Wednesday, 23 November 2011

(9.30 am)

DR ROBERT PERRY (continued)

Questions by MS DUNLOP

THE CHAIRMAN: Good morning. Yes, Ms Dunlop?

MS DUNLOP: Thank you, sir. Good morning, Dr Perry.

A. Good morning.

Q. Welcome back. Today we are exploring with you our topic C4, which we have described as the interval between the availability of tests for the Hepatitis C virus in 1989 and their introduction for screening blood in the UK in 1991 -- or, at least, screening blood in Scotland, I should more correctly say.

You have provided a statement on that topic, which is [PEN0172108]. Could we have that on the screen in front of us, please?

In common with other witnesses, you were asked to answer a list of questions and really just to focus on those you felt you could answer. We also asked you to look at pages 272 to 320 in our preliminary report. We, in fact, also sent out an extended narrative of part of the chapter to reflect material additional to that which we had when we published the preliminary report. So I think you had all of that from which to work. Is that right?

A. Yes, thank you.
Q. Right. You were a member of the Advisory Committee on the Virological Safety of Blood --
A. Yes.
Q. -- from its inception?
A. Yes, yes, indeed.
Q. It's really on that particular aspect of this question that you are able, I think, to assist us most.
A. I hope so.
Q. Because you attended -- well, almost all of the key meetings of that body.
A. Yes.
Q. At the beginning of the schedule of questions we asked about the need for the two different groups; that is, the Advisory Committee on the Virological Safety of Blood and the Advisory Committee on Transfusion-transmitted Diseases. You say in your answer that you have no direct knowledge of discussions within the Blood Transfusion Services or the government Health Department which led to the separate evolution of these two committees, but you go on to say, in the next paragraph, that your understanding is that ACTTD was established by the UK transfusion services, in the absence of any other suitable mechanism at the time, to coordinate its professional view on the need for

additional measures concerning the virological safety of blood and any operational research considered necessary to support proposals for new or revised safety interventions. The original intention, as described in the preliminary report, was that it would provide advice to departments of health, either on request or at its own instigation.

We are going to look at some of the documents surrounding the establishment of these two committees with Dr McClelland, who has also commented on this topic, and also with Mr Tucker, who is coming tomorrow to give evidence from an SHHD perspective, so I don't want to take you to all of those.

A. Okay, thank you.

Q. But I wondered, particularly given your use of that term, "The absence of any other suitable mechanism", you thought that ACTTD may have been formed because the transfusion directors felt that not much was happening?

A. As I say, I didn't really have much knowledge of the creation of either the ACVSB or the ACTTD. It was an area peripheral to my main role in the Blood Transfusion Service. But my understanding is, around about that time, 1988 and 1989, the transfusion directors, the UK transfusion directors, largely drawing on the experiences, I think, of HIV and its introduction

of testing, which was -- and HIV testing was the first major change in terms of screening policy within the UK, and I think transfusion directors in the UK felt that it would be better if there was a formal process or a committee that could primarily bring together all the expert views on various subjects, but also expecting there to be quite serious and important discussions around surrogate testing. Indeed, I think it was created around about the same time as Chiron had published the sequence of Hepatitis C.

So there was the prospect of at last there being some sort of test that could detect Hepatitis C. My understanding -- and it is no more than that; I certainly wasn't involved in the discussions -- was that the transfusion directors thought it a good idea to set up an advisory committee. I think the advisory bit was primarily to advise and to bring a sort of collegiate expert view from transfusion experts but also including expert virologists in the UK, but also with a view, as I have said, to advise departments of health on issues that they thought the Department of Health should be acting on.

Now, whether or not ACTTD came before ACVSB, I'm not absolutely sure. I think it probably did.

Q. As you point out, ACTTD did originally see itself as

providing advice to the government departments as well.

A. I think so. I wasn't a member of ACTTD but that's my understanding, listening to discussions or taking part in discussions, primarily within the SNBTS, on the activities of the ACTTD. I think Dr Gunson, who was the chairperson of that committee at the time, was the main interface with the Department of Health.

So I think the ACTTD was also set up to provide Dr Gunson with expert views and expert positions and expert information that he could then transmit to the Department of Health when called upon to provide advice. I think Dr Gunson was the expert adviser to the Department of Health, as well as being the national director of the so-called National Blood Transfusion Service in England and Wales.

Q. Right. Keeping Dr Perry's statement open, could we have a look at another document, please, [SNB0019761]? That is the set of minutes from 24 April 1990, at which there was some discussion of the respective roles of the two bodies and we asked you about that. I think if we look particularly at the end of this set -- so if we could go to the last page, please --

A. Yes, indeed.

Q. You have been asked to look recently at that paragraph, 32.

A. Yes.

Q. So this is 24 April 1990, so just over a year after both committees have started meeting really, there is this statement from the deputy chief medical officer about the respective roles of the two different committees. Dr Gunson, who by this time was on both committees, is to be the recipient of a letter concerning the respective roles and Dr Gunson, in fact, confirming that he shared the view that was being expressed. That is that ACVSB advises ministers, the Blood Transfusion Service committee considers the operational implications of policy and gives the department advice on safeguards against non-viral threats to blood and contributes to the advice on viral safety through input to ACVSB.

Can we go back to the statement, please, your statement, and look at page 2. I think, prompted by noticing that particular passage in those minutes, we wondered if there were difficulties about the boundaries between the two committees. You tell us, in your response -- can we go a little bit further down? -- that you don't recollect the chairman providing an explanation of why he was saying this and you don't remember taking the time or trouble to find out. Then you explain to us what you think underpinned what he was saying.

A. Yes, my response is speculative in that sense, yes.
Q. Right. Your speculation is that the statement was intended to be an assertion of the authority of ACVSB to make policy recommendations and that ACTTD was subordinate to this authority. You say:

"There was obviously overlap between the committees, both membership and agendas, although I do not recall this being perceived as unhelpful. It was more likely that Department of Health officials, including Dr Metters, were concerned that discussions at ACTTD might pre-empt any future decision in principle by ACVSB to introduce (or not) HCV testing."

Do you remember, during that first year or so, any sense of there being an awkwardness or any sense of the two bodies bumping into each other?

A. No, but that maybe is partly because I wasn't closely involved in the work of the ACTTD. I think, just to underline my role on ACVSB, I was there because I was a fractionator, not because I had an expertise in microbiological safety of blood and blood products. I wasn't, as I say, a member of ACTTD.

I think there was possibly a concern by the Department of Health that ACTTD, using the sort of colloquial expression, might be getting beyond itself. I think there was a very great concern held at high

level that the views of ACTTD could be represented or misrepresented as being the policy of the government. I think what Dr Metters was trying to do -- or this was my take on it at the time -- was that he was basically stamping the authority of ACVSB as being the body that provided policy advice to ministers and made the big decisions in terms of policy. ACTTD's job was to implement these policies.

Now, of course, neither can operate without the other, I don't think, and I think, certainly during the first 12 months and, indeed, throughout all discussions on Hepatitis C, there was a vigorous exchange of information between work being done by ACTTD and presented to the ACVSB by Dr Gunson.

I always regarded both committees as being complementary in that sense. I don't think ACVSB could have functioned without the ACTTD, without creating an operational group to explore some of the details that it needed to make its decisions.

Q. Right. Can we go a little bit back up this page, please and note what you say at the top about the emphasis, at the first meeting of ACVSB, on the need for confidentiality --

A. Yes.

Q. -- and that it was considered to be -- ACVSB was

considered to be the authoritative source of advice for health departments and ministers. So that certainly seems to have been the vision for ACVSB set out, right from the start.

A. Yes.

Q. As far as the Transfusion-transmitted Diseases Committee is concerned, you then say that:

"The Transfusion Service directors held the view that a professional group remained an essential source of information and advice for ACVSB".

I took it that your use of the word "remained" was really meant to convey that, even once the Transfusion-transmitted Diseases Committee was up and running and they knew that the ACVSB committee was there too, they felt that there was a continued need for their existence?

A. Absolutely, and for the reasons that I have described, it was very much a body of expert individuals, which I have -- who I have mentioned also in my evidence, were also -- they were represented on both ACVSB and ACTTD. So, in that sense, there was a quite a considerable amount of overlap between the two committees in terms of membership and expertise. But I think -- my understanding from the discussions was that, although we had this ACVSB thing -- which was perceived as slightly

over secretive and the confidentiality being slightly overdone -- then I think transfusion directors, who were responsible for delivering the products and services that they were charged to do, took the view that they needed an expert committee within the UK to consider all the various issues of product safety. Often beyond those which were being considered by ACVSB.

Q. Right.

A. So much of the operational detail, as you will have seen from the minutes of ACTTD, considered the creation of flowcharts, donor counselling algorithms and so on. Much of the detail that made policies actually translate into effective and safe working practice.

Q. Perhaps if I just call them TTD and VSB for short, since they both begin AC; it will save using the five letter abbreviations all day.

TTD, as we saw yesterday, first met on 24 February 1989 and VSB first met on 4 April 1989. So in terms of who was first off the blocks, it was the TTDs who had their first meeting. But in terms of the genesis, as I think we will see when we look at some of the documentation, it might perhaps have been the other way round.

A. Yes.

Q. Can we go further down the page, please, and look at the

question relating to membership. Indeed, I think we can look at a document, [SNB0061922]. This lists the members of the TTD committee in February 1989, I think actually from the top. That document has been prepared in January 1989 and we can see names we recognise.

A. Yes.

Q. In fact, I think the only name we wouldn't know by now is Mr Cosgrove, but we will come to him. Very roughly speaking, three members from Scotland, Professor Cash, Dr Follett and Dr Mitchell, and four from England.

A. That's correct.

Q. Dr Gunson, Dr Contreras, Dr Mortimer and Dr Wagstaff.

A. Yes.

Q. Yes. Can we look at [SGH0031235], please? Go to page 5. This is a submission dealing with the formation of ACVSB and, at that point, the membership, which was envisaged, is as contained in appendix 2, which we can see in front of us. I suppose the first thing to note, since this is a Scottish Inquiry, is that there isn't the same rough parity that there was in TTDs.

A. No, there is a -- there two members from Scotland on the committee, which I guess, in population proportion, is not doing too badly.

Q. Yes, that would be taking us into a whole other range of questions, all of which are interesting but probably not

for today.

A. Yes.

Q. But we can see there is one representative of SHHD in the observer category. In the membership there is you, obviously, from PFC Liberton and there is Dr Urbaniak, and I think for reasons which were not very clear, but we probably don't have to probe, for some reason Dr Urbaniak became Dr Mitchell.

A. It was Dr Mitchell, I don't remember Dr Urbaniak ever attending the meeting.

Q. Dr Mitchell I think was there from the start.

A. I don't think there is anything particularly mysterious about that. Dr Mitchell had a much greater personal experience and expertise in large-scale testing systems compared to Dr Urbaniak. I think he had the right skill set, I think, to do the work.

Q. I didn't, Dr Perry, find it totally easy -- and no doubt this is my fault. I didn't find it totally easy to work out who ended up on VSB. There were a few changes here and there and people arrive in the minutes without there having been any record of their having been appointed as a member of committee or someone else having left.

Perhaps I could try a few other names on you who do not feature on this list but do start appearing in the minutes. Dr Tedder appears from quite early on.

A. My recollection -- and had you asked me without reference to this document, I would say that Dr Tedder was an important, an influential, member of the committee. He was and still is a recognised expert, certainly in terms of infectious disease. He is an expert virologist and certainly had a track record and an interest in the work of the transfusion services. So, yes, Dr Tedder, to my recollection, attended most, if not all of the meetings.

Q. Yes, and Dr Philip Mortimer, who I think must have come instead of Dr Gill, we see there there is a Dr Gill from CDSC. I don't think he or she ever attended.

A. Not to my recollection, but Dr Mortimer certainly did and Dr Mortimer from the Public Health Laboratory Service as it was known then, was again a recognised expert and well regarded individual. So he brought a useful public health perspective to the discussions. He was also an expert virologist with particular interest in the work of the transfusion services. But both of those individuals were also on TTD.

Q. Dr Viner is shown, from NIBSC, but I wonder if that might just be a mistake because I think it was Dr Phil Minor.

A. Yes, it would have been Dr Philip Minor. I think this is a transcription error, or a misunderstanding, by

whoever typed up this document at the time.

Q. Right. As far as the observers go, we see representative for SHHD and in fact that became Dr McIntyre from pretty early on.

A. That's right.

Q. The secretariat, Dr Pickles appears to have moved from the secretariat into the category of observer and a Dr Rejman, was part of the secretariat.

A. Yes.

Q. I just wanted to ask you about the secretariat. Did they contribute to meetings, those individuals?

A. Yes, they were -- certainly Dr Rejman and Dr Pickles -- and I'm trying to recall if there were others -- and Dr Purves from the Department of Health medicines division, certainly involved in the Committee on Safety of Medicines and the licensing of plasma products.

Yes, periodically they were called upon specifically to report on a particular issue, but also took a full part in the discussions of the committee. I think that was probably less the case with the Welsh, the Northern Irish and the Scottish departmental representatives, who tended to be, as they were described there, more observers than participants --

Q. Right.

A. -- but that's not a criticism. That's just an observation on how it worked.

Q. Right. Can we look, just, I think, to fortify our understanding or strengthen our understanding of these early meetings, at [SNF0011219], which is the first VSB meeting, we can see the list of individuals there. Dr Summerfield, he is there as a haematologist. He didn't feature on the suggested list but, by this point, as I was saying, the secretariat has changed and is Dr Rejman and Mr Canavan. Dr Pickles has become an observer.

A. Yes.

Q. Dr Rotblat.

A. Yes.

Q. That's somebody I think you knew from your work --

A. Yes, I had quite a longstanding relationship with Frances Rotblat from the medicines division, primarily through my role in the Committee on Safety of Medicines. She was part of the secretariat of the biological subcommittee on the Committee on the Safety of Medicines. So I had a regular interaction with Dr Rotblat in terms of product licensing and so on.

Q. Right. Just while we are here, as it were, if we have a look at the rest of the minutes: The chairman reminding everybody, at the outset, that their advice on

the subjects under discussion could be publicly sensitive and should not be discussed outside the committee unless specifically indicated. I think that reflects the point you were making about discretion, if not secrecy?

A. Yes, I think the minutes slightly understate what was actually said at the meeting and I remember this -- there are a few moments in one's life that you do remember and I think Ed Harris, who was the deputy chief medical officer at the time, did really underline and emphasise this point, almost threatening you with the tower of London if you were to breach that confidentiality.

Q. Right. Then the terms of reference. The chairman spoke to a paper on the terms of reference and we can see the committee has been set up to give advice to the UK health ministers and then that comment that:

"It was hoped to avoid conflicting views to government from other committees."

Then that attempt perhaps to make the distinction between policy and operation --

A. Yes.

Q. -- and that the committee was dealing with major policy issues and the implementation would be for others.

A. Yes. I think the other committees, just for

clarification, didn't necessarily refer to the TTD. I think it referred to all the various other expert groups that had been established: things like the Expert Advisory Group on AIDS and those government committees, where there is always an element of overlap. I don't think it was specifically referring to TTD at the time.

Q. Right. Can we just look on through the minutes? This is not a meeting at which hepatitis really was dealt with. We can see the other topics on page 3. A lot of discussion of human growth hormone.

A. Yes.

Q. Then, page 4, discussion of the Directive which was to be coming, discussion of testing for HTLV-I and then finally, on page 5 at paragraph 30, the chairman said that:

"Hepatitis could be in the agenda of the next meeting. Members were invited to submit papers."

A. Yes, that's correct. There was no discussion of hepatitis, surrogate testing or candidate HCV tests at that time.

Q. Right. Quite interesting just to glance at an SHHD paper at this point, Dr Perry, [SGH00031228]. This is Dr McIntyre's own note of that first meeting. Have you seen this before? You are complimented in paragraph 1.

A. Yes, I see that, he must have been thinking of somebody

else. I certainly didn't see this at the time. I think this was typical of Dr McIntyre's response to attendance at the meeting. He would return back to the Scottish Home and Health Department and brief colleagues through these minutes and notes that he wrote.

I think that was important because, given the confidentiality of the discussions at ACVSB, I think the role of Dr McIntyre was, he was the conduit for providing information formally from the department down to the SNBTS, when they considered it was necessary for individuals to be briefed. I think again, while we are on that subject, it was important to recognise that I was -- and indeed Dr Mitchell was -- appointed to ACVSB, as was often typical at the time, in our individual capacities, not as representatives of our host or parent organisations.

So it was not appropriate, or it was indicated to us that it was not appropriate for either myself or Dr Mitchell or other members to return from the committee and brief colleagues in SNBTS on the activities of the committee. That was precluded by the terms of confidentiality.

Q. Yes. Professor Cash in his statement on this topic has taken up this point about it being difficult to find out what had been discussed and any decisions that had been

taken. There is, in fact, a separate chain of documentation about that particular issue, about just how far members of the committee could go in discussing what had happened with their colleagues. I'm planning to look at that with him, but I certainly hear what you say, Dr Perry, about that being a concern. You maybe recollect that Professor Cash was troubled by the need to find out what had been discussed?

A. I think so and understandably so. He was the head of the Scottish service. These were important and weighty matters that were being considered and, whilst they might only have been discussed at policy and in principle, that more often than not turned into operational practice. So he was very anxious to understand what discussions were taking place and what processes were in place so he could be in a state of readiness for operational implementation.

Q. Yes.

A. I think Professor Cash always liked to be slightly ahead of the curve, if he could be.

Q. Right. Can we just have a look at that paper, just quickly, to conclude. The rest of it following, unsurprisingly, the same order as the discussion we saw in the minutes. On to the next page, please. Then over the page.

THE CHAIRMAN: Sorry, could we go back to the page before? We see there is a conclusion, the very first conclusion.

MS DUNLOP: I think that's HTLV-I, sir.

THE CHAIRMAN: Oh, that's HTLV-I.

MS DUNLOP: That's the whole discussion of screening for HTLV-I.

THE CHAIRMAN: I picked up one line.

MS DUNLOP: It's difficult when the heading is on the page before, but the reference to hepatitis comes towards the end. Could we go back to page 3 and then on to page 4, please, AOCB. Then page 4:

"It was agreed that hepatitis would be the main subject for discussion at the next meeting."

So that's Dr McIntyre's note of the meeting?

