewed for the purposes of the publications we looked at, the paper by Professor Preston published in 1978 was not one of those which you reviewed?

A. It wasn't supplied to me, no.

Q. Do you recall how or when you became aware of that?

A. I have to tell you that I became aware of Professor Preston's paper through the Inquiry, but I have of course since read it.

Q. I want to go then to your memo of 15 September 1980, to which you've just referred.

Soumik, it's WITN0282008, please.

We'll come back to this memo at a later stage in terms of the issue about BPL but I just want to look for present purposes at what you say about hepatitis. So the context is the Blood Products Laboratory, the possible takeover by industry and Beechams then being the company whose involvement was being contemplated.

Then you say in the paragraph numbered 1, picking it up in the second sentence:

"Unless it were Beecham's intention to process such plasma in an entirely separate plant or with complete duplication of all facilities in a single plant, it would be impossible to prevent contamination

of the UK material with imported hepatitis viruses.

"I must emphasise that 90 per cent of all post transfusion (and blood product infusion) hepatitis in the USA and elsewhere is caused by non-A, non-B hepatitis viruses which (unlike hepatitis B) cannot, at present, be detected by testing donor blood. This form of hepatitis can be rapidly fatal (particularly when acquired by patients with pre-existing liver disease) or can lead to progressive liver damage. It can also result in a chronic carrier state, thus increasing the 'pool' of these viruses in the community."

If we just look at the top of the page, we can see, as you said a few moments ago, it's addressed to Mr Harley.

Now, leaving aside for present purposes the rest of it and the context of the memo, which, as I say, we'll come back to when we look at BPL, you were describing non-A, non-B hepatitis there, if I may say so, in no uncertain terms as a serious condition.

A. Yes.

Q. We can see it's addressed to effectively your equivalent number in -- was he HS1?

A. Yes. Well, yes --

Q. Or in HS?

A. In HS.

Q. So you're not saying it's a largely benign condition?

A. No.

Q. You're recognising the consequences and you are sharing those consequences with your administrative and policy colleagues. Did you ever get a sense that what you were saying to Mr Harley came as a surprise in relation to the risks of non-A, non-B?

A. I couldn't say that necessarily. I did copy this minute. Because I wasn't sure how much the Department, my colleagues, were aware that this was potentially a much more serious disease than they may have actually thought it was, I copied it pretty widely. So copied it to his boss and my boss as well.

Q. Can we go to the second page. You are right to point that out, Dr Walford.

So we can see it's published to Dr Oliver, who was your boss, so in the medical division, Mr Wormald, who was a senior civil servant in the administrative side?

A. Who was Mr Harley's boss.

Q. And Mr Godfrey?

A. Was the principal in his, in Mr --

Q. And Mr Hart?

A. He was head of the supply division.

Q. Dr Wintersgill?
A. He was, I think, the medical opposite number to Mr Hart. I could be wrong about that but I seem to recall.
Q. Mrs Firth.
A. Finance, as far as I know.
Q. Mr Brechin?
A. Brechin, yes --
SIR BRIAN LANGSTAFF: Probably Brechin.
A. Thank you.
He was also finance as far as I can recall.
MS RICHARDS: Mr Sharpe?
A. Probably supply, I don't --
Q. Don't worry if you can't recall. Dr Davie?
A. I don't know who Dr Davie -- I must have known but I don't know now.
Q. Then we have Miss Helson and Mr Connor?
A. I do not know, unless Mr Connor is the same chief architect Mr Connor.
Q. No doubt in part the reason for the wide circulation was because this was dealing with the issue about commercial takeover, hence the involvement of supplies and finance?
A. Yes, and Mr Hart.
Q. But in terms of what you were saying about non-A,

non-B hepatitis, this is going, as it were, to those who are above you --
A. Yes.
Q. -- in terms of seniority, both in the medical hierarchy and in the administrative/policy hierarchy?
A. Yes.
Q. So whatever their state of knowledge, and I appreciate you can't speak for what other individuals might have known at any given time prior to that, no-one receiving this memo could have been under any illusion from this point onwards about non-A, non-B hepatitis?
A. I hope not.
Q. Do you know whether this information you were providing, this advice you were providing, about non-A, non-B hepatitis was shared more widely within the Department?
A. I couldn't say. I don't know.
Q. Then can you recall the extent to which you or your colleagues on the question of hepatitis, and in particular non-A, non-B hepatitis, ever took advice from or sought the input of hepatologists?
A. Not directly but I do remember hearing Professor Arie Zuckerman talk about -- this is on one of my visits out -- or my committee meetings with the MRC, I think, post-transfusion hepatitis MRC

meeting. Actually, what Professor Zuckermann said at this particular meeting that I have in mind, which came as a surprise to me, was that the researchers had shown that non-A, non-B hepatitis, unlike hepatitis B, did not seem to be sexually transmitted. That was a revelation to me. I didn't know that.
Q. Then if we can look at your witness statement, I think it's 63.
And again, if we put this up on screen, Soumik, it's WITN4461001, and if we go to page 153, you set out in paragraph 63.1 the question you were asked by the Inquiry, which was an explanation of:
"... what, if any, steps were taken (and when and by whom) to ensure that the serious nature of non-A, non-B hepatitis (as summarised in my minute of 15 September 1980 ...) was known to, and understood by: ministers; clinicians; NHS bodies; patients who were or might be treated with blood or blood products; the public."
Then if we just go through what you then say in response to that, you say in paragraph 63.2 that:
"[You] do not believe that, at the time, the potential severity of non-A, non-B hepatitis was in any way well known, outside of a body of relevant researchers and hepatologists."

I'm not going to ask you further in relation to that. The Inquiry has asked its own questions of clinicians in relation to what they did know or what they should have known.
You then refer to Haemophilia Centre Directors getting the reports from Dr Craske. You then, at paragraph 63.4, deal with a question of information to patients. You say:
"The DHSS would not have regarded itself as having a role in advising clinicians what to tell their patients about hepatitis risks, as that was a matter which lay within the boundaries of the individual clinician/patient relationship; however
"ii) The Licensing Authority's regulation of blood products covered the issue of product information."
Then you are not able to state what information would have been conveyed by labels on blood products or patient information leaflets.
Then you refer to there being posters and other information available where patients were having blood tests, which described the risks of hepatitis.
Now, just pausing there, perhaps if we go back to the previous page and go back to the question that's asked --

A. Could I just intervene for a moment?
Q. Yes, of course.
A. In relation to the licensing authority, I am pretty certain that the product information, the leaflets, which went to both patients and the professional -- the leaflets for doctors, will have mentioned hepatitis, but they may not have mentioned specifically non-A, non-B because, of course, we knew next to nothing about that in terms of, you know, what exactly it was. But it will have mentioned hepatitis, I'm pretty certain.
Q. And the Inquiry will be looking at the content of those leaflets in a later hearing.

Can we go back to the question, and I want to put it in perhaps slightly different terms than the way it's put in question 63.1. My question is: what, if any, steps were taken by the Department to ensure that the serious nature of non-A, non-B hepatitis, as summarised in the document we've just looked at, was known to and understood by -- leave aside ministers for a moment -- clinicians, NHS bodies, patients or public?

Other than through product information leaflets and the licensing authority's role, would it be right to understand that the Department itself took no

particular steps to explain the serious nature of non-A, non-B to either clinicians, NHS bodies or patients or the public?
A. It would not have expected to explain the nature to clinicians. It would have expected -- in the generality of clinicians, if we're not talking about Haemophilia Centre Directors, and we know that they had the information from Craske -- they had the information from Craske that the rest of the Department, if you like, or those of us who were involved, were privy to. So the Haemophilia Centre Directors were certainly well aware or should have been aware of almost as much, if you like, as I have described, if not as much, and the generality of clinicians -- because we must remember that this was transmissible through blood and cryoprecipitate, it sort of knew no boundaries. It wasn't simply commercial or NHS Factor VIII concentrates, this was completely transmissible by blood.

Basically, I think the Department will have relied on information coming from the usual sources. It will have been descriptions in the medical journals, for example, or any specialist societies who were putting out anything.

But basically I think the Department took the

view that these were -- this was clinical material which doctors ought to make themselves aware of through their own reading or their own studies or through -- they should be made aware of them through their specialist societies or, in the case of the haemophiliacs, the Haemophilia Centre Directors. We would not have been describing this to patients -- to doctors directly.
Q. If we just then go to paragraph 63.2, that's even though there was potentially an information gap, because you have said in terms there you don't think at the time the potential severity of non-A, non-B hepatitis was well known outside of researchers and hepatologists. You have explained why you think haemophilia clinicians should have known through Dr Craske and the Hepatitis Working Party, and so on, but you appear to be recognising there that there would be a large cohort of clinicians who wouldn't necessarily know.

Is it right to understand, maybe for all the reasons we discussed earlier about the Department's view of its role, but it's right to understand, simply as a matter of fact, that the Department itself didn't take any steps to address that particular information gap?

A. I don't know how necessarily that the gap -- there needed to have been a gap because it was absolutely open to doctors to read The Lancet, to read the Preston document publication, to read those publications that I have mentioned, for example, the publication by Wyke about the fatal cases in The Lancet before I actually described it in the Department.

So it was in the medical journals. It would be impossible for the Department of Health to take every new development and go out to clinicians and say, by the way, you have heard of this, haven't you, you do know? One did rely -- these were professionals. One relied on professionals making themselves aware of issues within their sphere of interest and, if not the professionals themselves reading journals -- it's impossible to read everything comprehensively -- on the professional societies that they belonged to or any of the training materials that they would have had. I can't conceive really of a position in which the Department could constantly update the profession, the medical profession, on every advance or every new development in every sphere because this was one sphere of information but, of course, the Department was dealing across the board with every single

disease.
Q. Then if we go to the next page, paragraph 63.5, the question also asked you about the provision of information to ministers and you said, I think in terms in section 63.5, you don't know if the potential for chronic liver damage and severe disease from non-A, non-B hepatitis was particularly flagged up to ministers.
A. I don't know.
Q. Are you able assist with this: what, if any, consideration was given by the Department in the late 1970s/early 1980s to the possibility that pooled products might transmit viruses not yet known to medical science; in other words, was there a recognition of known unknowns, that there could potentially be things out there, things in blood, that could be dangerous but which weren't yet identified and understood?
A. I think it was implicit in anybody who had to do with blood transfusion that you knew that, potentially, blood transfusion could transmit an agent that we'd never hearing of before, never seen before, didn't know about. Of course, that transpired to be the case with AIDS and it also transpired to be potentially the case with new variant CJD.

