

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

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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

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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

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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

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

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

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

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

6 **A.** I don't remember that, no.

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

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

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

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

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

10 **A.** Yes.

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

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

25 **Q.** Do you remember anything specifically as part of your

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1 different intervals.

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

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

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

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1 A. Absolutely.

2 Q. So you worked, is this right, four days a week for the

3 Department of Health and one day a week as an honorary

4 consultant haematologist at the Central Middlesex

5 Hospital?

6 A. Yes, initially it should have been one day a week but,

7 of course, the exigencies of work at the Department

8 meant that it was usually half a day, but I did the

9 sickle cell clinic, because there was a big population

10 of patients with sickle cell disease in Central

11 Middlesex.

12 Q. So you, I think, took out-patient sessions for

13 patients with sickle cell disease. Did that work

14 involve administering blood or blood products to

15 patients?

16 A. Not at all.

17 Q. Before we look at the specific posts you then held

18 within the Department of Health, you told us your

19 witness statement broadly how the Department was

20 organised at the time, and I just wanted to ask you

21 about that in fairly general terms.

22 You have described two parallel hierarchies: an

23 administrative hierarchy, the career civil servant who

24 would report up the chain, ultimately to a Permanent

25 Secretary, in the Department of Health and Social

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1 world.

2 So we attended various meetings of experts in

3 their own field outside, and we brought back to the

4 Department information that we had gleaned from that.

5 So we were sort of intel, we were gathering

6 intelligence for use by the people who were actually

7 at the business end of doing the policy work or

8 briefing ministers.

9 Q. Would it be fair to say, and again we will obviously

10 look at some detailed examples of decision-making in

11 the course of today and tomorrow, but would it be fair

12 to say that the boundaries between the medical branch

13 and the administrative branch and their respective

14 roles were not always absolutely black and white?

15 Policy on medical matters inevitably brought you and

16 your colleagues and the Chief Medical Officer and the

17 Deputy Chief Medical Officer into advising on from

18 a medical perspective but advising on the merits of

19 policy proposals.

20 A. Yes, absolutely, and I considered that to be an

21 important part of my work. I think the problem

22 sometimes was that, although I'd thought I put forward

23 fairly cogent arguments in favour of something or

24 against something else, it wasn't always the line that

25 was adopted ultimately, but that was the way the

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1 Security; and then a medical and scientific hierarchy

2 which reported to the Chief Medical Officer. Is that

3 right?

4 A. That's right.

5 Q. You joined the latter, the medical hierarchy?

6 A. Yes.

7 Q. You have said in your statement that it was the

8 administrative hierarchy that took the lead on policy

9 development, financial matters and supporting

10 ministers. What was the role then of the medical and

11 scientific branch? In broad terms. We'll look at

12 your specific jobs in a moment.

13 A. Well, in broad terms, the medically qualified and

14 scientifically qualified staff actually provided the

15 relevant advice (be it medical or the scientific) to

16 the administrative colleagues, who took the lead, as

17 you have described, precisely. And essentially we

18 were there almost to act as a resource for the

19 administrative side and also, very particularly, to

20 act as a kind of interlocutor with the wider world, so

21 that essentially we were not sitting there simply

22 behind a desk, we were going forth and trying to find

23 out from professionals in the relevant policy areas,

24 if you like, what was the thinking going on in the

25 professional side of things, in the wider outside

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1 system was structured. But I definitely felt that,

2 when I could, I should use my medical training to the

3 best effect.

4 Q. In your statement at paragraph 2.2.5 you say that:

5 "This separation into parallel divisions of

6 'professionals' and 'administrators' ..."

7 Sorry, I will wait until you've got that.

8 A. Thank you. It's always the page that you can't just

9 get to.

10 Q. I think it's page 27.

11 A. Thank you very much. Yes, I have it.

12 Q. It's just two sentences. I won't put them on the

13 screen, I'm just going to read them out. You say:

14 "This separation into parallel divisions of

15 'professionals' and 'administrators', was the same

16 arrangement that Lord Fulton, in his 1968 report on

17 reforming the Civil Service, had recommended should be

18 abolished. It was the system that had been described

19 as 'the expert on tap, but not on top!'"

20 A. Yes.

21 Q. Could you just elaborate upon that, please?

22 A. Yes, well, obviously, as I've been preparing this,

23 I've been thinking back to the parallel hierarchy

24 system and, about 20 years ago, I think, I wrote

25 a small think piece for the Department because there

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

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

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

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

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

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

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

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

25 **A.** Yes.

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

7 **Q.** Sir, for your note and for the benefit of the Core
8 Participants and legal representatives, relevant
9 extracts from the 1968 report from Lord Fulton
10 addressing this issue are on relativity. I'm not
11 going to put it on screen but the reference is
12 FLTNO000001.

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

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

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

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

10 The way in which they acted was on the
11 defendants of the Committee on Safety of Medicines and
12 the Committee on Safety of Medicines itself had been
13 set up under the Statutory Medicines Commission in
14 1968.

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

18 **A.** Yes.

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

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

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1 Medicines Division. It had a slightly different
2 structure.

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

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

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

15 I would need to take --

16 **Q.** If you don't remember --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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- 1 **Q.** What, if any, role did the Medicines Division play in
2 relation to the content of product information
3 leaflets, the information that would accompany the
4 blood product or the pharmaceutical product?
- 5 **A.** That was always looked at very carefully, and also it
6 was a matter for the National Institute of Biological
7 Standard and Control for Biological Products. They
8 were involved in the so-called batch release system
9 for biological products and they would take great care
10 to see that what was said in the product information
11 leaflet, if you like, for patients and for doctors
12 actually was in conformity with what the licence
13 required should be there.
- 14 **Q.** Now, you have described in your statement -- you
15 recall at some point during this period visiting the
16 manufacturing premises of a pharmaceutical company in
17 the States that was producing Factor VIII
18 concentrates. You can't, I think, recall which
19 company it was. Can you recall anything about the
20 purpose of the visit?
- 21 **A.** Yes, I can. The only thing I can remember about it,
22 because I was really trying to think which one could
23 it possibly have been. It was a very long haul flight
24 it was about 13 plus hours, I know. I mean,
25 I actually spent most of the inspection in a fog of,

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- 1 happened, from time to time. I mean, a lot of the
2 manufacturing was in the UK and they would be going
3 off to UK manufacturing facilities. I don't know how
4 often others went. I just recall my own visit to
5 an extent.
- 6 **Q.** We'll look at the medicines inspection of BPL and the
7 consequences for that at a later stage today.
8 Did you have a role with the Medicines
9 Inspectorate? Was it part of your work -- were you
10 involved with the processes of medicines inspections
11 generally?
- 12 **A.** Not generally. I mean, this was very -- for me, it
13 was very unusual and, actually, quite an enjoyable
14 thing to do. I don't remember doing that to any
15 extent otherwise.
16 I was also trying to remember whether I went on
17 any of the formal BPL inspections and I don't remember
18 because I was always in and out of BPL quite a lot, so
19 I don't remember whether I went on any of the formal
20 inspections. I might have done; I just don't
21 remember.
- 22 **Q.** You said in your statement that it was part of your
23 role during the time when you were in the Medicines
24 Division with responsibility for blood and blood
25 products to liaise with BPL and you mentioned Dr Lane

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- 1 you know, not being able to concentrate because of the
2 long haul flight. But it was because the inspectorate
3 wanted to inspect the manufacturing capabilities, the
4 manufacturing capacity, and I went out, I think, with
5 two inspectors and we -- I seem to recall that we
6 looked at two different establishments or sites,
7 I think, fairly close to each other, and made a report
8 and the report was not a happy one for the
9 manufacturers.
- 10 **Q.** Can you recall what your concerns were about the
11 manufacturing?
- 12 **A.** Well, we were very unhappy, as I recall, about the
13 facilities, more than anything else and, I mean, one
14 thing that I remember, because ended up writing it up
15 in the report, and I do remember this, was that the
16 clean area -- the big clean area that was not
17 a sterile area but a big clean area, and the toilets
18 opened up into and off the clean area and people were
19 just toing and froing and there was no changing of
20 clothes, and so on, and that was not good practice,
21 and we wrote it up, amongst other things.
- 22 **Q.** How common was it for those within the Medicines
23 Division to do that, to go and inspect
24 a pharmaceutical premises abroad?
- 25 **A.** I don't actually know. I think that it obviously

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- 1 in your statement. Was it initially with Dr Maycock
2 or had Dr Lane taken over, do you think, by the time
3 you took up that role?
- 4 **A.** No, Dr Lane had taken over. He had joined BPL to be
5 the Deputy Director as for the year that Dr Maycock
6 was about to retire, and then it was Dr Lane that
7 I was liaising. I did meet Dr Maycock when I was in
8 Medicines Division. I have some memories of meeting
9 him when I was in Medicines Division. I can't
10 remember, obviously it was to do with blood but
11 I can't remember what, in particular, but I know that,
12 really, all my liaison with BPL was with Dr Lane.
- 13 **Q.** Now I'd asked you for an overview in relation to the
14 process of licensing pharmaceutical products, blood
15 products. What role did the Medicines Division play
16 in relation to manufacturing licences?
- 17 **A.** Oh, completely. That was -- it was manufacturing
18 licences and product licences. That was their job.
- 19 **Q.** Then did the Medicines Division have any role in
20 relation to clinical trial certificates or clinical
21 trial exemption certificates?
- 22 **A.** Yes, same thing.
- 23 **Q.** Again, in broad terms, what was the nature of that
24 role?
- 25 **A.** Well, it was Medicines Division. I mean, again, if

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

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

13 **A.** Yes.

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

17 **A.** Yes.

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

21 **A.** Yes.

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

24 **A.** Yes.

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

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

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

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

27

1 and work with the health services branch.

2 **A.** Yes.

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

5 **A.** Yes.

6 **Q.** There were two divisions: HS1 and HS2?

7 **A.** Yes.

8 **Q.** They both reported to the Permanent Secretary?

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

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

17 **A.** Yes.

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

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

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

26

1 just do it.

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

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

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

16 **A.** That's right.

17 **Q.** What was his area of clinical expertise?

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

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

28

- 1 A. That's right.
- 2 Q. Who was Deputy Chief Medical Officer. Do you know
3 what his background was, no?
- 4 Then Dr Harris would report in turn to the Chief
5 Medical Officer, who was Henry Yellowlees and then,
6 I think from October '83, Donald Acheson?
- 7 A. That's right.
- 8 Q. To what extent did you have direct interactions with
9 the Chief Medical Officer?
- 10 A. With Henry Yellowlees, very little. Very little.
11 I don't actually recall having a single direct meeting
12 with him during my time in Med SEB and of course he
13 then left Med SEB and Donald Acheson took over, and
14 I had far more interaction and in fact, in some cases,
15 a lot of interaction with Donald Acheson, but
16 initially not.
- 17 I mean, after Henry Yellowlees left, it was
18 roughly the time that I moved from Med SEB to Medical
19 Manpower, which had nothing to do with the business of
20 this Inquiry, and there I would have had some
21 interaction with Donald Acheson because Medical
22 Manpower involved a lot of face-to-face working with
23 the British Medical Association and other medical
24 bodies. So that was something of interest to him.
- 25 Q. To what extent were there regular meetings within

29

- 1 A. Yes.
- 2 Q. Who was chair of the Regional Transfusion Director
3 meetings at that time.
- 4 A. Yes.
- 5 Q. Can you just tell us a little how he, from your
6 perspective, went about that role.
- 7 A. Yes. There were very few consultant advisers for the
8 Chief Medical Officer. There were just a few
9 disciplines, and I think cardiology may have been one
10 of them, I don't recall, but very few. He had
11 a handful of consultant advisers, and he had
12 a consultant adviser in blood transfusion and he
13 always had a consultant adviser in blood transfusion.
14 Dr Tovey, who chaired the Regional Transfusion Centres
15 Directors' meetings, was the consultant adviser when
16 I joined Med SEB.
- 17 He met the Chief Medical Officer from time to
18 time, I don't know how often those meetings took
19 place, but they were always in private, and I never
20 knew what was going on. He was obviously advising,
21 that's what his role was, but he didn't feed back to
22 me what he was saying and there was no way that
23 I seemed to be able to understand what had gone on.
24 There were no notes of those meetings as far as I'm
25 aware.

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- 1 Med SEB? Was there any kind of system of once a week
2 or once a fortnight or once a month that the medical
3 professionals would get together and discuss things,
4 share information about things that had come to light?
- 5 A. From recollection, we did meet together. We were very
6 small, a very small division. There were only
7 a handful of doctors and a few scientists and one or
8 two sort of administrative support at the secretarial
9 level. So we -- and we were in the same corridor, so
10 we would meet and talk.
- 11 We did have I think from time to time what you
12 would call a divisional meeting but it wasn't --
13 I don't remember saying, "Well, every Monday morning
14 we were having a meeting". We might have done but
15 honestly I don't remember.
- 16 Q. You told us in your statement that the Chief Medical
17 Officer was advised by various external doctors known
18 as consultant advisers.
- 19 A. Hm-mm.
- 20 Q. I think that was across a range of different
21 disciplines but one of the consultant advisers was in
22 blood transfusion.
- 23 A. Yes.
- 24 Q. When you first joined, the consultant adviser was
25 Dr Geoffrey Tovey.

30

- 1 Q. Did you ask perhaps not the Chief Medical Officer
2 himself, if you rarely if ever met him, but did you
3 ask those above you in the hierarchy if they could
4 find out what was being discussed or else raised
5 a concern about the fact that you were being kept, as
6 it were, in the dark?
- 7 A. Well, I actually used to ask Dr Tovey what had gone on
8 and I don't think that I found the answers terribly
9 satisfactory. I think that's one of the issues.
- 10 If he spoke to anyone, he tended to speak to
11 Dr Oliver, who was my boss, but he was only in post
12 while I was there for about a year, I think it was,
13 and then Dr Harold Gunson took over, who was entirely
14 different. He did meet the CMO in private (it seems
15 that the CMO liked these meetings to be private), but
16 Dr Gunson always told me what had been discussed and
17 I, broadly speaking, knew what was happening because
18 he was somebody who would just communicate with me.
- 19 Q. Can you just assist with this: where physically was
20 Med SEB located?
- 21 A. Hannibal House, I think. But, you know, I moved
22 buildings quite often. I think it was Hannibal House.
- 23 Q. Was the HS division, branch, however it was termed,
24 were they in the same building?
- 25 A. They may have been in Alexander Fleming House.

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

8 **Q.** I'm sure we can check.

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

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

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

1 **A.** Yes.

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

5 **A.** That's right.

6 **Q.** That was Med IMCD?

7 **A.** That's right.

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

11 **A.** Yes.

12 **Q.** -- the surveillance of infections, the surveillance of
 13 communicable diseases was the responsibility of
 14 Med IMCD?

15 **A.** Yes.

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

18 **A.** Exactly where they were.

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

22 **A.** That's right.

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

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

1 intervals while secretaries searched for the official
 2 file.

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

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

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

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

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

25 **Q.** And you would retain a copy presumably?

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

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

14 **A.** Yes.

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

16 **A.** I can't remember.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6 **Q.** Was there any?