A. Yes.

Q. As you said, that appears to have been his practice, to prepare his own note?

A. I think that was very typical of his response to attending their meeting. He would go back and brief his professional colleagues in the Scottish Home and Health Department and they would then take a view as to whether any specific information or advice needed to be given to the service.

Q. Yes. Just to think a little bit more about the meetings, they appear to have been quite significant

events and to have involved the circulation of quite a lot of reading material in advance. Is that correct?

A. Yes, I think -- I'm not quite sure how the agenda was put together but it was put together, I think primarily by the Department of Health, by the secretariat. They would either seek -- commission, reports to be written on particular subjects, not from an expert point of view but to provide context, for example for HTLV-I testing. They would have brought papers together, either published documents, and then these would form the basis for discussion amongst the so-called experts.

Q. Right.

THE CHAIRMAN: Can you just remind me what Dr McIntyre's position was? Was he a member of the secretariat --

MS DUNLOP: No, he is an observer.

A. He was an observer.

THE CHAIRMAN: So he was not covered by the strictures on confidentiality that applied to you and your colleagues?

A. Well, certainly not within the department itself, not within the Scottish Home and Health Department. I don't think he was allowed to, or expected or permitted to write articles in the Scotsman or anything of that nature, but certainly within his own professional environment, I think the confidentiality really applied to a sort of within government confidentiality.

THE CHAIRMAN: Yes.

MS DUNLOP: One of the things that is noticeable about the different style of the minutes is that VSB, as it said, has these different papers, which have obviously been circulated in advance, and frequent reference is made to them in the minutes. TTDs does, however, have something that VSB doesn't have, which is that, in the minutes, there are initials of people who are, as we say nowadays, tasked with taking action on certain points.

A. Yes, but I think that reflected the different focuses of the meeting. I think the ACVSB's job was to ingather information and expert views and come to a decision, which is what it tended to do. I think ACTTD -- sorry, TTD also operated in that role, but was also an organisation or a body of professionals who would identify the need for additional work, additional studies.

I have given the example of flowcharts, detailed implemental policies, standard operating procedures and so on, which wouldn't have come to ACVSB, but nonetheless were essential elements of implementation of any new development. So ACTTD, again without implying any criticism of VSB, was much more action centred. It did generated a work stream from its meetings, whereas VSB tended to be more reflective on the information that

it gave. If indeed it did require additional works, then it would, more often than not, commission that through Dr Gunson and ACTTD.

Q. I see.

A. So, in that sense, both committees were complementary.

Q. Right. Can we go back to the statement, please and we are now at page 2110. This is still on the question of how the members were actually chosen and you thought perhaps you were nominated by Dr Rotblat in light of your experience on the Committee on Safety of Medicines. That was the biological subcommittee you were on?

A. Yes, I was a member of the biological subcommittee on the Committee on the Safety of Medicines. As I said previously, I worked closely with Dr Rotblat in that committee and this is pure speculation because I would be interested to find out who did nominate me. My best guess is it was Dr Rotblat, but I might be wrong.

Q. Certainly we are finding out many things, Dr Perry, and if we come across the answer to that, we will let you know.

A. Thank you.

Q. You say about the overlap in membership and I think we have established certainly that would cover Dr Gunson, Dr Mitchell and Dr Mortimer?

A. Yes.

Q. Then you say:

"It's not surprising that Dr Mitchell was a member of both committees."

A. Yes, I should perhaps also add in terms of membership, certainly on TTD and fairly frequently at VSB, to the best of my recollection, there were various other people that were invited. Dr Mitchell took his expert technical team with him often to TTD, people like Archie Barr, Mr Archie Barr, who was the laboratory manager responsible for enacting these things.

So its participants often were -- included people that are not specifically members and I think periodically VSB would call in a particular expert to talk about particular subjects.

Q. Can we look now at the second meeting of VSB, and this is actually something we covered, I think, in our question 5, which is not a question you have specifically focused on. I don't mean any criticism by that but just for our information, can we look at [SNB0019416]? This is the second VSB meeting. This is 22 May 1989. Can we move on to the next page, please? Then we can see at the bottom of page 2 there is a discussion of Hepatitis B and then on to following page, non-A non-B. I must say, Dr Perry, I have struggled with the typographical error. Just in

passing. I don't myself see any difference but --

A. I think --

Q. Perhaps there is a typographical error in the typographical error?

A. I think there is a typographical error in the minute identifying the typographical error. I have no recollection of this, but this would be typically Professor Zuckerman, who was understandably and quite rightly so, fairly obsessive about the correct terminology because, you know, a lot of misunderstanding can occur through inappropriate terminology. So he was simply making sure that the record was accurate.

Q. Well, indeed. I think we will come on to see an instance of that later on, which is of slightly more significance. So I certainly won't risk any more derision from my colleagues by spending any more time on this.

THE CHAIRMAN: I don't know. It's fascinating. Is there an answer?

MS DUNLOP: No; no: and this -- perhaps of slightly more substance, this discussion in paragraph 17, about there possibly being two or more viruses causing NANB:

"The Chiron test was estimated to pick up approximately 50 per cent."

22 and a half years ago, Dr Perry. I don't expect

you remember where that 50 per cent came from?

A. I have no idea, I'm sorry. I think it may have come from the observation that the Chiron test only picked up 50 per cent of known infectious donations; therefore, there must be a virus causing the other 50 per cent.

Q. It was the 50 per cent figure actually. I have looked for literature around this time and I could not find anything that said 50 per cent. There are a lot of figures again -- anyway, it has obviously been in someone's mind, 50 per cent.

A. Yes.

Q. Then --

A. There was, certainly, a widely held view that, at that time, hepatitis non-A non-B was not necessarily a single entity. That was fairly well accepted, though not proven wisdom.

Q. Perhaps more significantly, the paragraph 20:

"It was agreed NANB testing should not be introduced into the NBTS, prior to the results of the UK BTS non-A non-B trial. Anti-HB testing was not without problems."

Then 21:

"The department would keep the issue of testing under review. The use of Chiron or surrogate testing would be influenced by Chiron data, once released."

What do you think that means, that sentence:

"Chiron data, once released"?

A. I think this minute is April 1989, isn't it?

Q. This is May 1989.

A. May 1989 the meeting took place. I think that was prior to the formal release. I think the Chiron work and the expectation of them having discovered the sequence of Hepatitis C was coming to be well-known amongst professionals. But I think this preceded, if I'm correct here, the point at which Chiron formally and officially released the data into a peer-reviewed publication.

Q. Well, they did publish in April 1989. It's also interesting, that reference at the end of 17, to testing without recourse to Chiron.

A. I think --

Q. Details were published on 21 April 1989. What I'm wondering, Dr Perry, is is there a feeling at the meeting that it might be possible to make a British test and we won't need the American tests? Do you recollect that?

A. No, I don't recall that being a significant consideration. I think it was simply saying that, once the sequence has been published and that's in the public domain, then it's possible for any organisation to make a clone and develop their own test methodology. I think

that's what's being implied there.

It wouldn't necessarily have to be a British company; it could be from anywhere in the world, but it's simply advising that Chiron didn't necessarily have a global monopoly on this particular test. I think they found that reassuring. I don't think it was a made in Britain argument.

Q. It's just that other providers may enter the market?

A. That's right.

Q. I see.

A. That's my understanding.

Q. Right. Can we go back to the statement now, please? At our paragraph 6 we referred to Professor Cash initiating a study of the new tests. We asked whether the Scottish project was the equivalent of the assessment in England, which had been initiated by Dr Gunson, and your answer is that:

"The Scottish study sought to establish the prevalence of HCV in the Scottish donor population and any geographical variations, which also appeared to be the objective for the study at North London, Bristol and Manchester, but the Scottish study had a series of other objectives."

Actually we looked at these yesterday. I think there are a total of nine different objectives in that

particular project?
A. Yes.
Q. I suggested to Dr Dow it was quite an ambitious project. I don't know if you would agree with that?
A. Yes, but it was quite a powerful group of -- it was quite a powerful database of samples that was available and, I think fairly uniquely in the West of Scotland, they did have these small panels of patient samples and donor samples that were associated with other markers perhaps, that they could use to explore more -- in more depth what the test was actually picking up. I don't think those panels were available in England and Wales at the time.
Q. We did ask whether this was -- I think either the Scottish study on its own or the combination of the Scottish and English studies -- whether that was seen as capable of providing an answer to the question of whether these tests should be introduced. You say you weren't involved in design, execution or analysis of these studies, but you think that that would have been going too far too fast, basically, to put it like that?
A. Yes, I think this was the first time anyone had had their hands on a -- on something that purported to be specific for Hepatitis C. I think the first study would have been more a proof of principle than a decision to

go or not go with a particular test and I think that would have been typical of all these sorts of interventions at the time.

Q. Certainly, if one posed that question in relation to the Scottish study on its own, then, given the background that there was a decision that the UK should move together, then that would not have happened because the Scots weren't going to be taking a decision on their own anyway.

A. Absolutely, I think Scotland always liked to have its own analysis of these important technological advances, but it would have done it with a very enthusiastic and full view that this would contribute to the UK data on the test overall. So it would have been seen as a Scottish contribution to decisions to introduce the test or not and, more often than not, would have gone to ACTTD for discussion.

Q. Right. You refer there to acquiring further in-house operational evaluation, validation and then assessment of wider UK and international experience of its suitability. So international experience was seen as relevant too?

A. Yes, I think SNBTS and indeed the UK services overall would have always had an eye to the rest of the world to learn from other people's experience. That would have

been commonplace and typical, not only in transfusion but in any area of science or medicine. I think the international perspective is always important.

Q. I suppose, insofar as other countries are reporting their experience with this new form of test, there presumably has to be a note of caution because there may be differences in the population?

A. Indeed and I think that's -- if I understand you correctly, that's part of the reason why it's useful to keep a close eye on international developments. There could be a particular subtype or where the test kit is not effective or some such example. I think the point I'm making there is, in response to your question: was this initial evaluation designed or expected to provide a green light for introduction of testing?

I'm just simply saying there were many other considerations before you would do that, even if our small study in Scotland had revealed that it seemed to be effective and there were -- false positives and false negatives were under control and so on. I think if, at the same time, we had learned of an international experience where there were significant issues and problems, then clearly that would have affected our decision to introduce.

Q. Right. Can we move on to the next page, please? We

dealt with a question that we posed in our paragraph 7. I think we were puzzled by another supposed assessment, the assessment of samples of special interest. But you think that the special interest samples were included in the Scottish study.

A. Yes.

Q. Yes. Can we look now, please, at the third meeting of VSB. That's 3 July 1989, [SNB00019513]. We note that Dr Metters is taking over from Dr Harris as DCMO?

A. That's correct.

MS DUNLOP: So he is going to be chairing VSB from now on. Actually here is the answer, I'm sorry, sir. I think sir, it's only you and I who are interested but there is a correction of the correction.

THE CHAIRMAN: I have to tell you that Professor James got it right in one.

MS DUNLOP: Right, yes. So it should have been "anti-HBc" instead of "anti-HBs."

A. They actually are significant differences, certainly to a scientist.

Q. That probably explains the derision, Dr Perry. If we move on through this particular meeting and look at the state of play: human growth hormone and HTLV-I again and then non-A non-B Hepatitis. Reference to a Council of Europe paper stating that anti-HCV testing

alone was not sufficient to eradicate post-transfusion hepatitis. Then a reference to the surrogate testing study. Members are cautioning against the overtly commercial stance of test manufacturers.

A. Yes.

Q. Then interestingly, the Chiron test had been used in first time recipients of 8Y:

"Preliminary results had shown no positives. Most recipients of earlier concentrates were Chiron positive."

I suppose that kind of discrimination would be as expected with a test for the virus?

A. Yes, but I think it was also seen as quite a significant piece of data; that populations which were well understood in terms of their risk of transmission of non-A non-B Hepatitis, as it was at the time -- to have a specific group of patients that were anti-HCV negative and none of the other markers of hepatitis was actually quite a significant -- it wasn't definitive.

It didn't lead to any overarching conclusion but I think it is seen as a very useful piece of data because you had a control group as well, which was those that had been infected and treated with unheated products. So, not just in terms of Factor VIII product, but in terms of evaluating whether this test is really picking

anything up real.

Q. Indeed, yes. Can we look on to the next page, please?

"Dr Mortimer had attended a recent conference and he considered the findings represented a persuasive case that Chiron test results were reliable."

A. Yes.

Q. The chairman is asking for all the data to be compiled and given to the committee for the next meeting.

A. Yes, I think Dr Mortimer was signalling there that he had seen this -- he had -- and I think he was simply signalling to the committee that, in his view, the test was effective, it was real, it was identifying something real. It was -- his most likely guess was that it would emerge as a useful and reliable screening test.

Q. Right.

A. Although he is noting, at that time, that it was ready to go, as it were. He was simply expressing cautious optimism.

Q. Right. At that point the date of the next meeting was expected to be 17 October. So this is the 3 July and looking to 17 October for a discussion. If we can go back to the statement, please, I think we suggested to you that there is no real detectable sense of urgency from this, so -- and I think you really agreed with that observation?

A. Yes, I think I would agree that there was a greater emphasis on understanding the science than there was in saying, "We must introduce a test as soon as possible". That paints it in very stark terms, but that's certainly my recollection. There was certainly no discussion, as I recall from that meeting, of a putative date at which the test could or should be introduced.

Q. Right. We asked also about ACVSB considering commissioning its own evaluation. I think you suggest that they felt -- VSB and the Department of Health felt that there was sufficient expert information coming in, and also that some of those who were on the committee were themselves involved in evaluations anyway.

A. Yes.

Q. So there was no need for an independently commissioned piece of work. Is that right?

A. Yes.

Q. We then went on to ask a little bit more about decision-making and you point out -- I think this is really covering the same ground, but you point out in answer 10 that there was no stated or agreed policy for the introduction of new screening tests. You say:

"Many believed it to be only a matter of time."

Would you have been one of those who, around about the summer of 1989, was thinking it was only a matter of

time before testing for Hepatitis C was undertaken?
A. No, I wouldn't actually include myself in that group. I think I was fairly neutral at that time. As I have mentioned, this wasn't an area of expertise, so I was very much on the learning curve here. But I did come to that view fairly soon after that.
Q. Right. Next page, please. Dr McIntyre is mentioning his understanding that any new test would be introduced simultaneously throughout the UK and we asked about the source of that understanding. I suppose it would be accurate to say that there weren't really any dissenters from that, both in terms of government departments: SHHD and Department of Health, and also the transfusion services in the two countries at that time. The understanding seems to have been that the introduction of any testing would be a common UK move.
A. That would have been my view at the time. That was a given. It was the default condition for obvious reasons that I wouldn't wish to expand on at the moment, but, yes, that was certainly my understanding. I think it was the accepted view of the committee, that this would be a UK decision and implemented in a coordinated manner across the UK.
Q. Right. Then paragraph 11, more correspondence and really I think we were focusing mainly on what might

have been Professor Cash's thinking at that point on timescales. I suppose Professor Cash is wanting to make sure that Scottish centres -- as you say, Scottish centres could be ready, so if a decision were to come, perhaps at quite short notice, to introduce testing, all the practical steps being in place would be very advantageous?

A. Absolutely.

Q. Yes. Then we have paragraph 12, we have reference to a meeting with Ortho in London in August 1989. We have glanced at a letter from Dr Mitchell reporting on that and it would be my intention really to go into that more with Dr Mitchell, since he was there.

A. Sure.

Q. We asked you too about a turnkey system. Can we go on to the next page, please? Your explanation is that a turnkey system is a complete system for testing, including equipment, reagents, precise operating instructions and result analysis. So something that's ready to roll out, clearly?

A. Absolutely, but bear in mind that comes from somebody that has never done a Hepatitis C or other test in his life. That would be my understanding of a turnkey analytical system.

Q. I think it was just our unfamiliarity with the term. We

wondered if someone could explain it.

Dr Mitchell -- again we can ask him about whether the figures he presented were coming from the ongoing work in Scotland.

Then question 13. We asked about the decision-making process, trying really to get a feel for how it could best be described. You have said that the subtle distinctions that we were attempting to draw in our questioning were probably best clarified by SHHD officials.

But you say your impression was that:

"... for all practical purposes the decision and timing of the introduction of HCV testing was led by the Department of Health and in particular by the DCMO."

A. Yes, and I would still take that view now from -- and that was certainly our belief at the time, that this was very much a process that was led by the Department of Health. I'm not aware, and I wasn't aware at the time, that there were detailed meetings between the various health departments to debate the issues for and against Hepatitis C testing, for instance. I think there were probably conversations and discussions about implementation but I think the decision was primarily one taken by -- well, by ACVSB and also the Department of Health people behind the scenes.

Q. Right. You say that:

"Participation or involvement of the ..."

What are sometimes referred to as the territorial departments, the Scottish, Northern Irish and Welsh, departments of health:

"... appeared to be limited to the presence of officials as observers ... at the meetings."

A. Yes.

Q. Then we asked about the formal position and you say that:

"It was understood that a decision by the Department of Health, and presumably English ministers, would be replicated in Scotland."

A. Yes.

Q. Can we go on to the next page, please? We tried to focus on confirmatory testing and the letter that we were highlighting is a letter we looked at yesterday. It's a letter from Dr Cash and others, in The Lancet of 26 August 1989.

So there were various steps that could be taken to, as it were, conduct a second test once a positive screening test had been obtained. I think we have a preliminary understanding that there were seen to be drawbacks with certain types of test which didn't really do anything very different from the first kind of

test --

A. That's right, they were using the same principle --

Q. -- to put it in that very colloquial manner at the moment. Then, 15, we asked about the symposium in Rome and again Dr Mitchell was at that. There were meetings in quick succession in Rome and also in Durham in the autumn of 1989 and Dr Mitchell was at both of those. So it would seem sensible to ask Dr Mitchell and we will do that.

You say in your answer that you think the material already assembled, so the preliminary report, the minutes of meetings, and the judgment from A v The National Blood Transfusion Service Authority:

"... provide a fairly comprehensive account of discussions and events at that time."

The meeting, which was originally intended to take place on 17 October -- that is the next VSB meeting -- was in fact postponed until 6 November. So the fourth meeting didn't take place until then.

I think it's useful if we can look at [SNF0011383], please in relation to that. These are the papers for that meeting. If we look at page -- we can see the agenda there. We can see the same sort of topics: human growth hormone, the EC directive, HTLV-1 and then non-A non-B Hepatitis.