What one knew was that potentially there was -- blood transfusion was inherently hazardous. You did everything possible in the Blood Transfusion Service to reduce the hazard, the risk, coming out of blood transfusion. So anything you could screen for, you should screen for, any donors that should be asked not to donate you dealt with but, inherently, you don't know what you don't know. You only know that it could happen and, in fact, it did happen.
Q. Now, I just want to ask you next about some of the expert groups, advisory groups, working parties that were involved with hepatitis late 1970s/early 1980s.
You've referred in your statement, and I'm not going to take you to it because you weren't there, but just to get some dates understood, you have referred in your statement to a February 1979 *ad hoc* meeting at the Medical Research Council attended by your predecessor -- sorry, in fact, I think your predecessor, Dr Waiter, wasn't there. Someone else from the DHSS attended in her place.
A. Yes.
Q. So that was an *ad hoc* meeting out of which there appears to have grown something called the working party on post-transfusion hepatitis, which you were then part of and I just want to look at those two sets

of minutes briefly with you.
So if we can go to MRCO0000029_003. So we'll see from this it's headed "Medical Research Council, Blood Transfusion Research Committee, Working Party on Post-Transfusion Hepatitis", first meeting 14 February 1980. Then if we look at the list of attendees we can see Dr Gunson there, Dr Craske, Dr McClelland, Dr Howard Thomas is there, and then you are there and Professor Zuckermann's there.
What was your role in this working party?
A. That's a very good question because I was there, I was representing the Department. I don't know specifically why I was there, except perhaps as a sort of liaison from the MRC over to any of the other working parties that I might have been associated with. I don't know and we may look but I don't know if I actually said anything at this meeting at all.
Did I contribute?
Q. I'm afraid I can't remember without checking.
A. Neither can I.
Q. In any event, if we pick things up at the bottom of that page we can see the purpose of the working party and then there's reference to the Advisory Group on Testing for the presence of hepatitis B antigen and its antibody, we'll come on to that. There's

reference to the *ad hoc* group that met in February 1979, that's the one I referred to.
There, here we are, you do contribute:
"Dr Walford said that a new DHSS Advisory Group would shortly be formed to advise on the public health aspects of hepatitis."
So we will look at that committee in a while:
"It was agreed that the function of the MRC WP [so to MRC Working Party] was to promote research to assess the nature and size of the problem of [post-transfusion hepatitis] in the UK, with particular reference to changes in transfusion practice, eg the use of products prepared from pooled plasma from large numbers of donors and the introduction of commercial products from abroad. Studies should include (1) an assessment of any further need for research into hepatitis B ... (2) investigations to assess the incidence of non-A, non-B hepatitis in the UK, particularly with the risk of introducing the infection by blood transfusions, and (3) the position of research to characterise the agent(s) associated with this form of hepatitis, and to derive diagnostic tests."
So that's the purpose of it. Would it be right to understand that's why it's under the auspices of

the medical research council because its focus is on research, specifically into post-transfusion hepatitis, including non-A, non-B?

A. Yes.

Q. If we go a little further down that page we can see the heading "The problems of non-A, non-B hepatitis viruses". There's reference to a wide ranging discussion and there's contributions from Professor Zuckermann, Dr Craske, cases at the Oxford Haemophilia Centre. Then if we go to the next paragraph, we can see it's recorded there there's a problem of non-A, non-B hepatitis related to freeze-dried Factor VIII and IX both of NHS and commercial types imported from Austria and the USA. There's reference to a study at the Royal Free described by Dr Thomas, and it talks about evidence obtained by liver biopsy that a proportion of these cases might suffer chronic sequelae, and so on.

Now, I'm not going go through the detail of everything that was discussed at the meeting but, broadly speaking, would it have been part of your role to feed this back, at least if there was any new information, to colleagues in the Department?

A. If there had been something new and revelatory yes, I would have said so but I don't know whether there

was at that particular meeting. I mean, in general, I tried to be quite helpful as between what I'm hearing at meetings and what I'm saying back at the Department, and vice versa.

Q. Then there's a second meeting of this particular working party. So this first one's February 1980. The second one's June 1981, NHBT0000068_049.

So we can see from the top it is the second meeting, 25 June 1981, similar attendees. Again, you're there. There's just one aspect of the discussion I wanted to ask you about. So if we go to page 5, if we just go to the previous page, so we can put it in context, bottom of the previous page, there's a heading "Hepatitis in Haemophilia -- report by Dr Craske", and then if we go to the next page, he continues his report and I think refers to the data he's gathered through his surveillance programme.

Then if we look at the last main paragraph:

"Dr Craske concluded by saying there was little information about the incidence of symptomless hepatitis and the relative risks of hepatitis due to different brands of Factor VIII and IX."

Then this:

"The DHSS were keen that a prospective study of patients undergoing elective treatment requiring

concentrate should be undertaken to provide answers to these problems, and to provide a collection of well documented sera and other specimens for the use in development of serological tests for non-A, non-B hepatitis. The Working Party agreed to recommend to the Medical Research Council that such a study should be undertaken."

Can you assist us with why the Department were keen that this study should be undertaken?

A. Well, as far as I can see, there must have been a suggestion that such a study should be undertaken. We probably had a proposal, probably from Dr Craske, but I can't tell from this paper as it's drafted here. But, basically, really trying to elucidate what was going on with regard to these various concentrates and this would have been -- obviously the study is talking about patients undergoing elective treatment requiring concentrate. So the patients would have needed the concentrate and those would be the patients who could be followed then, because they were going to get concentrate, and they could be followed prospectively to see what the consequences were in terms of whether they got non-A, non-B. But this was definitely a study relating to patients who required concentrate for their treatment.

Q. This working party is then disbanded in, I think, March -- in or by March 1982, so it only met on two occasions. The problem of non-A, non-B hepatitis and understanding it and the need to learn more obviously hadn't gone away. I think the minutes of another meeting which refer to it being disbanded just talk about not wanting too many -- or duplication of effort. Can you recall why this particular working party didn't proceed further?

A. No. Because, of course, the MRC was entirely separate from the Department. This was a decision taken by the systems board or whatever -- the MRC had a reasonably complicated structure. It made the Department look quite clear and easy, I think. But the systems board then had another group, in my recollection, and this working party responded to it, and, as far as I have understood from reading the papers, the reason they disbanded it was that they thought that actually this was an area of study and potential research that was being handled by a number of other relevant bodies and that they didn't seem to have a specific role because actually essentially what was being looked at here was, again, operational research. It wasn't really fundamental research. They were not looking at the virus particles and other sort of thing that the MRC

got involved in. They were actually doing studies, epidemiological studies and so on, and they, I believe, looking at the papers, didn't necessarily feel that they needed to be involved, given that they could see there were a number of other bodies that were actually doing that sort of work, and potentially funding it too.

Q. So that's the working party on post-transfusion hepatitis. We've then got the Advisory Group on Testing for the Presence of Hepatitis B Antigen and its Antibodies. So something of a mouthful?

A. Yes.

Q. Broadly speaking, would it be right to understand that the title of that advisory group indicates what its role and remit was?

A. Absolutely. Completely.

Q. If we go to CBLA0007195, please, the top of the page is not terribly clear but it's a meeting of that particular advisory group. It's held on 6 March 1980, and we can see from the list of attendees that you were there, as was Dr Sibellas. Dr Sibellas was in Med IMCD, was she not?

A. Yes.

Q. So infectious communicable diseases were her area of specialty.

I think you referred to this earlier but it's right to understand, isn't it, that this particular advisory group had, as I think you said earlier, been around for a number of years?

A. Yes.

Q. But it didn't meet on a regular basis, it met and produced -- from time to time, produced reports from time to time?

A. Yes. I don't know how regularly it may have met in order to prepare the reports but from, again, reading the papers, I think I was attending in the sort of third tranche of meetings. There had been two previous reports from the earliest days. The first one, I think, when the working party was set up, when it was first discovered that there was a thing called the Dane particle, which was the virus of hepatitis B, and then the Australia antigen, the surface antigen. So there was -- they met, they considered, they produced a report and then there were obviously developments. I don't exactly know what the developments were. They met, they considered and they produced another report.

Then I came in on the considerations which led to the third report. That's my recollection.

Q. If we go to the second page, we can see -- it's quite

faint, but paragraph 3, "Terms of reference of the advisory group", and we can see why it's meeting again. So it's said that the advisory group's field of activity appeared to need some re-examination.

Then if we go to the next paragraph we can see that you and Dr Sibellas are recorded as explaining that a new committee was being set up to deal with all aspects of communicable hepatitis and it was the intention that this advisory group should become one of its subcommittees.

Now, we'll look at the new committee in a few minutes. So that's the advisory group on hepatitis that was set up by the Department?

A. Mm-hm.

Q. The plan was that this hepatitis B advisory group would then become a subcommittee of the overarching advisory group?

A. That's right.

Q. Then if we just look further down the page we've got there "Non-A, non-B Hepatitis - Work of the MRC Group", so that's the one we were just looking at. I just want to look at the last paragraph on that page. We can see it records:

"Members [being] concerned about the incidence of non-A, non-B hepatitis ... possibility that new

viruses were perhaps being introduced through the use of commercial blood products, namely, Factor VIII and IX. Professor Zuckermann reported that he knew of 2 haemophiliacs who had suffered severe non-A, non-B hepatitis after receiving commercial concentrates. In both cases the disease had a short incubation period."

Then this:

"Members agreed that the hazard from non-A, non-B hepatitis should now be recognised and brought to the attention of the appropriate Departmental bodies responsible for the control of hepatitis."

And then there's a record of the chair saying he'd asked Regional Transfusion Directors to provide Professor Zuckerman with sera for research.

So who would have been the appropriate departmental bodies responsible for control of hepatitis to which the hazard of non-A, non-B hepatitis should be brought to their attention?

A. I would have said that the reason that the Deputy Chief Medical Officer, Dr Evans, proposed to the Chief Medical Officer that there should be a hepatitis advisory group, an overarching entity, was because there was a realisation that this was becoming an issue and that the Department -- there shouldn't be a whole lot of disparate committees or groups looking

at things in isolation but that it should come under an overarching hepatitis advisory group. That would have been the Department's expert advisory group on hepatitis then, which they would have looked to to provide ongoing advice on hepatitis.