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

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

40

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

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1 hepatitis, not AIDS, no.
 2 Q. You then returned in 1987 to the Department as
 3 a senior principal medical officer in Med IMCD, so the
 4 division that we were talking about which was
 5 responsible for infectious diseases.
 6 A. Yes.
 7 Q. You then had responsibility for the AIDS unit which
 8 had been created by that time.
 9 A. Yes.
 10 Q. You were in that post for I think a couple of years.
 11 A. Yes.
 12 Q. Then in 1989 you became Deputy Chief Medical Officer?
 13 A. Yes.
 14 Q. And Director of Healthcare for the NHS Management
 15 Executive?
 16 A. Yes.
 17 Q. You were one of three Deputy Chief Medical Officers,
 18 is that right?
 19 A. That's right, yes.
 20 Q. That was from '89 to '92. Again, very broadly, what
 21 did that job entail?
 22 A. As Deputy Chief Medical Officer?
 23 Q. As Deputy Chief Medical Officer.
 24 A. Well, broadly speaking, of course, deputising for the
 25 CMO. He couldn't be everywhere. He had an incredibly

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1 large brief, so you deputised for the Chief Medical
 2 Officer. I think I have put -- though I'd need to
 3 find it in the papers -- the exact areas of
 4 responsibility I had. It was quite schizoid, if you
 5 like, because I was not only part of the policy
 6 division, if you like, in the Department of Health but
 7 I was also a director of healthcare on the NHS
 8 Management Executive, which was based in Leeds, or
 9 moved to Leeds, and essentially I was doing two fairly
 10 separate things: policy on the one hand, with the
 11 Chief Medical Officer, and operations on the other
 12 hand, NHS operations, with the chief executive,
 13 Duncan Nichol.
 14 So I mean the areas of responsibility broadly
 15 mirrored each other but were not identical.
 16 Q. Then, 1993, you took up a role as director of the
 17 Public Health Laboratory Service?
 18 A. Yes.
 19 Q. You remained in that role until 2002?
 20 A. Yes.
 21 Q. We'll come back to that, I think, a little later at
 22 the end of your evidence?
 23 A. Right.
 24 Q. I have been asked to ask you this, Dr Walford: in the
 25 course of the work that we've been talking about, were

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1 you ever asked to sign the Official Secrets Act and,
 2 if so, did that or does that restrict the evidence you
 3 are able to give to the Inquiry?
 4 A. I did sign the Official Secrets Act and, furthermore,
 5 when I was DCMO I had this special vetting, if that's
 6 the right word, very particular, every article of my
 7 financial, you know, matters, and so on, were taken
 8 apart, I was questioned for this particular extra
 9 vetting, to receive secret material, or whatever was
 10 the classification at the time, I can't remember.
 11 I don't actually remember ever having had the pleasure
 12 of seeing something that was particularly secret but
 13 I may have done.
 14 It doesn't inhibit me at all in this Inquiry
 15 because I have been -- I am quite clear that I must
 16 tell the truth, the whole truth and nothing but the
 17 truth and so, if I inadvertently overstep the mark
 18 terms of the Official Secrets Act, I hope somebody
 19 will defend me.
 20 Q. I want to turn to just now the relations between the
 21 Department and others bodies and look, first of all,
 22 at the Department and NHS bodies. You've said in your
 23 witness statement that the Department was fairly hands
 24 off in relation to day-to-day operation of the
 25 National Health Service and essentially it left

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

4 **A.** That is right.

5 **Q.** Why was that?

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

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

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

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

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

25 **A.** Yes.

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

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

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

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

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

4 **A.** That's right.

5 **Q.** Why was that?

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

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

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

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

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

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

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

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

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

25 **A.** Yes.

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

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

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

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

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

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

1 **Q.** -- that was your perception?

2 **A.** Yes.

3 **Q.** What about the Chief Medical Officer, though?

4 A consultant might not want to hear what Dr Walford or
 5 Dr Waiter or Dr Smithies or Dr Oliver had to say but
 6 wouldn't something going out with the imprimatur of
 7 the Chief Medical Officer be something that doctors
 8 would abide by or at least consider and be assisted
 9 by?

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

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

25 But in terms of just issuing statements based on

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

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

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

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

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

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

25 **A.** Yes.

53

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

5 **A.** Thank you.

6 **(11.15 am)**

7 **(A short break)**

8 **(11.50 am)**

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

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

14 **A.** Yes.

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

25 I just want to pick up on a couple of issues

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

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

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

18 **SIR BRIAN LANGSTAFF:** Yes. We'll take a break then until
19 10 to 12.

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

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1 relating to that.

2 **A.** Yes.

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

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

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

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

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

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

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1 of them there.

2 Then, over the page, top of the next page, you

3 have observed that:

4 "... there was no overarching advisory committee

5 on blood safety, such as the Committee on the

6 Virological Safety of Blood which was set up, some

7 years later, to advise the Government on blood safety

8 issues."

9 Just pausing there, you have recognised that

10 there was no overarching body, and you've identified

11 a number of different bodies, committees, working

12 parties, organisations with a role in relation to this

13 issue. Looking back, do you think it would have been

14 a good idea to have a body such as the Committee on

15 the Virological Safety of Blood at an earlier stage;

16 in other words, one overarching body with

17 responsibility for this issue?

18 **A.** Indubitably. Obviously it would have been a good

19 thing.

20 **Q.** Was it something that you can recall ever being

21 discussed during the period you were involved, so up

22 to the end of '83?

23 **A.** Not at all.

24 **Q.** Then you say in the next paragraph this:

25 "Unless there were an identified hazard, with

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1 given advice was once the advisory group on testing

2 for hepatitis B, surface antigen and its antibody, had

3 recommended certain screening programmes to be

4 undertaken and for hepatitis B, remember, all blood

5 was potentially infectious, all blood would

6 potentially transmit hepatitis B, and therefore it was

7 a very wide public health significance.

8 Once there was a way of dealing with it, which

9 was screening for hepatitis B surface antigen and its

10 antibody in the blood system, then it would be

11 perfectly appropriate for an alert to go out, advice

12 to be given to the transfusion authorities, to people

13 who were donating blood and so on, that actually here

14 was a risk, here was what we were doing about it or

15 what could be done about it and, of course,

16 subsequently there was a hepatitis B vaccine.

17 So areas where actually there is some action

18 people can take, something that you can do potentially

19 to avoid actually finding infections that could have

20 been avoided, then the Chief Medical Officer would put

21 out appropriate guidance.

22 But, remember, I think that you will know, that

23 this particular recommendation came from the third

24 meeting of the advisory group on testing for

25 hepatitis B and its antibody. So there had been three

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1 risks to public health, which required a national

2 response, the wider [Department] generally did not

3 become involved in decision-making or risk mitigation,

4 as this was best done by the responsible organisation,

5 or through the Licensing Authority ... In the event

6 that a hazard that identified with potential national

7 or serious ramifications for the public health, the

8 DHSS would become involved and would work with

9 Regional and local public health officials and the

10 PHLS to take the necessary action and offer guidance

11 to the responsible bodies. In such circumstance,

12 Ministers would be promptly informed, briefed,

13 submissions provided and would be asked to take

14 decisions as necessary."

15 Now, I don't know whether it's possible to

16 answer what I'm going to ask you in the abstract or

17 not but can you assist us with, really, when did

18 something that was a matter of clinical practice or

19 a concern about risks of treatment, when did that

20 become a risk of such proportions that it became

21 a public health matter in which the Department and

22 Secretary of State would become involved?

23 **A.** Well, I suppose, strictly sticking with blood and

24 blood products if I can, the area where I think

25 appropriately the Chief Medical Officer would have

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1 meetings over a period from about 1973/74 or something

2 until the date that the guidance was put out, and then

3 firm recommendations put out as to the screening

4 necessary for the blood products, blood and blood

5 products.

6 **Q.** That suggests -- and this, again, is very much by way

7 of inviting you to give general observations or

8 general reflections, that suggests that potentially

9 the Department was reactive rather than proactive in

10 relation to assessing risk and taking action.

11 **A.** I don't -- I think, if I may say so, to characterise

12 it as reactive is not appropriate. Essentially, the

13 Department had to take advice. It didn't of itself

14 have the capacity to formulate what needed to be done.

15 It needed to rely on the committees that it

16 established in order to do this.

17 So I don't think it's reactive to describe that

18 a report is produced and the Department acts on it,

19 and acts on it quickly, which it seems to me they did

20 in that particular instance. I think that's the

21 appropriate reaction, rather than saying it was

22 somehow or other too slow or retrograde in some way.

23 **Q.** Going back to the question of assessment of the risks

24 arising from blood and blood products, again, during

25 the period you were there (so from '76 through to the

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1 end of '83, and leaving aside what happened thereafter
 2 because you weren't then involved with blood or blood
 3 products for some years), in that period of time did
 4 the Department ever have available to it
 5 a comprehensive assessment of the risks from blood or
 6 blood products?
 7 **A.** Comprehensive assessment seems to imply that all the
 8 information might have been brought together in
 9 a large and compendious document which contained all
 10 the possible risks, and the answer to that is, as far
 11 as I'm aware, no, it didn't.
 12 Knowledge of risks obviously accumulated over
 13 time, and essentially, when we sort of start off this
 14 period, people were beginning to know about
 15 hepatitis B, and then of course gradually moving on to
 16 non-A, non-B, and then, alas, gradually moving on
 17 to AIDS. But those were not -- that was not knowledge
 18 that could have actually been there in a kind of
 19 compendium of what we know. There was a huge amount
 20 known about the fact that blood transfusion itself
 21 carried risks. There was no way, even today, that
 22 blood transfusion doesn't carry a risk, however small
 23 it may be now because of all the wonderful screening
 24 that can be done. But there is always a risk
 25 inherently in having foreign material from some other

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1 general exploration at this stage, the role of
 2 ministers. First of all, I think the various
 3 ministers involved with blood, blood products in
 4 relation to the years that you were there were
 5 Dr Vaughan, Mr Finsberg, Lord Glenarthur, now
 6 Lord Clarke then Mr Clarke, and now Lord Fowler then
 7 Mr Fowler; is that right?
 8 **A.** Yes.
 9 **Q.** Can you recall whether you yourself had direct
 10 meetings with any of those ministers?
 11 **A.** While I was in Med SEB, really very few. I was too
 12 junior, in effect, so I didn't -- I often provided
 13 material for briefing but I didn't have very many
 14 face-to-face meetings. I did accompany -- it's
 15 obvious from the papers, I accompanied Mr Finsberg,
 16 I think (and possibly Dr Vaughan as well; I don't
 17 recall), to BPL as part of an add-carrying contingent,
 18 but very rarely was I actually briefing ministers
 19 face-to-face.
 20 **Q.** Who was it who would decide that a matter needed to go
 21 to the minister, a decision needed to be made, the
 22 minister needed to be either informed of something or
 23 asked to take a decision?
 24 **A.** In general, it would be the administrative divisions.
 25 **Q.** At what level would that kind of decision be taken?

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1 person introduced into the body of another person.
 2 There is always a risk.
 3 **Q.** What you described in that section of your statement
 4 could be said to be a somewhat fragmented system,
 5 multiple organisations, bodies --
 6 **A.** Yes.
 7 **Q.** -- involved in assessing different aspects and taking
 8 decisions or making recommendations on different
 9 aspects of risk and how to mitigate risk. Do you see
 10 disadvantages or down sides to that and if so what
 11 were they?
 12 **A.** Well, there are disadvantages. If you are
 13 particularly looking at blood transfusion, I mean,
 14 what has evolved over time, apart from the Virological
 15 Safety of Blood Committee, which was something
 16 obviously would have been wonderful to have had it at
 17 the time that I was there, but we didn't -- but then
 18 there is the -- a really important system of what's
 19 called haemovigilance, which the National Blood
 20 Transfusion Service now operates, which is called
 21 SHOT -- the SHOT system, which is the serious hazards
 22 of transfusion, and that really monitors everything
 23 very, very closely. That's the sort of thing that we
 24 could have done with but we didn't have it.
 25 **Q.** Then I just want to pick up again, as a matter for

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1 **A.** Round about -- well, the decision would actually be
 2 sitting between the grade 5, who was called an
 3 assistant secretary in those days, and the grade 3,
 4 the undersecretary. So, taking some of the
 5 BPL material, it would be Mr Harley, as the grade 5,
 6 the assistant secretary, Mr Wormald, the grade 3, the
 7 undersecretary.
 8 **Q.** Were you aware of any, as it were, yardstick or
 9 criteria by which those in the administrative division
 10 would decide this is a matter that has to go to the
 11 minister, this one doesn't?
 12 **A.** No, no, it was a rather arcane art actually, from my
 13 perspective, because, as I mentioned, we didn't
 14 receive any training when we came into the -- I came
 15 into a policy division, if you like, the Med SEB, and
 16 I have no recollection of being trained in that or
 17 even understanding what a PQ was or -- all this
 18 I learned on the job, I didn't know, and it just
 19 seemed to me to be natural that, okay, they decided
 20 something was going to go.
 21 Now, obviously there could be pressure from
 22 the Deputy Chief Medical Officer, for example, as
 23 there was on a number of occasions, because he was
 24 chairing some very important committees, but then that
 25 would be him saying to administrative colleagues,

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

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

5 **A.** Yes.

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

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

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

25 **Q.** So decisions affecting Scotland on the areas in which

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

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

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

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

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

3 **A.** Yes, yes.

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

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

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

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1 meeting.

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

8 **A.** No.

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

12 **A.** Yes.

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

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

25 **Q.** What about home treatment and prophylactic treatment,

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1 did you have any understanding of the extent to which
 2 those were part and parcel of the clinical care of
 3 patients with bleeding disorders?
 4 **A.** I'm just trying to think when I might have become
 5 aware of it in terms of the sort of dates because that
 6 gradually increased and I couldn't be certain
 7 exactly -- I can't identify exactly the time, but
 8 certainly by the time I was in Med SEB and talking to
 9 the UKHCDO, I was well aware that they were getting
 10 more and more into home therapy with concentrates and,
 11 as time went on, prophylactic therapy with
 12 concentrates -- not everywhere but that was available
 13 during my time in Med SEB.
 14 **Q.** By the time you were in Med SEB and in that sort of
 15 four-year period, '79 to '83, would UKHCDO have been,
 16 or the Reference Centre Directors have been the
 17 primary source of your information about how
 18 haemophiliacs were treated?
 19 **A.** Absolutely.
 20 **Q.** Do you recall being aware of DDAVP or the extent to
 21 which that was being used?
 22 **A.** Not the extent to which it was being used but I recall
 23 the various discussions in the UKHCDO meetings where
 24 it was always very -- once DDAVP was actually
 25 discovered, if you will, and its effect on releasing

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1 **A.** Yes.
 2 **Q.** Now, in your capacity as principal medical officer at
 3 Med SEB, you sometimes attended the Annual General
 4 Meetings of UKHCDO?
 5 **A.** Yes.
 6 **Q.** I think, looking at the documents, you attended in
 7 November 1979, which would have been your first -- was
 8 that your first attendance probably?
 9 **A.** It should have been, yes.
 10 **Q.** Then you attended the next one a year later in
 11 September 1980. I want to look at that really just to
 12 get a flavour of UKHCDO meetings. So it's PRSE0003946
 13 please, Soumik.
 14 **A.** Do you, by any chance, have a number for my statement?
 15 **Q.** It's not referred to in your statement. It's one of
 16 the additional documents that we were provided with,
 17 Dr Walford.
 18 So we can see the date there. Glasgow,
 19 30 September 1980. The chair is Professor Bloom.
 20 There's a list of apologies for attendance of those
 21 who are not present, so we won't look at that.
 22 If we then go -- I really want to get a sense of
 23 how the meetings work from your perspective. That's
 24 the purpose of going to this section. If we go to
 25 page 4 please, Soumik. If we look at the bottom of

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1 Factor VIII from endothelial cells in the patient, it
 2 became definitely a part of the therapeutic
 3 armamentarium of directors or haemophilia treaters to
 4 use that for von Willebrand's disease, to use it for,
 5 mild haemophiliacs; in other words, to avoid using
 6 Factor VIII concentrate. But it really needed to be
 7 in a mild haemophiliac so that it can actually produce
 8 the Factor VIII level that you need to stop the
 9 bleeding. But it was definitely their policy, as far
 10 as I can recall, to use it as appropriate for such
 11 patients.
 12 **Q.** Would it be right to understand that the use of DDAVP
 13 was something which the Department itself did not
 14 become involved in; it was regarded as part of that
 15 clinical freedom that you have described?
 16 **A.** Yes, because the Department, again, I would say, never
 17 became involved in what treatment was administered to
 18 what patient in any area, heart disease,
 19 gastrointestinals -- it didn't become involved.
 20 **Q.** Would the same be true in relation to then the
 21 approach to treating children or the approach to the
 22 treating mild haemophiliacs more generally that would
 23 be regarded as something for haemophilia clinicians
 24 under the auspices of UKHCDO to formulate their own
 25 policies?