If we look at -- I think it might be easier actually to keep these papers open and look at, as a separate exercise, at a set of minutes which are [SNB0019563]. If we can keep both these documents open, so that we can go between them.

Although the minutes are contained within that set of papers, it looks to have been your practice, Dr Perry, to bundle up the papers for the meeting and the minutes --

A. Of the same meeting, yes.

Q. -- and file it altogether. Is that right?

A. Yes.

Q. If we look at the minutes, one of the things to note is that, in fact, you weren't at this particular meeting, you had sent your apologies. Then, if we move through, I think we really need to look at page 4 of the minutes and we see the discussion of non-A non-B Hepatitis.

So we have Dr Gunson speaking to a paper which was before the meeting, and summarising the meeting in Rome. Conclusions of the BTS committee. I think that means TTDs?

A. Yes.

Q. "... were that the test will detect a viral marker to NANB, a positive test may mean that blood is infected (but not always) and that routine testing for anti-HCV

will reduce NANB. Estimates of the extent of the reduction range from 20 per cent to 60 per cent.

"The problems that were identified were the lack of a confirmatory test and a question mark hanging over the status of the ALT and anti-HBc testing. The recommendations were that routine screening should be introduced only after a confirmatory test becomes available, after the FDA have approved the test and urgent pilot studies have been carried out in this country."

I think we can read for ourselves the summary of the discussion.

A. Yes.

Q. On to the next page. (Pause).

So there is this reference to the need for confirmatory testing, then also a focus on the FDA. The background to this, as I understand it, Dr Perry, is that the FDA would be deciding whether or not to approve the Ortho test?

A. Yes.

Q. This view is recorded that, "It could be difficult if the FDA do not decide in favour of the test."

I suppose we can understand the logic of that; that if the UK had somehow started testing with the Ortho test and then the FDA had said that they didn't approve

it: what would be the position then?

A. Assuming the FDA's negative decision was based on a good premise, but, yes, in any event it would have been difficult -- particularly as the UK didn't, at that time, have any regulatory process for evaluation of these kits --

Q. Yes.

A. -- or diagnostics in general. So, to an extent, the UK and I think other European countries, relied on the FDA licensing of these materials to give it at least a high degree of comfort that it had been through a rigorous regulatory process.

Q. Yes. Then a rejection in paragraph 29 of surrogate testing. But we can see that one of the things to emerge from this meeting is a decision to undertake further studies. So pilot studies to go on in Birmingham, Sheffield and Brentwood to show the feasibility of adding this test to routine practice.

A. Yes.

Q. Can we go back to the papers for the meeting, please. That was [SNF0011383]. Now go to page 19. This is actually Dr Gunson's report, so this is what's being discussed in that section of the minutes we just looked at. The usual sort of introduction about the cloning by Chiron, and this paper, which although I'm calling it

Dr Gunson's paper, was something that had been discussed and approved at the TTD's meeting of 9 October 1989.

A. Yes.

Q. In fact, I think slightly changed as a result of that discussion and this is the final version. So this paper, poses a number of questions, which I think we should just read for ourselves. (Pause).

So seven questions there.

Then on to the next page, please. (Pause).

So just to explain again, Dr Perry, this is from your bundle of papers from the meeting?

A. Sure.

Q. Yes, and this is -- your bundle of papers contains the report that had come from Dr Gunson through TTDs and was being considered at the VSB meeting?

A. Yes.

Q. Your bundle of papers does include a set of minutes as well?

A. That's right.

Q. But I thought it might be easier, for technical reasons, to keep the minutes separate and look at them as a separate document so we are not always scrolling backwards and forwards in this one.

So comments on different tests. In the group of patients defined as suffering from NANBH by clinical

observation, we can see in 3.4 that:

"The tests have shown consistent results. It seems that anti-HCV seropositivity indicates that a patient is suffering from NANBH and that the test is detecting a viral marker associated with NANBH."

A. Yes.

Q. So for diagnostic purposes, the test is proving useful?

A. That would be my conclusion from this report, yes.

Q. Then blood donors:

"Several countries have tested blood donations ... Consistency in the numbers of seropositives usually between 0.5 and 1 per cent. The exception is Italy, well-known for high prevalence of NANBH, where considerably higher seropositivity was found in parts of that country."

A. Yes.

Q. Then on to the next page. Results in the USA. Perhaps unexpectedly showing comparable seropositivity to that found in northern Europe and postulating that there has been a changing pattern of donors following self-exclusion for HIV risk categories.

A. Yes.

Q. Then saying:

"It can't be assumed that all anti-HCV-positive donors will transmit non-A non-B Hepatitis."

And the relationship with non-specific tests. On to the next page, please. Before we leave that page, we should note that the Scottish study is referred to:

"It is estimated that use of the test would have prevented only 21 per cent of cases of non-A non-B Hepatitis."

If we read on.

A. Yes, that was the initial Scottish --

Q. Yes.

A. -- done by Dr Dow.

Q. Yes, we looked at that yesterday. That was the six out of 28 figure in that paper.

A. Yes.

Q. So if we go on to the following page:

"21 per cent of transfusion-transmitted NANBH".

Then some answers to the questions posed. Interesting to see what's said about confirmatory tests, Chiron Corporation have issued a statement. They have said that:

"The question of confirmatory tests has been an issue for several months. The circular argument for a confirmatory approach utilising the same antigen as the screening test has been brought to everybody's attention."

They were pursuing feasibility studies of a RIBA or

HCV --

A. Yes.

Q. -- and were going to provide more information about that. Then the next page, please. Some further comments on non-specific markers.

A. Yes.

Q. Then a section headed "Recommendations". Dr Perry, it's probably important not to overplay this, but this report does contain a specific recommendation about approval, doesn't it?

A. Yes, it does, yes.

Q. Yes.

A. Absolutely, I think it's Dr Gunson who was the -- well, he was the national director of the blood service in England and Wales and his -- and I think what he is saying, he is not saying we are ready to go. He is saying that he has seen enough of this test to demonstrate to him that we should be planning on the basis that the test will be effective and ultimately it will be introduced.

He is basically advising the committee that they should -- well, he is suggesting to the committee that they should take a positive decision, in terms of the policy for introduction, not necessarily with a timescale but simply saying: can we work on this

basis, that this test is going to take place and it will be implemented?

I think for an operational manager, albeit it a high level one, I think that's quite important information to have; to know whether the government or whoever is making the final policy decision is likely to fall one way or another, because there is a great deal of planning required to introduce this and I think his recommendation is that it should.

Q. Noting that, we see that in 7.2, the second recommendation, there is mention of the confirmatory test:

"Every effort must be made to ensure that a confirmatory test is available at the time routine donor screening is introduced."

A. Yes.

Q. Then on to the next page, please. Can we look at the FDA? Not yet licensed by the FDA:

"Routine testing won't commence in the USA until such a licence is obtained. This is expected in the first half of 1990. The routine use of the test in the UK should not commence before an FDA licensing procedure is effected."

Then there is, 7.4, a reference to further pilot studies involving the routine prospective use of the

test in RTCs. It may just be a matter of impression but, having noted that first recommendation that a decision should be taken in principle, it's interesting that, in the minutes in the paragraph 23, which is summarising the recommendations in that very paper, it is said that the recommendations were that routine screening should be introduced only after a confirmatory test becomes available:

"After the FDA have approved the test and urgent pilot studies have been carried out in this country."

A. Yes.

Q. How would you put it? How would you describe the change, if there is one, from the recommendations to what's in the minute?

A. I think the minute simply reflected the discussion of the committee. This was Dr Gunson's, and maybe the transfusion service's view, of how they saw this unfolding and I think the minute, which it might be useful to go back to --

Q. Yes, certainly.

A. -- records a slightly different position and a much more cautious position, advised -- and I don't recall this exactly. This was the meeting that I wasn't at, isn't it?

Q. Yes, it is, I know.

A. So it's no wonder I don't recall it.
Q. I'm sure you read the minutes when they came in?
A. Of course I read the minutes and I knew the -- I knew how the committee worked. My understanding was that Dr Gunson put this view. I think there would be a very influential -- very knowledgeable people, like Professor Zuckerman, Dr Tedder and others who were presumably counselling for a much more cautious approach to this.

I think -- my recollection again is that Dr Metters, as chairman of this, was very anxious that the policy decision should not be taken until it was absolutely clear that all the various details associated with the test had been resolved.

That, certainly, was at slight variance with my own personal view, not that that means a great deal. I thought, fairly early on in the process, that there could have been a point earlier where the government, the Department of Health, had, subject to a number of conditions been satisfied -- that the testing would go ahead. The conditions had been identified and I think they were valid then and they are probably valid now, which is a confirmatory test, FDA licensure and proper operational validation, i.e. making sure the kit works, on a day-to-day basis, by the transfusion services.

But, clearly Dr Gunson's particular position, where he is urging the government to make a policy decision, Dr Metters and the Department of Health and presumably with discussions behind the scenes, I think took a slightly less enthusiastic view --

Q. Right.

A. -- and was very anxious not to send a signal that the government had taken a decision to introduce a Hepatitis C test. But that's my interpretation.

Q. Yes. Dr Gunson then reported back to the next meeting of TTDs, which is on 22 November and I think it's -- just to finish this train of thought -- if we have a look at that. That's [SNB0062041]. We can move on through the minutes, please. We can see what Dr Gunson reported back to the TTDs. So:

"ACVSB had agreed to most of the points put forward in the committee's paper. It was agreed the test was a major step forward."

Then his report of the decision. Certainly there doesn't appear to be, at least communicated by the minutes, any particular dismay that some anticipated step had not been taken at the VSB meeting?

A. No, it was probably an outcome that was predicted and had been, if I may be a little cynical, had probably been rehearsed before the ACVSB took place. I think

everyone knew at that point that the UK was not ready to implement HCV testing.

I think the FDA is important as well, that -- I'm not quite clear in my chronology when -- prior to the FDA granting a licence for the Hepatitis C kit, it would not have been able to export the product, unless under a specific export licence, which I think was -- I'm not sure whether that was -- at which point -- I can't recall offhand --

Q. The export permit is at the end of November.

A. That's right.

Q. So both of these meetings are before --

A. That's right.

Q. -- it is known that the export permit has been granted.

A. That's right. So a decision at this stage to go forward would have been fairly hypothetical because it wasn't known that the export licence would be available. It wouldn't have been possible for any routine use for the UK to receive or for the company to export outside of the US.

I think that position has changed slightly nowadays but at the time that's my best understanding of how it worked. But I think you are right, there was no display, there was no great shock. I think the transfusion services still hadn't -- were absolutely

clear that there was a need for a confirmatory test, for obvious reasons given the knowledge that was accruing about false positives. You needed to have a way of sorting out what were real positives from biological false positives. Without that, the test was dangerous and certainly not in the public interest to introduce. So that was absolutely clear.

TTD and VSB both knew that that wasn't available at the time. Although I think informally everyone saw the direction of travel of this discussion and that it was ultimately likely to move towards a test which was going to be satisfactory in use, but there was much more work to be done.

Q. I suppose what we have is a difference between a decision maker saying, "I will do A once X has happened," and a decision maker who says, "I will not do A until X has happened."

It's a sort of distinction that interests lawyers, but in a practical sense there is probably not much difference between the two?

A. My take on it is that the department is saying: I will not take a policy decision in principle until I know the consequences of that policy decision and at the moment I don't know that there is a confirmatory test, and so on. So, letting the cat out of the bag, as it were and

announcing and making some government policy decision that we will introduce Hepatitis C testing, however you frame that, creates an expectation -- and maybe I'm being a little sympathetic here to the government -- you create an expectation that ultimately may not be deliverable.

Q. Right. So you think --

A. Therefore the Department of Health -- this is an interpretation, this is speculation -- my interpretation is that they were, typically were much more cautious in making, you know, the policy decision than others that were at the operational, sharp end of the practice would have liked.

Q. Would it be to misrepresent your position to say that you think there is a significant difference between the two, but it's explicable?

A. I think there is a difference of emphasis and I think -- I'm sure you will come on to it -- at a slightly later stage. I thought that there was quite compelling evidence to demonstrate that we could have taken the policy decision to introduce Hepatitis C testing earlier than was necessary. But I think there was always going to be a conflict between the operational sharp end of these things and those that are making policy decisions in government.

I think the operational people will always want a much -- an early and definitive view from the government so that they can begin to plan for these things, both in terms of financially, training and operational implementation. But I didn't ever see this as a major difference and certainly, at this stage in the process, this was fairly early on in the process, there wasn't widespread implementation throughout Europe or elsewhere. So, in a sense, we were still ahead of the curve, or certainly on the curve here at least. So I don't think there was great disappointment or hand wringing that Jeremy Metters and his committee had failed to actually deliver the positive result that they had sought.

Q. Let's move along the curve after a break.

THE CHAIRMAN: After a break. If we just step off the curve for a moment, paragraph 5.1 contains Dr Gunson's report of the VSB meeting. The third subparagraph says:

"The ACVSB had noted the need for a confirmatory test, either before or shortly after any routine testing of donations."

That doesn't seem to reflect the decision as ultimately minuted.

A. No.

THE CHAIRMAN: I suppose Dr Gunson wouldn't have seen the

minutes by this stage?
A. He wouldn't have seen the minutes before he submitted his paper, that's for sure.
THE CHAIRMAN: Sorry, he wouldn't have seen the minutes of the VSB, would he?
MS DUNLOP: Between 6 and 22 November, who can say? Do the minutes come out quickly or slowly?
A. Not terribly quickly, I seem to recall.
THE CHAIRMAN: So this, perhaps, is an aspirational account.
A. I think it's a paper put forward to VSB to seek their view on it. I think this was probably written, although Dr Gunson is no longer with us, I'm sure he would say, if he was here, that this was part of a well-rehearsed process that took place between the operational services and the leaders of power, as it were.

So I think this may have been submitted with an expectation that there would still be caution expressed by VSB. But I think overall, as the minute of the ACTTD suggests, I think -- I would imagine they would have been fairly pleased, or reassured that at least we were on the same track here.

THE CHAIRMAN: We will have a break.
A. Thank you.
(11.11 am)

(Short break)

(11.33 am)

THE CHAIRMAN: Yes, Ms Dunlop?

MS DUNLOP: Thank you, sir. We have reached the end of 1989 and we need to go back to Dr Perry's statement, [PEN0172108]. The foot of page 7. We have really dealt with this question with Dr Dow about the dev kit. Go on to the next page, please. You make the point, Dr Perry, that there were, according to SNBTS, significant differences in test sensitivity between the dev kit and later standard manufactured versions.

A. That's my understanding, but not from any direct intervention by myself, just discussions with Dr Dow and others.

Q. Right. 21 goes back to this concept of the Ortho test kit being approved by the FDA. We looked, yesterday, at the information about the grant of an export permit in November 1989. So, even though it hadn't been approved for use in the United States, the FDA had approved it for export.

A. Yes.

Q. Yes. Dr Gunson was notified by Ortho on 27 November. So the FDA approved an export permit, so Ortho was free to make the assay available for screening in the United Kingdom --

A. Yes.

Q. -- if they wanted.
A. I also think -- I think the export licence was also -- I don't wish to underplay that -- I think it was seen as a very strong signal that the FDA licensure was fairly certain. I think an export licence wouldn't be granted without some degree of confidence that the final evaluation was going to be okay.
Q. Right. You have given us an answer to our question about why it was necessary to tie introduction of the test in the UK to approval by the FDA. Perhaps a slightly unorthodox position that there was this licensing regime in America but not in Britain?
A. Yes.
Q. So: how then did the UK position itself in relation to the grant or refusal of a licence in the United States?
You have made the point that we discussed earlier that early introduction in the UK and subsequent refusal by the FDA to authorise routine use in the US would have been awkward, to say the least?
A. Yes.
Q. But I hear what you say about this being an optimistic early signal that this was less likely to happen.
A. Yes.
Q. Now, at this point I would like to look at the meeting of ACVSB on 17 January, which you haven't specifically

rehearsed in your statement. So can we go, please, to the minutes of that meeting, which are [SNB0019657]. This is minutes and papers, actually. This is a long document and the minutes form pages 1 to 9. I'm sorry, no, this is the separate set of minutes and then the minutes are in the other bundle of papers, which I think we need to open up as well. That's [SNF0011491]. Yes, 105 pages. That's exciting.

Pages 1 to 9 in this bundle -- I don't know if it's easier technically for us to do what we did before, to have the minutes open as a separate document and that stops us having to scroll back and forward in this.

So can we keep the minutes, which are 9657 and also the relative papers.

THE CHAIRMAN: Just a minute. I have got a warning notice coming up here about an unhandled exception.

MS DUNLOP: So within the minutes, that is 9657, can we look at 9658, please, so second page. There is non-A non-B Hepatitis, beginning at the foot. Dr Gunson is giving details of the pilot trial financed by the department. Go on to the next page, please. Financed by the procurement directorate in fact. That's the one that involved Birmingham, Brentwood and Sheffield. Then a bit of information about it.

Some aspects to be discussed with Ortho. Then 15:

"It was noted that Ortho were holding a symposium on Hepatitis C in London in February on the same day that Abbott, who were expecting to produce a test shortly, would be holding one in Chicago. Members of the committee would be attending both symposia."

Then something headed "non-A non-B cost/benefit analysis". It does seem really to be a full discussion of the whole topic and the chairman is inviting the committee to address the question of whether the time has now come to introduce routine Hep C testing.

Professor Zuckerman spoke to his paper, which I would like to look at. That is page 21, please. It's a letter, a letter to Dr Rejman and perhaps we shall take a moment to read it ourselves. (Pause).

Then on the second page it gives some recommendations. (Pause).

Putting the matter in a nutshell, at least in his letter, Professor Zuckerman seems to be saying: don't introduce the test until after the FDA decision on licensing?

A. Yes, he has established that as a key milestone.

Q. Yes, that's quite clear from 1. Then what he says about confirmatory testing seems to be a proposal:

"To defer reactive donors until a confirmatory test, or a test for another marker becomes available, probably

within 12 months."

That doesn't seem to be absolutely essential. It looks as though he is saying in his letter that that doesn't have to be actually up and running before screening can be introduced?