Then if we go to page 4, please, Soumik.

We can see, bottom half of the page, again there's a discussion on Factor VIII and IX associated transfusion hepatitis presented by Dr Craske. If we go to the next page, it's the second paragraph from the top:

"Commercial concentrates had been available for use in the UK over the last [I think it says] 5 years and evidence suggested that there would be a continued association of cases of non-A, non-B hepatitis with their use in the future. Members were informed that this information was already available to the Department in an Annual Report on the study which was supported by a research grant. Dr Craske intended to continue the study for several years, visiting centres which were associated with hepatologists, to obtain more details which might isolate the aetiological agents. Members agreed that the new hepatitis committee should be informed of Dr Craske's study and should be notified of the concern and views of this

Group."

So two things, Dr Walford. The first is, it would appear that the Department was in receipt of annual reports directly from Dr Craske, perhaps because it was funding his research; is that right?

A. We did. We got them. We sometimes saw them, as I've explained before, when he was presenting to the UKHCDO, and then we would get the final report. Often he was presenting before he'd completely finalised his report but then it would come to the Department, and undoubtedly would have gone to the new hepatitis advisory group.

Q. So the second issue to emerge from this paragraph is the new hepatitis committee is to be notified of the concerns and views of the group, and that's obviously on the topic of non-A, non-B hepatitis?

A. Yes, yes.

Q. Then if we go to CBLA0001167, it is described as the "fifth meeting of the reconvened advisory group on testing for the presence of hepatitis B surface antigen and its antibody". It's the Hepatitis B Advisory Group for shorthand. Meeting 17 September 1980. You and Dr Sibellas and, indeed, others from the Department are there.

If we could go to the bottom of page 3, please,

we can see reference, under the heading "The Hepatitis Advisory Group", to Dr Sibellas saying this:

"Dr Sibellas informed members that as a result of numerous requests to the Department for advice [and I think that may be the word "on" or something like that] diverse problems regarding Viral Hepatitis B, non-A, non-B being particularly problematic -- and about questions relating to occupational hazards affecting staff and patients, it was decided that it was essential to set up an advisory group which would consider and advise on these matters."

So it's clear from this, taking what Dr Sibellas is saying at face value, that the Department was receiving numerous requests for advice, including in relation to non-A, non-B hepatitis. Are you able to assist us with what those requests might have been or would that have gone to Med IMCD?

A. I'm just interested to see here -- I don't recall reading this paper but I've probably seen it -- but I'm interested to see that it's Dr Sibellas that is telling the committee, because basically it is possible that Med IMCD was receiving numerous requests for advice. I don't actually recall necessarily -- but I can't be sure, but I don't particularly recall that and it would actually -- that advice would be

more -- or that request, or requests, would more properly be sent to Med IMCD.

Q. So you may not have been receiving those in Med SEB but the Department was clearly receiving them?

A. Yes.

Q. Before we turn then to the new advisory group on hepatitis, just finishing off with the hepatitis B advisory group, can we go to PRSE0000862, please. So this is the "Third report of the advisory group on testing for the presence of hepatitis B surface antigen and its antibody". Unsurprisingly, much of the content of the report relates to hepatitis B and I'm not proposing to ask you about that.

But if we could go to, first of all, page 9, we can see that this a short reference to non-A, non-B hepatitis at the bottom of the page so:

"Non-A, non-B hepatitis viruses are a common cause of [post-transfusion hepatitis] in the [US] and are thought to have been responsible for cases ... in the UK. Hepatitis due to these viruses is common among haemophiliacs and follows the administration of imported, and occasionally of British Factor VIII and Factor IX. There is evidence for the occurence of sporadic cases of non-A, non-B in the general adult population and in association with cryoprecipitate

therapy in the UK."

Then over the page, second paragraph, so the paragraph numbered 24:

"We recommend that research is undertaken in the UK to determine the extent and severity of [post-transfusion hepatitis] due to non-A, non-B hepatitis viruses."

There's an explanation in the next sentence as to why.

Then this:

"Regional Transfusion Directors should encourage hospital haematologists to report all cases of post-transfusion jaundice and where these could be due to non-A, non-B hepatitis, the facts should be reported to the appropriate Adviser in Blood Transfusion at the Department of Health and Social Security or Scottish Home and Health Department."

So it appears to be a recommendation in the report for there to be a reporting system of post-transfusion non-A, non-B hepatitis cases or possible cases to the Department or to its Scottish equivalent. Can you assist us any more with what that reporting system comprised and who was the appropriate adviser?

A. It would be Dr Gunson, the consultant adviser. We

were not ourselves, as officials, called advisers. So if they are saying the "appropriate adviser", this will be the consultant adviser in blood transfusion and this is coming from the Regional Transfusion Directors to the consultant adviser in blood transfusion and, therefore, into the Department.

But then I think it would have gone into Med IMCD after that.

Q. But, in any event, through whatever form, that information coming to Dr Gunson should then have gone through his meetings with the CMO or through whatever route --

A. Yes.

Q. -- it should have been passed on within the Department?

A. Yes.

Q. So that then leads us to what was described as the new committee, the new group, the advisory group of hepatitis, which is the third committee on hepatitis I wanted to ask you about.

If we go to DHSC0002195_062, this is not a note that was copied to you at the time but it is one which I know you have seen since. It's from T Geffen, dated 6 November 1979, and it's addressed to Dr Evans. Dr Evans was the Deputy Chief Medical Officer --

A. Deputy Chief Medical Officer with responsibility in relation to hepatitis but also the other infectious disease.

Q. We can see, if we look at the first paragraph, it refers to a decision in July -- so that would have been July 1979, because this minute is dated November 1979 -- to proceed with measures to obtain professional advice on the various problems of hepatitis. Then if we go to the third paragraph, it says this:

"We are of course faced with the need not to establish new advisory or other bodies without very good reason ..."

Then there's a discussion about whether to attach it to the existing hepatitis B advisory group or whether it should be an advisory group in its own right. I don't want to get into the ins and outs of that.

Were you aware that there was, as it were, a policy or a practice of not establishing new advisory or other bodies without very good reason?

A. Yes, I think it was the general thought that you thought very carefully before you established or asked to establish a new body. It has to be said that we needed to go to ministers to establish such a new body

so you thought very carefully for the rationale and what you would actually say could be done away with. I mean, essentially, in terms of the use of staff within the DHSS, who had to often service these meetings, and so on, it made sense to be rational about the bodies and also to make sure that advice was coming to you, most -- the most authoritative advice you could get was coming from a properly constituted body.

So there was, at the time -- my recollection is that, basically, you thought hard and long before recommending yet another advisory group.

Q. As I think you alluded to a moment ago, it was something that required ministerial sign off?

A. Yes.

Q. Then if we just look at the last paragraph on this page, there's a discussion about an alternative option about having an *ad hoc* group rather than a formal group and then what's said about it is this:

"One disadvantage of this would be that we do really expect to need the advisory group not only in the immediate future, for example ... but for some time ahead."

Then there's reference to hepatitis B problems being with us for a long time.

Now, would it be right to understand, whether from this or from your own knowledge more generally, that this was regarded as something which needed to be set up sooner rather than later, put it that way?

A. I think from what I read now, though it wasn't the area in which I was directly involved, the setting up of this committee, but from what I read now it was clearly felt by Dr Evans and Dr Geffen, who was the head of Med IMDC before Dr Field, must have felt this was really necessary and therefore advised the CMO there should be such a committee and I assume they will have done that because they will have known that this wasn't a problem that was going to go away.

Q. Now, having seen the reference in here -- there's an in-principle decision to do this in July 1979. The group of which you were then part didn't meet until October 1980.

A. Really.

Q. I just wanted to ask you a little about that. I'm not suggesting that that was somehow your responsibility because you weren't involved in the formal decision-making processes but you were copied into some of it so I want to see if you can assist.

If we look at DHSC0000857, we can see we're now February 1980. This is from Dr Evans to Dr Geffen and

it's apparent that it's been discussed with the CMO the previous week. So it seems to have taken a further period of time to get to CMO level and agreement that is then reached we can see recorded in the second sentence:

"It was agreed that the numerous problems arising in relation to hepatitis need to be brought together into one Advisory Group on Hepatitis rather than be dealt with in a scattered fashion by various *ad hoc* groups."

Then we can see from the second paragraph that there's then got to be a note for the CMO to essentially seek ministerial approval. Is that the right way of understanding the decision-making process?

A. Yes, it is. I suppose the question is why did it take so long to get to that point and the answer is, as you have rightly pointed out, I don't actually know. But clearly it did and it was clear that the CMO was going to be involved in actually briefing ministers and getting their approval.

Q. Then there are aspects in which you were directly involved. I don't think we need to go to that but I think you were asked to draw up terms of reference, for example, and did so, and I'm not suggesting that

contributes to the delay.

But if we go to just a memo from you and Dr Sibellas, I think -- no, sorry, it's a memo addressed to you and to Dr Oliver, DHSC0000884. So it's from Phyllis Furnell in Med SN4 -- that's Med SEB, isn't it, that's your division --

A. Yes.

Q. -- to you and to Dr Oliver, it's dated 27 June 1980 and it's referring to -- essentially, I'm going to paraphrase for speed, what should now happen to the advisory group on the testing for hepatitis B antigen and its antibody. But if we look at the second paragraph:

"Dr Sibellas has told me that Ministers have agreed to the setting up of the "Hepatitis Advisory Group" with the strict proviso that there should be no other Committees concerned with Hepatitis in operation, and this means that on no account should a meeting of the [Advisory Group of Hepatitis B] be arranged."

So it would appear that by the end of June 1980 there's now ministerial approval but we're now nearly a year on from when the decision in principle to recommend it has been made.

A. Mm-hm.

Q. Do you have any idea as to why it took almost a year to get to that stage?

A. No, I'm afraid I can't help on that. It's obviously a long time.

Q. Then would it be right to understand what's said in paragraph 2 -- and I know it's Dr Sibellas not you -- but this is essentially, is it, a sort of case of too many cooks spoil the broth. We want there to be a single overarching group that looks at everything?