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1 the page, there's a heading "Report on the 1979 Annual
 2 Returns from Haemophilia Centres". Then there's
 3 a reference to Dr Rizza presenting a report on the
 4 annual returns and then there's a long discussion
 5 about, essentially, what they show and issues about
 6 self-sufficiently and commercial concentrates, and so
 7 on.
 8 You were there and present. We see you
 9 interjecting from time to time. Would you, as far as
 10 you can recall, get these reports on the annual
 11 returns in advance of these meetings?
 12 **A.** Oh no, not in advance of the meeting. Whether we got
 13 them afterwards as part of the minutes, I don't know,
 14 but certainly not in advance.
 15 **Q.** But you would get them at some point?
 16 **A.** We might but it depends. Basically, if they were
 17 appended to the minutes, yes. If not, no.
 18 **Q.** Then, if we just go over the page, there's a long
 19 discussion recorded about product usage and I just
 20 want to pick it up about six or seven lines down --
 21 no, actually, I'll pick it up five lines down. It
 22 says:
 23 "Dr Rizza said that there appeared to be total
 24 inconsistency between the usage in various regions.
 25 Professor Stewart said that there were difficulties

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

4 Then two or three lines further down, it says:
5 "Professor Stewart said he was worried about the
6 increasing usage of Commercial factor VIII. He
7 suggested that the Department of Health should look
8 into the question of licensing a commercial firm or
9 firms to make NHS material. Dr Diana Walford said
10 that the Department of Health at the moment, was
11 actively discussing this question" and then the
12 discussion continues.

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

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

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

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

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

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

18 **Q.** So you attended the Annual General Meeting in 1979,
19 1980. You attended the 1981 meeting, I'm not going to
20 take you to that.

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

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1 particularly slow in coming forward.

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

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

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

25 **A.** Yes.

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

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

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

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

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1 didn't get sent to you?
 2 **A.** No.
 3 **Q.** Then, is this right, you didn't routinely attend the
 4 Reference Centre Director meetings but you did attend
 5 some of them specifically either because you asked to
 6 or you were asked to?
 7 **A.** Yes. It was not considered to be appropriate for
 8 departmental observers, if you will, to go to the
 9 Reference Centre Directors' meetings. Essentially,
 10 they were their private meetings and officials didn't
 11 go.
 12 **Q.** So when you say "not considered appropriate", do you
 13 mean not considered appropriate by the Reference
 14 Centre Directors?
 15 **A.** Yes.
 16 **Q.** We will look, when we look at AIDS tomorrow, at
 17 a couple of the meetings in 1983 that you attended but
 18 one of which was a Reference Centre Director meeting
 19 on 19 September 1983. I don't want to look at those
 20 minutes now but I want to look at an exchange of
 21 correspondence between Dr Jones and Professor Bloom
 22 after that meeting, just to invite really your
 23 comment. So if we could have OXUH0000882, please.
 24 This is a letter from Dr Peter Jones from the
 25 Royal Infirmary in Newcastle, the Newcastle

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1 on that. That didn't make sense to the National Blood
 2 Transfusion Service, who felt that the handle was
 3 necessary for safety reasons and so this idea kept
 4 emerging, if I can put it that way, and it was
 5 obviously, at that time, something that had bubbled up
 6 to the surface again.
 7 In particular, of course, it turned out -- and
 8 I can't remember whether it was at this meeting or
 9 some other meeting -- must have been probably another
 10 meeting later on, I'm not sure what the date of this
 11 meeting was -- that it was discovered that some of the
 12 Factor VIII concentrate that had actually been used to
 13 treat the unfortunate man in Bristol who had succumbed
 14 unfortunately to -- he was the first case to succumb
 15 to AIDS, had actually found its way into other
 16 hospitals but nobody could trace it, and that seemed
 17 to be a major safety problem and that we really
 18 shouldn't -- that shouldn't happen and it could be
 19 avoided by making the NBTS responsible for keeping
 20 records of wherever the material went.
 21 So that was the object.
 22 **Q.** I think we'll see, if we look further down this
 23 letter, it certainly didn't go down very well with
 24 Dr Peter Jones. So if we see the third paragraph:
 25 "However, if the new scheme means that firms are

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1 Haemophilia Centre, 13 October 1983, to Professor
 2 Bloom, and it refers in the first paragraph to the
 3 last meeting of Reference Centre Directors:
 4 "... you asked us to write in with our views
 5 about centralised purchasing."
 6 Just pausing there, the idea, as I understand
 7 it, and it was an idea that you brought up at the
 8 Reference Centre Directors' meeting was that, rather
 9 than haemophilia centres purchasing their own
 10 commercial products, it would all be done centrally.
 11 **A.** Yes. This wasn't an idea of my own, this was
 12 something that had been brought up and had been in
 13 discussion in the various meetings on the national
 14 Blood Transfusion Centre service for a long time.
 15 I think it was first talked about in 1979 in one of
 16 their meetings, I noticed that. Essentially, there
 17 was a significant worry that material was being
 18 purchased and it was being purchased by individual
 19 haemophilia centres, and it was also being written up
 20 in prescriptions by general practitioners and it was
 21 also finding its way into hospitals that weren't
 22 haemophilia centres, not even associate haemophilia
 23 centres.
 24 So there was a real sense that, well, actually
 25 where's it all going? We simply don't have a handle

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1 going to be asked to tender for the market on a purely
 2 financial basis, then I am very frightened that this
 3 will lead to restrictions on our prescribing rights.
 4 There are two things to which I am totally opposed.
 5 Firstly, that my choice of product for prescription to
 6 any particular patient should be affected in any way
 7 regardless of cost. Secondly, that any Authority, be
 8 it the DHSS or the Blood Transfusion Service, should
 9 have any control over my clinical responsibility for
 10 my patients."
 11 Is that what you are talking about when you talk
 12 about clinicians jealously guarding their clinical --
 13 **A.** Yes, and what's more though that it was really
 14 horribly misguided because nobody was intending to
 15 interfere with anybody's prescription. People were
 16 free to prescribe, it was just keeping tabs on what
 17 was being prescribed, and I think the Inquiry has
 18 given me a paper where I looked at this rather
 19 ruefully, really, where I wrote a report, whether it
 20 was from this meeting or not I don't recall, but
 21 I wrote a report about how the concept of Regional
 22 Transfusion Centres holding the material and having
 23 it, as it were, controlled in that way, had been the
 24 subject of almost wilful misunderstanding by the
 25 Haemophilia Centre Directors. They would -- really

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

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

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

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

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1 haemophilia organisations."
 2 Now, that is Professor Bloom's comment but do
 3 you have any sense of what he meant by that?

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

8 **Q.** Then it continues:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

17 **A.** Paragraph?

18 **Q.** 44.4.

19 **A.** Okay, yes.

20 **Q.** So you have said there that:

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

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1 and rehabilitation and other services for
 2 haemophiliacs and the need to purchase commercial
 3 concentrates."
 4 I just want to focus on the first line or so
 5 there: UKHCDO represented the group with relevant
 6 expertise in haemophilia and related bleeding
 7 disorders. Again, really building on that and what
 8 you have said already, is it right to understand that,
 9 on questions of treatment, risks and benefits of
 10 different types of treatment, how to strike the
 11 balance in terms of risks, would the DHSS very much be
 12 guided by and defer to what UKHCDO's views were?
 13 **A.** Completely.
 14 **Q.** At the meetings which you attended, was there --
 15 whether it's reference centre directors or the annual
 16 general meetings -- was there a dominant voice or
 17 voices?
 18 **A.** At UKHCDO?
 19 **Q.** Yes, in terms of individual clinicians.
 20 **A.** Well, that should appear in the minutes. If it
 21 doesn't -- if you are asking me, possibly, whether
 22 Professor Bloom dominated the conversations, which
 23 I suspect you might be asking me, I think sometimes he
 24 did and sometimes he didn't. I think there was quite
 25 a free flow of information between the different

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1 we would have relied upon him to do that to the best
 2 of his ability and not to put a particular individual
 3 spin that wasn't held by other members of the UKHCDO.
 4 **Q.** Would it be right to say that you'd have no way of
 5 knowing, either at the time or probably now, whether
 6 what he was doing was, as it were, conveying his own
 7 view or whether he was more broadly representing the
 8 views of others?
 9 **A.** Well, only from the meetings I attended, and obviously
 10 I could hear what other people were saying. I don't
 11 recall particular dissent in those -- I mean, there
 12 were -- obviously some issues were picked up, there
 13 was various discussion, but it didn't seem as if these
 14 were very sort of vociferous meetings, it wasn't that
 15 people were disagreeing vehemently. On the whole
 16 I think they were vehemently agreeing.
 17 **Q.** Did you or any of your colleagues in the Department,
 18 your medical colleagues, ever think of challenging or
 19 interrogating what was being said to you about the way
 20 haemophilia clinicians thought matters should be
 21 conducted?
 22 **A.** Well, when I was in the meetings, I mean, there were
 23 breaks and I talked to people. I don't particularly
 24 remember any kind of what I would call a significant
 25 difference of view that I was putting across.

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1 directors, as I recall.
 2 **Q.** Professor Bloom was obviously chair of UKHCDO and, as
 3 we'll see as we look in more detail, perhaps later
 4 today, probably tomorrow, at some of the underlying
 5 documents, he was then involved in a multiplicity of
 6 other meetings, organisations, interactions with the
 7 Department of Health. Again, we'll see when we look
 8 at AIDS tomorrow, he's the person you write to or have
 9 telephone conversations with in early '83 as AIDS
 10 becomes a pressing issue.
 11 Looking back, do you think the Department was
 12 too reliant upon the voice and views of what was
 13 ultimately one individual clinician; in other words,
 14 Professor Bloom?
 15 **A.** He ought to have been able to represent to us the
 16 views, insofar as they were aggregatable, of the UK
 17 Haemophilia Centre Directors. He should have been
 18 able, and we had no reason to suppose he wasn't able,
 19 to take the temperature of any given meeting or to
 20 deal with a particular policy.
 21 We did rely upon him, just as we would have
 22 relied upon the chair of the National Blood
 23 Transfusion -- the regional transfusion directors'
 24 meeting to represent the views of, if you like, the
 25 body of membership of their committees and essentially

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1 Obviously, yes, on organisational matters, that didn't
 2 go down well, but in terms of clinical matters, it
 3 would not have been (a) appropriate, (b) nor did
 4 I have the expertise and nor did I, as far as I can
 5 remember, actually intervene.
 6 **Q.** Well, I may want to pick that up as a theme when we
 7 look at documents relating to AIDS again tomorrow.
 8 Other than through your attendance at those
 9 meetings and then your attendance, and we'll look at
 10 some of the minutes at other meetings at which
 11 Professor Bloom might be present or sometimes
 12 Dr Craske was present --
 13 **A.** Yes.
 14 **Q.** -- were there other individual clinicians, either in
 15 relation to haemophilia care or virology or
 16 transfusion, that you had regular dealings with?
 17 **A.** Regular dealings, no. I mean, obviously I saw in
 18 different fora different people. So Dr Arie
 19 Zuckerman -- Professor Arie Zuckerman, in terms of
 20 research, certainly I saw him on a number of
 21 occasions. You've referred me to a meeting which
 22 I had with Dr Tedder, a virologist, and Dr Mortimer,
 23 a virologist, whom I came to know very well when I was
 24 in the PHLS. But particularly -- I'm trying to think
 25 if there were any specific individuals to whom I would

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1 turn. Of course Dr Gunson and then, needless to say,
 2 on BPL and so on and on fractionation it was Dr Lane.
 3 **Q.** Can I ask you to look at a particular document. It's
 4 the minutes of a meeting of the Hepatitis Working
 5 Party. You weren't present but you are referred to.
 6 It's HCDO0000546.
 7 So you'll see, Dr Walford, it's the minutes of
 8 the third meeting of UKHCDO's Hepatitis Working Party,
 9 November 7, and it's 1978, although that doesn't
 10 appear on that.
 11 Could we go to the top of the second page. This
 12 is whilst you're still in the Medicines Division.
 13 Under the heading "Study of NHS Factor VIII", the
 14 first paragraph, top of the page, says:
 15 "Dr Craske said that this would be assessed
 16 after 1 year. Dr Ellis said that he would like a more
 17 definite procedure for the investigation of cases of
 18 hepatitis, and a clearer definition of 'Factor VIII
 19 associated hepatitis'. Dr Craske agreed to discuss
 20 this with Dr Lane and Dr Walford of the Medicines
 21 Commission."
 22 Then there's a discussion in the next paragraph
 23 about what would happen when a batch of Factor VIII
 24 was known to be contaminated with hepatitis B.
 25 Are you able to assist us in understanding more

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1 this doesn't refer to you by name but under the
 2 heading "Supra-regional Directors Meeting", it says,
 3 in the second line:
 4 "The DHSS Small Grants Committee had requested
 5 that the Directors consider whether patients might be
 6 kept on one batch or a single product for some time,
 7 as this might reduce the incidence of transfusion
 8 hepatitis."
 9 Then it goes on to set out what the directors'
 10 opinion was.
 11 First of all, can you assist us with what the
 12 Department's Small Grants Committee was?
 13 **A.** As far as I can recall, it was a committee set up to
 14 administer some small, and it was small, grants to
 15 people wanting to do particular research.
 16 It is possible -- I don't know for sure -- that
 17 Dr Craske's surveillance of hepatitis, the Hepatitis
 18 Working Party surveillance, which he chaired, was
 19 funded from the Small Grants Committee. I don't know
 20 but it -- that sounds as if it could have been.
 21 **Q.** We see there reference to a possible approach of
 22 patients being kept on a single product or a single
 23 batch. The Inquiry has heard evidence that some
 24 clinicians adopted that approach for safety reasons
 25 and some clinicians, the vast majority of clinicians

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1 what the first paragraph is referring to, and why
 2 there Craske was envisaging he would have a discussion
 3 with you about this issue?
 4 **A.** Well, I don't know -- by the way, I didn't attend the
 5 UKHCDO Hepatitis Working Party. I was not invited.
 6 This was, of course, before I was in Med SEB.
 7 This is when I was in the Medicines Division. Now, my
 8 role in Medicines Division was the licensing of blood
 9 products, if you like, and essentially it sounds as if
 10 Dr Craske wanted to talk to me and Dr Lane about
 11 products which might be known to be associated with
 12 hepatitis.
 13 This is probably going to be hepatitis B. Now,
 14 by then you could actually diagnose that. You could
 15 know that that product was associated, because you
 16 would have found the agent, if you like, in the
 17 product or maybe in recipients. But it's most likely
 18 at this point -- which must be, what, '78?
 19 **Q.** November '78.
 20 **A.** Then it's most likely to be hepatitis B.
 21 **Q.** But you have no specific recollection --
 22 **A.** None at all.
 23 **Q.** -- of discussing this?
 24 **A.** No.
 25 **Q.** Then if we go to the next page, top of the next page

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1 did not. Do you recall that ever coming up in
 2 discussions within the Department of Health, that kind
 3 of approach?
 4 **A.** No, I don't remember.
 5 **Q.** Then just again, on the Small Grants Committee, it
 6 might just help join the pieces, help join the dots,
 7 if we go to DHSC0001121. This is a minute authored by
 8 you and we can see your name at the bottom of the
 9 page, and then a handwritten date "December 1980". We
 10 can see you are now in Med SEB. Then, if we go to the
 11 top of the page, it's entitled:
 12 "Studies of the epidemiology and chronic
 13 sequelae of [Factor]VIII and IX associated hepatitis
 14 in the United Kingdom".
 15 **A.** Mm-hm.
 16 **Q.** Then you refer to not having -- you refer to a project
 17 number, to not having inherited a file on the project
 18 from Dr Waiter, who was your predecessor. You refer
 19 to talks being delivered by Dr Craske and it records
 20 there:
 21 "... it is generally acknowledged that Dr Craske
 22 et al are performing a valuable and necessary study."
 23 Then it says:
 24 "The study has 1 more year to run and I would
 25 have no hesitation in supporting it. I see that

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

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

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

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

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

1 getting to the same point which you might be getting
 2 to with cryoprecipitate because if you have to use
 3 20 bags of cryoprecipitate, that's 20 donors, if you
 4 like, you could have a small pool, if this research
 5 showed that you could do it, a small donor pool which
 6 would be another way of administering a relatively
 7 low-risk product.