A. That's my reading as well, although Professor Zuckerman, from my recollection, was a great proponent of the need for a scientifically robust confirmatory assay, based on an independent method and a different antigen and so on. He was quite consistent about that.

But you are absolutely right, in this particular letter, which responds to a question from Dr Rejman, he is suggesting that you don't need the confirmatory test immediately but you do need to know that one is inevitably going to come forward within the next 12 months. I don't think he is leaving that completely open.

I'm not sure what the -- what a transfusion centre's response to that might be; to build up a large panel of donors who you have detected to be positive for something and you are not -- I think even then there would have been some interesting ethical questions about whether that was an appropriate thing to do or not.

Q. He makes another point in paragraph 2 about cost:

"Projected cost, at least initially, is very high

but considering the overall morbidity of chronic non-A non-B Hepatitis, including the very serious consequences and litigation which would be indefensible, the introduction of screening could not be delayed much beyond FDA approval."

Then pointing to the fact that Abbott are expected to come into the market.

A. Yes.

Q. Looking forward to a more comprehensive discussion.

Then if we go back to the minute, please, at 9659, we can see him speaking to his paper and, in fact, the first note of substance is that he is emphasising problems.

A. Yes, and he is suggesting that there is a problem, specifically to samples that have been frozen and thawed, but also suggests, I think, in his letter that that may not be important or relevant to the transfusion services. I apologise, I'm not sure whether samples taken for microbiological testing are frozen. I don't think they are. I think there is a very specific circumstance in which he is saying that does seem to generate an inordinately high level of false positives.

Q. It was really actually before that, Dr Perry. I was noticing that in paragraph 17 he is recorded as emphasising the problems posed by the lack of

a confirmatory test.

A. Yes.

Q. Which may be slightly different in emphasis from what the letter said.

A. Absolutely. I can only comment from my general understanding and participation in these discussions and often just listening. These were highly authoritative expert virologists and some of the subject matter was certainly outside my competence. But he was certainly a very powerful advocate of the need for a very -- as I have said before -- a very robust confirmatory testing system.

Q. Right. In the next paragraph, where he is attempting to give some figures, he is offering a figure of 5,000 members of the donor population who could be excluded from donating, but 50 per cent could be false negatives. That's not terribly easy to follow, that sentence. It might -- I offer this tentatively, but it might make more sense if it was false positives, not false negatives.

A. A figure of -- I think that's right. I think it should read "false positives".

Q. That was not corrected at the next meeting?

A. No, that doesn't surprise me either.

Q. Maybe that's one that should have been corrected, if

indeed it's a mistake.

A. I'm sure it must mean false positives.

Q. Unless there was a separate sentence where he says:

"50 per cent of the test results could be false negatives."

As a separate problem. I don't know. But anyway, as it's written, it's a little hard to follow.

A. I think it's probably a little late to have this corrected now.

Q. Yes, I wouldn't know how to go about it.

Then paragraph, 20, let's keep an open mind about other tests:

"It was unlikely that the FDA would license the Ortho test in the absence of confirmatory tests and it would be difficult for us to approve a test which was not approved in its country of origin."

A. Yes.

Q. Dr Rotblat also saying it was her understanding that the FDA was unlikely to approve the test at this stage.

A. Yes.

Q. So they are not drawing the same reassurance from the issue of the export permit as you were suggesting a moment or two ago, but their prediction wasn't right, as it turned out.

A. Sorry, which prediction, that -- I think --

Q. The prediction that it was unlikely -- sorry, at the top of this page:

"It was unlikely that the FDA would license the Ortho test in the absence of a confirmatory test ... Dr Rotblat added that it was also her understanding that the FDA was unlikely to approve the test at this stage."

A. That's correct. They were incorrect there and the FDA did license them as two separate -- and again with hindsight that's not surprising. They were two different diagnostic systems, so they would not be provided, sold or authorised as a single kit. Therefore they were two separate products, so they would have been subject to separate regulatory processes.

Q. What seems to come over, from this discussion in the minutes, Dr Perry, is really a lot of different views. Dr Mortimer, we can highlight from paragraph 24 -- he is saying that:

"As the perceived risk is higher than that of HIV..."

Presumably he means in numerical terms or statistical terms?

"... we would be inconsistent in our screening procedure if we did not introduce routine testing... If we began routine use of this test we should soon have a better test to move on to."

Dr Mitchell was concerned about donors. Dr Gunson: "Each centre must now consider how to set up the test and what extra resources they would need."

So more of a focus on the practical, which would be consistent with where he is coming from.

A. I think, in response to your suggestion and, again from my experience of taking part in these meetings, not as an expert but as an attendee at the meetings, I don't think it's quite accurate to suggest that there were widely divergent views. I think these divergent views were on -- I wouldn't say matters of detail, but matters of timing, matters of scientific rigour and what can actually be confidently stated about the test.

I think there was a general undercurrent within all the discussions that HCV testing was, every week that passed, becoming a much more likely, realistic prospect and the most likely outcome was that it would be introduced into the UK.

The difference of opinion was about timing, what needed to be done and what individuals were preoccupied with and Philip Mortimer, who was a public health person, he was quite preoccupied with public health considerations. Dr Mitchell and Dr Gunson were transfusion experts. So they were interested in both donor and patient implications. The government

representatives were interested in government issues and so on.

But I don't think it's correct to say that there were widely divergent views on the basic subject matter, which was whether or not HCV testing should be introduced.

Q. Right. Dr Perry, on a previous occasion you have used the expression "rate determining factor". If that is so, and you are -- and the committee was moving towards the introduction of anti-HCV screening, was there a "rate determining factor"?

A. I think the rate determining factor was, in my view -- and I think reflects -- again reflects the general discussion in the committee -- was that it was basically satisfying the three conditions that had been established for the introduction of HCV testing. That was FDA licensure, the availability of what was accepted as an adequate confirmatory test and proper and full validation and testing of the kits at a routine, operational level.

I'm not sure that's rate determining. I guess the rate determining factor in that was the availability of confirmatory tests.

Q. Right.

A. Because that was a progressive process rather than --

whereas FDA licensure was a point at which it was expected that the product would be licensed by the FDA.

Q. Right. Just to deal with one or two of these points, can we look at page 15, please? That's page 15 of our numbering of the document, rather than the pages at the foot. That's Dr Gunson's report on the pilot trial. So that's the one that had been decided upon at the meeting of 6 November.

A. Yes.

Q. We have seen this before, just to show that that was one of the papers before the meeting of 17 January. The emphasis of this exercise seems to have been more on the practical?

A. Yes.

Q. Is that fair?

A. Yes. That's correct. Its user friendliness, but also there is a epidemiological element to that. That's identifying how much donors are likely to turn positive and so on.

Q. Just to have a quick look at that, if we look down to the bottom and on to the next page. Anything insurmountable?

A. Well, I hesitate to answer that actually because --

Q. All right. I don't want --

A. For very good reasons of competence.

Q. I don't want to take you out of your comfort zone. We also within this -- if we go on to the next page, there is a cost/benefit exercise which I think is also being carried out by Dr Gunson. I don't think this featured particularly prominently. As the paper itself says, it includes a number of guesses, so I don't think we should really spend very much time on it. Perhaps we should just note that it was there.

A. Yes. There may have been quite feverish activity below the water line on this particular topic, but it was never a major topic for discussion at the ACVSB meetings other than recognising that cost was an important consideration in all interventions in blood safety, and medicine generally.

Q. Right. That's between our pages 17 and 20, that paper. We have looked at 21 and 22, which is Professor Zuckerman's letter. There is then a letter from, I think a Professor Elwyn Elias, which doesn't seem to have featured in the discussion, and a long chunk of paperwork about HIV testing. Then, if we look at page 59 on our numbering please. That's a very large tranche, again, of guidelines, which were being discussed, and I think that takes us to the end of the 105 papers to orientate people. There is some duplication, I think, in some of the paperwork.

But what seems to be missing from the minutes is this notion of a recommendation or a decision in principle. Is that a fair comment?

A. Well, I'm not sure. I would have --

Q. Let's go back to the minutes, sorry.

A. If we go back to the minutes. But certainly at that stage the committee had -- well, I think the way it worked was that Dr Metters, who was chairman of the committee, summarised what he considered to be the view of the committee and the committee would then be invited to agree or disagree with his conclusions.

So, in that sense, it was a perfectly robust inclusive process and, at that stage, my understanding is that Dr Metters took the view that there was insufficient evidence or data or information to justify the announcement of a policy decision on Hepatitis C testing.

Q. Yes. I'm sorry, Dr Perry, I should have let you have a look at that section of the minutes. We can see it starting there at the bottom of the page on the screen, paragraph 29 --

A. That's it.

Q. -- and on to the next page.

A. Yes, I think it reflects the mood of the -- certainly the mood of the virologists and the Department of

Health, and again this isn't intended as a pejorative comment but it's saying: scientifically not enough is known yet. So there was quite an emphasis on scientific rigour and wanting to understand the scientific principles and the downsides and the upsides of the test before the government was minded to create a policy decision to introduce testing.

Q. Right. Let's just work our way down that page in its entirety, please (Pause).

We haven't finished looking at the meeting papers, though, Dr Perry, your bundle -- because I think it's your bundle, this.

A. Yes.

Q. Because the other thing we have to look at is our page 10. Is this your note?

A. It certainly looks like it.

Q. It does, doesn't it?

A. It does.

Q. It's the same typeface as all your notes of that period. If we look at the bottom, there is a sort of cryptic reference.

A. "BP", yes, that's fine.

Q. That's you, Bob Perry?

A. That's correct.

Q. 22 January 1990. In our preliminary report we have said

that this is Dr Mitchell's note, but it's your note.

Now, can we go back then up, please, and just see what you were saying.

A. Yes.

Q. It's actually that numbered paragraph 4, "HCV testing."

A. Hm-mm.

Q. Have you looked at this particular note recently?

A. No, I haven't.

Q. I had better give you a minute then.

A. Yes, it's definitely from me. (Pause).

Q. Yes, it has been pointed out to me there is a signature on the next page but I didn't want to presume it was yours, Dr Perry. Although I have seen a signature that looks very like this and had it identified as yours. But -- I don't want to offend you, but it's perhaps not the most legible signature one has ever seen.

A. No, it's not intended to be, no.

THE CHAIRMAN: Could you share it with the rest of us, first of all the bottom of this page, which I have yet to see and then over --

MS DUNLOP: Yes.

A. My goodness.

PROFESSOR JAMES: It looks as if you did the signature writing part of the course that doctors go through.

A. I think that's possible. Or it's just a process of

progressive deterioration.

MS DUNLOP: What's interesting about this, Dr Perry -- you can probably see where I'm going to zoom in -- is the second paragraph in your numbered paragraph 4. Is that a bit more definite than what we see in the minutes?

A. It's a view from my perspective.

Q. Yes.

A. I don't know how I judged whether it was a majority or not. I think what I'm signalling there was the sort of growing inevitability that the test was going to be introduced but it also -- and I think this comes up at the next meeting as well, where a similar position is taken.

I'm not quite sure what I mean by, "Overriding factor was question of product liability". I think it's probably --

THE CHAIRMAN: This is Professor Zuckerman's point perhaps?

MS DUNLOP: Yes.

A. Well, I think Professor Zuckerman used to make many points and they were certainly worth listening to.

I think the issue of product liability was probably to do with a slightly defensive position that, you know, it would be indefensible not to introduce testing and so on. But I think when that was combined or synthesised with the lack of scientific understanding and good,

solid, peer-reviewed data on the performance of the test, I think -- as is recorded in the minutes, the evidence still failed to achieve the critical mass necessary for Dr Metters and apparently the committee and indeed the wider Department of Health, to authorise or recommend the introduction of testing.

THE CHAIRMAN: What I had in mind was the comment, on page 21 in his letter that, "Litigation would be indefensible."

A. That's right.

THE CHAIRMAN: Yes.

A. Yes, that's right.

PROFESSOR JAMES: Could I just ask about your remark below that that says:

"Department of Health indicated that new money would be made available."

Actually the minutes of the meeting. In the penultimate paragraph, Dr Metters states that no new money would be made available, it would have to be met within existing budgets.

A. Yes, I can't explain that. Again this is --

PROFESSOR JAMES: I mean, it may be that there was a conversation around money which Dr Metters didn't wish to have recorded and that your impression is totally correct, if you see what I mean. But, for the record he

wished to say, at that juncture, that no new money was available. Obviously that is compete speculation.

A. I think that's a perfectly feasible proposition that what was discussed at the meeting or informally -- and these notes are not a formal record of formal proceedings, they are informal discussions where I'm bringing back information to colleagues and so on.

PROFESSOR JAMES: Thank you.

MS DUNLOP: It's just that that second paragraph just sounds as though, if a completely independent observer, a fly on the wall, had called it, they would have called it in favour of taking a decision in favour of implementation, the clincher being the question of product liability. That's how it reads.

A. Yes, it does. What I have not recorded is the counter arguments against introduction. So I think what I'm trying to signal here, in what was probably a very hastily written note for -- not with an expectation we would be talking about it now, I hasten to add as well -- but I think it was simply saying, "the proposition is moving forward now that -- and the majority of the committee seem to be in favour of the introduction of testing. However, there are still concerns about the scientific rigour and various other issues that need to be resolved before the Department of

Health is going to give the green light to this."

But I think that's -- if I have written it there, it would have reflected, I think, at least a mood and a position that I was detecting at the actual meeting.

Q. Yes.

A. It certainty wasn't the case that the committee had the discussions and everyone voted in favour of introducing testing, and then the Department of Health went into its back room and changed the decision --

Q. No.

A. -- it was a perfectly competent process and I think -- and I recall Dr Metters always doing that, summarising the discussion and then reflecting it back to the committee and seeking their approval.

Q. I'm sure you didn't vote at all really, did you?

A. No.

Q. No. Right. Let's leave that meeting and look at the next meeting, please, which is 24 April. Can we look at the minutes for it? That's [SNB0019761].

Usual format. That's your writing, isn't it: "Bring forward for 2 July meeting"?

A. Yes.

Q. Yes. On to the next page, please and we find Hepatitis C on the next page. Hepatitis C, Ortho symposium. We saw that referred to. That was in London

in February 1990:

"The abstracts from this symposium had been circulated with the secretariat's comments. Dr Rejman said the overall expression was that the test was not sensitive or specific enough for reliable testing ... Dr Mortimer thought there had been an underlying feeling against screening because of the lack of confirmation ... Professor Zuckerman showed disappointment at the outcome of the symposium ... the non-specificity of the tests being the main talking points."

Dr Rejman was a member of secretariat?

A. Yes, he was a medical officer within the Department of Health, with specific responsibility for blood issues.

Q. Right. Do you know if he came from a transfusion service background or anything like that?

A. I think he was Icelandic in origin and I think he trained in the UK but, no, I don't think he had a -- he may have had a haematology background but I'm not clear on that. He was fairly young. He wasn't -- he didn't have sort of 40 years experience under his belt but he was still very able and very competent and knew the subject matter fairly well.

Q. I would like to look at the Ortho papers, which we have as well. [SNF0011628]. These are the papers from that symposium in London on 8 February 1990 and they have

been sent out as one of the pieces of background reading for the meeting in April. We can see that from the note at the top:

"ACVSB 6/2." The note says:

"We append the Ortho abstracts recently received and supplementary notes. The overall impression, reinforced by informal discussion with delegates is that the test is not sensitive or specific enough and, in the absence of appropriate confirmatory testing, is unable to give data upon which appropriate clinical decision-making can be reliably based."

A. That's a report from Dr Rejman, isn't it?

Q. That was going to be my next question. The format of this bundle, if we perhaps just glance through it, bearing in mind that typeface.

A. Yes.

Q. Can we maybe look at the first few pages to see. The pattern is that there appears a document which looks to be the abstract of a paper by an individual, always prefaced, if we can go back, please, by a paper, a separate paper, in that typeface, which looks to have been something written by somebody in the Department of Health.

A. But it's headed "Professor Howard Thomas, Department of Medicine, Saint Mary's. HCV virus and disease."

Q. It may be that someone from the Department of Health who was at the meeting took notes and went back and typed them up.
A. Yes, okay.
Q. We are speculating, but it seems to make sense.
A. I don't know what the specific content of the meeting was but presumably Howard Thomas, I would expect him to be there, was talking about this and it's quite possible, given the slightly complex reference at the bottom, which does look suspiciously like a Civil Service reference system.
Q. It could be described as "delphic".
A. Yes.
Q. Professor Thomas' paper seems to have been about the disease.
A. Hm-mm.
Q. Entirely to be expected. So if we look at the next page --
A. Yes.
Q. -- we can see what he said. Information about the disease and indeed about the cloning, if we can call it that?
A. Yes.
Q. Then epidemiology, and then on to the next page please, I suppose showing the limited contribution of blood

transfusion to the overall epidemiology?

A. Yes. This certainly wasn't written by Dr Rejman.

Q. I think this is Professor Thomas' abstract.

A. Yes. This is a publication, yes, or an abstract.

Q. On to the next, please. Summary. The virus has been found and a test has been created.

A. Yes.

Q. So that seems to have been his contribution, to speak mainly about the state of knowledge of Hepatitis C --

A. Yes.

Q. -- really. Then, if we go on to the next contribution, please. I think it's actually page 9 -- well, if we go to page 8 we find -- yes, here is the same pattern. This looks to be a note taken by someone else, of the talk and this is Dr Barbara's talk.

A. Yes.

Q. This is interesting because of who Dr Barbara is:

"The original Chiron format was that radioimmunoassay ... and gave much cleaner results ... The Ortho ELISA format too long for comfort in BTS, three hours ... Non-availability of a confirmatory protocol seen as a severe drawback."

A. Yes.

Q. Then, looking at the bits that are underlined, I think technically, the second of the underlined parts:

"Several 'HCV-positive' donors have not transmitted either transaminitis or HCV. How can 'false positives' be addressed, this is of great concern?"

The possibility of insect vectors -- serious possibility.

Then the next page is the actual abstract from Dr Barbara:

"The anti-HCV assay is another step along the path of the very successful but largely unnoticed contribution of transfusion microbiology to preventive medicine and rapid viral diagnosis ... The anti-HCV assay from Chiron and Ortho... has been the turning point of years of frustrating search for the agent of non-A non-B Hepatitis ..."