A. I understood from this exchange, looking at it now, that basically ministers were not keen on extra groups and essentially didn't want the advisory group on testing for hepatitis B to continue as a stand-alone committee. The way we tackled that, if you like, because that was a very valuable committee -- it was a part of the consideration that could well stand alone the testing for hepatitis B and its antibody, very technical discussion, was to make that committee a subcommittee of the main hepatitis advisory group.

So it didn't then operate as a freestanding committee, it was a subcommittee reporting to the hepatitis advisory group.

Q. Then, just for the sake of completeness, if we go to DHSC0002201_011 -- sorry, Soumik -- it sets out matters of background, which I'm not going to go to

but we can look at the bottom of the page at what the terms of reference are. We pick it up just above the paragraph referring to terms of reference. We can see it says:

"At the request of the Health Departments in Scotland, Wales and Northern Ireland the Group advises all the Departments in the United Kingdom, each of which have an officer present at meetings."

Then the terms of reference:

"To provide medical advice to the Chief Medical Officers of the Health Departments of the [UK] on all aspects of communicable hepatitis."

So that has finally been established, there's a list of members but there's a first meeting in October 1980. Now, you were present at, I think, the majority of the meetings between 1980 and 1983. I'm quite happy to take you to each of the sets of minutes if necessary but I will be doing so for the purpose of, as it were, perhaps demonstrating a negative and I'm very happy to do so if it would assist you in answering what I'm going to ask you.

My reading of the minutes, Dr Walford, is that, although we were told that non-A, non-B hepatitis was a pressing issue and the Department was receiving numerous requests for advice, when one looks at each

of the sets of minutes from 1982 to 1983, there's very little discussion about non-A, non-B hepatitis and the focus -- almost the entire focus is hepatitis B. Now, I know you've had and had the opportunity to read the minutes. Are you able to comment on that without looking at them or able to assist us in understanding why there doesn't appear, in fact, to have been much of a discussion about non-A, non-B hepatitis?

A. Well, I can't really. I mean, I absolutely accept that the three sets of minutes or whatever you described just don't seem to have much by way of non-A, non-B in it. I don't know why that was. I don't know -- of course, I was not responsible for setting the agenda. The agendas would have been down to the chair of the committee. I think Sir Robert Williams was the chair of this --

Q. Let's just look at one set of minutes to see who was involved. So if we just look at the first meeting, DHSC0002199_066.

A. Yes, it was Sir Robert.

Q. You're right. So Sir Robert Williams was chair and who was he?

A. He was the -- a former director of the Public Health Laboratory Service.

Q. Then I think we can see certainly some names of

Regional Transfusion Directors there. Dr Lane of course.

A. Mm-hm.

Q. Dr Sibellas is the medical secretary. Then there's a number of representatives from the Department of Health, including you, and including Dr Harris, as Deputy CMO. Then we have at that meeting a representative from Scotland and Northern Ireland.

So the agenda would have been set, would it, by Sir Robert Williams?

A. Yes.

Q. What was your role, and indeed the role of your DHSS colleagues, on the committee or the group?

A. I mean, appeared from being in attendance at the meetings, it was obviously a DHSS convened meeting and therefore DHSS representatives were in attendance, if they weren't being secretaries or having a membership of a particular committee. So I was clearly in attendance. Dr Sibellas, as medical secretary, would be in the lead for any talk about the agenda with Sir Robert and I don't think I had a very specific role. I can't remember without looking, of course, again, without being shown, the extent to which I did or did not contribute to the discussion.

Q. There's certainly no particular contribution from you

that I wanted to draw to your attention or ask you about.

A. Okay.

Q. Sir, just so that others, in particular legal representatives, if they wish to can look at the minutes -- I'm not going, as I say, to take Dr Walford through them she's read them, I've read them, to show what's not there, but it means that anyone who wants to can have a look at the minutes themselves, so I'm just going to read out the URNs if I may.

DHSC0002199_066 is the minutes for this first meeting. The second meeting of 5 December is DHSC0002201_070. The third meeting is 11 May 1981, DHSC0000128.

There's then a meeting in October 1981. This was not provided to Dr Walford but I will just give this again for broader benefit: NHBT0000068_048; and then there's a meeting in October 1982, NHBT0000068_021B; and then there's a meeting in October 1983, BBPLL0008168.

Sir, if anyone wants to look at those, they can. As I say, Dr Walford's seen all of them bar I think the 1981 meeting, which I'm not sure whether you were present, Dr Walford.

Can I then just ask you in general terms this:

do you think the Department was slow to pick up on and respond to the significance of and the risks of non-A, non-B hepatitis?

A. Just listening to what you've got to say about it, and listening to the length of time it took us to set up this particular meeting, I mean, it was not slow in terms of the generality of the way in which the Department operated, because there are instances in the papers that you've given me where really and truly the pace was not what one desirably would want to see in terms of moving things along. The Department was quite monolith. It was quite -- there was an element of bureaucracy involved. So it didn't move with the speed of summer lightning, how shall I say. So this was probably not slower than other working parties or other working groups would work but clearly, with the benefit of hindsight and looking at the time it was taking, and of course, as you've drawn out now, which may have been less apparent when one was up close, was that one of the issues that should have been of considerable concern, which was non-A, non-B, was not perhaps getting the attention that it should have got, at least not overtly as recorded in the minutes.

Q. Now, I'm going to move now to a fresh topic, which is

the question of self-sufficiency and the redevelopment of BPL. I've got a handful of general questions I'm going to ask you first of all which I think we can probably fit it in before the break, and then start looking at some of the detail with you after the break.

A. Yes.

Q. When you took up your role in the Department of Health, and certainly in Med SEB, what was your understanding of the Department's or the Government's policy on self-sufficiency?

A. I think it was always understood that that was the policy. I mean, basically that was the policy and that it had been the policy for a long time.

Q. The Inquiry's heard evidence from Lord Owen and looked at what some of Lord Owen decided and stated in the period of time when he was Secretary of State for Health in the mid-1970s. I think just before your time in terms of your first position with Medicines Division at the Department.

Do you recall whether you were aware specifically of what Lord Owen had said or of those commitments, pledges, whatever one wants to call them, that had been made?

A. I don't think early on I was. It's very difficult

now -- because I know what I know now it's very difficult for me to be absolutely certain what I -- I don't think I was particularly aware of it when I joined Med SEB, nor when I had been in Medicines Division, but joining Med SEB I don't think I was particularly aware of it. I knew in broad terms that that was the aim but not really the detail of Dr Owen's -- Lord Owen now -- involvement, nor the fact that I subsequently learnt that money had been provided to go some way towards self-sufficiency. So in general terms it felt as if it was a policy that had been sort of ongoing for some time.

Q. Would it be right to understand -- again, please correct me if this is wrong -- certainly by the time you've joined Med SEB was there any policy of achieving self-sufficiency in existence already at that time within a particular time-frame? So had a date been fixed?

A. No.

Q. What was your understanding -- I may be asking you the obvious -- but what was your understanding of the reasons for the policy of working to achieve self-sufficiency?

A. I think that the World Health Organisation's avowed policy, which was what we were espousing at the time,

was that it was wrong to deprive other countries of their human resource, if you will, the plasma from, maybe the developing countries, that essentially every country should rely on its own population to supply the amount of plasma that they needed to make whatever products they needed to make. That was I think the avowed reason for the World Health Organisation.

If it subsequently, or at the time, and I couldn't say, actually then involved the fact that some countries might have a higher incidence of an infectious organism in their plasma, that was -- I got the impression -- sort of second order to it, to the fact that every country should provide its own plasma from its own donors and not seek to exploit, if you will, the human resource of people in underdeveloped countries.

Q. So the safety issue, the risk issue was, as it were, secondary? I don't mean in your mind, I mean your understanding of the reason for the policy?

A. I can't tell really how the two -- because I wasn't around when the WHO pronounced how the two things came together but I think that what I've talked about was the fundamental reason, and I would have supposed that coupled with that maybe, but there must be documentation which will show that, that the risk of

transmission of infectious diseases was obviously going to be greater if you move from one population with one incidence of a particular infection to another population's recipients who -- maybe that country had a lower incidence of a particular infection.

Q. My understanding is you wouldn't have been directly involved in personally briefing a new minister about -- certainly about self-sufficiency?

A. No.

Q. Would you have any knowledge or expectation of whether new ministers would be briefed on that, would you have expected them to have been briefed that that was the policy?

A. I would expect not necessarily new ministers in general but actually whatever minister had the blood and blood products brief, because each minister had their own area, I would have expected probably as a matter of general underlying principle that they would have a brief on that.

Q. Then, just dealing with BPL, first of all, again in quite general terms, BPL was, as your statement makes clear, a manufacturing facility wholly owned and funded by the Department by the time at which we are concerned or you are concerned and accountable to the

Secretary of State?

A. Yes.

Q. Then in your statement you've given us an overview of the management and decision-making structure in relation to BPL. Could we put your statement back on screen. It's WITN4461001, it's paragraph 15.4.

SIR BRIAN LANGSTAFF: May I just check something for my own in satisfaction? You've said that the BPL was wholly owned and funded by the Department throughout the time of which you are aware. It had been the Lister Institute, had it not?

A. Yes.

SIR BRIAN LANGSTAFF: Which was not a governmental organisation as such --

A. No.

SIR BRIAN LANGSTAFF: -- though it supplied to the NHS. That arrangement finished in 1978.

A. Yes.

SIR BRIAN LANGSTAFF: My understanding was that after that it had been jointly run by the Department and by the region.

A. That's right.

SIR BRIAN LANGSTAFF: The region's funding was not centrally controlled?

A. No, but the funding for BPL all came from the

Department of Health. The region did not fund BPL. It was a device to allow the employment of BPL staff, and so on, because the North West Thames Regional Health Authority had employed many staff and had all sorts of departments which the Department itself didn't have. So it was necessary to have another entity (which turned out to be the North West Thames Regional Health Authority because BPL was based in the North West Thames area) to, as it were, partner with the Department. But the funding came exclusively from the Department.

SIR BRIAN LANGSTAFF: So it wasn't a case of the North West Thames Regional Health Authority spending any money or putting up any money?

A. No, on the contrary.

SIR BRIAN LANGSTAFF: It wasn't a question of -- was it a question of cross-accounting? Do you know that detail?