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

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

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

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

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

5 **Q.** Not that I'm presently aware of.

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

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

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

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

7 **A.** That's right.

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

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

18 **A.** I think that's right, yes.

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

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

1 blood products, including risks from hepatitis, for
 2 *Meyler's Side Effects of Drugs*, the Ninth Edition.
 3 This was a reference work which was in medical
 4 libraries, it was placed in medical libraries.
 5 They, at the same time, asked me if I would also
 6 write an article or rather a review piece in the *Side*
 7 *Effects of Drugs Annual*, number 4, I think, for that
 8 year. So I thought it would be a good idea, actually,
 9 to do that, a good exercise for me, and not unhelpful
 10 to my CV, I thought at the time, to do this work. So
 11 I did, and basically they provided me with
 12 a significant tranche of publications and they gave me
 13 the hard copies to review, and they only wanted me to
 14 focus on what was in the papers that they gave me to
 15 review, and I duly did.

16 **Q.** Was this publication *Meyler's Side Effects of Drugs*,
 17 you said it would be in medical libraries, so it was
 18 for clinicians or for clinical investigators?
 19 **A.** Everybody really, medical libraries. Essentially, it
 20 was deemed to be a reference document. As far as
 21 I know, it's ongoing. It's just one of those
 22 publications which is used as a reference work for
 23 people who are studying a particular subject.
 24 **Q.** If we go to the third page, please, Soumik, we can see
 25 the chapter, which your name and co-author's name

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1 "Prior to the introduction of sensitive methods
 2 for the detection of [the hepatitis B antigen], about
 3 30 per cent of cases of post-transfusion hepatitis
 4 were caused by [hepatitis B virus]."
 5 Then there's a discussion -- I'm not going to go
 6 through it in detail -- about how that figure has been
 7 reduced and the value of the screening test.
 8 If we go to the next column, so the same page
 9 but the right-hand column, pick it up just a little
 10 higher than that, please. So about six lines down, it
 11 says:
 12 "Despite the introduction of systematic
 13 screening ... the risk obvious post-transfusion
 14 [hepatitis B virus] infection remains greater for
 15 certain pooled plasma derivatives than for single
 16 donations. Plasma fractions such as fibrinogen,
 17 antihæmophilic factor and the prothrombin-complex
 18 concentrates are associated with a high risk of HBV
 19 infection ..."
 20 You then go on to say:
 21 "Partly this high infectivity may be explained
 22 by the fact that these fractions are often prepared
 23 from paid-donor plasma in which the incidence of ...
 24 positivity is 10 times that in plasma from
 25 a non-commercial source ..."

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1 appears at the top "Blood and blood products" and then
 2 the first paragraph says:
 3 "The transfusion of whole blood or blood
 4 products into man may be associated with a variety of
 5 adverse reactions. The presentation adopted in this
 6 chapter classifies these effects according to the
 7 blood component involved ..." and you give examples.
 8 So it encompasses a number of different adverse
 9 reactions but if we go to what is of interest to the
 10 Inquiry, which I think is probably page 16,
 11 electronically, Soumik, that's it. So bottom
 12 right-hand corner, "Transmission of disease by blood
 13 products":
 14 "Many viral, bacterial and protozoal diseases
 15 can be transferred from the donor to the recipient
 16 with transfused blood or blood products. Some of
 17 these complications will be discussed below."
 18 Then you have a heading "Hepatitis":
 19 "Post-transfusion hepatitis may result from the
 20 transmission of several viruses namely, hepatitis A
 21 ... hepatitis B ... non-A, non-B virus(es),
 22 cytomegalovirus and the Epstein Barr virus."
 23 Then if we go to the next page, we can then see,
 24 I'm going to skate over hepatitis A, but there's then
 25 a discussion about hepatitis B. It talks about how:

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1 Then, again I'm not going to go through the
 2 detail of the rest of what you say about hepatitis B,
 3 but you discuss the hepatitis B. Go over the page.
 4 We have a heading "Non-A, non-B hepatitis":
 5 "In the USA at present, some 60 to 90 per cent
 6 of the post-transfusion hepatitis is unrelated to
 7 either hepatitis A or hepatitis B ... Neither
 8 cytomegalovirus nor the Epstein Barr virus have been
 9 implicated in such cases ... at least one additional
 10 human hepatitis virus is suspected. Recently, three
 11 studies have provided convincing evidence for a
 12 transmissible agent of non-A, non-B hepatitis."
 13 Then you refer to three studies, one of
 14 volunteers who developed non-A, non-B after
 15 inoculation of stored sera from donors, and then the
 16 other two studies, non-A, non-B hepatitis was
 17 transmitted from infected human sera to chimpanzees,
 18 and then it goes on to say:
 19 "The latter studies also confirmed the existence
 20 of a chronic carrier state in humans ..."
 21 Then a couple of lines further down:
 22 "Further confirmation oh chronic carrier state
 23 has come from a follow-up of 44 patients with proven
 24 non-A, non-B hepatitis ..."
 25 Then if we just look at the paragraph below

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

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

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

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

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

24 Then you refer to data from the United States,
 25 20 to 30,000 cases of post-transfusion hepatitis and

1 Then you refer to a paper by Wyke et al
 2 demonstrating:
 3 "... the transmission to chimpanzees of an agent
 4 responsible for two fatal cases and one non-fatal case
 5 of non-A, non-B hepatitis in patients with liver
 6 disease who received the same broach of commercial
 7 prothrombin-complex concentrate prior to liver biopsy.
 8 A further death apparently from non-A, non-B hepatitis
 9 occurred in their series of 17 patients with liver
 10 disease who received four different batches of
 11 concentrate."

12 Then you say:

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

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

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

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

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

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

9 **A.** Yes.

10 **Q.** We can see the two themes are:

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

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

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

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

22 You say:

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

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

4 **A.** Yes.

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

7 **A.** Yes.

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

14 **A.** Yes.

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

18 **A.** Yes.

19 **MS RICHARDS:** Thank you.

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

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

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

7 **A.** Yes.

8 **SIR BRIAN LANGSTAFF:** What did you understand the
9 30 per cent figure to be based upon? A sort of
10 retrospective analysis? And if so, what was the other
11 70 per cent and when was the other 70 per cent, the
12 missing 70 per cent which wasn't B, first known? Do
13 you know? Can you help?

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

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

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1 hepatitis B, but it was not detected or detectable.

2 **SIR BRIAN LANGSTAFF:** The article was going on to say,
3 well, now we've reduced it perhaps to about
4 10 per cent, leaving 90 per cent for something or
5 something else --

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

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

13 **MS RICHARDS:** Thank you, sir.

14 (1.03 pm)

(Luncheon Adjournment)

15 (2.05 pm)

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

23 **A.** In terms of plasma, absolutely -- not necessarily in
24 terms of large pool concentrates though.
25

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

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

13 **A.** Absolutely.

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

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

21 But I suspect -- I don't know -- that the
22 30 per cent was demonstrably known to be hepatitis B
23 because there was a way of determining the fact that
24 it was hepatitis B, and the other 70 per cent,
25 significant proportion, might well have been

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

5 **A.** Yes.

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

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

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

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1 statement is you think within the Department the risk
 2 of hepatitis B through transfusion was pretty well
 3 known and understood.
 4 **A.** Yes.
 5 **Q.** You have said you think that there was -- non-A, non-B
 6 hepatitis was a problem known to the Department, known
 7 within the Department, but you think there was a less
 8 of an appreciation of the risks of serious liver
 9 disease from non-A, non-B hepatitis.
 10 **A.** Yes. Of course, I'm not in a position to know for
 11 sure but I think it was the case that everybody knew
 12 about non-A, non-B. They were not necessarily aware
 13 or conscious of the fact that it potentially could
 14 give rise to severe chronic disease. I mean, they
 15 knew that it would give rise to hepatitis, and maybe
 16 they knew that sometimes it was asymptomatic and
 17 sometimes it was overt, the hepatitis, but I don't
 18 think at this remove -- and I'm trying to not to
 19 overlay it with thoughts that I have now rather than
 20 thoughts that I had then -- I don't think they
 21 appreciated that it was potentially more severe than
 22 they might have thought it was. And that was one of
 23 the reasons why I spoke about it really quite forcibly
 24 in my minute through to Mr Harley, 15 September 1980.
 25 **Q.** And I'm going to to look at that with you in just

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1 of the UK material with imported hepatitis viruses.
 2 "I must emphasise that 90 per cent of all post
 3 transfusion (and blood product infusion) hepatitis in
 4 the USA and elsewhere is caused by non-A, non-B
 5 hepatitis viruses which (unlike hepatitis B) cannot,
 6 at present, be detected by testing donor blood. This
 7 form of hepatitis can be rapidly fatal (particularly
 8 when acquired by patients with pre-existing liver
 9 disease) or can lead to progressive liver damage. It
 10 can also result in a chronic carrier state, thus
 11 increasing the 'pool' of these viruses in the
 12 community."
 13 If we just look at the top of the page, we can
 14 see, as you said a few moments ago, it's addressed to
 15 Mr Harley.
 16 Now, leaving aside for present purposes the rest
 17 of it and the context of the memo, which, as I say,
 18 we'll come back to when we look at BPL, you were
 19 describing non-A, non-B hepatitis there, if I may say
 20 so, in no uncertain terms as a serious condition.
 21 **A.** Yes.
 22 **Q.** We can see it's addressed to effectively your
 23 equivalent number in -- was he HS1?
 24 **A.** Yes. Well, yes --
 25 **Q.** Or in HS?

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1 a moment. Before I do that, am I right in
 2 understanding that, amongst the papers you reviewed
 3 for the purposes of the publications we looked at, the
 4 paper by Professor Preston published in 1978 was not
 5 one of those which you reviewed?
 6 **A.** It wasn't supplied to me, no.
 7 **Q.** Do you recall how or when you became aware of that?
 8 **A.** I have to tell you that I became aware of
 9 Professor Preston's paper through the Inquiry, but
 10 I have of course since read it.
 11 **Q.** I want to go then to your memo of 15 September 1980,
 12 to which you've just referred.
 13 Soumik, it's WITN0282008, please.
 14 We'll come back to this memo at a later stage in
 15 terms of the issue about BPL but I just want to look
 16 for present purposes at what you say about hepatitis.
 17 So the context is the Blood Products Laboratory, the
 18 possible takeover by industry and Beechams then being
 19 the company whose involvement was being contemplated.
 20 Then you say in the paragraph numbered 1,
 21 picking it up in the second sentence:
 22 "Unless it were Beecham's intention to process
 23 such plasma in an entirely separate plant or with
 24 complete duplication of all facilities in a single
 25 plant, it would be impossible to prevent contamination

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1 **A.** In HS.
 2 **Q.** So you're not saying it's a largely benign condition?
 3 **A.** No.
 4 **Q.** You're recognising the consequences and you are
 5 sharing those consequences with your administrative
 6 and policy colleagues. Did you ever get a sense that
 7 what you were saying to Mr Harley came as a surprise
 8 in relation to the risks of non-A, non-B?
 9 **A.** I couldn't say that necessarily. I did copy this
 10 minute. Because I wasn't sure how much the
 11 Department, my colleagues, were aware that this was
 12 potentially a much more serious disease than they may
 13 have actually thought it was, I copied it pretty
 14 widely. So copied it to his boss and my boss as well.
 15 **Q.** Can we go to the second page. You are right to point
 16 that out, Dr Walford.
 17 So we can see it's published to Dr Oliver, who
 18 was your boss, so in the medical division, Mr Wormald,
 19 who was a senior civil servant in the administrative
 20 side?
 21 **A.** Who was Mr Harley's boss.
 22 **Q.** And Mr Godfrey?
 23 **A.** Was the principal in his, in Mr --
 24 **Q.** And Mr Hart?
 25 **A.** He was head of the supply division.

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1 Q. Dr Wintersgill?
 2 A. He was, I think, the medical opposite number to
 3 Mr Hart. I could be wrong about that but I seem to
 4 recall.
 5 Q. Mrs Firth.
 6 A. Finance, as far as I know.
 7 Q. Mr Brechin?
 8 A. Brechin, yes --
 9 **SIR BRIAN LANGSTAFF:** Probably Brechin.
 10 A. Thank you.
 11 He was also finance as far as I can recall.
 12 **MS RICHARDS:** Mr Sharpe?
 13 A. Probably supply, I don't --
 14 Q. Don't worry if you can't recall. Dr Davie?
 15 A. I don't know who Dr Davie -- I must have known but
 16 I don't know now.
 17 Q. Then we have Miss Helson and Mr Connor?
 18 A. I do not know, unless Mr Connor is the same chief
 19 architect Mr Connor.
 20 Q. No doubt in part the reason for the wide circulation
 21 was because this was dealing with the issue about
 22 commercial takeover, hence the involvement of supplies
 23 and finance?
 24 A. Yes, and Mr Hart.
 25 Q. But in terms of what you were saying about non-A,

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

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1 meeting. Actually, what Professor Zuckermann said at
 2 this particular meeting that I have in mind, which
 3 came as a surprise to me, was that the researchers had
 4 shown that non-A, non-B hepatitis, unlike hepatitis B,
 5 did not seem to be sexually transmitted. That was
 6 a revelation to me. I didn't know that.
 7 Q. Then if we can look at your witness statement, I think
 8 it's 63.
 9 And again, if we put this up on screen, Soumik,
 10 it's WITN4461001, and if we go to page 153, you set
 11 out in paragraph 63.1 the question you were asked by
 12 the Inquiry, which was an explanation of:
 13 "... what, if any, steps were taken (and when
 14 and by whom) to ensure that the serious nature of
 15 non-A, non-B hepatitis (as summarised in my minute of
 16 15 September 1980 ...) was known to, and understood
 17 by: ministers; clinicians; NHS bodies; patients who
 18 were or might be treated with blood or blood products;
 19 the public."
 20 Then if we just go through what you then say in
 21 response to that, you say in paragraph 63.2 that:
 22 "[You] do not believe that, at the time, the
 23 potential severity of non-A, non-B hepatitis was in
 24 any way well known, outside of a body of relevant
 25 researchers and hepatologists."

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

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1 A. Could I just intervene for a moment?
 2 Q. Yes, of course.
 3 A. In relation to the licensing authority, I am pretty
 4 certain that the product information, the leaflets,
 5 which went to both patients and the professional --
 6 the leaflets for doctors, will have mentioned
 7 hepatitis, but they may not have mentioned
 8 specifically non-A, non-B because, of course, we knew
 9 next to nothing about that in terms of, you know, what
 10 exactly it was. But it will have mentioned hepatitis,
 11 I'm pretty certain.

12 Q. And the Inquiry will be looking at the content of
 13 those leaflets in a later hearing.
 14 Can we go back to the question, and I want to
 15 put it in perhaps slightly different terms than the
 16 way it's put in question 63.1. My question is: what,
 17 if any, steps were taken by the Department to
 18 ensure that the serious nature of non-A, non-B
 19 hepatitis, as summarised in the document we've just
 20 looked at, was known to and understood by -- leave
 21 aside ministers for a moment -- clinicians,
 22 NHS bodies, patients or public?

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

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1 view that these were -- this was clinical material
 2 which doctors ought to make themselves aware of
 3 through their own reading or their own studies or
 4 through -- they should be made aware of them through
 5 their specialist societies or, in the case of the
 6 haemophiliacs, the Haemophilia Centre Directors. We
 7 would not have been describing this to patients -- to
 8 doctors directly.