A. Yes.

Q. Then the validity of the assay dealt with in the next paragraph. And this exercise, which we have discussed already, of looking at patients with haemophilia --

A. Yes.

Q. -- who provide a very neat group to study, "An ideal control", as Dr Barbara says.

A. Yes.

Q. But he goes on to say at the bottom of the page:

"The predictive value of a positive anti-HCV result in a blood donor, in relation to transmissability of

NANBH is still under active study."

Then on to the next page:

"The imminent availability of supplementary recombinant immuno-blots from Ortho diagnostics is very welcome and should reveal if anti-yeast reactivity is responsible for any of the positive reactions with the anti-HCV assay."

Then:

"Alter has reported much better correlations of anti-HCV and PTH (more than 80 per cent) than Reesinck... "

Who had found 50 per cent.

PROFESSOR JAMES: I think that must be where that 50 per cent, that you were alluding to earlier on Ms Dunlop, came from.

A. Yes.

MS DUNLOP: Well, possibly. I'm not sure. Sir, it has been very difficult to find because it's about ten months beforehand that someone is talking. I think we probably need to find the Reesinck work to try and get a feel for where that 50 per cent that was mentioned so much earlier comes from.

PROFESSOR JAMES: Comes from.

A. Yes, I don't know. Without looking at the studies again, it's difficult to explain that.

MS DUNLOP: Yes.
A. But these were patient samples that Harvey Alter was looking at, I think --
Q. Yes.
A. -- rather than donor samples. The patient samples are derived from a group of patients who are known clinically to have had non-A non-B Hepatitis. So you would expect a high correlation between HCV positivity and post-transfusion hepatitis.
Q. Indeed. So these points about serious concern and severe drawback and so on, they don't actually appear in the abstract. I suppose one has to assume that they were made orally by Dr Barbara in his presentation for them to feature in someone's note?
A. Or it's Dr Rejman's personal interpretation of what he was listening to, together with his own views. I think it was a synthesis of views.
Q. Right. There is also an abstract from Dr Philip Mortimer. There are many abstracts in this bundle but the next one I want to look at is the Philip Mortimer one. Can we go to our page 14, please? This is the notes of Dr Mortimer's presentation.
A. Okay.
Q. "No confirmatory tests at present. The Ortho antibody is a late antibody appearing 130 to 150 days

post-transfusion. The presence of antibody does not mean/imply infectivity."

That would be quite surprising as it stands, maybe necessarily needs to be put in there?

A. I think that's right. I think it needs a "necessarily" for it to be more precise in one's understanding.

Q. Yes.

A. But that's simply raising the false positive issue --

Q. Yes.

A. -- and expressing it in a slightly different way.

Q. Yes. Then just looking to the bottom of the note, if we could, please. Some epidemiology and then on to the abstract on the following page. Sorry, that's the end of the note. There is the abstract.

This is quite a big group of contributors, including Dr Barbara --

A. Yes.

Q. -- and Dr Bassendine, whom we have seen referred to before, from Newcastle. Finding an incidence of 0.6 per cent in 10,316 blood donors.

A. Yes.

Q. Various different findings in those with hepatitis. 83 per cent of intravenous drug users, 15 per cent of homosexual men, 6 per cent of patients in a hospital for the mentally handicapped. 9 recipients of untreated

Factor VIII, none of 19 recipients of dry-heated concentrates.

A. That's right.

Q. And the conclusion that:

"Except among certain groups, the prevalence of anti-HCV in England is probably low."

A. Yes, all these measurements are relative, relative to other -- certainly relative to the US.

Q. Well, yes. Then the protection of haemophilia patients.

A. Yes.

Q. Then just to skip over the -- for the record, the following papers are to do with HCV and the drug addict. HCV and tropical studies, HCV and liver cancer. Then there is a paper from Sheila Sherlock, which is something we can look at. This is page 23 on our numbering. The suggestion is that:

"The relationship between anti-HCV and autoimmune chronic hepatitis is due, usually, to a wrong diagnosis. This team suggests that more sensitive tests are required."

I don't know whether that is meant as an absolute or just meant to elucidate the problem in this particular group of patients. Anyway, let's turn over to the Abstract, talking about autoimmune chronic hepatitis.

A. I'm wondering whether Professor James might be able to

help us here. I hazard to make a guess that the symposium was not just about blood safety; it was about the introduction of a diagnostic test for Hepatitis C. So it covered a broad range of potential applications in (inaudible) hepatitis.

Q. It does look to have been probing whether this particular class of patients, namely those with autoimmune chronic hepatitis, would show a high prevalence of anti-HCV.

A. Yes.

PROFESSOR JAMES: That's correct and in fact I have to complement the anonymous summariser because the sentence:

"The suggestion is that the 'relationship' between anti-HCV and autoimmune chronic hepatitis is due usually to a wrong diagnosis."

Turned out to be absolutely correct.

MS DUNLOP: "More sensitive tests are required." Does that mean for the group of people -- we don't know because we don't have the writer of the note. It could mean: for the group of people with autoimmune chronic hepatitis or it could mean for everybody.

PROFESSOR JAMES: People with autoimmune chronic hepatitis had raised globulin levels, which gave a variety of kind of possibly non-specific positive results for a variety

of things. I think that was the problem.

MS DUNLOP: Right.

PROFESSOR JAMES: Then finally, very rarely in Italy and perhaps in Spain, there was a slight relationship between the two and finally, finally -- to confuse things further, of course -- when the liver biopsy histology appearance of Hepatitis C was further clarified, there were a small proportion of individuals whose liver histology looked very like the liver histology of autoimmune chronic hepatitis, although they just did not -- you know, the two diseases are completely separate.

MS DUNLOP: Right. Can we look on to the next page, please? There is that sentence:

"Better tests are needed for the Hepatitis C virus."

A. Yes.

Q. Then I think, just to show two further papers contained in this collection, can we go to our number 27, please? This is hospital diagnosis of HCV:

"A Serological diagnostic test that's accurate and reliable is obviously needed."

Then just looking at the -- well, some figures given:

"Patients tested by this group, 54 per cent positive after 15 weeks, rose to 67 per cent positive at 24

weeks."

Then the last comment:

"The Ortho test is in its infancy, it is not infallible and there are no quality control panels available to check its reactivity."

Then on to the paper, the next page, please. And the following page talking about the findings in groups of patients who are ill, pointing out that the diagnosis of acute disease:

"The diagnosis of acute disease is difficult and no test is yet available for early anti-HCV and/or neutralising antibodies."

Then can we go to our page 32, please? It's a postscript. So there is a second generation test coming from manufacturers who may have Japanese connections. But Chiron are expecting to be in clinical evaluation of their own second generation test in mid 1990. The world market, now worth $237 million. I think we saw a suggestion yesterday it was about $85 million, something like that. Then a pricing strategy:

"Non-US market. The blood donor test, $1.85 and the diagnostic market, $3.35 per test. This dual strategy is at variance with what ..."

I guess that's "procurement division"?

A. Yes, I think that's probably right.
Q. The Blood Transfusion Service had been led to believe --
A. Presumably they are referring to the dual pricing strategy.
Q. Yes.
A. So this was presented at the same time as the report back from the Ortho symposium and --
Q. And included in the bundle of papers you were sent for reading.
A. Included in the bundle of papers, yes.
Q. Then, just 33 to 37, this is a set of guidelines. If we can just look at it, we can see. This document appears in a number of different places and it does appear to be the guidelines from the United States --
A. Yes.
Q. -- planning the implementation of testing.
A. Yes. I think it's an FDA document, I believe but I'm not sure.
Q. Well, or an AABB and ARC document. But this version is a version that we have that's in American because the word "center" is spelt "er". This version is not. So whether it was retyped or whether there were different versions of it produced, I'm not very sure but they do seem to be in the same terms.
I think we can see, if we were to go back -- we will

be going back to the minutes of 24 April 1990 -- this appears to have been the document that Dr Mitchell had brought back from his trip to America, to find out about the Abbott test. He had brought back a set of the guidelines. That's the final pages in this bundle.

A. This document was in preparation for the introduction of the testing in the US.

Q. Yes. If we look at the end of it, so that's our numbered page 37.

A. Yes, I see.

Q. You see there, "American Association of Blood Banks, American Red Cross and the Council of Community Blood Centres, February 8th 1990"?

A. Yes.

Q. Now, it feels like a long time ago that we were looking at the actual minutes. Could we go back to the minutes, please, and we can see that this is the Ortho symposium, the first of the events reported on in the discussion and then the Abbott symposium. I think, at an earlier stage, we assumed that Dr Mitchell had tendered an actual paper on the Abbott symposium, but I think it's more likely that what Dr Mitchell tendered was that set of guidelines. We can ask him if he is able to remember what it was he had when he returned.

The other contribution made, if we just flip on to

the next page of the minutes, please, this is Professor Zuckerman and he has been to a conference, I think, in Houston where he had provided some notes and can we have a look at them, please? I think that's [SNF0011700]. Yes.

Just have a look at what is contained in that. Here we are. Information from Dr Miriam Alter. Then an interesting little table at the bottom of the page. This is from the transfusion-transmitted viruses study in open heart surgery. Number tested, 166 with no hepatitis, however defined, 77 of the group having non-A non-B Hepatitis. Then how many were anti-HCV-positive of those who had non-A non-B Hepatitis, 74 per cent were anti-HCV-positive.

A. Using the first generation test, of course.

Q. Yes. Then on to the next page, please. That figure of 74 per cent featuring in the first conclusion, and then:

"64 per cent of the NANB recipients have at least one anti-HCV-positive donor. This increases to 77 per cent when only anti-HCV positive recipients are considered. Donors without anti-HCV may still be infectious and transmit non-A non-B Hepatitis to recipients. A donor who has been found to be anti-HCV-positive should be excluded permanently from further donations, since anti-HCV titres may fluctuate while the

donor remains infectious."

Then mention of the RIBA and you have written --

A. "But RIBA not available."

Q. Yes I suppose, are you thinking when you wrote that, you may be thinking of in the UK, are you?

A. I'm searching to find an explanation for what that meant. It might have been a note that I was taking during the discussion while the data was being presented at the meeting.

Q. Right.

A. But I can't reconstruct what I actually meant by "RIBA not available". Presumably on those samples.

Q. Yes. Then, just to look at the next couple of pages -- I don't think there is anything --

A. I think actually it means that the 13 -- where it says "not confirmed" is actually, rather than saying they were negative, ie not confirmed, I'm just simply saying I don't think they were tested. I think that's the implication of that note.

Q. Right. Yes. I see, yes. So those who were not implicated were not actually tested, so there is a slight logical flaw in --

A. Yes.

Q. I understand. Then tables about -- including figures on intravenous drug abusers?

A. Yes, indeed.
Q. Then the final page. Now, can we go back then to the minutes, please? There must have been an awful lot to read before the meeting and an awful lot to keep up with at the meeting?
A. Hm-mm, yes.
Q. Do you remember this particular meeting?
A. Well, I do, but not for reasons of -- this is the April meeting, isn't it?
Q. Yes.
A. This is the April 1990 meeting and I remember it, not because the bulk of the information and data which actually would have gone through -- I don't think it would have been discussed in detail. I think Dr Rejman would have presented this as summary, others would have discussed that.

I remember it really for the latter parts, where we were asked to consider whether we thought the time was right to recommend introduction of testing and, as my personal note to Professor Cash and others records -- so I remember it for that. I remember it being the first point at which -- and you may wish to come on to this, of course.

For me I remember the meeting because it was the first point at which I thought that the information

available, the epidemiological evidence available and the test kit performance data to me suggested that there was quite a good case for introduction -- for at least taking a decision in principle --

Q. Right.

A. -- to introduce testing.

Q. I have gone to the external papers, if we can call them that: the Ortho symposium, the guidelines from the Abbott symposium and Professor Zuckerman's conference report, so that we can try to see what it was the members of the committee had been sent, in advance, to read.

A. Yes.

Q. Certainly as far as the Ortho symposium is concerned, Dr Rejman gave a very crisp summary of all of those papers by saying that the overall impression was that the test was not sensitive or specific enough for reliable testing.

Let's work on through the minutes.

A. I think I must be careful what I say, but I think you wouldn't include Dr Rejman amongst those who were the most enthusiastic about introduction of Hepatitis C testing, so that comment was -- that distillation of the symposium in these papers we were only seeing through Dr Rejman's prism.

Q. Right.
A. I'm not suggesting that he was wrong but I'm suggesting that it's only one person's view of the key data that was presented at the symposium and I think others may have taken a slightly more positive view of the data --
Q. And certainly the committee is fortunate to have wide expertise and all of the papers have been sent out to people to read.
A. Absolutely.
Q. And one must presume that they did read them.
A. Absolutely, yes.
Q. Then there is the discussion. We can see:

"Before he opened up the subject for general discussion, the chairman reported that France, Belgium and Luxembourg had introduced routine screening ..."

This is April 1990:

"Italy had introduced the test on a voluntary basis."

We can see for ourselves what the chairman is minuted as having said.

A. Yes.
Q. And then on to the next page. Dr Mitchell commenting, mentioning a report from Harefield Hospital. Professor Zuckerman. He is concerned that the Ortho test had a false positive rate of 50 per cent but the

litigation concerns might force its use.

A. Yes.

Q. Dr Gunson. And Professor Zuckerman is still concerned, a little concerned, that the FDA had not approved the Ortho test.

A. Hm-mm.

Q. Dr Mortimer mooting a further study:

"The Ortho and Abbott tests to be run together in some regional transfusion centres and the positive samples referred for PCR testing. A sample which would produce 50 to 100 reactive donors would be sufficient. Estimated this would require 25,000 to 50,000 donors."

A big study?

A. Yes, but certainly not undoable within -- we are talking about at that time 3 million blood donors in the UK, so it was not an undoable exercise. But a substantive undertaking. But I think also Dr Mortimer was, as I recall, a very practical individual and he was basically saying -- it is recorded in the minute here -- that in principle his belief is that we should introduce testing. The only question is what needs to be done to the tests to make them more reliable and more robust.

Q. Yes.

A. But his advocacy was to take that bold step to a positive decision in favour of testing, rather than

waiting for perfection before you made the policy decision to introduce, as it were.

Q. Then in the chairman's summing up there does again perhaps seem to be missing any decision in principle.

A. Yes. Well, at that point it was quite clear that the chairman took the view, having listened to those at the meeting and having heard the reports, that there was not a justification to recommend to ministers the introduction of a new microbiological test for the blood supply.

Q. Can we just look at the final page of the minutes, please? Also of relevance is Dr McIntyre's parallel note.

A. Yes.

Q. I'm saving your note for last, Dr Perry.

Dr McIntyre's parallel note, which is [SGH0027947]. Bottom of the page, please, "Hepatitis C". Dr McIntyre's recording that:

"It was agreed by those who attended that this was a rather disappointing symposium."

A. That's correct, yes.

Q. Yes. Then Abbott. I think this takes us a little bit further on the question of what it was Dr Mitchell tendered. I think the paper that he tendered was the set of guidelines.

A. Yes.
Q. I think, just to mention, you are not really involved in answering the question about the hornet's nest, but this is the hornet's nest paper.
A. Okay.
Q. So Professor Cash said -- and we will ask him all about it, but he said:

"Ruthven has returned from America with a press release and this has stirred up a hornet's nest."

A. Okay.
Q. Just to link that in for those who were wondering about the hornet's nest.
A. I wasn't in that hornet's nest.
Q. Right. Then we have Dr McIntyre's report of Dr Mitchell's report of Chicago. Then, I suppose, a rather dry sentence at the end of the second paragraph.
A. Yes.
Q. And here we all are.

The chairman's disappointment being noted:

"[The] RIBA was becoming available ... but [costing] £20 per test."

Then:

"... inadequate information to introduce full routine testing ... should be a confirmatory test ...

FDA had not so far licence ... need to investigate the donor panel..."

An even larger study mentioned by Dr McIntyre:

" ... a large pilot study involving 100,000 blood donors."

Well, whatever, a large study either way, and a small committee set up to draw up the protocol.

A. That's right, and, interestingly, that would have been done via ACTTD. That would have been perceived or -- that would have been enacted through the TTD --

Q. Right. Then, just before lunch, let's look at your note, [SNF0011710]. This is 2 May. You set high standards for yourself, Dr Perry; you apologise for the notes being belated on 2 May and the meeting was only on 24 April.

A. Thank you. I knew they would get me into trouble eventually, though.

Q. Can we turn to "HCV testing", at the bottom of the page:

"Main agenda item -- dominated by reports and discussion from academic virologists!"

Exclamation mark! Then on to the next page, please.

Eight bullets.

A. Yes. These are, I guess, the key points that I drew from the meeting --

Q. Yes.

A. -- and the discussions.
Q. And then the conclusion.
A. I think, looking back, it's a reasonably faithful perspective on the discussion and I think I would probably still stand by the last paragraph as well.
Q. Right. It is, of course, the last paragraph that has leapt out at us.
A. Of course, yes.
Q. That's Dr Gunson and yourself?
A. Yes.
Q. " ... felt that there was sufficient data to justify testing now, based on US data suggesting 50 per cent reduction in PTH but the majority and DOH preferred more cautious approach."
A. Yes.
Q. "More details from Dr Mitchell."
A. Yes.
Q. Perhaps we could just let it speak for itself, Dr Perry.
A. I think, other than to -- just some health warnings with it. This wasn't a carefully crafted document; it was intended, and its purpose really, was to provide information to Dr Cash, effectively, because at that time we were still bound by confidentiality and so on. So I chose to make a personal decision to slightly breach that confidentiality, and briefing on matters

that I thought were important.

So it was written, not for a wide audience, but for a very selective audience. But it was my view. And when I say there was "sufficient data to justify testing now", I think that's far too simplistic. What I was actually implying was that I felt there was compelling information available, at least from what I had heard, suggesting that the current technology available had the capability of reducing post-transfusion non-A non-B Hepatitis by about 60 per cent -- this is what I was listening to at the meeting -- and took the view, without going into the deep scientific inadequacies and the flaws and the absence of confirmatory testing, that that suggested to me that we, the committee, should be taking a view now that this is a test that should be refined and ultimately introduced and I thought we were being over cautious in raising these continued scientific concerns as the sole basis for not introducing it.

So it wasn't suggesting that in April 1990 we were ready to introduce the test, it was simply saying that I thought there was enough information available for the government to make a policy decision that we can and should, particularly in the light of the fact that other countries were already beginning to adopt it. We knew

the US was, we knew France and Belgium, Luxembourg and so on were in the process of introducing it and it just seemed to me and, I think, Dr Gunson -- and we both expressed this view -- that we should be advocating a more positive approach than simply saying, "We are still waiting for the science to improve."