A. I wouldn't know the detail.

SIR BRIAN LANGSTAFF: That would be for the finance side, would it?

A. It would be for the finance.

MS RICHARDS: We can see the structure discussed. If you go to page 43, you can see bottom of the page, paragraph 15.4, Dr Walford says:

" ... it may be useful to summarise the decision-making structures at the time."

Then if we go over the page we can see, Dr Walford, you describe the Central Blood Laboratories, and it's important to understand that because we see that phrase used in some of the documents, which comprised BPL, PFL in Oxford and the Blood Group reference laboratory. Then until October 1978, they were managed for the Department by the Lister Institute. Again, I don't think we need to trouble you with particular dates but the Department purchased the site, did it not, from the Lister Institute around that time?

A. Yes.

Q. Is it right to understand -- again, I'll pick this up later, I think but there had been some form of joint arrangement between the Medical Research Council and the Lister, I think, earlier --

A. Earlier on.

Q. Then by the mid-'70s it was the Lister on its own and then, as you set out here, from October 1978 managed jointly by the Department and North West Thames Regional Health Authority. That was only ever intended to be temporary, wasn't it?

A. Yes.

Q. Then there were two committees. I'm just going to identify them now because we're going to look at a number of their minutes.
A. Yes.
Q. So there was the Joint Management Committee, chaired by the Deputy Chief Medical Officer, and then there was the Scientific and Technical Committee and I think you are often in attendance at both those meetings?
A. Yes.
Q. So again we'll look at that.

Then you explain how from December 1980 there was an additional committee, the Advisory Committee on the National Blood Transfusion Service, and then various *ad hoc* working parties, in particular in relation to the redevelopment and aspects of the redevelopment of BPL. Again, we'll look at those to the extent necessary.

Then over the page, those *ad hoc* working parties included, and we see at (iii), a policy steering group for the redevelopment of BPL -- again, we'll look at that -- and then you explain in the next sub-paragraph that in December 1982 the JMC (so the joint management decision-making structure) was replaced by the Central Blood Products Laboratories Authority, the CBLA. That was a special health authority set up by the Secretary

of State to manage BPL?
A. Yes.
MS RICHARDS: Sir, that overview brings me perfectly to 3.15, obviously as planned for the break, and then if we pick up on some of the detail after the break.
SIR BRIAN LANGSTAFF: Yes. Shall we come back at 20 to 4. So 15.40 -- 20 to 4.
(3.15 pm)
(A short break)
(3.41 pm)
SIR BRIAN LANGSTAFF: Dr Walford, I want to ask you first a handful of questions about BPL prior to the Medicines Inspection report.
A. Right.
Q. I'm going to ask you about some matters which pre-date your time but which you have at least referred to in a document you authored and which -- you may have picked up upon these matters from your subsequent involvement. If you are not able to assist then obviously you will say so.

So it's really looking at the position by the second half of the 70s with BPL, in quite general terms. First of all, looking at an extract from Dr Lane's draft witness statement.

If we could go, Soumik, to CBLA0000005, please.

It might be 0000005_002, actually, sorry.

So it's draft proof of evidence of Richard Spencer Lane and, if we go to page 74, I just want to pick up on a couple of paragraphs. So, 180, Dr Lane says this:

"The problem was that the basic infrastructure of BPL remained one which was appropriate to laboratory engaging in research and relatively small scale production. The buildings dating back to the 1950s were old, small and not appropriately designed for manufacturing."

Then he refers to the Medicines Inspectorate report which we will come on to, and then says:

"... whilst still inadequate, it was now a facility making a significant contribution to the increasing requirements of haemophiliacs for Factor VIII concentrate."

Then if we look at his next paragraph, he sets out some observations by Dr Maycock from what I think was Dr Maycock's valedictory statement when he retired, Dr Maycock saying this:

"There is probably a moral to be drawn from the building history of the present BPL.

"1954 building: planned in 1949-1952 mainly as a civil defence project to prepare freeze-dried large

pool UVL irradiated plasma, the preparation of plasma which was abandoned during erection of the building, in favour of a return to freeze-dried ten donor small pool plasma. The potential value of plasma fractions had not been appreciated in any countries, and a combination for fractionation was included own as an afterthought.

"1962 extension: a make and mend operation, which by moving the bacteriology and enlarging the small pool plasma laboratories, relieved some of the pressures on the laboratory which were becoming intolerable."

Then:

"1972 extension: this enlargement originated from the relatively immense need for immunoglobulin to prevent rubella in exposed pregnant women. Later it was decided that the plan should include means for meeting the estimated needs of Factor VIII concentrate and, later still, that the building should accommodate means for fractionating all plasma and that freeze-dried small-pool plasma should be replaced by albumin and PPF."

He says:

"It was now known that the estimates for Factor VIII concentrate and albumin concentrate on

which the plan was based were totally inadequate. Planning, completed in 1965, was affected by the severe constraints imposed by the site and, in spite of these impediments, reductions in floor space were nevertheless imposed by the Department."

Now that's one description. I'm not going to ask you about details of it, but there's a broad description there.

Now I want to go to a document authored I think by you which also looks at the position in the 70s. It's DHSC0002305_011.

Now, if we look at the top, this is a draft ministerial submission.

A. Yes.

Q. It was amended quite substantially before the final submission went to ministers, and we'll look at a later stage at the final submission, but we can see someone's handwritten on there "By D Walford 19 [December 1979]", and I think there are other documents that refer to you producing a draft. So is it right to understand that this is a document that you authored?

A. When I saw this -- I was given this, I think I produced quite a bit of what's in the draft, and I think that top page, which says "By D Walford" is

probably -- the sort of historical perspective and discussing what products were being produced was me. Subsequently I can see bits of this draft that will have been administrative colleagues and not me. So I think it was, as often happened, an amalgam, but certainly that front page will have been me.

Q. Well, I only want to ask you about the historical perspective currently, so that's useful to know.

Bottom of the page, therefore, we can see:

"History of the BPL ...

"In 1952 a unit was set up at Elstree to undertake research ..."

Go to the next page:

"... and development in the field of blood products and to manufacture freeze-dried plasma. The unit was managed by the Medical Research Council but funded entirely by the Department. Subsequently, methods of processing plasma were developed which yielded preparations containing specific individual components of blood, such as the clotting factor, Factor VIII. In the 1960s the unit greatly expanded its rate of production of such products and in 1972 a new unit - the present BPL - was commissioned.

"6. In 1975, following a decision by Dr David Owen that there should be much less reliance

on commercial sources of blood products, particularly factor VIII, [half a million pounds] was allocated from Central Funds to Regional Blood Transfusion Centres to produce more plasma for processing at BPL. Production at BPL therefore expanded far beyond the level which had been allowed for in its design and beyond that which could be considered reasonable for safe production.

"7. In 1976 the Medical Research Council ceased to manage the BPL since it was felt that the unit had become less of a research laboratory and more of a production unit - in effect, a factory. Management was transferred to the Lister Institute of Preventative Medicine, one of whose activities was the manufacture of vaccines.

"The Lister Institute appeared content to leave the manufacturing aspect of the BPL almost entirely in the hands of its director, Dr Maycock (later Sir William Maycock), who was also Consultant Adviser in Blood Transfusion to the Department."

Just pausing there, so he was Dr Tovey's --

A. Predecessor, yes.

Q. "The first intimation that the laboratory had serious shortcomings followed informal visits by the Medicines Inspectors in 1977 but Dr Maycock advised

the Department that there were serious doubts that the Inspectorate's standards for pharmaceutical manufacture could or should be applied to the manufacture of blood products. Dr Maycock's views had the support of several Regional Transfusion Directors, perhaps because they feared that the same standards might also be applied to the preparation of various blood components produced by the Regional Centres themselves.

"9. Further criticism of the Laboratory's capability and manufacturing conditions was voiced by Dr Richard Lane shortly after his appointment as Deputy Director and Director Designate in 1977. Later that year, the Department met Dr Maycock and Dr Lane at the BPL and asked them to begin to plan for the phased redevelopment of the BPL. More immediately, they were asked to plan for necessary improvements (a so-called 'stop-gap' development) which would remedy the laboratory's worst shortcomings and lead to an increased output of factor VIII and albumin. The increased output was felt to be essential since the BPL was only supplying about one third of the NHS requirement for blood products, the shortfall being met by the purchase of costly commercial products to the tune of several million pounds per year.

"10. In 1977, the inadequacies of the Lister Institute as a production unit management was starkly revealed by a formal inspection by the Medicines Inspectorate, culminating in the closure of the Lister Institute's own vaccine manufacturing unit at Elstree."

So that's the Medicines Inspectorate, not to be confused with the later inspection of BPL itself. That's the Medicines Inspectorate inspecting the Lister Institute's facilities.

Then paragraph 11:

"The BPL had not yet been formally inspected so that the demise of the Lister Institute did not affect the running of the BPL except that a new management structure had to be devised."

Then we see the reference there to the Joint Management Committee and the Scientific and Technical Committee.

Then paragraph 12:

"Both Committees endorsed fully the need to implement the 'stop-gap' proposals for improving the laboratory but implementation of these plans was deferred since it was known that the laboratory was shortly to be inspected and it was possible that the 'stop-gap' proposals would conflict with the

anticipated requirements by the Inspectorate for improvements to laboratory."

Then you go on to talk about the report by the Medicines Inspectors.

So I just wanted to stop there in terms of the history. Now, this won't have been, for the most part, material from your own direct knowledge. You'll have gleaned this from Dr Lane or sources within the Department?

A. Sources, yes.

Q. But it's accurate to the best of your knowledge?

A. It is.

Q. So I just want to put three things to you and ask for your comment, ask if you agree with them.

Would you agree with this: firstly, that it was or should have been known to all those involved with -- in relation to BPL in the second half of the 1970s that the demand for blood products was rising?

A. Yes.

Q. Secondly, it was or should have been obvious that BPL was outdated and too small and that significant investment was required in order to be able to meet the rising demand?

A. Yes.

Q. Thirdly, the Government had determined that BPL should meet equivalent standards to commercial plants, notwithstanding Crown immunity, but it was or should have been obvious that BPL would not meet those standards?

A. That's right.

Q. As we saw referred to in that document, by the time you first became involved, and I think we can certainly trace you having some involvement by the beginning of 1979 whilst you're still in the Medicines Division, possibly in the course of 1978 as well, the BPL had devised this stopgap programme --

A. Yes.

Q. -- intended to allow for upgrading of the plant to allow for an increase in production in preparation for a bigger redevelopment?