9 Q. If we just then go to paragraph 63.2, that's even
 10 though there was potentially an information gap,
 11 because you have said in terms there you don't think
 12 at the time the potential severity of non-A, non-B
 13 hepatitis was well known outside of researchers and
 14 hepatologists. You have explained why you think
 15 haemophilia clinicians should have known through
 16 Dr Craske and the Hepatitis Working Party, and so on,
 17 but you appear to be recognising there that there
 18 would be a large cohort of clinicians who wouldn't
 19 necessarily know.

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

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1 particular steps to explain the serious nature of
 2 non-A, non-B to either clinicians, NHS bodies or
 3 patients or the public?

4 A. It would not have expected to explain the nature to
 5 clinicians. It would have expected -- in the
 6 generality of clinicians, if we're not talking about
 7 Haemophilia Centre Directors, and we know that they
 8 had the information from Craske -- they had the
 9 information from Craske that the rest of the
 10 Department, if you like, or those of us who were
 11 involved, were privy to. So the Haemophilia Centre
 12 Directors were certainly well aware or should have
 13 been aware of almost as much, if you like, as I have
 14 described, if not as much, and the generality of
 15 clinicians -- because we must remember that this was
 16 transmissible through blood and cryoprecipitate, it
 17 sort of knew no boundaries. It wasn't simply
 18 commercial or NHS Factor VIII concentrates, this was
 19 completely transmissible by blood.

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

25 But basically I think the Department took the

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

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

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1 disease.

2 **Q.** Then if we go to the next page, paragraph 63.5, the
 3 question also asked you about the provision of
 4 information to ministers and you said, I think in
 5 terms in section 63.5, you don't know if the potential
 6 for chronic liver damage and severe disease from
 7 non-A, non-B hepatitis was particularly flagged up to
 8 ministers.

9 **A.** I don't know.

10 **Q.** Are you able assist with this: what, if any,
 11 consideration was given by the Department in the late
 12 1970s/early 1980s to the possibility that pooled
 13 products might transmit viruses not yet known to
 14 medical science; in other words, was there
 15 a recognition of known unknowns, that there could
 16 potentially be things out there, things in blood, that
 17 could be dangerous but which weren't yet identified
 18 and understood?

19 **A.** I think it was implicit in anybody who had to do with
 20 blood transfusion that you knew that, potentially,
 21 blood transfusion could transmit an agent that we'd
 22 never hearing of before, never seen before, didn't
 23 know about. Of course, that transpired to be the case
 24 with AIDS and it also transpired to be potentially the
 25 case with new variant CJD.

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1 of minutes briefly with you.

2 So if we can go to MRCO000029_003. So we'll
 3 see from this it's headed "Medical Research Council,
 4 Blood Transfusion Research Committee, Working Party on
 5 Post-Transfusion Hepatitis", first meeting
 6 14 February 1980. Then if we look at the list of
 7 attendees we can see Dr Gunson there, Dr Craske,
 8 Dr McClelland, Dr Howard Thomas is there, and then you
 9 are there and Professor Zuckermann's there.

10 What was your role in this working party?

11 **A.** That's a very good question because I was there, I was
 12 representing the Department. I don't know
 13 specifically why I was there, except perhaps as a sort
 14 of liaison from the MRC over to any of the other
 15 working parties that I might have been associated
 16 with. I don't know and we may look but I don't know
 17 if I actually said anything at this meeting at all.
 18 Did I contribute?

19 **Q.** I'm afraid I can't remember without checking.

20 **A.** Neither can I.

21 **Q.** In any event, if we pick things up at the bottom of
 22 that page we can see the purpose of the working party
 23 and then there's reference to the Advisory Group on
 24 Testing for the presence of hepatitis B antigen and
 25 its antibody, we'll come on to that. There's

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1 What one knew was that potentially there was --
 2 blood transfusion was inherently hazardous. You did
 3 everything possible in the Blood Transfusion Service
 4 to reduce the hazard, the risk, coming out of blood
 5 transfusion. So anything you could screen for, you
 6 should screen for, any donors that should be asked not
 7 to donate you dealt with but, inherently, you don't
 8 know what you don't know. You only know that it could
 9 happen and, in fact, it did happen.

10 **Q.** Now, I just want to ask you next about some of the
 11 expert groups, advisory groups, working parties that
 12 were involved with hepatitis late 1970s/early 1980s.

13 You've referred in your statement, and I'm not
 14 going to take you to it because you weren't there, but
 15 just to get some dates understood, you have referred
 16 in your statement to a February 1979 *ad hoc* meeting at
 17 the Medical Research Council attended by your
 18 predecessor -- sorry, in fact, I think your
 19 predecessor, Dr Waiter, wasn't there. Someone else
 20 from the DHSS attended in her place.

21 **A.** Yes.

22 **Q.** So that was an *ad hoc* meeting out of which there
 23 appears to have grown something called the working
 24 party on post-transfusion hepatitis, which you were
 25 then part of and I just want to look at those two sets

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1 reference to the *ad hoc* group that met in
 2 February 1979, that's the one I referred to.

3 There, here we are, you do contribute:

4 "Dr Walford said that a new DHSS Advisory Group
 5 would shortly be formed to advise on the public health
 6 aspects of hepatitis."

7 So we will look at that committee in a while:

8 "It was agreed that the function of the MRC WP
 9 [so to MRC Working Party] was to promote research to
 10 assess the nature and size of the problem of
 11 [post-transfusion hepatitis] in the UK, with
 12 particular reference to changes in transfusion
 13 practice, eg the use of products prepared from pooled
 14 plasma from large numbers of donors and the
 15 introduction of commercial products from abroad.
 16 Studies should include (1) an assessment of any
 17 further need for research into hepatitis B ... (2)
 18 investigations to assess the incidence of non-A, non-B
 19 hepatitis in the UK, particularly with the risk of
 20 introducing the infection by blood transfusions, and
 21 (3) the position of research to characterise the
 22 agent(s) associated with this form of hepatitis, and
 23 to derive diagnostic tests."

24 So that's the purpose of it. Would it be right
 25 to understand that's why it's under the auspices of

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1 the medical research council because its focus is on
 2 research, specifically into post-transfusion
 3 hepatitis, including non-A, non-B?
 4 **A.** Yes.
 5 **Q.** If we go a little further down that page we can see
 6 the heading "The problems of non-A, non-B hepatitis
 7 viruses". There's reference to a wide ranging
 8 discussion and there's contributions from
 9 Professor Zuckermann, Dr Craske, cases at the Oxford
 10 Haemophilia Centre. Then if we go to the next
 11 paragraph, we can see it's recorded there there's
 12 a problem of non-A, non-B hepatitis related to
 13 freeze-dried Factor VIII and IX both of NHS and
 14 commercial types imported from Austria and the USA.
 15 There's reference to a study at the Royal Free
 16 described by Dr Thomas, and it talks about evidence
 17 obtained by liver biopsy that a proportion of these
 18 cases might suffer chronic sequelae, and so on.
 19 Now, I'm not going go through the detail of
 20 everything that was discussed at the meeting but,
 21 broadly speaking, would it have been part of your role
 22 to feed this back, at least if there was any new
 23 information, to colleagues in the Department?
 24 **A.** If there had been something new and revelatory yes,
 25 I would have said so but I don't know whether there

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1 concentrate should be undertaken to provide answers to
 2 these problems, and to provide a collection of well
 3 documented sera and other specimens for the use in
 4 development of serological tests for non-A, non-B
 5 hepatitis. The Working Party agreed to recommend to
 6 the Medical Research Council that such a study should
 7 be undertaken."
 8 Can you assist us with why the Department were
 9 keen that this study should be undertaken?
 10 **A.** Well, as far as I can see, there must have been
 11 a suggestion that such a study should be undertaken.
 12 We probably had a proposal, probably from Dr Craske,
 13 but I can't tell from this paper as it's drafted here.
 14 But, basically, really trying to elucidate what was
 15 going on with regard to these various concentrates and
 16 this would have been -- obviously the study is talking
 17 about patients undergoing elective treatment requiring
 18 concentrate. So the patients would have needed the
 19 concentrate and those would be the patients who could
 20 be followed then, because they were going to get
 21 concentrate, and they could be followed prospectively
 22 to see what the consequences were in terms of whether
 23 they got non-A, non-B. But this was definitely
 24 a study relating to patients who required concentrate
 25 for their treatment.

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1 was at that particular meeting. I mean, in general,
 2 I tried to be quite helpful as between what I'm
 3 hearing at meetings and what I'm saying back at the
 4 Department, and vice versa.
 5 **Q.** Then there's a second meeting of this particular
 6 working party. So this first one's February 1980.
 7 The second one's June 1981, NHBT0000068_049.
 8 So we can see from the top it is the second
 9 meeting, 25 June 1981, similar attendees. Again,
 10 you're there. There's just one aspect of the
 11 discussion I wanted to ask you about. So if we go to
 12 page 5, if we just go to the previous page, so we can
 13 put it in context, bottom of the previous page,
 14 there's a heading "Hepatitis in Haemophilia -- report
 15 by Dr Craske", and then if we go to the next page, he
 16 continues his report and I think refers to the data
 17 he's gathered through his surveillance programme.
 18 Then if we look at the last main paragraph:
 19 "Dr Craske concluded by saying there was little
 20 information about the incidence of symptomless
 21 hepatitis and the relative risks of hepatitis due to
 22 different brands of Factor VIII and IX."
 23 Then this:
 24 "The DHSS were keen that a prospective study of
 25 patients undergoing elective treatment requiring

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1 **Q.** This working party is then disbanded in, I think,
 2 March -- in or by March 1982, so it only met on two
 3 occasions. The problem of non-A, non-B hepatitis and
 4 understanding it and the need to learn more obviously
 5 hadn't gone away. I think the minutes of another
 6 meeting which refer to it being disbanded just talk
 7 about not wanting too many -- or duplication of
 8 effort. Can you recall why this particular working
 9 party didn't proceed further?
 10 **A.** No. Because, of course, the MRC was entirely separate
 11 from the Department. This was a decision taken by the
 12 systems board or whatever -- the MRC had a reasonably
 13 complicated structure. It made the Department look
 14 quite clear and easy, I think. But the systems board
 15 then had another group, in my recollection, and this
 16 working party responded to it, and, as far as I have
 17 understood from reading the papers, the reason they
 18 disbanded it was that they thought that actually this
 19 was an area of study and potential research that was
 20 being handled by a number of other relevant bodies and
 21 that they didn't seem to have a specific role because
 22 actually essentially what was being looked at here
 23 was, again, operational research. It wasn't really
 24 fundamental research. They were not looking at the
 25 virus particles and other sort of thing that the MRC

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

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

12 **A.** Yes.

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

16 **A.** Absolutely. Completely.

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

23 **A.** Yes.

24 **Q.** So infectious communicable diseases were her area of
 25 speciality.

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

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

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

14 **A.** Mm-hm.

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

18 **A.** That's right.

19 **Q.** Then if we just look further down the page we've got
 20 there "Non-A, non-B Hepatitis - Work of the MRC
 21 Group", so that's the one we were just looking at.
 22 I just want to look at the last paragraph on that
 23 page. We can see it records:
 24 "Members [being] concerned about the incidence
 25 of non-A, non-B hepatitis ... possibility that new

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

5 **A.** Yes.

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

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

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

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

1 viruses were perhaps being introduced through the use
 2 of commercial blood products, namely, Factor VIII
 3 and IX. Professor Zuckermann reported that he knew of
 4 2 haemophiliacs who had suffered severe non-A, non-B
 5 hepatitis after receiving commercial concentrates. In
 6 both cases the disease had a short incubation period."

7 Then this:
 8 "Members agreed that the hazard from non-A,
 9 non-B hepatitis should now be recognised and brought
 10 to the attention of the appropriate Departmental
 11 bodies responsible for the control of hepatitis."

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

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

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

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

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

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

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

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

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

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

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

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1 Group."

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

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

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

- 17 **A.** Yes, yes.

- 18 **Q.** Then if we go to CBLA0001167, it is described as the
19 "fifth meeting of the reconvened advisory group on
20 testing for the presence of hepatitis B surface
21 antigen and its antibody". It's the Hepatitis B
22 Advisory Group for shorthand. Meeting
23 17 September 1980. You and Dr Sibellas and, indeed,
24 others from the Department are there.

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

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

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

- 5 **A.** Yes.

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

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

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

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1 therapy in the UK."
 2 Then over the page, second paragraph, so the
 3 paragraph numbered 24:
 4 "We recommend that research is undertaken in the
 5 UK to determine the extent and severity of
 6 [post-transfusion hepatitis] due to non-A, non-B
 7 hepatitis viruses."
 8 There's an explanation in the next sentence as
 9 to why.
 10 Then this:
 11 "Regional Transfusion Directors should encourage
 12 hospital haematologists to report all cases of
 13 post-transfusion jaundice and where these could be due
 14 to non-A, non-B hepatitis, the facts should be
 15 reported to the appropriate Adviser in Blood
 16 Transfusion at the Department of Health and Social
 17 Security or Scottish Home and Health Department."
 18 So it appears to be a recommendation in the
 19 report for there to be a reporting system of
 20 post-transfusion non-A, non-B hepatitis cases or
 21 possible cases to the Department or to its Scottish
 22 equivalent. Can you assist us any more with what that
 23 reporting system comprised and who was the appropriate
 24 adviser?
 25 **A.** It would be Dr Gunson, the consultant adviser. We

1 **A.** Deputy Chief Medical Officer with responsibility in
 2 relation to hepatitis but also the other infectious
 3 disease.
 4 **Q.** We can see, if we look at the first paragraph, it
 5 refers to a decision in July -- so that would have
 6 been July 1979, because this minute is dated
 7 November 1979 -- to proceed with measures to obtain
 8 professional advice on the various problems of
 9 hepatitis. Then if we go to the third paragraph, it
 10 says this:
 11 "We are of course faced with the need not to
 12 establish new advisory or other bodies without very
 13 good reason ..."
 14 Then there's a discussion about whether to
 15 attach it to the existing hepatitis B advisory group
 16 or whether it should be an advisory group in its own
 17 right. I don't want to get into the ins and outs of
 18 that.
 19 Were you aware that there was, as it were,
 20 a policy or a practice of not establishing new
 21 advisory or other bodies without very good reason?
 22 **A.** Yes, I think it was the general thought that you
 23 thought very carefully before you established or asked
 24 to establish a new body. It has to be said that we
 25 needed to go to ministers to establish such a new body

1 were not ourselves, as officials, called advisers. So
 2 if they are saying the "appropriate adviser", this
 3 will be the consultant adviser in blood transfusion
 4 and this is coming from the Regional Transfusion
 5 Directors to the consultant adviser in blood
 6 transfusion and, therefore, into the Department.
 7 But then I think it would have gone into
 8 Med IMCD after that.
 9 **Q.** But, in any event, through whatever form, that
 10 information coming to Dr Gunson should then have gone
 11 through his meetings with the CMO or through whatever
 12 route --
 13 **A.** Yes.
 14 **Q.** -- it should have been passed on within the
 15 Department?
 16 **A.** Yes.
 17 **Q.** So that then leads us to what was described as the new
 18 committee, the new group, the advisory group of
 19 hepatitis, which is the third committee on hepatitis
 20 I wanted to ask you about.
 21 If we go to DHSC0002195_062, this is not a note
 22 that was copied to you at the time but it is one which
 23 I know you have seen since. It's from T Geffen, dated
 24 6 November 1979, and it's addressed to Dr Evans.
 25 Dr Evans was the Deputy Chief Medical Officer --

1 so you thought very carefully for the rationale and
 2 what you would actually say could be done away with.
 3 I mean, essentially, in terms of the use of staff
 4 within the DHSS, who had to often service these
 5 meetings, and so on, it made sense to be rational
 6 about the bodies and also to make sure that advice was
 7 coming to you, most -- the most authoritative advice
 8 you could get was coming from a properly constituted
 9 body.
 10 So there was, at the time -- my recollection is
 11 that, basically, you thought hard and long before
 12 recommending yet another advisory group.
 13 **Q.** As I think you alluded to a moment ago, it was
 14 something that required ministerial sign off?
 15 **A.** Yes.
 16 **Q.** Then if we just look at the last paragraph on this
 17 page, there's a discussion about an alternative option
 18 about having an *ad hoc* group rather than a formal
 19 group and then what's said about it is this:
 20 "One disadvantage of this would be that we do
 21 really expect to need the advisory group not only in
 22 the immediate future, for example ... but for some
 23 time ahead."
 24 Then there's reference to hepatitis B problems
 25 being with us for a long time.