Q. Right. Sir, that would be a good moment to break.

A. Thank you.

(1.01 pm)

(The short adjournment)

(2.00 pm)

THE CHAIRMAN: Yes, Ms Dunlop.

MS DUNLOP: Thank you, sir. There are a couple of loose ends from this morning which I would like to clear up, if I could. The first is the reference to the hornet's nest. I think I said that Professor Cash had used the term "hornet's nest". That's wrong, if we look at [SGH0028477]. The context of this is that it's that set of guidelines we looked at, the guidelines for the introduction of testing in the United States. Professor Cash sent it to Dr McIntyre and there is his covering letter, 19 February 1990:

"Dear Archibald, Ruthven has returned from the States armed with the enclosed press statement issued jointly by three bodies that control US blood collection

for whole blood. I thought you should be aware of its existence and contents."

Then there are some manuscript notes. That is Mr Panton saying take it to Dr McIntyre's personal secretary, "Keep a copy for our files."

Then this note at the bottom, which I think is penned by Mr Angus:

"Spoke to Pam Reenay..."

Who is a lady in the department of Health:

"This press statement was copied to Dr Pickles by Dr McIntyre and has stirred up a hornet's nest."

She asked for further info on it, "In particular was the statement issued?"

Just to explain the reference to the hornet's nest, which is in the preliminary report as well.

The other loose end is that we have obviously spent a lot of time looking at the abstracts from the Ortho symposium. They were sent with a covering letter, which is [PEN0160208], if we could have that, please. That's a covering letter from Ortho, dated 26 March 1990. It's relevant to note that it comes from Ortho in High Wycombe, so UK Ortho, if you like:

"To all participants of HCV meetings, please find enclosed a copy of the abstracts."

What is also interesting is the last paragraph:

"I'm pleased to inform you that the Ortho HCV ELISA test is now available from stock should you, or any of your colleagues, be considering placing orders for it."

So that is as at 26 March 1990 and plainly the whole discussion we are having about the possible introduction of screening would have needed kits, so information about when, in time, the kits were available to order must be relevant to that exercise. Can we go back, please, to Dr Perry's statement, [PEN0172108]?

Dr Perry, your numbered paragraph 23 deals with the topic we were exploring before lunch.

A. Yes.

Q. We have looked at that note.

THE CHAIRMAN: Ms Dunlop, could we go back just briefly to the question of the availability of Ortho ELISAs.

Do you know whether, at this stage, these kits would have been used in liver units in hospitals; is this something within your knowledge?

A. No, I don't know the answer to that question, I'm sorry.

THE CHAIRMAN: You can take it that's an inspired question.

PROFESSOR JAMES: I believe the point about this marketing managers thing is -- and we have discussed this before -- that individual units or major hospitals would have been using the Ortho ELISA to test patients with possible liver disease --

MS DUNLOP: Yes.
PROFESSOR JAMES: -- so they would have been in quite a different position. They wouldn't have been, you know, gearing it up for screening, which is -- and furthermore they would certainly have been testing people who were suspect letter of having possibly got Hepatitis C. So they would be a rather specific "high risk group".
MS DUNLOP: Yes. Certainly one of the individuals whose circumstances we examined in March, had a diagnostic test for Hepatitis C quite a long time before screening tests were introduced.
PROFESSOR JAMES: I would be astonished if they weren't using it in the virology labs in both Glasgow and Edinburgh from some time around this. If the test was available, they would have been using it.
A. I think that's probably right, the burden of regulatory evidence and so on for a patient diagnosis system would be much less. I think it would be classified, for instance, as a research kit at that time and doctors would have access to those, but the burden of scientific and regulatory evidence for introduction of a mass screening test for healthy donors would have been at a much higher level. So I think Professor James is probably right. I have no direct knowledge or

information on that.

MS DUNLOP: I think, Dr Perry, we have really dealt with the whole matter covered in your answer 23 that we can see there. I think the answer actually continues on to the following page of your statement, so if we can turn the page. Thank you.

So that was matters as they stood at the end of April 1990. The next document which I would like to look at is the one mentioned in the next paragraph. There are actually two related documents, [SNB0020245], and [SNB0020247], which is the annex to the letter. This is a letter that was sent to you by Dr Metters, the DCMO in England. It's dated 5 June 1990. It does look as though it must have been a circular type of letter.

A. It wasn't just me, it was to all members --

Q. It was to all members, yes. When we left the story just before lunch, there was this large study -- whether it needed 50,000 donors or 100,000 donors is not entirely clear -- but a large study, with a subgroup to devise a protocol for it.

The deputy chief medical officer is wanting to bring forward the next meeting of ACVSB.

A. Yes.

Q. In fact, the changed circumstances are principally that there has been a grant of approval for the test by the

FDA. So one of the matters that had been mentioned in the VSB meetings has been resolved.

Can we look at the other document, the annex then, please? This is a meeting to be held on 2 July. Just to confirm, for the record, that that announcement -- or the licensing of the Ortho test, had occurred on 2 May in America. There is a list of questions annexed to Dr Metters's letter:

"What new information is available about the screening tests themselves or on the use of supplementary (RIBA) and confirmatory (PCR) testing methods?"

You have written. It looks like, "Not well enough validation", is that, "Not well enough validated"?

A. "Not well enough validated."

I don't know -- I am not sure whether that is a reflection of the discussion or whether it was just a note I had made in preparation for the meeting to make that point. I think, at that stage, it would have probably reflected a comment that I would have wished to have made at the time, ie that there was still some work to be done to ensure that, in routine use, these were reliable and effective tests.

Q. Right:

"I'm wondering if the FDA's decision has been

influenced by some scientific or other information which has now become available. Are there advantages attached to either of the tests, Abbott or Ortho in respect of specificity, sensitivity, operational ease of use, cost?"

You have written --

A. :

"Carefully evaluated."

Q. Then:

"If routine testing were to be introduced, what implications would this have for the UK BTS? How would positive findings be dealt with, what supplementary or confirmatory testing would be required, and where would this be carried out? How and when would the donor be counselled?"

A. Yes.

Q. I can't actually remember if this goes on. Is there a further page of this we should look at? Yes, thank you:

"UK BTS are reconsidering their action chart, tabled at the last meeting and will put forward a revised version for discussion. If testing is to be introduced in the UK, should it be limited to whole blood or also extended to plasma donations. Bearing in mind the supposed efficacy of heat treatment ..."

And so on. Sorry, can we go back to the terms of the letter? Dr Metters is saying in the third paragraph:

"I feel the committee need to consider further whether UK blood donations should be routinely screened for Hepatitis C antibody. A special meeting will be devoted entirely to Hepatitis C screening... Events are now moving fast."

That's 5 June. We should also note another letter from Ortho, [SNB0045013]. So this is actually something else which has happened since the last meeting. This is a letter dated 11 May 1990, and this is relating to the RIBA, the Ortho RIBA:

"This exciting new assay is designed to detect the presence of antibodies to Hepatitis C virus in samples that have given a positive result with the Ortho HCV antibody ELISA test."

Can we just look at the rest of this letter? Thank you. It's not very easy to understand for us, Dr Perry.

A. Nor for me.

Q. Right. Fine. Then can we --

A. But what we do know -- it was the long awaited confirmatory assay for Hepatitis C testing and I think it had been subject to an evaluation, so this was one of the key milestones towards making the decision. One

could now tick this particular box, that a confirmatory assay which broadly had the support of the scientific community, was now available.

Q. Yes. There was a bit of discussion yesterday, Dr Perry, about the use of the terms "confirmatory" test and "supplementary". I don't think we want to go there again. But anyway, would it be your field?

A. Goodness me. I think there is a significant distinction, a supplementary assay just adds a little bit of confidence to the original assay, whereas a confirmatory assay is what it says it is. It does what it says on the tin; it confirms that the result is either positive or negative.

So a supplementary assay, for instance, would be repeating the ELISA test in a different manufacturer's test system and seeing whether you get the same result. But it is not a confirmatory test in the same sense that a RIBA is; that uses a different technique and different antigens to actually carry out the analysis. So I think there is a difference, but I have no particular wish to debate it in any great detail.

Q. Thank you. Excuse me a moment. (Pause).

Would it be correct to say that a confirmatory test has a higher specificity?

A. Yes.

Q. Or a good one?
A. A good one. Certainly a higher one than -- in my lexicon I would say that a confirmatory assay has a much greater utility for its purpose than a supplementary assay.
Q. Right.
A. I'm trying to think of a good analogy but I can't come up with one quickly.
Q. I think we were trying to manufacture different analogies yesterday afternoon, but I don't think we should waste our time --
A. Certainly the view in Scotland was, I think -- and again this is not from a personal expert position -- but in the various discussions that were proceeding at this time, I think latterly in this process in Scotland we took the view that even the RIBA wasn't a perfect test system for confirmatory testing. Our preference was the use of PCR testing, which is actually detecting the virus itself. But I think that was later on in the chronology.
Q. Right.
A. For us that was the gold -- that became the gold standard for confirmatory testing.
Q. I see. Can we just look at the next page of the letter, please? This is quite a technical letter really. It

becomes steadily more technical as you read on. Ortho are saying that:

"The solid phase and the conjugate used in the RIBA assay are different from those used in the ELISA."

A. That's correct, yes.

Q. They said:

"There was the addition of a second antigen, expressed in a different organism."

A. That's right. So it increases its specificity quite substantially.

Q. Right. Then the last page, please. I think is there one more? Yes, there we are. Interesting to note the pricing.

So really a lot more expensive than the basic screening tests?

A. Yes, but intended to be used on far fewer donations, obviously.

Q. Yes.

A. But it became significant if you had a screening assay that was generating large numbers of false positives. Apart from the operational difficulties of handling such -- this cost difference may have become significant but I don't have enough information on that.

Q. Right. So can we move on then to the next meeting. This is the meeting of 2 July and its minutes are

[SNF0011705]. That's the agenda, obviously.

A. Yes.

Q. Then we see the minutes there, and you were there.

A. I was, yes.

Q. The chairman is reiterating the confidentiality of the committee's proceedings and then, paragraph 5, Dr Rejman was asked:

"To summarise the course of events since the last meeting in April, resulting in the necessity of a reconsideration of the committee's decision."

There is that reference to the FDA decision to approve Hepatitis C screening and that America had already introduced screening and other countries were following:

"More studies had been carried out confirming that Hepatitis C testing reduced infection and RIBA was now available as a supplementary test."

Let's avoid going there, shall we?

A. Yes, I can see Professor Zuckerman behind that particular minute.

Q. Right:

"It was now felt that a study along the lines of those talked about in April was no longer viable and the meeting had therefore been brought forward so that a decision on the introduction of UK Hepatitis C testing

could be reached."

A. Yes.

Q. Then on to the next page, please. There is Professor Zuckerman's comment in paragraph 7.

A. Yes.

Q. He is now thinking it was time for the screening to go ahead:

"There is still concern about the subject of counselling anti-HCV-positive ..."

Donors, I imagine:

"...Very difficult public relations exercise." He felt that, "The screening test should be introduced as a public measure ..."

And you have written in -- I think that's your writing --

A. Yes, "Public health measure", yes.

Q. "After further discussion, the committee concluded that they should recommend to ministers that Hepatitis C testing should be introduced in the UK. But that first a pilot study using the Ortho and Abbott tests was necessary to decide which was the better test for the regional transfusion centres."

Then there is reference in paragraph 9 to the fact that Wellcome are developing a test.

A. Yes.

Q. Then there had been prepared a protocol for the comparison exercise.

A. Yes.

Q. Dr Gunson is discussing that. Some more practical issues.

Then on to the next page, testing of plasma, which is obviously a matter of interest to you. Then the heading, "Pilot scheme to compare the Abbott and Ortho tests." Cost was discussed. Then:

"It was estimated that the overall timescale for the study would be approximately four months after finance had been agreed."

A. Yes.

Q. Then the chairman sums up. In the fourth bullet:

"The decision as to which Hepatitis C test to use will be made after the results of the Ortho and Abbott tests are known."

That seems perhaps to be straying into the territory that I had understood to be covered by ACTTDs. Is that -- or --

A. Yes, I agree. I know the boundaries between these two committees did become blurred. But I agree, that's -- but I think the -- the analysis would have been done by TTD and people involved in that and that recommendation would have been taken to VSB, where a decision would

have been homologated or approved or --

Q. There is there that decision in principle, really, the first bullet:

"The UK should introduce Hepatitis C testing."

A. Yes. But importantly it doesn't mention a date. It's really just establishing the principle.

Q. Yes. In fact, to be strictly accurate, this is the committee's recommendation --

A. Yes.

Q. -- that the UK should introduce Hepatitis C testing.

A. That's right.

Q. That's a recommendation to government.

A. Yes.

Q. In view of that in paragraph 21, it's recorded that:

"A submission outlining the committee's recommendations would be put to ministers for their approval."

It's actually coming under the heading of the pilot scheme but I think it is probably meant to relate to the whole thing.

A. I think it does actually.

Q. Yes.

A. It was always the case at these meetings that Dr Metters always emphasised that the views of the committee were advisory. It was an advisory committee and it didn't

have the final say. So it always carried the caveat that ministers may or may not agree.

Q. Yes. Can we go back then to the statement, please? In paragraph 29 you are covering this particular meeting.

A. Yes.

Q. I suppose what struck us when we were looking at this, is the letter is suggesting -- that's the letter of 5 June, the circular letter -- is suggesting that because the changed circumstances, the study that had been decided on in April might no longer be appropriate.

A. Hm-mm.

Q. But the outcome of the meeting of 2 July is that there is to be another study.

A. Yes, I think they had different objectives, these two studies. I think the first study, which was the 50,000 or 100,000 donors, was to actually get a better idea of the performance of the Ortho kit, whereas this study was to try and differentiate any performance characteristics of the two candidate tests; the Abbott and the Ortho one, to see if there was a clear benefit in using one or either/or both of them. So I think they had slightly different -- and this was a much smaller -- my understanding is this was to be a smaller evaluation.

Q. Yes.

A. I think that would have been a perfectly sensible and

responsible thing to do. I think there was this problem that both the kits identified two quite distinct and different populations of positive donors, although they overlapped to a considerable extent, but only to the extent of about 50 or 60 per cent. So I think it was an attempt to see whether there was any particular weighting in favour of one test or another --

Q. Right.

A. -- and also to get some operational experience of using these kits at fairly large-scale.

Q. You did say, Dr Perry, getting experience of the Ortho test; you mean Ortho rather than Abbott?

A. Well, both.

Q. Right. I was just thinking Abbott was more of a newcomer.

A. It was, that's right, but my understanding is that this was a comparative trial. As I said in my statement:

"Useful to identify any problems or advantages associated with the large-scale routine operational use of both tests."

There could have been information gathered on false positivity rate, ease of use, robustness, cost and so on that may have led to a conclusion that one of the tests was superior to the other in our particular population. You could argue -- well, perhaps this has already been

done in the US but I don't think we had access to these data. In any event, the epidemiology was different in the US and also I think we always have to bear in mind that this was only about 12 months on from having discovered the Hepatitis C virus in the first place.

So I think understanding the complex epidemiology was certainly not as well advanced then as it is now. So I think this notion of wanting to evaluate tests that had already been evaluated in the US sounds a bit overkill now, but at the time -- I think there is always a possibility that our particular population, with its peculiar and local epidemiology, may have produced different results.

Q. I should have said -- I don't think it's necessary to go back to the minutes but paragraph 10 of the minutes does record that the three centres, North London, Newcastle and Glasgow would each be performing 3,500 tests. Initial positive results would be identified and repeated against both the Ortho and Abbott tests. Repeat positives were to go to Drs Mortimer, Tedder, and Follett for supplementary testing in their specialist laboratories by the Ortho RIBA and the Abbott confirmatory test procedure, followed by PCR.

A. That's right.

Q. So that was the plan. That study did begin, although it

took a little bit longer than four months. We suggested that the outcome, being that each centre was to be free to make its own choice, might mean that the time taken for this study was wasted and you think the answer to that is not necessarily.

A. Well, for the reasons I have described before, I think there was some -- whether or not it needed to take four months or whether it was done in reasonable time, I can't comment on, I wasn't involved in the design, the execution or the analysis of the studies. But the notion of doing a -- such a trial, I would suggest, from my perspective, seemed sensible, reasonable and professionally valid.

Q. Right. Can we look then at the next meeting, VSB meeting which is 21 November 1990. I should perhaps point out that there is quite a significant gap in the chronology of the meetings of ACTTD. They met on 16 March 1990 and then didn't meet again until 8 January 1991. So that's why we haven't been looking at them.

But here we are on 21 November and similar format. Then, on the second page, a reference to Hepatitis C testing. Dr Gunson is introducing a paper on the results of the pilot study and also papers from Dr Tedder and Dr Mortimer, results from Glasgow were not

yet available. I think we can actually probably come back to that because we were a bit puzzled with Dr Dow yesterday as to the end point of this study and I think there is a separate report relating to Glasgow, but we will not go to that at the moment.

A. Yes.

Q. Then Professor Zuckerman is saying:

"The study was very worthwhile and encouraging, but [he felt that] it was impossible to choose between the two screening tests because of the discordant results."

The figure being quoted from France and Germany by Professor Zuckerman. He is saying that:

"Studies in France and Germany, where the HCV screening tests had been used extensively in combination with surrogate tests, only identified 30 per cent of post-transfusion hepatitis. The committee agreed it was important to start screening as soon as practicable as a measure which would further enhance the safety of the blood supply."

A. Yes.

Q. Then a bit of reassurance, in paragraph 11, about the size of the problem of counselling donors. Really quite a bit of this meeting actually is discussing practicalities.

A. Yes, it does.

Q. Yes. It goes on to talk about counselling on the next page. In fact, before that we should note paragraph 18, where the chairman is summing up as he generally does. The chairman summed up the discussion by saying that:

"There was agreement that the UK should introduce Hepatitis C testing as soon as practicable. RTCs would decide individually whether to use Ortho or Abbott test."

And so on. If we just move to the end of this -- counselling, and then there is a section on anti-HB core testing and then other discussion which doesn't really relate to the topic we are discussing.