A. Yes.

Q. Then we're going to look at the implications then of what then happened --

A. Yes.

Q. -- Dr Walford, over the -- immediately before and then following the Medicines Inspectorate report.

I want to pick things up in January 1979 with a meeting that you attended. Soumik, it's DHSC0002191_067. So we can see it's the Joint

Management Committee for the Central Laboratories meeting on -- I said 21 January -- 21 February 1979, and we can see that you're in attendance, there's Dr Glass, Mr Brechin, Dr Walford, Mrs Yuille. This is before you joined Med SEB, so in what capacity were you attending this meeting?

A. Are we able to go a bit further down to remind myself because, basically, Dr Waiter was doing my job that I got then.

Q. Dr Waiter is there we can see --

A. So I must have been there for some other reason to do with Medicines Division. I was there representing Medicines Division, undoubtedly. There was nothing else I could be representing. It depends, are you going to go through --

Q. I will. It may assist you in answering the question. So if we go to page 3, we can see, bottom half of the page there's a subheading "Progress with the setting up of the Scientific and Technical Committee". So we can see that that's being set up. Reference there to Dr Waiter and Mr Dutton being joint secretaries.

Then, bottom of the page, and this may be why you were there, Dr Walford, I don't know:

"The requirements of the Medicines Act and the conditions which BPL and PFL would be required to

fulfil.

"Dr Walford asked for the Committee's agreement to withdraw the document entitled 'Standards for the collection and processing of blood and blood components and the manufacture of sterile fluids in the NBTS'. She drew the Committee's attention particularly to the requirements of HSC(IS)144 and recommended that the [Regional Health Authority] should formally designate Dr Lane as the 'person responsible'. Dr Harris pointed out that although the same licensing requirements did not apply to the NHS as to industry, successive Secretaries of State had emphasised that NHS should be required to attain the same standards as manufacturing industry. Dr Walford explained that the procedures which BPL had developed for the manufacture of albumin would require to be approved by the appropriate Sub-Committee of the Committee on Safety of Medicines."

Then there's also reference to the possibility of having to seek a product licence for albumin. Then, although there's some markings on this, it says:

"Dr Walford said that she expected to make her formal visit to the BPL in April and to PFL somewhat later. Mr Harley asked what the situation would be if Medicines Division recommended changes for which there

was no financial provision. Dr Harris explained that in this case the options would have to be put to Ministers."

A. Yes.

Q. Does that help in understanding why you were there?

A. Well, obviously, I seem to be there to provide whatever information I could about the role of product licensing, if you like, of what is required formally under the Medicines Act for Factor VIII or albumin production. I think somewhere later on -- I don't know whether you want to deal with it now -- that I dealt with the whole subject of whether BPL products were formally licensed by the licensing authority but, essentially, I had obviously been invited here. Unfortunately, I cannot remember at all what was in HSC(IS)144. Something to do with standards in blood transfusion centres.

The question which was going to be considered was whether the Medicines Inspectorate needed to inspect Regional Transfusion Centres as well as inspecting BPL, and I think that was an issue. I don't know why I might have suggested that the document that was referred to just over the page should be withdrawn but clearly it was accepted by the Committee that it should be withdrawn. I mean, unless

I saw what was in that document I really can't comment. I really don't know.

Q. This appears to envisage that you would be making a formal visit to BPL --

A. Yes.

Q. -- and the reference is April. We know April was the medicines inspection visit.

A. Yes.

Q. Would you normally be part of a medicines inspection visit? I know you told us about the visit to the States.

A. Do you know, I don't know whether I was or I wasn't. Clearly, it seemed to imply that I was going to be making a formal visit. I don't think I, on my own, would be making a formal visit. Maybe I was -- I accompanied to the Medicines Inspectorate. I simply don't remember at this remove. As I say, I went around BPL quite a bit.

This is very early on in my, as it were, relationship with BPL because this is February 1979.

Q. Yes.

A. I hadn't actually started in my new job. I didn't even know I was getting a new job in Med SEB. So what it might have been was that I was needing to visit BPL so that I knew what I was talking about if I was asked

to call upon -- to talk about something by the Inspectorate. But it could have been that I went on the visits. I really can't remember. I don't know if you've got any papers which suggest that I did. I haven't seen any.

Q. I don't think we've got any one way or another that answers that question, Dr Walford. Don't worry if you can't remember. We'll look at what the inspection report said, in any event, in due course.

I just want to ask you next to look at a meeting from March 1979. This is one you weren't at --

A. Yes.

Q. -- which is BPLL0008430_001 and we can see it's a meeting of the Scientific and Technical Committee for the Central Laboratories, 26 March 1979. It appears to be the first meeting of the Scientific and Technical Committee. I will come back to the membership of that when we look at some of the meetings you attended but if we go a little further down we see joint secretaries included Dr Sheila Waiter, so your predecessor in Med SEB?

A. Mm-hm.

Q. Then if we go to the second page, I just want really to then ground what comes next, look at some of the discussion here. So second paragraph refers to

Dr Lane outlining the constraints on the development of BPL and reference to the Department purchasing the site and then there's then a discussion about usage.

Then the next paragraph records Mr Smart, and Mr Smart was a member of the Committee who was himself, I think, involved with the pharmaceutical industry.

A. Glaxo.

Q. He was a senior adviser with Glaxo:

"... pointed out that with expenditure of this order likely to be incurred, there appeared to be every incentive on economic grounds for speedy investment aimed at optimising Factor VIII production at BPL."

We'll pick this up in later documents, Dr Walford, when we look more closely at your involvement but I think it's right to say Mr Smart, certainly from this stage onwards, notwithstanding or perhaps because of his own experience working in the private sector, was very firmly of the view that there was a strong economic case for BPL to be redeveloped as an NHS fractionation centre, without private industrial participation, wasn't there?

A. That's absolutely right and he was absolutely right.

Q. So we can see from the beginning of the scientific and

technical committee that's Mr Smart's view and then if we go to the next page, top of the page, we can see Dr Dunnill, I'm not sure if you can assist us with whose that was?

A. He was a scientist, a bio-medical engineer at UCL.

Q. He says:

"[He] reminded members that he had pointed out to the Department some 12 months ago that it was improvident to expect the major BPL plant to continue to function much longer without major breakdown."

Then again we have Mr Smart recommending the need for planning for the future and then we can see Dr Lane pointing out in the next paragraph that:

"... the 'stop-gap' programme, which was designed to give maximum production capacity essentially within the constraints imposed by existing plant and premises, was not capable of being repeated, and there was an urgent need for planning for substantial additional capacity."

Now, I'm not going to go into the details of everything else that was discussed, and I'm conscious you weren't there, but would it be right to understand that really it's being made very clear by members of the Scientific and Technical Committee in March 1979 that this was something that needed to be urgently

addressed?

A. Yes.

Q. Then if we just look at the very bottom of the page, there's a paragraph there referring to Dr Gunson and he talks about the possibility of looking at two distinct functions in which BPL was engaged. The first was essentially a research and development role and then the second was a routine production process turning out large quantities of plasma proteins by established methods:

"He wondered whether there was a place for industrial participation in the latter process."

Now, one of the themes I am going to explore with you tomorrow morning probably is the consideration that was given by the Department to commercial industrial involvement in BPL.

A. Yes.

Q. This appears to be a tentative suggestion, a wondering by Dr Gunson. Do you know from either your own recollection or the material you've read whether this was something that had been floated as an idea prior to this?

A. The only thing that I knew about that I can recall now and from the papers that I've seen was a paper by Dr Waiter shortly before -- this was probably August

just before I --

Q. I'm going to come to that.

A. So that's where I think I first -- was I at this meeting?

Q. You weren't at this particular meeting, no.

A. That's when I think I first became aware, probably, that there were considerations of should there be commercial participation in some form or another.

Q. We'll come to that very shortly. Just before we do that, I just want to invite your attention to a document produced by Mr Smart. So one of the agreements of the Scientific and Technical Committee on this date was that Mr Smart would produce a report looking at options for BPL. It's CBLA0001004_004.

We can see it's headed "Blood Products Laboratory: Redevelopment", and he explains in the first paragraph that:

"At the meeting [we just looked at, he] undertook to prepare a short paper seeking to apply the techniques of evaluation of alternative strategies which would be used in an industrial context."

Then he sets out three -- if we go back to the main page, he sets out three basic sources of action:

"1. Close down production of blood products in the National Blood Transfusion Service and acquire all

supplies of necessary fractions from external commercial sources."

So forget NHS product; commercial product only:

"2. Continue production of a proportion of the country's needs, on one footing or another making good any shortfall by purchase from commercial suppliers."

So that's, as it were, the maintenance of the status quo:

"Continued production might be:

"(a) at the present levels of capacity within BPL, with no further injection of capital and with expenditure limited to essential repairs and replacements as they became absolutely unavoidable.

"or (b) at the raised levels to be achieved by the implementation of the 'Stop-gap' programme but with no thought of further expansion."

So option 2 is maintain the status quo, perhaps with some modest improvements. That's my paraphrasing. Then option 3:

"Bring BPL up to the standards and operating capacity which one would expect to find in a purpose-built industrial unit capable of meeting the entire national requirement for blood products."

So three years, complete redevelopment, and he goes on, I'm not going to go through the detail of it,

but to set out, in very broad terms, the cash flow, the economic case in relation to each and, if we just go to page 4, second half of the page is his evaluation of option 3, which is complete redevelopment, and he says, bottom of the page:

"This pattern shows, as might be anticipated, that there is a rapid and growing return on the investment with all the capital expenditure paid back in the first 15 months of full-scale operation."

Essentially he's talking about you'd save your money that you're spending on commercial concentrates and that you'd get that money back, put crudely.

A. Yes.

Q. Do you know whether, when you took over the job a few months later, did you see Mr Smart's report?

A. I certainly saw it. I think I saw it during the course. I don't exactly know when I saw it but I certainly saw it probably fairly early on, yes.