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

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

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

18 **A.** Really.

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

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

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1 contributes to the delay.

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

7 **A.** Yes.

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

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

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

25 **A.** Mm-hm.

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

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

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

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

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

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

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

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

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

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

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

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

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

9 Then the terms of reference:

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

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

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

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1 Regional Transfusion Directors there. Dr Lane of
2 course.

3 **A.** Mm-hm.

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

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

11 **A.** Yes.

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

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

25 **Q.** There's certainly no particular contribution from you

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

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

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

20 **A.** Yes, it was Sir Robert.

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

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

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

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

3 **A.** Okay.

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

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

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

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

25 Can I then just ask you in general terms this:

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1 do you think the Department was slow to pick up on and
 2 respond to the significance of and the risks of non-A,
 3 non-B hepatitis?
 4 **A.** Just listening to what you've got to say about it, and
 5 listening to the length of time it took us to set up
 6 this particular meeting, I mean, it was not slow in
 7 terms of the generality of the way in which
 8 the Department operated, because there are instances
 9 in the papers that you've given me where really and
 10 truly the pace was not what one desirably would want
 11 to see in terms of moving things along. The
 12 Department was quite monolith. It was quite -- there
 13 was an element of bureaucracy involved. So it didn't
 14 move with the speed of summer lightning, how shall
 15 I say. So this was probably not slower than other
 16 working parties or other working groups would work but
 17 clearly, with the benefit of hindsight and looking at
 18 the time it was taking, and of course, as you've drawn
 19 out now, which may have been less apparent when one
 20 was up close, was that one of the issues that should
 21 have been of considerable concern, which was non-A,
 22 non-B, was not perhaps getting the attention that it
 23 should have got, at least not overtly as recorded in
 24 the minutes.

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

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

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

19 **A.** No.

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

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

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

7 **A.** Yes.

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

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

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

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

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

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

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

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

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

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1 transmission of infectious diseases was obviously
 2 going to be greater if you move from one population
 3 with one incidence of a particular infection to
 4 another population's recipients who -- maybe that
 5 country had a lower incidence of a particular
 6 infection.
 7 **Q.** My understanding is you wouldn't have been directly
 8 involved in personally briefing a new minister
 9 about -- certainly about self-sufficiency?
 10 **A.** No.
 11 **Q.** Would you have any knowledge or expectation of whether
 12 new ministers would be briefed on that, would you have
 13 expected them to have been briefed that that was the
 14 policy?
 15 **A.** I would expect not necessarily new ministers in
 16 general but actually whatever minister had the blood
 17 and blood products brief, because each minister had
 18 their own area, I would have expected probably as
 19 a matter of general underlying principle that they
 20 would have a brief on that.
 21 **Q.** Then, just dealing with BPL, first of all, again in
 22 quite general terms, BPL was, as your statement makes
 23 clear, a manufacturing facility wholly owned and
 24 funded by the Department by the time at which we are
 25 concerned or you are concerned and accountable to the

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1 Department of Health. The region did not fund BPL.
 2 It was a device to allow the employment of BPL staff,
 3 and so on, because the North West Thames Regional
 4 Health Authority had employed many staff and had all
 5 sorts of departments which the Department itself
 6 didn't have. So it was necessary to have another
 7 entity (which turned out to be the North West Thames
 8 Regional Health Authority because BPL was based in the
 9 North West Thames area) to, as it were, partner with
 10 the Department. But the funding came exclusively from
 11 the Department.
 12 **SIR BRIAN LANGSTAFF:** So it wasn't a case of the North
 13 West Thames Regional Health Authority spending any
 14 money or putting up any money?
 15 **A.** No, on the contrary.
 16 **SIR BRIAN LANGSTAFF:** It wasn't a question of -- was it
 17 a question of cross-accounting? Do you know that
 18 detail?
 19 **A.** I wouldn't know the detail.
 20 **SIR BRIAN LANGSTAFF:** That would be for the finance side,
 21 would it?
 22 **A.** It would be for the finance.
 23 **MS RICHARDS:** We can see the structure discussed. If you
 24 go to page 43, you can see bottom of the page,
 25 paragraph 15.4, Dr Walford says:

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1 Secretary of State?
 2 **A.** Yes.
 3 **Q.** Then in your statement you've given us an overview of
 4 the management and decision-making structure in
 5 relation to BPL. Could we put your statement back on
 6 screen. It's WITN4461001, it's paragraph 15.4.
 7 **SIR BRIAN LANGSTAFF:** May I just check something for my
 8 own in satisfaction? You've said that the BPL was
 9 wholly owned and funded by the Department throughout
 10 the time of which you are aware. It had been the
 11 Lister Institute, had it not?
 12 **A.** Yes.
 13 **SIR BRIAN LANGSTAFF:** Which was not a governmental
 14 organisation as such --
 15 **A.** No.
 16 **SIR BRIAN LANGSTAFF:** -- though it supplied to the NHS.
 17 That arrangement finished in 1978.
 18 **A.** Yes.
 19 **SIR BRIAN LANGSTAFF:** My understanding was that after that
 20 it had been jointly run by the Department and by the
 21 region.
 22 **A.** That's right.
 23 **SIR BRIAN LANGSTAFF:** The region's funding was not
 24 centrally controlled?
 25 **A.** No, but the funding for BPL all came from the

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1 " ... it may be useful to summarise the
 2 decision-making structures at the time."
 3 Then if we go over the page we can see,
 4 Dr Walford, you describe the Central Blood
 5 Laboratories, and it's important to understand that
 6 because we see that phrase used in some of the
 7 documents, which comprised BPL, PFL in Oxford and the
 8 Blood Group reference laboratory. Then until
 9 October 1978, they were managed for the Department by
 10 the Lister Institute. Again, I don't think we need to
 11 trouble you with particular dates but the Department
 12 purchased the site, did it not, from the Lister
 13 Institute around that time?
 14 **A.** Yes.
 15 **Q.** Is it right to understand -- again, I'll pick this up
 16 later, I think but there had been some form of joint
 17 arrangement between the Medical Research Council and
 18 the Lister, I think, earlier --
 19 **A.** Earlier on.
 20 **Q.** Then by the mid-'70s it was the Lister on its own and
 21 then, as you set out here, from October 1978 managed
 22 jointly by the Department and North West Thames
 23 Regional Health Authority. That was only ever
 24 intended to be temporary, wasn't it?
 25 **A.** Yes.

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1 Q. Then there were two committees. I'm just going to
 2 identify them now because we're going to look at
 3 a number of their minutes.
 4 A. Yes.
 5 Q. So there was the Joint Management Committee, chaired
 6 by the Deputy Chief Medical Officer, and then there
 7 was the Scientific and Technical Committee and I think
 8 you are often in attendance at both those meetings?
 9 A. Yes.
 10 Q. So again we'll look at that.
 11 Then you explain how from December 1980 there
 12 was an additional committee, the Advisory Committee on
 13 the National Blood Transfusion Service, and then
 14 various *ad hoc* working parties, in particular in
 15 relation to the redevelopment and aspects of the
 16 redevelopment of BPL. Again, we'll look at those to
 17 the extent necessary.
 18 Then over the page, those *ad hoc* working parties
 19 included, and we see at (iii), a policy steering group
 20 for the redevelopment of BPL -- again, we'll look at
 21 that -- and then you explain in the next sub-paragraph
 22 that in December 1982 the JMC (so the joint management
 23 decision-making structure) was replaced by the Central
 24 Blood Products Laboratories Authority, the CBLA. That
 25 was a special health authority set up by the Secretary

1 It might be 0000005_002, actually, sorry.
 2 So it's draft proof of evidence of Richard
 3 Spencer Lane and, if we go to page 74, I just want to
 4 pick up on a couple of paragraphs. So, 180, Dr Lane
 5 says this:
 6 "The problem was that the basic infrastructure
 7 of BPL remained one which was appropriate to
 8 laboratory engaging in research and relatively small
 9 scale production. The buildings dating back to the
 10 1950s were old, small and not appropriately designed
 11 for manufacturing."
 12 Then he refers to the Medicines Inspectorate
 13 report which we will come on to, and then says:
 14 "... whilst still inadequate, it was now
 15 a facility making a significant contribution to the
 16 increasing requirements of haemophiliacs for
 17 Factor VIII concentrate."
 18 Then if we look at his next paragraph, he sets
 19 out some observations by Dr Maycock from what I think
 20 was Dr Maycock's valedictory statement when he
 21 retired, Dr Maycock saying this:
 22 "There is probably a moral to be drawn from the
 23 building history of the present BPL.
 24 "1954 building: planned in 1949-1952 mainly as
 25 a civil defence project to prepare freeze-dried large

1 of State to manage BPL?
 2 A. Yes.
 3 MS RICHARDS: Sir, that overview brings me perfectly to
 4 3.15, obviously as planned for the break, and then if
 5 we pick up on some of the detail after the break.
 6 SIR BRIAN LANGSTAFF: Yes. Shall we come back at 20 to 4.
 7 So 15.40 -- 20 to 4.
 8 (3.15 pm)
 9 (A short break)
 10 (3.41 pm)
 11 SIR BRIAN LANGSTAFF: Dr Walford, I want to ask you first
 12 a handful of questions about BPL prior to the
 13 Medicines Inspection report.
 14 A. Right.
 15 Q. I'm going to ask you about some matters which pre-date
 16 your time but which you have at least referred to in
 17 a document you authored and which -- you may have
 18 picked up upon these matters from your subsequent
 19 involvement. If you are not able to assist then
 20 obviously you will say so.
 21 So it's really looking at the position by the
 22 second half of the 70s with BPL, in quite general
 23 terms. First of all, looking at an extract from
 24 Dr Lane's draft witness statement.
 25 If we could go, Soumik, to CBLA0000005, please.

1 pool UVL irradiated plasma, the preparation of plasma
 2 which was abandoned during erection of the building,
 3 in favour of a return to freeze-dried ten donor small
 4 pool plasma. The potential value of plasma fractions
 5 had not been appreciated in any countries, and
 6 a combination for fractionation was included own as an
 7 afterthought.
 8 "1962 extension: a make and mend operation,
 9 which by moving the bacteriology and enlarging the
 10 small pool plasma laboratories, relieved some of the
 11 pressures on the laboratory which were becoming
 12 intolerable."
 13 Then:
 14 "1972 extension: this enlargement originated
 15 from the relatively immense need for immunoglobulin to
 16 prevent rubella in exposed pregnant women. Later it
 17 was decided that the plan should include means for
 18 meeting the estimated needs of Factor VIII concentrate
 19 and, later still, that the building should accommodate
 20 means for fractionating all plasma and that
 21 freeze-dried small-pool plasma should be replaced by
 22 albumin and PPF."
 23 He says:
 24 "It was now known that the estimates for
 25 Factor VIII concentrate and albumin concentrate on

1 which the plan was based were totally inadequate.
 2 Planning, completed in 1965, was affected by the
 3 severe constraints imposed by the site and, in spite
 4 of these impediments, reductions in floor space were
 5 nevertheless imposed by the Department."
 6 Now that's one description. I'm not going to
 7 ask you about details of it, but there's a broad
 8 description there.
 9 Now I want to go to a document authored I think
 10 by you which also looks at the position in the 70s.
 11 It's DHSC0002305_011.
 12 Now, if we look at the top, this is a draft
 13 ministerial submission.
 14 **A.** Yes.
 15 **Q.** It was amended quite substantially before the final
 16 submission went to ministers, and we'll look at
 17 a later stage at the final submission, but we can see
 18 someone's handwritten on there "By D Walford
 19 19 [December 1979]", and I think there are other
 20 documents that refer to you producing a draft. So is
 21 it right to understand that this is a document that
 22 you authored?
 23 **A.** When I saw this -- I was given this, I think
 24 I produced quite a bit of what's in the draft, and
 25 I think that top page, which says "By D Walford" is

1 on commercial sources of blood products, particularly
 2 factor VIII, [half a million pounds] was allocated
 3 from Central Funds to Regional Blood Transfusion
 4 Centres to produce more plasma for processing at BPL.
 5 Production at BPL therefore expanded far beyond the
 6 level which had been allowed for in its design and
 7 beyond that which could be considered reasonable for
 8 safe production.
 9 "7. In 1976 the Medical Research Council ceased
 10 to manage the BPL since it was felt that the unit had
 11 become less of a research laboratory and more of
 12 a production unit - in effect, a factory. Management
 13 was transferred to the Lister Institute of
 14 Preventative Medicine, one of whose activities was the
 15 manufacture of vaccines.
 16 "The Lister Institute appeared content to leave
 17 the manufacturing aspect of the BPL almost entirely in
 18 the hands of its director, Dr Maycock (later
 19 Sir William Maycock), who was also Consultant Adviser
 20 in Blood Transfusion to the Department."
 21 Just pausing there, so he was Dr Tovey's --
 22 **A.** Predecessor, yes.
 23 **Q.** "The first intimation that the laboratory had serious
 24 shortcomings followed informal visits by the Medicines
 25 Inspectors in 1977 but Dr Maycock advised

1 probably -- the sort of historical perspective and
 2 discussing what products were being produced was me.
 3 Subsequently I can see bits of this draft that will
 4 have been administrative colleagues and not me. So
 5 I think it was, as often happened, an amalgam, but
 6 certainly that front page will have been me.
 7 **Q.** Well, I only want to ask you about the historical
 8 perspective currently, so that's useful to know.
 9 Bottom of the page, therefore, we can see:
 10 "History of the BPL ...
 11 "In 1952 a unit was set up at Elstree to
 12 undertake research ..."
 13 Go to the next page:
 14 "... and development in the field of blood
 15 products and to manufacture freeze-dried plasma. The
 16 unit was managed by the Medical Research Council but
 17 funded entirely by the Department. Subsequently,
 18 methods of processing plasma were developed which
 19 yielded preparations containing specific individual
 20 components of blood, such as the clotting factor,
 21 Factor VIII. In the 1960s the unit greatly expanded
 22 its rate of production of such products and in 1972
 23 a new unit - the present BPL - was commissioned.
 24 "6. In 1975, following a decision by
 25 Dr David Owen that there should be much less reliance

1 the Department that there were serious doubts that
 2 the Inspectorate's standards for pharmaceutical
 3 manufacture could or should be applied to the
 4 manufacture of blood products. Dr Maycock's views had
 5 the support of several Regional Transfusion Directors,
 6 perhaps because they feared that the same standards
 7 might also be applied to the preparation of various
 8 blood components produced by the Regional Centres
 9 themselves.
 10 "9. Further criticism of the Laboratory's
 11 capability and manufacturing conditions was voiced by
 12 Dr Richard Lane shortly after his appointment as
 13 Deputy Director and Director Designate in 1977. Later
 14 that year, the Department met Dr Maycock and Dr Lane
 15 at the BPL and asked them to begin to plan for the
 16 phased redevelopment of the BPL. More immediately,
 17 they were asked to plan for necessary improvements
 18 (a so-called 'stop-gap' development) which would
 19 remedy the laboratory's worst shortcomings and lead to
 20 an increased output of factor VIII and albumin. The
 21 increased output was felt to be essential since
 22 the BPL was only supplying about one third of the NHS
 23 requirement for blood products, the shortfall being
 24 met by the purchase of costly commercial products to
 25 the tune of several million pounds per year.

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

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

11 Then paragraph 11:

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

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

19 Then paragraph 12:

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

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

6 **A.** That's right.

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

13 **A.** Yes.

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

17 **A.** Yes.

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

20 **A.** Yes.

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

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

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1 anticipated requirements by the Inspectorate for
2 improvements to laboratory."

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

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

10 **A.** Sources, yes.

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

12 **A.** It is.

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

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

20 **A.** Yes.