Two parallel notes of this meeting. The first is Dr McIntyre's, [SGH0028501].

A. Yes, I think that accurately records the --

Q. So --

A. -- discussions.

Q. Dr McIntyre is saying that the:

"The chairman started by referring to his summing up on 2 July ... The meeting went on to consider a comparison of the tests using the Abbott and Ortho kits ... Glasgow played an important part in this study."

The 69 samples appear to have gone to all three of the laboratories participating:

"All 69 repeatable positive samples were referred to three specialist laboratories. There then followed a long and detailed discussion about the results of the highly specialised tests."

A. Yes.

Q. Then donor counselling. Then this figure again:

"Other causes of non-A non-B hepatitis. Routine testing for Hepatitis C would only reduce the incidence by 30 per cent. This was considered a valuable contribution."

A. Hm-mm.

Q. Then on to the next page. Dr McIntyre's summary.

A. Yes.

Q. Yes.

A. Importantly, I'm not quite sure who were the "some" that wanted to start forthwith, whether that was Dr Gunson -- I think at this stage, having established that the policy or principle of introduction of testing, it wasn't for me to have a view on when it should be introduced. It wasn't part of my operational responsibility and so on, but it may have been others, such as Dr Mortimer, that were advocating a very rapid introduction, now all the criteria for introduction of the test had been met.

Q. Yes. Dr Perry, because it now becomes more of

a practical exercise or an operational exercise, I'm not really going to take you through all the steps in 1991 that led to the screening finally being introduced. We can do that with others. But it is interesting to note from this meeting note that the date that was being discussed was 1 April 1991.

A. Yes, indeed.

Q. Dr McIntyre has that in his note.

A. Yes, and that came from the chairman, so presumably that was the chairman having rehearsed that date with officials within the Department of Health to make sure that that was a viable and particularly sensible date.

Q. This may be me, but I can't find that in the actual official minute of the meeting.

A. No, it might not have been recorded. But --

Q. Just a conundrum.

A. I think if Dr McIntyre had put that in, he would have heard it. I think that would be an accurate recollection of a comment or a particular point that had been made. I think it was probably edited out of the minute for very good reasons of government caution; that it didn't want to record in that particular minute any particular date, before that date had been properly discussed and validated and so on.

Q. Then there is a letter also from Dr Mitchell. This is

[SNB0053696]. Dr Mitchell reported back to Professor Cash.

A. Hm-mm.

Q. We can see again -- no doubt Dr Mitchell would be technically disappointed not to have the results from Dr Follett.

A. Yes.

Q. Somewhat belatedly we will be able to show them to him tomorrow. I guess he has seen them in the interval?

A. I think he has been waiting a long time.

Q. Yes.

PROFESSOR JAMES: He is blaming Edinburgh for the delay in the results, I note.

MS DUNLOP: Yes.

A number of different bullets made by Dr Mitchell in his letter, to keep Dr Cash informed.

A. Yes.

Q. Then, on to the second page. We can see reference to Ortho introducing a second generation test.

A. Yes.

Q. Much discussion on counselling.

It's possibly worth recording that that 30 per cent figure about prevention of 30 per cent of the cases, did undergo some further scrutiny. If we look -- I don't think it's necessary to go to it, but the minutes of the

meeting of ACVSB on 25 February 1991, which are [SNB0018934]. Professor Zuckerman appears in effect to be saying he wants to confirm the percentage of post-transfusion hepatitis cases identified by HCV screening in combination with surrogate tests in France and Germany. The ultimate figure given for that is in fact 70 per cent. So just to mention that at the moment, without necessarily --

A. Certainly my recollection -- and again not from an expert position but I thought 30 per cent was quite low and I think it was subsequently raised to -- the figure I have in mind is 50 or 60 per cent.

Q. Yes. Anyway -- so that is the November meeting and the reports back from Dr McIntyre and Dr Mitchell. We note that reference to the 1 April 1991.

A. Hm-mm.

Q. Then can we go back to the statement, please? We are now on page 2116. We asked about submissions going in line with what was said in the minutes, submissions going to government. There is quite a long narrative by us and I think that's something that we can explore with Mr Tucker, if we look on to the next page.

A. Yes.

Q. We also asked about the commencement of testing by Newcastle. I think that question may actually not be

accurate, in that I don't know that the actual testing began in Newcastle until July 1991 but, at any rate, Newcastle did start their testing ahead of other centres.

A. They did, yes.

Q. We will look at that in more detail with other witnesses.

A. Yes.

Q. Then you have given your answer on really the whole matter of whether individual areas, individual centres, could have, as it were, done their own thing.

A. Yes. Well in a practical sense I think my response is yes, it would have been possible for different parts of the UK services, for all sorts of different reasons, to have gone at different times in terms of state of readiness. So from a practical viewpoint, yes, it would have been possible, I think, for the SNBTS to have gone in -- on the original date of April. I think we were in a reasonable state of readiness by then.

But underpinning the whole exercise was this UK --

Q. Common start date.

A. -- common start date. So I think there is different answers from different perspectives. From a practical, political, management perspective, I think the idea of SNBTS going ahead outside of this common UK start

position -- maybe I'm being unimaginative, but I can't imagine how that could have been made to work without causing a major problem.

We wouldn't have had the authority from the Scottish Home and Health Department to do that. We wouldn't have had the authority from the Department of Health, so I can't begin to imagine the circumstances in which that might have occurred. You know, there were funding issues as well from the Scottish Home and Health Department and so on. So I think, from a practical point of view, Scotland happened to be -- as a result of its really quite vigorous involvement in this whole activity -- ready some time before 1 September. But in a practical sense, in a management sense, I'm not quite sure that we could have opted out of a UK common start date.

THE CHAIRMAN: Dr Perry could I ask you just a little about the sentence dealing with the Glasgow centre? What you say in inverted commas was, "The extended study".

A. Yes.

THE CHAIRMAN: Did the 50 per cent figure mean in effect that everyone in Glasgow was being screened?

A. Well, the West of Scotland -- the Glasgow and West of Scotland centre covered 50 per cent of the UK population. So I'm basically --

MS DUNLOP: The Scottish population.
A. What I'm saying is that all of the donations that were collected from that population were screened for Hepatitis C and positive donations were taken out of the blood supply.
THE CHAIRMAN: It rather suggests that, in that area at least, testing, comprehensive testing, started considerably earlier than the agreed date.
A. It started in May. But it was part of a process, I think -- and I think you will perhaps discuss this with other witnesses. There was a need to accommodate the activities of Newcastle and what started out as a study became an extended study, really to accommodate people who had -- or one particular organisation that had broken away from the pack, as it were.

But I think, as time moved on in 1991, certainly colleagues who were at the sharp end of this, were beginning to become concerned that the clear policy of a common starting date, particularly in Scotland, where 50 per cent of the -- 50 per cent of donations were already being screened, was becoming increasingly difficult to reconcile and sustain.
PROFESSOR JAMES: When they were screened, obviously, you know, we may hear much more about this from other witnesses but, I mean, is it your understanding that,

for example, these people were postponed, counselled or anything at all was done, or they were just screened out on that particular occasion? Do you know what the sort of operational policy was with the positive screened individuals at that time?

A. I think you would need to get confirmation from people that were actually involved, Dr McClelland, Dr Mitchell and so on. My understanding is that it wouldn't have gone through the whole counselling algorithm and follow up. Donations that came up positive were certainly set aside, at the very least. At the very least, the blood supply would have had these positive donations removed from it. Whether there was any follow-up action for donors I can't say with any confidence.

PROFESSOR JAMES: Thank you.

MS DUNLOP: You do mention in your answer, Dr Perry, that there was a bit of debate around this issue -- that is the common UK start date -- at the SNBTS board meeting on 11 and 12 June 1991 and you say:

"It was finally agreed to remain firm on the agreed date of 1 September 1991 for introduction of testing, as is very briefly recorded in the minute."

Just so we can see that for ourselves, can we have [SNB0027666]? Go to page 4, please. Someone has circled it.

A. Yes.
Q. "Anti-HCV testing: agreed. Routine donation testing to begin on 1 September 1991."
A. Yes, that's correct.
Q. So, not really any discussion recorded but there was discussion?
A. No, there was no discussion recorded but there was a very substantial discussion that took place.
Q. Differing views?
A. Yes.
Q. Can we go back to the statement, please, and go to page 2118? Really you have said this already:

"It's difficult to imagine how this ..."

That is earlier testing in Scotland:

"... would have been achieved without SHHD or CSA authority which bodies presumably continued to be bound by UK health departments' agreement for a common starting date. Also SNBTS had (through Professor Cash) consistently expressed its commitment to a common UK start date."

That really brings us back to what I described earlier and you agreed, to a position from which there were no dissenters. Both the government departments: the politicians, the ministers, the civil servants and the blood transfusion services, at earlier points in

this story, were unanimous in wanting a common UK start date.

A. Yes, I think that's an accurate description, absolutely.

Q. "A near disaster". I think we know a bit more about that now and we don't really need to ask to you elaborate on your answer. I think you're right, but we will explore that with other witnesses.

[SNB0054822] appears to be a recognition that there had been failings in the process leading to the introduction of screening.

You were asked if you agreed with the views of Mr McIntosh, who is the writer of that letter. This is Mr McIntosh's letter to Professor Cash of 30 August 1991.

A. Yes.

Q. If we could work down to the bottom, and then over the page. (Pause).

There are things in the letter that one would be interested in picking up. We will pick up some of them and Mr McIntosh is going to come and comment on his own views as well, but you have really broadly endorsed what he says.

Can we go back to the statement, please, at the last paragraph, paragraph 37 and you have obviously, Dr Perry, put some thought into composing your answer,

here, so I suspect we should probably let it speak for itself but just to let everyone have a look at what you said. (Pause).

I suppose, before we leave --

THE CHAIRMAN: Can we go down a little bit; is there more?

Q. There is more on the next page. I just didn't want to leave this page without observing, Dr Perry, that that gap -- the fact that ACTTDs had met on 16 March 1990 and didn't meet again until 8 January 1991 -- perhaps takes your fourth bullet there on a little further because, if the body that was supposed to be more responsible for operational matters wasn't actually meeting in this period, it's more difficult to see how the baton was going to be passed on.

A. I think that's a very good observation and I don't know enough about the detailed discussions that took place outside VSB with people like Dr Mitchell and Dr Gunson and Professor Cash to follow up on the decisions from VSB.

Q. Then can we turn over the page, please? Right, Dr Perry, is there anything in that answer you want to change or supplement?

A. No, I think the -- certainly the penultimate bullet point, I think, was an important -- it was a particularly confused period. I think from the

original putative date of April 1991, following the November agreement of ACVSB when policy decisions were being made, it did seem to slip, as a result of the introduction of the second generation -- the coming along of the second generation kit in a sense ambushed that decision, rightly or wrongly, and led to this sort of slippage -- what I would describe as slippage from April, then to July and then to September.

It was never absolutely clear to me or to colleagues why this was actually happening and why this was taking place. I think all sorts of, perhaps, with hindsight, urban myths began to emerge about funding difficulties and so on. But from my perspective it did -- and, with hindsight, in answer to your question, I think that process could have been tighter.

Having made the decision to go, we had a testing system in place, we had a confirmatory testing system -- without greater knowledge of what actually caused this delay from April to September, it's -- I think it's something that in an honest answer to your question, we could have done better -- as a process.

Q. Thank you very much, Dr Perry.

PROFESSOR JAMES: Can I ask two questions briefly? Could you summarise these delays, which were effectively from something around about mid 1990 to September 1991,

effectively in two parts. You have alluded to the fact that perhaps "scientific rigour" was a very important influence on the advisory committee.

A. Yes.

PROFESSOR JAMES: So that perhaps the scientific rigour, "manana, manana" of new and better tests just over the road, beyond the horizon, might have accounted for delays, let's say, from June/July 1990 until, let's say, April 1991. Then you have alluded to these other rather different sort of financial/managerial/communication-type difficulties for the last period of four or five months. Would that be correct?

A. I think that's broadly correct. It wasn't just financial issues, I think, that contributed to the latter delays; I think it was the introduction of the -- what you could describe as changing the goalposts. It no longer became a timescale for introduction of the first generation test.

PROFESSOR JAMES: Quite.

A. That got thrown out of the window, as it were, in the belief that there was something much better coming along.

PROFESSOR JAMES: Quite.

A. So, if one is being critical of this process, it's

a case of the best being the enemy of the good on that particular occasion. Many other organisations and countries had already taken decisions to introduce --

PROFESSOR JAMES: The good?

A. The good, yes. But again I do offer the health warning that, you know, this is not my area of expertise and I think the discussions that took place and the motivation behind going for a second generation kit instead of a first one, were fairly well discussed and -- but it did seem to me that, against an international backdrop of many other organisations, having introduced first generation testing, then it became difficult for me to understand why we had completely abandoned that and had gone for a second generation --

PROFESSOR JAMES: My second, brief question is: do you think actually in retrospect that the composition of that committee was perhaps too -- well, didn't contain enough sharp end transfusionists, in particular. There were only two on the committee and they were outnumbered by strong-minded and authoritative "virologists" for example, so that the committee might have paid rather more cognisance, in that important period in 1990 in particular, and the beginning of 1991, to the virology, as against the public health/needs of the screening

service; or do you think that's not correct.

A. I was just -- no, I think I agree with your analysis to an extent and the reason I was hesitating was because this was something that I considered before I wrote my statement. I thought composition of the committee was, perhaps with hindsight, unduly biased to the science, the expert virologists, who are very authoritative people. I have to say this, it is not a criticism of them. But, standing back, and perhaps 20 or 30 years on, the public health perspective was not as dominant in fact as it possibly could have been.

PROFESSOR JAMES: When the committee was constituted, that would have been appropriate but events moving on as far as, you know -- as Hepatitis C was concerned meant that there was this perhaps inherent flaw, which hadn't been appreciated, in the composition of the committee at its outset.

A. Yes, I think -- it's not for me to judge who was right to be on the committee but I think it would have benefited, and further value could have been added having a slightly increased presence of, not specifically public health doctors but people with a slightly greater public health perspective on it. Which is not to say that Professor Tedder and Professor Zuckerman don't have a knowledge of these

things but their area of specific expertise is in the virology and the science and the understanding of what the tests are actually doing.

PROFESSOR JAMES: Quite. Thank you very much. Thank you, sir.

THE CHAIRMAN: Mr Di Rollo?

MR DI ROLLO: Sir, I don't have any specific questions for Dr Perry but obviously that doesn't detract from the importance of the comments that he has made just now and in the course of his evidence.

THE CHAIRMAN: Mr Anderson?

Questions by MR ANDERSON

MR ANDERSON: I'm obliged. Dr Perry, just two matters. Towards the end of your evidence just now you used the phrase, "We could have done better". Who did you mean by we. Was this SNBTS, or was this everyone involved.

A. I think the entirety of the process. I think I'm perhaps slipping into Mr McIntosh language here, where I'm describing the collegiate "we" including all the agencies involved in that.

I think if you -- specifically, as far as SNBTS and there is element of "I would say this", but I think SNBTS were very, very active in this particular area. They were, certainly in terms of their contribution to the process and evaluating the test kits and developing

algorithms and developing the basic principles of donor counselling and all these very, very important operational details, the SNBTS were at the forefront of that. Which is why, in my view, but not as somebody who was responsible for enacting it, but from my view -- which is why I think SNBTS could have been in a position to implement sooner if that decision had been taken. But again I can't imagine how that decision would have been taken.

Q. I wonder, was this a case of too many cooks spoiling the broth?

A. I think it's as I have described in my slightly carefully worded comments. It's about not having, at the outset of this, a clear plan and strategy for implementation. It seemed to me that the decisions were being taken by VSB on a step by step basis. So we weren't considering the implications of introducing testing, ie the counselling and the follow-up and the evaluation, until such times as the policy decision had been taken.

It seemed to me -- as an operational manager, one usually plans on the basis that you do scenario planning. So VSB, for instance -- and this is all with hindsight of course -- could have said "in the event that we do take a decision to introduce the testing,

this is what the subsequent processes and steps might look like". And there was no element of that.

Q. One final matter, please, Dr Perry. We have seen the minute of the SNBTS directors' meeting in June 1991 which simply has the rather terse entry that:

"It was agreed that routine donation testing would begin on 1 September."

You went on tantalisingly to say that:

"There was very substantial discussion and that there were differing views."

A. Yes.

Q. If the decision had been different, in other words if the decision had been to press for earlier testing or an unilateral introduction in Scotland, if that is the decision that had been made at that SNBTS directors' meeting in June, do you think it would have made any difference in real terms?

A. I don't know. If the decision had been -- my assumption is it must have been because there were very capable proponents of the argument that there was a case for early introduction in Scotland and that case wouldn't have been made if it were not for the fact that it was a practically feasible proposition. I don't think the board would have wasted time considering hypothetical scenarios.

So I think it was a at a fairly advanced state of readiness in June 1991. So it's possible, but I think on the day the argument for maintaining a common UK start date, including Scotland, was the argument that won over.

Q. I'm obliged to you, thank you very much.

THE CHAIRMAN: Mr Johnston?

Questions by MR JOHNSTON

MR JOHNSTON: I have just one point I would like to ask you about which relates to your final answer, the first bullet point mentioning the unnecessary secrecy and confidentiality associated with the VSB committee. I'm wondering whether you can take that any further in two senses. One: why you think it was stressed so much and secondly in light of the fact we have seen reports from you and from Dr Mitchell, for example to Dr Cash, I wonder really whether this is something that mattered greatly, or whether, in fact, all those who needed to know on key matters were adequately informed in spite of the confidentiality?

A. I actually think it did matter. I think there was undue emphasis on this, for reasons which were never really clear. I think there was a nervousness in the UK committee under the chairmanship of Dr Harris and Dr Metters, that these were extremely sensitive issues

in terms of public perceptions and public communications. It really sought to make sure that any of these discussions about scenario plannings and these risks that existed, didn't inadvertently, without proper rehearsal and proper explanation, find their way out into the public domain. I think they saw that as potentially damaging in a public health perspective, but also exposes the government to all sorts of pressures in complex situations that it wasn't -- which it wasn't wishing to debate in an unstructured way.

So I think it was -- I don't think it's correct to say that, despite that, we dug tunnels underground to get the information out and this was successful. I think there were often frustrations about not being free to communicate the various ruminations of the committee.