Q. What was your view of what he was saying?

A. He was spot on.

Q. Now, we then have the medicines inspection -- Medicines Inspectorate inspection, April 1979, I think, and then if we look at the conclusions of the Medicines Division following the inspection, it's at DHSC0001812. So this isn't the full inspection

report, but I think it summarises the most salient points. First paragraph:

"[BPL] was developed in stages over a number of years as new products were introduced and new buildings were erected to facilitate their manufacture."

Paragraph 2 talks about:

"... as production [it] could not readily be adapted to large scale manufacture."

Then if we just carry on down the page, I'm just going to alight on some of the points. Paragraph 4 raises an issue about the personnel who had not had:

"... the opportunity to gain experience of modern large-scale sterile production requirements in the pharmaceutical industry ...

"5. Production is now on a scale which must be regarded as a large scale factory-type operation and has out-grown the premises in which it is undertaken.

"6. The Laboratory is so short of space for cold storage; quarantine of raw materials, in-process materials and finished products; receipt and despatch; packaging; and warehousing generally, that it is not practical or safe to increase throughput even if the necessary production facilities were available. For these reasons it is not practicable to consider

a double-shift system of working if it were possible to employ the appropriate additional staff."

Then this:

"If this were a commercial operation we would have no hesitation in recommending that manufacture should cease until the facility was upgraded to a minimum acceptable level."

Then, over the page, the Medicines Division say, at the top:

"However, as blood products are essential to the health and well-being of the nation and as alternative sources of supply are severely restricted, production at Elstree may continue provided certain aspects of the standards of production and control are improved immediately and that the planning of certain other essential improvements in these standards commences immediately with a view to very early implementation."

Then we can see a number of recommendations first of which is:

"Under no circumstances should production of any product be increased under the existing manufacturing conditions.

"... special need for the manufacture of Freeze-Dried Plasma to be upgraded immediately by locating it elsewhere on the premises as the present

facility is totally unacceptable. The alternative is to cease manufacturing of this product as the operation as currently undertaken is microbiologically hazardous."

Then paragraph 10 sets out a whole number of immediate measures that are said must be undertaken. I'm not going to go through each of those.

Next page, halfway down, paragraph 11:

"Planning of essential improvements must commence forthwith and, take into consideration the following ..."

Then reference to:

"The present facility [being] totally unsuitable for manufacture of sterile products and incapable of being upgraded to the required standards.

"(b) The existing buildings would be suitable as, or could be adapted for use as ..."

Then it describes the kind of facilities that could be, as it were, housed in the existing buildings. Then:

"(c) A new factory-type manufacturing facility is required."

Then the "Additional comment", bottom of the page, is:

"The arrangements originally intended for

increased production (known as 'Stop Gap Proposals') should be proceeded with as quickly as possible to provide additional cold storage space, warehousing, goods receipt and despatch, container washing and preparation, but only if such a development can be incorporated into a new manufacturing facility. However, in proceeding with 'STOP GAP' there should be no intention of increasing production in the present facility as it is already overloaded and seriously deficient in standards."

Then there are some recommendations as to what could be done to address that.

So it's a pretty damning report on BPL.

A. Yes.

Q. Would you agree it's something which called out for urgent action?

A. Yes.

Q. Do you happen to know why the inspection was taking place at that point in time and hadn't occurred earlier?

A. I don't know. I mean, from what we've said earlier, I think there was some discussion in 1977. I don't know whether there were proper inspections then. I've no idea why the Inspectorate chose to inspect then. I really haven't seen anything that helps.

Q. But what's being described, is this fair, is a state of affairs that wasn't new --

A. No.

Q. -- these weren't recent developments --

A. No.

Q. -- so it's something that must have been evident as a problem for some time?

A. I'm certain it was.

Q. Now, again I just want to look, before we get to Dr Waiter's memo to you as her successor, I just want to look at three other documents, just to take us through the period from the inspection in around April 1979 to Dr Waiter leaving and you joining in August/September 1979.

There's a meeting at CBLA0000952 of the Scientific and Technical Committee. So they meet on 7 June 1976, and we can see again that Dr Waiter, as your predecessor, was present. If we go to the third page, we've got the heading "The development of BPL" there's reference to Mr Smart's report, which I think is the report we looked at. There's reference to a memorandum by Dr Lane. I'm not going to ask you about that. There's then a discussion about Mr Harley preparing a paper containing the Department's appraisal of the options open to it.

Then, if we just look at the next paragraph, we can see Mr Dunnill saying that:

"[He] thought that further papers would not advance consideration of the problems facing BPL which were already well identified and the options were, in his view, also quite apparent. He wondered whether the better course might be for the Chairman to seek to see the Secretary of State and to express the Committee's disquiet that nothing was being done to put the defects at BPL right. Several members doubted whether there could be a useful discussion with the Secretary of State until the appraisal which Mr Harley proposed to cover in his paper had been carried out."

Ultimately, there is an agreement that Mr Harley should go away and produce a paper before the matter's taken further.

But would it be right to understand that, at least from the position of, again, the Scientific and Technical Committee in June 1979, they are now perhaps even more concerned that something needs to be done to address this because the medicines inspection has been so damning?

A. Yes.

Q. Then if we look at BPLL0008488, again this is before you've taken up the post, so it's 13 June 1979 and

this is a meeting of the Joint Management Committee for Central Blood Laboratories, so Dr Sheila Waiter, your predecessor, is there.

But if we go to page 4, we can see about a third of the way down the page there's reference to the Scientific and Technical Committee meeting, which we've just looked at and then if we go to the last paragraph:

"The relationship of 'Stop-Gap' [if you have that paragraph, Dr Walford] to the phased redevelopment of BPL was discussed. Mr Harley invited members to consider the advisability of proceeding with Stop-Gap in the light of the medicines inspectors report. The Committee was firmly of the view that the Stop-Gap should go ahead. There was no reason why it should be incompatible with emergency measures to meet those short comings which could not be tackled immediately or with longer term developments. There could be no question of replacing the laboratory for a number of years and the Stop-Gap development was therefore necessary."

Then there's a discussion of how it could be funded.

So, again, this is really just to place what's happening in context before you become involved. The

Joint Management Committee's view was that the stop-gap proposals and the stop-gap work should continue and then, if we go by CBLA0000955, this is a letter from Mr Harley, dated 13 July 1979, so in the Health Services Division of the DHSS, to Dr Lane confirming a telephone call. He says in the second paragraph:

"It is, as you know, likely that a report by the medicines inspectors will require at the very least an upgrading of the facilities at the Blood Products Laboratory."

So it sounds as though the full report's not yet available.

"You also know that no money has been allocated for this purpose. We do not, of course, know what the cost of upgrading may be but we could find ourselves in a situation where we should have to choose between upgrading and going ahead with the Stop-Gap programme. I therefore think it would be advisable to avoid incurring any further Stop-Gap expenditure until the financial position has been clarified. I need hardly say that this applies also to expenditure on the planning of the phased redevelopment of the BPL. I know what a disappointment this must be to you but I'm sure you will agree it is the wisest course."

So is it right to understand that the Department is saying to BPL no further expenditure until we considered the bigger picture, as it were?

A. It's right to understand that Mr Harley is saying that to BPL.

Q. Yes, you're right to point that out. But it appears from the letter that Mr Harley had or appears to think he had the authority to say that to Dr Lane?

A. Well, I think he probably had the authority because his role was for the finances and the budget for BPL, and he also chaired, whether now or later on, the Finance Committee for which was advising the Joint Management Committee. If I might say so, and I think subsequent papers will show, I think it was perhaps a misunderstanding on his part about how far the stop-gap arrangements would go to improve quality and I think he felt it was in some -- it looks as if -- I don't know what he felt but it looks as if he felt there was -- it was a dichotomous position. On the one hand, you did the stop-gap, on the other hand you made the remedial arrangements to fulfil the Medicines Inspectorate requirement, and I don't think that was like that.

It was on a continuum and I think there was a lot in the stop-gap proposals that would have gone

a long way towards addressing the Medicines Inspectorate report and, frankly, and even looking back on is this as now I must, it's really hard to understand why that instruction, if you will, was issued, because it did hold things up and it didn't need to in my opinion.

Q. That brings us then to Dr Waiter's memo to you -- well, sorry, it's memo to Dr Oliver, copied to you, but it's her reflections moving on from the job.

A. Yes.

Q. So if we go to DHSC0002195_020, so it's dated 23 August 1979 -- we don't need to go to the last page yet but that's where the date is -- and we can see it's addressed to Dr Oliver, "Future Supplies of Blood Products". She refers to visiting -- is it Kabi? -- in Stockholm, so a Swedish pharmaceutical company?

A. Yes.

Q. And then she says:

"This visit, coupled with my imminent remove from Med SM4 [so that's Med SEB] has prompted me to set down some of the problems as I see them of future supply of blood products and possible solutions.

"As you know I was interested to visit Kabi because of their involvement in the manufacture of blood products and their interest in extending Kabi

activities outside Scandinavia. They wish to build a plasma fractionation plant and approach us earlier to discuss the possibility a) of building such a plant in the UK and b) fractionating UK plasma on our behalf."

Then there's reference to some discussions in April 1979. Then she says:

"It is accepted that in order to meet the anticipated demand for the principal plasma fractions (factor VIII and protein solutions - mainly albumin) new plant, in relation to that already available in the UK, must be acquired. With this in mind plans for the future development of the Blood Products Laboratory have been drawn up. In addition to increasing production it will be necessary to upgrade existing plant to meet the requirements of the Medicines Act. Needless to say any new plant will have to be built to the same specification."

Just pausing there, do you know what plans she was referring to when she says "plans for the further development of the Blood Products Laboratory have been drawn up"?

A. I'm wondering if maybe she was referring to the stop-gap proposals, but I can't be certain.

Q. Then she goes on to say:

"There are a number of alternative schemes for making plasma derivatives available in sufficient quantities to meet demands of UK clinicians and some urgent discussions will be necessary.

"To meet the estimated demand several possible alternative schemes have been described - others may become apparent."

So she sets out five options:

"1. To invest sufficient money in the BPL, Elstree to build up its capacity to meet the level of demand for factor VIII and albumin - production of other fractions at 'self-sufficiency' levels will follow for almost all plasma derivatives."

So do whatever you need to do to BPL to become self-sufficient, in other words, is option 1.

Option 2:

"To re-examine the capacity, present and potential, at PFC, Liberton and to see whether this could be developed to meet UK demands."

So, look to see whether you can develop the Scottish facility and whether they can fractionate material for the whole of the UK.