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

25 **A.** Yes.

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

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

10 **Q.** Dr Waiter is there we can see --

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

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

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

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

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1 fulfil.

2 "Dr Walford asked for the Committee's agreement

3 to withdraw the document entitled 'Standards for the

4 collection and processing of blood and blood

5 components and the manufacture of sterile fluids in

6 the NBTS'. She drew the Committee's attention

7 particularly to the requirements of HSC(IS)144 and

8 recommended that the [Regional Health Authority]

9 should formally designate Dr Lane as the 'person

10 responsible'. Dr Harris pointed out that although the

11 same licensing requirements did not apply to the NHS

12 as to industry, successive Secretaries of State had

13 emphasised that NHS should be required to attain the

14 same standards as manufacturing industry. Dr Walford

15 explained that the procedures which BPL had developed

16 for the manufacture of albumin would require to be

17 approved by the appropriate Sub-Committee of the

18 Committee on Safety of Medicines."

19 Then there's also reference to the possibility

20 of having to seek a product licence for albumin.

21 Then, although there's some markings on this, it says:

22 "Dr Walford said that she expected to make her

23 formal visit to the BPL in April and to PFL somewhat

24 later. Mr Harley asked what the situation would be if

25 Medicines Division recommended changes for which there

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1 I saw what was in that document I really can't

2 comment. I really don't know.

3 **Q.** This appears to envisage that you would be making

4 a formal visit to BPL --

5 **A.** Yes.

6 **Q.** -- and the reference is April. We know April was the

7 medicines inspection visit.

8 **A.** Yes.

9 **Q.** Would you normally be part of a medicines inspection

10 visit? I know you told us about the visit to the

11 States.

12 **A.** Do you know, I don't know whether I was or I wasn't.

13 Clearly, it seemed to imply that I was going to be

14 making a formal visit. I don't think I, on my own,

15 would be making a formal visit. Maybe I was --

16 I accompanied to the Medicines Inspectorate. I simply

17 don't remember at this remove. As I say, I went

18 around BPL quite a bit.

19 This is very early on in my, as it were,

20 relationship with BPL because this is February 1979.

21 **Q.** Yes.

22 **A.** I hadn't actually started in my new job. I didn't

23 even know I was getting a new job in Med SEB. So what

24 it might have been was that I was needing to visit BPL

25 so that I knew what I was talking about if I was asked

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1 was no financial provision. Dr Harris explained that

2 in this case the options would have to be put to

3 Ministers."

4 **A.** Yes.

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

6 **A.** Well, obviously, I seem to be there to provide

7 whatever information I could about the role of product

8 licensing, if you like, of what is required formally

9 under the Medicines Act for Factor VIII or albumin

10 production. I think somewhere later on -- I don't

11 know whether you want to deal with it now -- that

12 I dealt with the whole subject of whether BPL products

13 were formally licensed by the licensing authority but,

14 essentially, I had obviously been invited here.

15 Unfortunately, I cannot remember at all what was in

16 HSC(IS)144. Something to do with standards in blood

17 transfusion centres.

18 The question which was going to be considered

19 was whether the Medicines Inspectorate needed to

20 inspect Regional Transfusion Centres as well as

21 inspecting BPL, and I think that was an issue.

22 I don't know why I might have suggested that the

23 document that was referred to just over the page

24 should be withdrawn but clearly it was accepted by the

25 Committee that it should be withdrawn. I mean, unless

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1 to call upon -- to talk about something by the

2 Inspectorate. But it could have been that I went on

3 the visits. I really can't remember. I don't know if

4 you've got any papers which suggest that I did.

5 I haven't seen any.

6 **Q.** I don't think we've got any one way or another that

7 answers that question, Dr Walford. Don't worry if you

8 can't remember. We'll look at what the inspection

9 report said, in any event, in due course.

10 I just want to ask you next to look at a meeting

11 from March 1979. This is one you weren't at --

12 **A.** Yes.

13 **Q.** -- which is BPLL0008430_001 and we can see it's

14 a meeting of the Scientific and Technical Committee

15 for the Central Laboratories, 26 March 1979. It

16 appears to be the first meeting of the Scientific and

17 Technical Committee. I will come back to the

18 membership of that when we look at some of the

19 meetings you attended but if we go a little further

20 down we see joint secretaries included Dr Sheila

21 Waiter, so your predecessor in Med SEB?

22 **A.** Mm-hm.

23 **Q.** Then if we go to the second page, I just want really

24 to then ground what comes next, look at some of the

25 discussion here. So second paragraph refers to

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

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

8 **A.** Glaxo.

9 **Q.** He was a senior adviser with Glaxo:

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

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

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

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

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1 addressed?

2 **A.** Yes.

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

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

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

17 **A.** Yes.

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

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

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

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

6 **Q.** He says:

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

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

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

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

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1 just before I --

2 **Q.** I'm going to come to that.

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

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

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

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

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

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

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

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

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1 supplies of necessary fractions from external
 2 commercial sources."
 3 So forget NHS product; commercial product only:
 4 "2. Continue production of a proportion of the
 5 country's needs, on one footing or another making good
 6 any shortfall by purchase from commercial suppliers."
 7 So that's, as it were, the maintenance of the
 8 status quo:
 9 "Continued production might be:
 10 "(a) at the present levels of capacity within
 11 BPL, with no further injection of capital and with
 12 expenditure limited to essential repairs and
 13 replacements as they became absolutely unavoidable.
 14 "or (b) at the raised levels to be achieved by
 15 the implementation of the 'Stop-gap' programme but
 16 with no thought of further expansion."
 17 So option 2 is maintain the status quo, perhaps
 18 with some modest improvements. That's my
 19 paraphrasing. Then option 3:
 20 "Bring BPL up to the standards and operating
 21 capacity which one would expect to find in a
 22 purpose-built industrial unit capable of meeting the
 23 entire national requirement for blood products."
 24 So three years, complete redevelopment, and he
 25 goes on, I'm not going to go through the detail of it,

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1 report, but I think it summarises the most salient
 2 points. First paragraph:
 3 "[BPL] was developed in stages over a number of
 4 years as new products were introduced and new
 5 buildings were erected to facilitate their
 6 manufacture."
 7 Paragraph 2 talks about:
 8 "... as production [it] could not readily be
 9 adapted to large scale manufacture."
 10 Then if we just carry on down the page, I'm just
 11 going to alight on some of the points. Paragraph 4
 12 raises an issue about the personnel who had not had:
 13 "... the opportunity to gain experience of
 14 modern large-scale sterile production requirements in
 15 the pharmaceutical industry ...
 16 "5. Production is now on a scale which must be
 17 regarded as a large scale factory-type operation and
 18 has out-grown the premises in which it is undertaken.
 19 "6. The Laboratory is so short of space for
 20 cold storage; quarantine of raw materials, in-process
 21 materials and finished products; receipt and despatch;
 22 packaging; and warehousing generally, that it is not
 23 practical or safe to increase throughput even if the
 24 necessary production facilities were available. For
 25 these reasons it is not practicable to consider

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1 but to set out, in very broad terms, the cash flow,
 2 the economic case in relation to each and, if we just
 3 go to page 4, second half of the page is his
 4 evaluation of option 3, which is complete
 5 redevelopment, and he says, bottom of the page:
 6 "This pattern shows, as might be anticipated,
 7 that there is a rapid and growing return on the
 8 investment with all the capital expenditure paid back
 9 in the first 15 months of full-scale operation."
 10 Essentially he's talking about you'd save your
 11 money that you're spending on commercial concentrates
 12 and that you'd get that money back, put crudely.
 13 **A.** Yes.
 14 **Q.** Do you know whether, when you took over the job a few
 15 months later, did you see Mr Smart's report?
 16 **A.** I certainly saw it. I think I saw it during the
 17 course. I don't exactly know when I saw it but
 18 I certainly saw it probably fairly early on, yes.
 19 **Q.** What was your view of what he was saying?
 20 **A.** He was spot on.
 21 **Q.** Now, we then have the medicines inspection --
 22 Medicines Inspectorate inspection, April 1979,
 23 I think, and then if we look at the conclusions of the
 24 Medicines Division following the inspection, it's at
 25 DHSC0001812. So this isn't the full inspection

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1 a double-shift system of working if it were possible
 2 to employ the appropriate additional staff."
 3 Then this:
 4 "If this were a commercial operation we would
 5 have no hesitation in recommending that manufacture
 6 should cease until the facility was upgraded to
 7 a minimum acceptable level."
 8 Then, over the page, the Medicines Division say,
 9 at the top:
 10 "However, as blood products are essential to the
 11 health and well-being of the nation and as alternative
 12 sources of supply are severely restricted, production
 13 at Elstree may continue provided certain aspects of
 14 the standards of production and control are improved
 15 immediately and that the planning of certain other
 16 essential improvements in these standards commences
 17 immediately with a view to very early implementation."
 18 Then we can see a number of recommendations
 19 first of which is:
 20 "Under no circumstances should production of any
 21 product be increased under the existing manufacturing
 22 conditions.
 23 "... special need for the manufacture of
 24 Freeze-Dried Plasma to be upgraded immediately by
 25 locating it elsewhere on the premises as the present

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

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

8 Next page, halfway down, paragraph 11:
9 "Planning of essential improvements must
10 commence forthwith and, take into consideration the
11 following ..."

12 Then reference to:
13 "The present facility [being] totally unsuitable
14 for manufacture of sterile products and incapable of
15 being upgraded to the required standards.

16 "(b) The existing buildings would be suitable
17 as, or could be adapted for use as ..."

18 Then it describes the kind of facilities that
19 could be, as it were, housed in the existing
20 buildings. Then:

21 "(c) A new factory-type manufacturing facility
22 is required."

23 Then the "Additional comment", bottom of the
24 page, is:

25 "The arrangements originally intended for

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1 **Q.** But what's being described, is this fair, is a state
2 of affairs that wasn't new --
3 **A.** No.
4 **Q.** -- these weren't recent developments --
5 **A.** No.
6 **Q.** -- so it's something that must have been evident as
7 a problem for some time?
8 **A.** I'm certain it was.
9 **Q.** Now, again I just want to look, before we get to
10 Dr Waiter's memo to you as her successor, I just want
11 to look at three other documents, just to take us
12 through the period from the inspection in around
13 April 1979 to Dr Waiter leaving and you joining in
14 August/September 1979.
15 There's a meeting at CBLA0000952 of the
16 Scientific and Technical Committee. So they meet on
17 7 June 1976, and we can see again that Dr Waiter, as
18 your predecessor, was present. If we go to the third
19 page, we've got the heading "The development of BPL"
20 there's reference to Mr Smart's report, which I think
21 is the report we looked at. There's reference to
22 a memorandum by Dr Lane. I'm not going to ask you
23 about that. There's then a discussion about Mr Harley
24 preparing a paper containing the Department's
25 appraisal of the options open to it.

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1 increased production (known as 'Stop Gap Proposals')
2 should be proceeded with as quickly as possible to
3 provide additional cold storage space, warehousing,
4 goods receipt and despatch, container washing and
5 preparation, but only if such a development can be
6 incorporated into a new manufacturing facility.
7 However, in proceeding with 'STOP GAP' there should be
8 no intention of increasing production in the present
9 facility as it is already overloaded and seriously
10 deficient in standards."

11 Then there are some recommendations as to what
12 could be done to address that.

13 So it's a pretty damning report on BPL.

14 **A.** Yes.
15 **Q.** Would you agree it's something which called out for
16 urgent action?
17 **A.** Yes.
18 **Q.** Do you happen to know why the inspection was taking
19 place at that point in time and hadn't occurred
20 earlier?
21 **A.** I don't know. I mean, from what we've said earlier,
22 I think there was some discussion in 1977. I don't
23 know whether there were proper inspections then. I've
24 no idea why the Inspectorate chose to inspect then.
25 I really haven't seen anything that helps.

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1 Then, if we just look at the next paragraph, we
2 can see Mr Dunnill saying that:
3 "[He] thought that further papers would not
4 advance consideration of the problems facing BPL which
5 were already well identified and the options were, in
6 his view, also quite apparent. He wondered whether
7 the better course might be for the Chairman to seek to
8 see the Secretary of State and to express the
9 Committee's disquiet that nothing was being done to
10 put the defects at BPL right. Several members doubted
11 whether there could be a useful discussion with the
12 Secretary of State until the appraisal which Mr Harley
13 proposed to cover in his paper had been carried out."
14 Ultimately, there is an agreement that Mr Harley
15 should go away and produce a paper before the matter's
16 taken further.
17 But would it be right to understand that, at
18 least from the position of, again, the Scientific and
19 Technical Committee in June 1979, they are now perhaps
20 even more concerned that something needs to be done to
21 address this because the medicines inspection has been
22 so damning?
23 **A.** Yes.
24 **Q.** Then if we look at BPLL0008488, again this is before
25 you've taken up the post, so it's 13 June 1979 and

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1 this is a meeting of the Joint Management Committee
2 for Central Blood Laboratories, so Dr Sheila Waiter,
3 your predecessor, is there.

4 But if we go to page 4, we can see about a third
5 of the way down the page there's reference to the
6 Scientific and Technical Committee meeting, which
7 we've just looked at and then if we go to the last
8 paragraph:

9 "The relationship of 'Stop-Gap' [if you have
10 that paragraph, Dr Walford] to the phased
11 redevelopment of BPL was discussed. Mr Harley invited
12 members to consider the advisability of proceeding
13 with Stop-Gap in the light of the medicines inspectors
14 report. The Committee was firmly of the view that the
15 Stop-Gap should go ahead. There was no reason why it
16 should be incompatible with emergency measures to meet
17 those short comings which could not be tackled
18 immediately or with longer term developments. There
19 could be no question of replacing the laboratory for
20 a number of years and the Stop-Gap development was
21 therefore necessary."

22 Then there's a discussion of how it could be
23 funded.

24 So, again, this is really just to place what's
25 happening in context before you become involved. The

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1 So is it right to understand that the Department
2 is saying to BPL no further expenditure until we
3 considered the bigger picture, as it were?

- 4 **A.** It's right to understand that Mr Harley is saying that
5 to BPL.
- 6 **Q.** Yes, you're right to point that out. But it appears
7 from the letter that Mr Harley had or appears to think
8 he had the authority to say that to Dr Lane?
- 9 **A.** Well, I think he probably had the authority because
10 his role was for the finances and the budget for BPL,
11 and he also chaired, whether now or later on, the
12 Finance Committee for which was advising the Joint
13 Management Committee. If I might say so, and I think
14 subsequent papers will show, I think it was perhaps
15 a misunderstanding on his part about how far the
16 stop-gap arrangements would go to improve quality and
17 I think he felt it was in some -- it looks as if --
18 I don't know what he felt but it looks as if he felt
19 there was -- it was a dichotomous position. On the
20 one hand, you did the stop-gap, on the other hand you
21 made the remedial arrangements to fulfil the Medicines
22 Inspectorate requirement, and I don't think that was
23 like that.

24 It was on a continuum and I think there was
25 a lot in the stop-gap proposals that would have gone

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1 Joint Management Committee's view was that the
2 stop-gap proposals and the stop-gap work should
3 continue and then, if we go by CBLA0000955, this is
4 a letter from Mr Harley, dated 13 July 1979, so in the
5 Health Services Division of the DHSS, to Dr Lane
6 confirming a telephone call. He says in the second
7 paragraph:

8 "It is, as you know, likely that a report by the
9 medicines inspectors will require at the very least an
10 upgrading of the facilities at the Blood Products
11 Laboratory."

12 So it sounds as though the full report's not yet
13 available.

14 "You also know that no money has been allocated
15 for this purpose. We do not, of course, know what the
16 cost of upgrading may be but we could find ourselves
17 in a situation where we should have to choose between
18 upgrading and going ahead with the Stop-Gap programme.
19 I therefore think it would be advisable to avoid
20 incurring any further Stop-Gap expenditure until the
21 financial position has been clarified. I need hardly
22 say that this applies also to expenditure on the
23 planning of the phased redevelopment of the BPL.
24 I know what a disappointment this must be to you but
25 I'm sure you will agree it is the wisest course."