But equally I think -- and this perhaps was lacking as well -- those departmental officials that attended the meetings as observers, specifically with the intention of either feeding into the discussions or communicating back to their respective health departments the outcomes of those, part of the reason for being there, from my understanding, was that they would then operate as the basis -- as the formal government communicator to the operational service.

So there was an expectation, certainly from my perspective that important decisions and positions adopted by VSB would and should have been communicated via Scottish Home and Health Department and the Welsh Office and the Northern Irish office. That's what they were there for; to take account of the discussions, see what was going on and see whether or not it was important for operational planning and policy purposes to communicate that to the SNBTS.

I think that was a sporadic process. There was no structured approach to that. I'm not sure if those -- for instance, those very useful and probably very accurate minutes by Dr McIntyre ever found their way to the SNBTS. I suspect they didn't.

MR JOHNSTON: So the way you view it is that the means in which information was gathered from experts and relayed to government which then took a view on it.

A. Yes, absolutely and the involvement of the operational part of the activity, which was ultimately charged with the responsibility of introducing these things and doing the donor follow-up and the counselling and so on really wasn't factored into the process and the structure in any meaningful or consistent way.

That is not to say it never happened, I'm just simply saying there was, at least by today's standards

you would expect a much clearer process for communicating these important decisions. So that's, I guess my observations on the process. I didn't put it in -- I think the membership of the committee, I didn't include in my comment because I didn't think it was a failure of the process; I think it was simply a decision that was taken and, whilst I may have a view that the members of the committee could have been more broadly based, I didn't see that as a part of a process failure.

Q. Right, thank you very much.

THE CHAIRMAN: Dr Perry, such limited experience as I have would suggest that committees advising government on policy formation are generally confidential and that the dissemination of policy would be back down via a department and not via members of the advisory committee. Do you have any wider experience, than membership of this committee, to instruct you on what the norms might be?

A. The only other experience I have where confidentiality was a vital and again reiterated at every meeting was when I was a member of the Committee on the Safety of Medicines. That was primarily for commercial -- that's commercial confidentiality and so on and that was very rigorously and rigidly observed. But I don't think

I have any other experience of that personally.

THE CHAIRMAN: I think that ministers would generally look upon policy with some jealousy as their preserve, including the sources of advice that fed into it, do you see?

A. Yes, indeed, certainly -- it was certainly never my -- sorry, it was always my view that it wasn't my role to communicate the formal outcomes of ACVSB's decisions to my operational colleagues, that was not part of my job and role. Although it became irresistible at times, not to communicate quite important bits of information that I knew were critical to the planning in SNBTS. But it was -- and that would have been fine had there been behind it a clear structure for communicating what the policy decisions were and how they were to be enacted and basically the ... erm ...

THE CHAIRMAN: Mr Johnston, I think you may be wanting to take this up with tomorrow's witness in some way, but I think certainly the constraints on dissemination of information are a matter for your interest. If there is something significant, perhaps I'll hear about it.

MS DUNLOP: Yes.

THE CHAIRMAN: Ms Dunlop?

MS DUNLOP: There is some correspondence on that matter, sir, which I can draw to your attention, but not just

now. I think it might be a good time for a break. Dr McClelland is here and I would certainly like to start him today. Fortunately he is available to come back tomorrow morning and I would be optimistic that we will finish him tomorrow morning.

THE CHAIRMAN: And the knock-on from that?

MS DUNLOP: It should be perfectly do-able tomorrow. Thank you.

(3.29 pm)

(Short break)

(3.46 pm)

DR BRIAN MCCLELLAND (continued)

Questions by MS DUNLOP

MS DUNLOP: Good afternoon. Dr McClelland. I'm sorry to have kept you waiting.

A. Good afternoon.

Q. You have provided for us a statement on this topic, topic C4, which is [PEN0172491]. Could we have that up? We can move past paragraph 1, because we have already looked at that correspondence. Paragraph 2 relates to the two different groups, ACVSB and ACTTD and we asked why it was necessary to have them both.

You said it has never been clear to you. You remember that:

"At some time in 1988 [you] discussed with Dr Gunson

the idea of establishing a single group to form policy in relation to transfusion-transmitted infections. Both were established early in 1989. [You] suspect there were two groups because both the Department of Health and the NBTS national director wished to influence the decisions that were taken. The committees had very similar remits."

Could we look, please, firstly, at [SNB0019366]? Here we have what I have been calling for short "VSB". This is their paper 1/1. So the first paper, considered at the first meeting. That is the remit that you have quoted:

"To advise the health departments of the UK on measures to ensure the virological safety of blood, whilst maintaining adequate supplies of appropriate quality for both immediate use and for plasma processing."

If we keep that open, please, and look at the remit of ACTTD, which I think really in effect it composed itself, which is [SNB0061923]. This is from February 1989 and the terms of reference were agreed at the first meeting:

"1. To consider the epidemiological, clinical and laboratory aspects of diseases which may be transmitted by the transfusion of blood and blood products.

"2. To determine the appropriate policy which should be implemented by the UK Blood Transfusion Services for the control of transfusion-transmitted diseases.

"3. To advise the departments of health accordingly."

So that bears out what Dr Perry pointed out that, originally ACTTD saw itself as providing advice directly to the departments of health as well as ACVSB.

THE CHAIRMAN: I wonder, is that necessarily so? The second paragraph begins:

"To determine the appropriate policy for the transfusion services ..."

Now, the words, "To advise", at the beginning of the third paragraph can have more than one meaning. Can you say whether this was to provide advice or to tell the department what the blood transfusion services' policies were?

A. I really don't know. It might have been a skilful ambiguity but I think, looking back at this -- I don't think that I was particularly aware of it at the time, but there was clearly a bit of a battle for territory going on here. I can understand why, you know, I think the -- Dr Gunson, who was a very responsible guy, who wanted to try and see that the best was done in the

National Blood Transfusion Service, was probably keen to do whatever he could to grasp the initiative and you know, make the running for the department rather than the other way round.

I think that's probably what this was about. It's interesting; in number 2 he used the words "Appropriate policy", which is not about operational detail, which is what was -- the term I think was used in later attempts to "clarify" the two remits.

THE CHAIRMAN: It's a typical lawyerly -- I wouldn't say it's a lawyer's approach, since I'm no longer a lawyer but it's a particularly lawyerly approach to pick the words in this way. But there is, of course, a difference between the policy of the blood transfusion services, to be implemented, and government policy. Yes. I don't want to take it any further, Ms Dunlop. It's just I think that this is either a very cleverly worded statement, full of ambiguity, or it perhaps is just ambiguous.

A. I honestly suspect the latter.

MS DUNLOP: Yes, I think just to look at these two groups at the outset, and if we can go back to your statement, you say -- and this is moving on to the second page that:

"Early in the life of these groups, the documents show evidence of difficulty in differentiating between

their respective roles."

And you say:

"At the first meeting of ACSVB, its chairman offered the following interpretation of its remit."

That's from the same paper, 1/1, that is [SNB0019366]:

"Our concern is matters of major policy, not the implementation of policy ... our specific remit is with blood donors ..."

In fact the other quote which you show, if we jump a paragraph and see the next quote:

"ACTTD will be considering many of the same issues as the present committee (ACVSB) but only from a transfusion point of view."

That also comes from that same paper. Then I think it might make slightly more sense if we read next the paragraph that you have beginning, "Some time later", because we have looked at this next extract and it comes from the minutes of 24 April 1990:

"Some time later the chair of ACVSB thought it necessary to make further comments which, as I read them now, seem to add to the confusion rather than clarify the role of the two groups."

That's that quote about, "There should be no confusion". In fact, a direct quote says:

"The UK BTS committee..."

This is reading from the end of the third line:

"The UK BTS committee considered the operational implications of policy ... contributed to the advice on viral safety through input to the ACVSB".

That was something that, according to the minutes of VSB in April 1990, Dr Gunson signed up to.

I think it's interesting to look a little more carefully at how the two groups began. Can we look, first, at [SGH0031265]. This is a minute from Dr Harris, the deputy chief medical officer, in the summer of 1988, more particularly dated 14 July, sent to quite a wide range of people, including Dr Forrester. We can see that actually there is a reference to EAGA, so the Expert Advisory Group on AIDS. The question was raised as to how advice should be given to the necessary steps for ensuring the virological safety of blood in the UK:

"Since viruses other than HIV-1 and HIV-2 are involved, EAGA is not the appropriate body."

Presumably because it's disease-specific. Then several groups with an interest in procedures for screening donors. Then the minute goes on to explain who these groups are:

"The Committee on Safety of Medicines, most

particularly the biological subcommittee."

Then there is reference to the FDA, lots of initials. Directed by the EC:

"The CSM would resent any interference with their independence. They are concerned about quality, safety and efficacy and have no responsibility for costs or supplies."

Then on to the next page, please. The CBLA and the NBTS. In fact PFC is mentioned in paragraph (b) also. 3.2:

"Since CSM gives advice for all health departments, we need to work together with the territorials."

So that's the Northern Irish office, the Welsh Office and SHHD, I guess:

"Any differences between the territorials, unless adequately justified, could be exploited in any litigation."

Then just some further thinking on the composition of such a group.

Then if we could scroll down and look at the infections that Dr Harris had in mind, including non-A non-B and he is suggesting a new advisory group under his chairmanship.

He is suggesting terms of reference and membership. Can we just move through the document, just to see for

ourselves how it continues. Here we are. Actually that document we looked at earlier, sir, is one of the appendices with the list of suggested members as at that stage.

THE CHAIRMAN: Could I see the whole sentence that ends:

"... is no need to consult ministers on this initiative."

MS DUNLOP: Yes.

THE CHAIRMAN: Why is -- just highlight why.

MS DUNLOP: That changed of course.

THE CHAIRMAN: I appreciate that, but I'm just wondering what the reason was at that stage from Harris. Could I see the page before, please? It's just, "I feel there is no need ..."

MS DUNLOP: So that's 14 July and Dr Forrester replied on 18 July that's [SGH0031264]. We can see from the bottom:

"Silent copies sent to Dr McIntyre, Mr Macniven."

It looks as though Mr Panton as well. I don't think there is anything under that. Perhaps if we scroll down just to check. CMO. The nomination of Dr Urbaniak has been agreed with Professor Cash. I think that's actually Mr Macniven's writing.

Then the next document from around this period is [SNB0061010]. I think it's not particularly difficult

to reconstruct, Dr McClelland, this minute has come in from Dr Harris, Dr Forrester has replied, there has been discussion with Professor Cash about who might serve from Scotland and this has triggered a letter from Professor Cash to Dr Pickles on 19 July 1988 and it's just the final paragraph:

"I was pleased to learn that there are now discussions taking place which hopefully will lead to the establishment of a UK group which will concern itself with the long-term problems associated with blood donations (microbial) screening. In due course I would much appreciate the opportunity of providing an input with regard to the membership of such a group."

There are documents between government departments in the autumn of 1988, and I plan to look at those with Mr Tucker, sir, but I don't see any evidence that they were revealed outwith the government departments. So an impression may have been created that nothing was happening and, if we move to the SNBTS directors meeting in December 1988 and look at that minute, which is [SNB0027350]. Here we have a meeting at which you were in attendance, although perhaps not for all of it. Professor Cash is there and Dr Gunson is also there.

It's worth noting that Dr Gunson has a new role as national director of the NBTS. So he has become the

English Dr Cash. Is that right. Yes, you are nodding.
A. I'm not sure that his role as national director was exactly equivalent to Dr Cash's role in Scotland. In fact I am sure it wasn't.
Q. All right. Do you want to expand on that for us, please, just to explain what you see were the main differences?
A. I probably would need a little bit of notice of that but I think in 1988 we were still in Scotland in the situation where Dr Cash was national director. He was effectively, if you like, general manager and medical director, because this, I think, preceded the appointment of the first general manager per se.

At this time I'm not certain who -- what was the composition, as it were of the top management team in the National Blood Transfusion Service but I think there may have been a senior managerial presence, possibly someone seconded from the Department of Health. So the roles could have been slightly divided in the National Blood Transfusion Service, whereas they were encompassed in one post in Scotland at that time.

Q. Right.
A. I hope that's historically accurate.
Q. Fine. Thank you. Can we move down the page, please? In fact look on in the minute -- if we go to the next

page -- yes, there we are. This is actually under a heading "AIDS", you see the last two paragraphs? Actually the whole thing really is worth study:

"Uniform advice on microbiological testing", is the subject covered:

"Dr Gunson recalled that advice on anti-HIV testing had come originally from the UK working party on AIDS and from EAGA. The latter had subsequently withdrawn from the field. Dr Pickles of DOH had indicated some nine months ago ..."

I think that must be the reference to the correspondence from July that we had looked at:

"... that the department would take an initiative and this had not happened and mean while certain problems needed to be addressed. Mr Panton reported that his medical colleagues would welcome the formation of a professional group on which the SHHD would wish to be represented.

"After discussion it was agreed that UK Blood Transfusion Services should establish a group to advise the departments of health on policies. It was noted that the matter was urgent since the USA would soon begin testing blood donations to HTLV-I and HG agreed to liaise with Dr Pickles as soon as possible.

"JDC and Dr Gunson, together with the SHHD would

exert pressure on the Department of Health."

I don't expect you remember this discussion, Dr McClelland? No.

But it does look as though there is a bit of a feeling that nothing much is happening. An initiative had been discussed by Dr Pickles, but it looks to those who are having this discussion recorded in the minutes as though not much progress has been made. Is that a reasonable --

A. It appears that this is an attempt to do something that they thought was needed and had not materialised from the departments of health, although it's interesting that there were two people from the Scottish department present at that meeting, who clearly weren't aware of some of the correspondence that you just showed us a moment ago. This is all new to me. I must have seen that minute before obviously but I hadn't appreciated the significance of it in relation to the question I was asked.

Q. It's the sort of archaeology on which we are all engaged I am afraid. Can we go back to the page before then, please. Certainly you can see Mr Panton is there and we know he is from SHHD. It's just your reference to 2. I think Dr Skinner is the other one, yes?

A. I think Dr Skinner was possibly pretty new to the

liaison role with the Blood Transfusion Service at that time --

Q. Right.

A. -- so she might well not have been completely up to speed with all these issues.

Q. Yes. Then next can we look at [SGH0031251]. So bearing in mind that's 13 December 1988 and presumably the minutes are typed up and sent out. Here is a letter from Dr McIntyre dated 9 January 1989 and he is writing to Dr Pickles. In the first paragraph he alludes to correspondence between Mr Macniven and Miss Webb of the Department of Health, concerning the setting up of the advisory committee on virological safety of blood. Then Dr McIntyre goes on to say:

"When I discussed this matter with you recently, when we met at the latest meeting of ACDP..."

The Advisory Committee On Dangerous Pathogens is that? I think that is what that stands for:

"...I indicated that we felt there was a measure of urgency about setting up this advisory committee. I now enclose, in confidence, an extract from an unconfirmed draft minute of a meeting of the directors of the Scottish National Blood Transfusion Service, held in Edinburgh on 13 December 1988, at which Dr H Gunson and Dr W Wagstaff were present.

"This extract, you will note, suggests that the UK Blood Transfusion Services should establish a group to advise the departments of health on policies related to microbiological testing. This method of approaching the problem we consider to be unsatisfactory, and we suspect that the decisions reached might be influenced, to a considerable extent, by the views of the transfusion directors. As this is a matter which has policy implications and will be of considerable interest to ministers we feel that this advisory committee should be set up jointly by the departments."

I may as well read the whole thing:

"In Scotland we are under considerable pressure from the SNBTS to fund the introduction of additional virological testing and, as this is a matter which we feel should be addressed on a UK basis, I should be grateful if you could let me know what steps your department intends to take in this matter as we would not like to be forced into a course of action which might have repercussions for the UK as a whole."

So, I suppose it's a get a move on letter, is it?

A. Among other things.

Q. Yes.

A. I think it's a remarkable exposition of aspects of the department's attitude which we have alluded to at other

times in the Inquiry.

Q. Well, it's just -- I suppose sometimes we come across letters, Dr McClelland.

A. I'm choosing my words very conservatively.

Q. Yes, just another letter we came across. We know that although, as I have been putting it, the transfusion directors committee was first off the blocks, having its first meeting in February 1989, and the VSB not starting until April 1989, it does really pretty conclusively look as though the idea for the Advisory Committee on the Virological Safety of Blood pre-dated the Transfusion-transmitted Diseases Committee, if it was being discussed in July 1988 and then it met for the first time in April 1989.

A. I have some recollection of the original idea, which went back earlier because I was a member of the expert advisory group an AIDS and I think Professor Cash was as well. We had both, I think, probably made ourselves quite unpopular on EAGA actually by, you know, exploring how other infection-related matters could be dealt with sensibly on a UK basis, because there wasn't at that time a forum for doing that.

The chair of EAGA said, I think very correctly, this is nothing to do with EAGA, we are about AIDS. So there was an imperative to take that away and try and

stimulate something. Where the idea originated -- was that the origin of the requirement? It's probably something -- it was probably a multi-focal origin because other people would have realised that there was a gap that needed to be filled because we anticipated that there would be virological challenges coming along that we would have to address in a sensible way across the country.

Q. Yes.

A. None of this, I think, still really explains to me adequately why we ended up with two committees. Although I do think this letter now, which I don't recall ever seeing before, does provide a very interesting clue, which is the view that it would be undesirable if the opinions of the transfusion directors were influential. The transfusion directors at the time probably did feel that they had, you know, a responsibility to have a say in these matters.

Q. Yes. I suppose it's just -- well, it's not entirely speculative, Dr McClelland, to say that the initiative that Dr Gunson and Professor Cash were taking was against a background where they felt that the initiative from the Department of Health had gone cold?

A. That's what I understand from looking again at that minute, yes.

Q. Yes.
A. Absolutely.
Q. Yes. Sir, it has been quite long day and I do still have quite a bit to put to Dr McClelland, but I think we can finish it comfortably tomorrow and deal with the other witnesses. I wonder if we might be able to rise at the moment and start again --
THE CHAIRMAN: I'm catching a train to Glasgow tomorrow evening and I intend to catch it.
MS DUNLOP: What time is the train?
THE CHAIRMAN: In time to get me to Glasgow University for, I think, half past six.
MS DUNLOP: Right, thank you.
(4.15 pm)
(The Inquiry adjourned until 9.30 am the following day)

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