"3. To seek a UK firm willing to undertake work under contract for the NHS and 'without profit'.

"4. To enter into a joint venture with

a foreign or UK commercial enterprise.

"5. Not to invest in UK plant for the production of the major plasmas derivatives, (Factor VIII and albumin) but to rely entirely on commercial sources, with the exception of PFL, Oxford and PFC, Liberton who will continue at their present level of production."

Then we can see she evaluates each of the options. I'm not going to go through all of it but I think it is probably quite important to see a lot of it.

So, option 1 she refers to a paper prepared by Dr Lane, which I haven't troubled you to look at today, and then to Mr Smart and she says this:

"The arguments, given the money to invest, appear convincing but I would question whether there is sufficient expertise within the BPL, even within the NHS, to plan, build and commission a plant on the required scale. If this option is taken up either staff or suitable calibre and experience should be recruited to BPL or a firm with the necessary expertise should be contracted to plan, build and commission new plant."

So in terms of redeveloping BPL as an NHS facility, she is doubtful that it can be done.

A. Doubtful but has found a way in which it might be done, and I must say I was sympathetic with the notion that you should be able to find a commercial company willing to provide the expertise to run under contract or to manage under contract this facility for the NHS.

Q. Then option 2, and this was the option of looking to Scotland to help out, she says:

"I have been convinced for a considerable time that its sensible to make a co-ordinated UK approach to solving the 'self-sufficiency' problem. Criticism has been levelled by the Directors at BPL (past and present) at the plant at PFC, Liberton and on occasion at the major products. Nevertheless Scotland is better provided with protein solutions and Factor VIII than England and Wales. The Medicines Inspectorate have not yet visited or reported on PFC ... but if the PFC proves to be satisfactory, or more readily brought up to the required standards, then we should consider further investment there, and manufacturing the major components at PFC ..."

Then just going to the next paragraph:

"Whichever option is pursued DHSS must examine the potential of PFC, Liberton."

A. Yes.

Q. Reference is made to some investment that has already

been made.

Then if we go to options 3 to 4, so this is the option of -- the options of commercial companies effectively taking over BPL, reference made to the good will of blood donors, so the UK's voluntary donation system, and she talks about the hazards associated with reliance on paid donors being well documented.

"If an enterprise outside the NHS undertakes to fractionate plasma on behalf of the NHS then it is believed by many that the good-will of donors will be lost to a significant extent and the Blood Transfusion Service will suffer. This consequence is debatable. It is possible the situation could be avoided if a nationalised UK firm could be interested in fractionating plasma exclusively for the NHS."

Then if we just -- sorry, the last sentence of that paragraph is important:

"However, at present, no UK firm appears to have the expertise nor the interest to enter the field of plasma fractionation ..."

So that's Dr Waiter's observation of the possibility of looking to a UK firm.

"... and an alternative might be to interest a foreign firm, some have already expressed an

interest ..."

And then she refers to Kabi AB, the Swedish firm, and she says two paragraphs further down:

"Again, with careful preparation, I believe this or a similar scheme could be presented in an acceptable way to the British blood donor."

Then option 5, next page, which was rely entirely on commercial concentrates, she says:

"In the long-term this is unacceptable. Previous ministers have declared their intention that the UK shall be self-sufficient. This policy is in line with WHO principles accepted by all nations with advanced medical care and would probably be the intention of present ministers."

Now, I just wanted to pick up on that latter point there. This is August 1979. There had been a general election in --

A. It was May.

Q. -- May of 1979, and so it would suggest, I think if this is a fair reading of what Dr Waiter is saying, that she's anticipating that the new Government would endorse the existing policy but is not certain of it?

A. Yes. That's right.

Q. And then if we just look at her summary, she says:

"To pursue any of the above options will bring

major problems to which there are no easy solutions. Some have been touched on in this paper. Expenditure of several million pounds would solve a few, but the greater problems would remain: the attitude of blood donors to what they might interpret as exploitation, the lack of expertise in the centres in which we might invest, the attitude of clinicians who look for increasingly large volumes of therapeutic materials. Some clearly have a responsible attitude to their use, others, as in many other fields of clinical practice, wish their demands to be met without question or payment. However, in summary, I believe self-sufficiency can be reached one way or another if the problems can be overcome. Blood donors will cooperate when difficulties are explained to them ... expertise is available in the UK and Europe for planning and building and running a new fractionation plant; clinicians' attitudes can be changed by education and by example or, in the last resort, by the constraints of limited resources."

Now, you were -- it doesn't tell us on this document but I think I understand that you were sent a copy of this?

A. Yes, she gave me a copy.

Q. We'll look tomorrow morning at an appraisal of options

that you yourself came up with a few weeks into your new job --

A. Yes.

Q. -- but can you recall what your reaction was to reading this?

A. Well, this was obviously a very helpful background paper for me. I mean, essentially I was able to use it as a quarry for my later -- I quite early on, as you say you're going to come to tomorrow, made some proposals within the Department to actually be getting on with things, and I used this paper as a very helpful background to my thinking.

Q. Just going back to something we were discussing this morning, Dr Walford, about, as it were, the blurring of lines between administrative/policy and medical/scientific hierarchies, would you agree that this is a fair comment, that what we've got here is Dr Waiter as a medical civil servant not waiting to be invited to comment upon policy options or limiting her advice to purely, as it were, the medical, she's putting forward a possible policy solution to a problem, is she not?

A. Yes, she is, but she is putting it forward within the medical hierarchy and, as we come to tomorrow maybe, when I put my suggestions forward it was within the

medical hierarchy, and it was only that I think Dr Harris picked up what I was proposing and thought it should go wider. Otherwise, it wouldn't, at that stage anyway, have occurred to me that I could put it up and show it to the administrative colleagues as well.

Q. So you and Dr Waiter were free to make suggestions about policy --

A. Certainly.

Q. -- directions, but you would ordinarily -- unless it's a response to an invitation, you would be doing it within your medical hierarchy so that it could be taken up at a senior level?

A. That's right.

Q. Or more senior level?

A. Yes.

Q. And then, just before we leave for today, I just wanted to pick up upon what she says about clinical practice in the last two paragraphs. The last sentence of the penultimate paragraph she talks about some clinicians having a responsible attitude to the use of therapeutic materials, others -- sorry, it's the paragraph before that, Soumik -- others wishing their demand to be met without question or payment. So I think perhaps, there, referring to clinicians,

possibly including haemophilia clinicians, who think they should be able to use whatever products they want as much as they want?

A. Yes.

Q. Then in the last paragraph she talks about how clinicians' attitudes can be changed by education and example or, in a last resort, by constraints of limited resources. So would it be fair to understand that Dr Waiter's not necessarily saying: well, clinical freedom must be respected at all costs, we might be able to influence clinical practice by education or, if that doesn't work, by limiting the funding available?

A. Well, you certainly would hope that you could influence clinical practice by education. That's the whole point about medical education, medical training. You will expect to be able to influence practice. But of course not universally, not everybody was paid the same attention maybe to elements of education but absolutely you would expect that an educational effort would be helpful.

Constraints of limited resources would always work because you could never actually overcome that. If, in fact, the region said, "We're not going to buy X or Y product", there was nothing that the clinicians

could do except maybe come to the Department and complain they were not getting the material that they wanted.

There was -- resources have always been a restraint on clinical expenditure. They are now. They always were. So that was the ultimate lever, if you will, and some Regional Health Authorities were actually rationing the amount of commercial Factor VIII that they were prepared to provide compared with other Regional Health Authorities, and very much depended on particular population of a particular region and their particular view as to how much money they were prepared to pay for commercial Factor VIII.

MS RICHARDS: Sir, I note the time. I'm going to suggest now might be a good point to end for the day. There's a number of documents we'll need to look at in the morning, including Dr Walford's own, as it were, response to this.

SIR BRIAN LANGSTAFF: Yes. There's just one thing which, if I may, I would like to ask you about. It's a document we saw. It is a very minor point and it is just for my understanding.

Can we go back, please, Soumik, to BPLL0008488. It's the Joint Management Committee meeting of

13 June 1979. Can we go to page 4.

Now, if we just look down to what is said about the Scientific and Technical Committee -- just stop there -- let me just see if I can find what I had in mind.

Yes, the largest paragraph just towards the bottom of the page beginning "the relationship of stop gap", if we look there there's a sentence which said there could be no question of replacing the laboratory for a number of years and the stop gap development was therefore necessary. It's the use of the word "laboratory" which just I want to understand. Am I correct in thinking that at Elstree there had been both a laboratory facility and a production facility?

A. Yes. I mean, essentially initially it began life almost as a research laboratory with a small production facility associated and, of course, it was called the Blood Products Laboratory; so I think this is simply shorthand for BPL.

SIR BRIAN LANGSTAFF: And the laboratory really hadn't done an awful lot of work for lack of finance during the '70s, as I understand it, dwindled off a bit, and the facilities were quite old.

A. The facilities were old but they definitely were not adequate for any larger scale production. It was

really, I think, and was over a period of time, quite remarkable how much laboratory*(sic)* BPL managed to make when it was absolutely not set up to do that.

SIR BRIAN LANGSTAFF: The stop gap proposals were about production, were they?

A. Half and half. I mean, they were definitely about improving quality but largely with a view to increasing, from memory, the amount of Factor VIII that could be produced by about 12.5 million international units after four years. So that would be after four years they'd have got to an additional 12.5 million international units. So certainly increasing production but, in the course of increasing production, a lot of quality improvements would have been made.

SIR BRIAN LANGSTAFF: So when it says there's no question of replacing the laboratory, the stop gap development is related to the laboratory, is it?

A. The existing laboratory, yes -- the existing BPL. There was then a thought that as well as doing stop gap, there should be a phased redevelopment. That was never really developed in a big way in terms of planning because what became apparent pretty shortly, and especially after the Medicines Inspectorate report, was that actually the only way you were going

to be able to proceed satisfactorily was with a complete replacement and building a whole new laboratory.

SIR BRIAN LANGSTAFF: Yes. Thank you very much. We'll take a break there and come back tomorrow at 10.00. The same rules apply at this break as they do at any break, of course, but I look forward to seeing you back refreshed tomorrow at 10.00.

A. Yes, thank you.

(4.36 pm)

(Adjourned until 10.00 am the following day)

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