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1 a long way towards addressing the Medicines
2 Inspectorate report and, frankly, and even looking
3 back on is this as now I must, it's really hard to
4 understand why that instruction, if you will, was
5 issued, because it did hold things up and it didn't
6 need to in my opinion.

- 7 **Q.** That brings us then to Dr Waiter's memo to you --
8 well, sorry, it's memo to Dr Oliver, copied to you,
9 but it's her reflections moving on from the job.
- 10 **A.** Yes.
- 11 **Q.** So if we go to DHSC0002195_020, so it's dated
12 23 August 1979 -- we don't need to go to the last page
13 yet but that's where the date is -- and we can see
14 it's addressed to Dr Oliver, "Future Supplies of Blood
15 Products". She refers to visiting -- is it Kabi? --
16 in Stockholm, so a Swedish pharmaceutical company?
- 17 **A.** Yes.
- 18 **Q.** And then she says:

19 "This visit, coupled with my imminent remove
20 from Med SM4 [so that's Med SEB] has prompted me to
21 set down some of the problems as I see them of future
22 supply of blood products and possible solutions.

23 "As you know I was interested to visit Kabi
24 because of their involvement in the manufacture of
25 blood products and their interest in extending Kabi

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1 activities outside Scandinavia. They wish to build
 2 a plasma fractionation plant and approach us earlier
 3 to discuss the possibility a) of building such a plant
 4 in the UK and b) fractionating UK plasma on our
 5 behalf."
 6 Then there's reference to some discussions in
 7 April 1979. Then she says:
 8 "It is accepted that in order to meet the
 9 anticipated demand for the principal plasma fractions
 10 (factor VIII and protein solutions - mainly albumin)
 11 new plant, in relation to that already available in
 12 the UK, must be acquired. With this in mind plans for
 13 the future development of the Blood Products
 14 Laboratory have been drawn up. In addition to
 15 increasing production it will be necessary to upgrade
 16 existing plant to meet the requirements of the
 17 Medicines Act. Needless to say any new plant will
 18 have to be built to the same specification."
 19 Just pausing there, do you know what plans she
 20 was referring to when she says "plans for the further
 21 development of the Blood Products Laboratory have been
 22 drawn up"?
 23 **A.** I'm wondering if maybe she was referring to the
 24 stop-gap proposals, but I can't be certain.
 25 **Q.** Then she goes on to say:
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1 a foreign or UK commercial enterprise.
 2 "5. Not to invest in UK plant for the
 3 production of the major plasmas derivatives,
 4 (Factor VIII and albumin) but to rely entirely on
 5 commercial sources, with the exception of PFL, Oxford
 6 and PFC, Liberton who will continue at their present
 7 level of production."
 8 Then we can see she evaluates each of the
 9 options. I'm not going to go through all of it but
 10 I think it is probably quite important to see a lot of
 11 it.
 12 So, option 1 she refers to a paper prepared by
 13 Dr Lane, which I haven't troubled you to look at
 14 today, and then to Mr Smart and she says this:
 15 "The arguments, given the money to invest,
 16 appear convincing but I would question whether there
 17 is sufficient expertise within the BPL, even within
 18 the NHS, to plan, build and commission a plant on the
 19 required scale. If this option is taken up either
 20 staff or suitable calibre and experience should be
 21 recruited to BPL or a firm with the necessary
 22 expertise should be contracted to plan, build and
 23 commission new plant."
 24 So in terms of redeveloping BPL as an NHS
 25 facility, she is doubtful that it can be done.
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1 "There are a number of alternative schemes for
 2 making plasma derivatives available in sufficient
 3 quantities to meet demands of UK clinicians and some
 4 urgent discussions will be necessary.
 5 "To meet the estimated demand several possible
 6 alternative schemes have been described - others may
 7 become apparent."
 8 So she sets out five options:
 9 "1. To invest sufficient money in the BPL,
 10 Elstree to build up its capacity to meet the level of
 11 demand for factor VIII and albumin - production of
 12 other fractions at 'self-sufficiency' levels will
 13 follow for almost all plasma derivatives."
 14 So do whatever you need to do to BPL to become
 15 self-sufficient, in other words, is option 1.
 16 Option 2:
 17 "To re-examine the capacity, present and
 18 potential, at PFC, Liberton and to see whether this
 19 could be developed to meet UK demands."
 20 So, look to see whether you can develop the
 21 Scottish facility and whether they can fractionate
 22 material for the whole of the UK.
 23 "3. To seek a UK firm willing to undertake work
 24 under contract for the NHS and 'without profit'.
 25 "4. To enter into a joint venture with
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1 **A.** Doubtful but has found a way in which it might be
 2 done, and I must say I was sympathetic with the notion
 3 that you should be able to find a commercial company
 4 willing to provide the expertise to run under contract
 5 or to manage under contract this facility for the NHS.
 6 **Q.** Then option 2, and this was the option of looking to
 7 Scotland to help out, she says:
 8 "I have been convinced for a considerable time
 9 that its sensible to make a co-ordinated UK approach
 10 to solving the 'self-sufficiency' problem. Criticism
 11 has been levelled by the Directors at BPL (past and
 12 present) at the plant at PFC, Liberton and on occasion
 13 at the major products. Nevertheless Scotland is
 14 better provided with protein solutions and Factor VIII
 15 than England and Wales. The Medicines Inspectorate
 16 have not yet visited or reported on PFC ... but if the
 17 PFC proves to be satisfactory, or more readily brought
 18 up to the required standards, then we should consider
 19 further investment there, and manufacturing the major
 20 components at PFC ..."
 21 Then just going to the next paragraph:
 22 "Whichever option is pursued DHSS must examine
 23 the potential of PFC, Liberton."
 24 **A.** Yes.
 25 **Q.** Reference is made to some investment that has already
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1 been made.

2 Then if we go to options 3 to 4, so this is the

3 option of -- the options of commercial companies

4 effectively taking over BPL, reference made to the

5 good will of blood donors, so the UK's voluntary

6 donation system, and she talks about the hazards

7 associated with reliance on paid donors being well

8 documented.

9 "If an enterprise outside the NHS undertakes to

10 fractionate plasma on behalf of the NHS then it is

11 believed by many that the good-will of donors will be

12 lost to a significant extent and the Blood Transfusion

13 Service will suffer. This consequence is debatable.

14 It is possible the situation could be avoided if a

15 nationalised UK firm could be interested in

16 fractionating plasma exclusively for the NHS."

17 Then if we just -- sorry, the last sentence of

18 that paragraph is important:

19 "However, at present, no UK firm appears to have

20 the expertise nor the interest to enter the field of

21 plasma fractionation ..."

22 So that's Dr Waiter's observation of the

23 possibility of looking to a UK firm.

24 "... and an alternative might be to interest

25 a foreign firm, some have already expressed an

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1 major problems to which there are no easy solutions.

2 Some have been touched on in this paper. Expenditure

3 of several million pounds would solve a few, but the

4 greater problems would remain: the attitude of blood

5 donors to what they might interpret as exploitation,

6 the lack of expertise in the centres in which we might

7 invest, the attitude of clinicians who look for

8 increasingly large volumes of therapeutic materials.

9 Some clearly have a responsible attitude to their use,

10 others, as in many other fields of clinical practice,

11 wish their demands to be met without question or

12 payment. However, in summary, I believe

13 self-sufficiency can be reached one way or another if

14 the problems can be overcome. Blood donors will

15 cooperate when difficulties are explained to

16 them ... expertise is available in the UK and Europe

17 for planning and building and running a new

18 fractionation plant; clinicians' attitudes can be

19 changed by education and by example or, in the last

20 resort, by the constraints of limited resources."

21 Now, you were -- it doesn't tell us on this

22 document but I think I understand that you were sent

23 a copy of this?

24 **A.** Yes, she gave me a copy.

25 **Q.** We'll look tomorrow morning at an appraisal of options

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1 interest ..."

2 And then she refers to Kabi AB, the Swedish

3 firm, and she says two paragraphs further down:

4 "Again, with careful preparation, I believe this

5 or a similar scheme could be presented in an

6 acceptable way to the British blood donor."

7 Then option 5, next page, which was rely

8 entirely on commercial concentrates, she says:

9 "In the long-term this is unacceptable.

10 Previous ministers have declared their intention that

11 the UK shall be self-sufficient. This policy is in

12 line with WHO principles accepted by all nations with

13 advanced medical care and would probably be the

14 intention of present ministers."

15 Now, I just wanted to pick up on that latter

16 point there. This is August 1979. There had been

17 a general election in --

18 **A.** It was May.

19 **Q.** -- May of 1979, and so it would suggest, I think if

20 this is a fair reading of what Dr Waiter is saying,

21 that she's anticipating that the new Government would

22 endorse the existing policy but is not certain of it?

23 **A.** Yes. That's right.

24 **Q.** And then if we just look at her summary, she says:

25 "To pursue any of the above options will bring

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1 that you yourself came up with a few weeks into your

2 new job --

3 **A.** Yes.

4 **Q.** -- but can you recall what your reaction was to

5 reading this?

6 **A.** Well, this was obviously a very helpful background

7 paper for me. I mean, essentially I was able to use

8 it as a quarry for my later -- I quite early on, as

9 you say you're going to come to tomorrow, made some

10 proposals within the Department to actually be getting

11 on with things, and I used this paper as a very

12 helpful background to my thinking.

13 **Q.** Just going back to something we were discussing this

14 morning, Dr Walford, about, as it were, the blurring

15 of lines between administrative/policy and

16 medical/scientific hierarchies, would you agree that

17 this is a fair comment, that what we've got here is

18 Dr Waiter as a medical civil servant not waiting to be

19 invited to comment upon policy options or limiting her

20 advice to purely, as it were, the medical, she's

21 putting forward a possible policy solution to

22 a problem, is she not?

23 **A.** Yes, she is, but she is putting it forward within the

24 medical hierarchy and, as we come to tomorrow maybe,

25 when I put my suggestions forward it was within the

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1 medical hierarchy, and it was only that I think
 2 Dr Harris picked up what I was proposing and thought
 3 it should go wider. Otherwise, it wouldn't, at that
 4 stage anyway, have occurred to me that I could put it
 5 up and show it to the administrative colleagues as
 6 well.

7 **Q.** So you and Dr Waiter were free to make suggestions
 8 about policy --

9 **A.** Certainly.

10 **Q.** -- directions, but you would ordinarily -- unless it's
 11 a response to an invitation, you would be doing it
 12 within your medical hierarchy so that it could be
 13 taken up at a senior level?

14 **A.** That's right.

15 **Q.** Or more senior level?

16 **A.** Yes.

17 **Q.** And then, just before we leave for today, I just
 18 wanted to pick up upon what she says about clinical
 19 practice in the last two paragraphs. The last
 20 sentence of the penultimate paragraph she talks about
 21 some clinicians having a responsible attitude to the
 22 use of therapeutic materials, others -- sorry, it's
 23 the paragraph before that, Soumik -- others wishing
 24 their demand to be met without question or payment.
 25 So I think perhaps, there, referring to clinicians,

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1 could do except maybe come to the Department and
 2 complain they were not getting the material that they
 3 wanted.

4 There was -- resources have always been
 5 a restraint on clinical expenditure. They are now.
 6 They always were. So that was the ultimate lever, if
 7 you will, and some Regional Health Authorities were
 8 actually rationing the amount of commercial
 9 Factor VIII that they were prepared to provide
 10 compared with other Regional Health Authorities, and
 11 very much depended on particular population of
 12 a particular region and their particular view as to
 13 how much money they were prepared to pay for
 14 commercial Factor VIII.

15 **MS RICHARDS:** Sir, I note the time. I'm going to suggest
 16 now might be a good point to end for the day. There's
 17 a number of documents we'll need to look at in the
 18 morning, including Dr Walford's own, as it were,
 19 response to this.

20 **SIR BRIAN LANGSTAFF:** Yes. There's just one thing which,
 21 if I may, I would like to ask you about. It's
 22 a document we saw. It is a very minor point and it is
 23 just for my understanding.

24 Can we go back, please, Soumik, to BPLL0008488.
 25 It's the Joint Management Committee meeting of

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1 possibly including haemophilia clinicians, who think
 2 they should be able to use whatever products they want
 3 as much as they want?

4 **A.** Yes.

5 **Q.** Then in the last paragraph she talks about how
 6 clinicians' attitudes can be changed by education and
 7 example or, in a last resort, by constraints of
 8 limited resources. So would it be fair to understand
 9 that Dr Waiter's not necessarily saying: well,
 10 clinical freedom must be respected at all costs, we
 11 might be able to influence clinical practice by
 12 education or, if that doesn't work, by limiting the
 13 funding available?

14 **A.** Well, you certainly would hope that you could
 15 influence clinical practice by education. That's the
 16 whole point about medical education, medical training.
 17 You will expect to be able to influence practice. But
 18 of course not universally, not everybody was paid the
 19 same attention maybe to elements of education but
 20 absolutely you would expect that an educational effort
 21 would be helpful.

22 Constraints of limited resources would always
 23 work because you could never actually overcome that.
 24 If, in fact, the region said, "We're not going to buy
 25 X or Y product", there was nothing that the clinicians

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1 13 June 1979. Can we go to page 4.

2 Now, if we just look down to what is said about
 3 the Scientific and Technical Committee -- just stop
 4 there -- let me just see if I can find what I had in
 5 mind.

6 Yes, the largest paragraph just towards the
 7 bottom of the page beginning "the relationship of stop
 8 gap", if we look there there's a sentence which said
 9 there could be no question of replacing the laboratory
 10 for a number of years and the stop gap development was
 11 therefore necessary. It's the use of the word
 12 "laboratory" which just I want to understand. Am
 13 I correct in thinking that at Elstree there had been
 14 both a laboratory facility and a production facility?

15 **A.** Yes. I mean, essentially initially it began life
 16 almost as a research laboratory with a small
 17 production facility associated and, of course, it was
 18 called the Blood Products Laboratory; so I think this
 19 is simply shorthand for BPL.

20 **SIR BRIAN LANGSTAFF:** And the laboratory really hadn't
 21 done an awful lot of work for lack of finance during
 22 the '70s, as I understand it, dwindled off a bit, and
 23 the facilities were quite old.

24 **A.** The facilities were old but they definitely were not
 25 adequate for any larger scale production. It was

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1 really, I think, and was over a period of time, quite
 2 remarkable how much laboratory(sic) BPL managed to
 3 make when it was absolutely not set up to do that.
 4 **SIR BRIAN LANGSTAFF:** The stop gap proposals were about
 5 production, were they?
 6 **A.** Half and half. I mean, they were definitely about
 7 improving quality but largely with a view to
 8 increasing, from memory, the amount of Factor VIII
 9 that could be produced by about 12.5 million
 10 international units after four years. So that would
 11 be after four years they'd have got to an additional
 12 12.5 million international units. So certainly
 13 increasing production but, in the course of increasing
 14 production, a lot of quality improvements would have
 15 been made.
 16 **SIR BRIAN LANGSTAFF:** So when it says there's no question
 17 of replacing the laboratory, the stop gap development
 18 is related to the laboratory, is it?
 19 **A.** The existing laboratory, yes -- the existing BPL.
 20 There was then a thought that as well as doing stop
 21 gap, there should be a phased redevelopment. That was
 22 never really developed in a big way in terms of
 23 planning because what became apparent pretty shortly,
 24 and especially after the Medicines Inspectorate
 25 report, was that actually the only way you were going

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1 to be able to proceed satisfactorily was with a
 2 complete replacement and building a whole new
 3 laboratory.
 4 **SIR BRIAN LANGSTAFF:** Yes. Thank you very much. We'll
 5 take a break there and come back tomorrow at 10.00.
 6 The same rules apply at this break as they do at any
 7 break, of course, but I look forward to seeing you
 8 back refreshed tomorrow at 10.00.
 9 **A.** Yes, thank you.
 10 **(4.36 pm)**
 11 **(Adjourned until 10.00 am the following day)**
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