

Friday, 30 September 2011

(9.30 am)

DR RUTHVEN MITCHELL (continued)

Questions by MS DUNLOP

THE CHAIRMAN: Good morning.

MS DUNLOP: Good morning.

THE CHAIRMAN: Yes, Ms Dunlop?

MS DUNLOP: Good morning, sir. We have Dr Mitchell with us again this morning.

Good morning, Dr Mitchell.

A. Good morning.

Q. We wanted to ask you some questions about the introduction of screening of donated blood for what later became known as the HIV virus.

So could I ask firstly that we have your statement on this topic in front of us? That's [\[PEN0171002\]](#).

Could we look at the first page? We can see in bold an extract from our snapshots and landmarks document and then a question, which is in bold and in italics. We are actually already rather familiar with the correspondence in Scotland in January 1985 and then the coordinating group meeting on 19 February. The question we posed was:

"What particular steps had the SNBTS taken with regard to the introduction of HTLV-III screening in

1 Scotland as at 24 January 1985?"

2 You say in your answer that:

3 "Major steps were being taken by the SNBTS well
4 before January 1985."

5 I just wondered what the major steps were.

6 A. Yes, well, we had lots of contact with many other people
7 throughout the world who were interested in this
8 problem. We were aware that through the MMWR reports
9 there was this new disease, mainly in America but some
10 other places, and we began to get information that there
11 might well be a transfusion-transmitted element to it.

12 That was the reason we began to consider the
13 possibility of doing individual testing of donations for
14 this virus, provided we could get sufficient materials
15 in which to do it. So far as I know there was no test
16 available in Europe at that time and the Americans were
17 only just beginning to start their various test systems,
18 mainly Abbott Laboratories and one or two others. There
19 were many American commercial companies who obviously
20 saw tremendous commercial advantage in introducing such
21 a test.

22 So they were very keen to liaise with Dr Gallo in
23 order to obtain samples of his materials, to develop
24 various types of detection system. So certainly we were
25 well aware of that but how we could fit into it was

1 another problem because we really didn't have access to
2 any of the materials at that time.

3 Q. Right.

4 A. We were aware that Dr Tedder of course, having tried
5 also unsuccessfully to get samples in order to evaluate
6 them in the UK, had been unable to do this with Gallo,
7 and he and Robin Weiss, of course, had prepared a eluate
8 themselves from a known patient in London. And so that
9 was the position, as I understood it, just
10 before January 1985.

11 Q. Right. Do you remember a point when Dr Crawford went to
12 visit Dr Tedder?

13 A. No, I don't actually, no, no, I'm sorry. It's not
14 unusual. Certainly there were lots of contacts
15 throughout that time.

16 Q. Yes. Don't worry at all. It's a very long time ago.

17 A. Many of us were attending meetings in various places,
18 including North London and elsewhere, with Dr Contreras
19 and John Barbara and many other people who were
20 involved.

21 Q. Perhaps you could just have a look at a letter which
22 Dr Crawford sent to you on 20 December 1984. It's
23 [\[SNB0048803\]](#). This is, as you can see, Dr Crawford
24 writing to report on a visit to Dr Tedder on
25 18 December.

1 A. Yes.

2 Q. If you don't really remember the event, then I suppose
3 you won't remember what had triggered it or why or how
4 Dr Crawford came to be making the visit?

5 A. Well, I understand why Bob would go because clearly he
6 would go with my blessing. Bob was very interested in
7 the whole question of AIDS and its transmission and so
8 on. He had a special interest in that and it was only
9 right and proper that he had been involved with
10 counselling of donors and that kind of thing.

11 It's quite natural that Bob would wish to do that.
12 He was also, of course, interested in the science of the
13 subject and this was just an example of trying to
14 determine how close we were to obtaining a suitable
15 test. I think the early work of Gallo was -- he was, of
16 course, a Glasgow alumni. He had spent some time with
17 the virology department at Glasgow University, which in
18 those days, I think there were only about eight people
19 in the whole world who knew much about retrovirus.

20 So I believe -- I think I remember that Gallo came
21 to Glasgow to give a talk on his interesting information
22 and one of the professors in Glasgow, I remember, coming
23 through Glasgow Airport and saying that -- at the time
24 of customs declaration -- he had many millions of virus
25 in his top pocket. Whether he was stopped or not,

1 I don't know. But that was really part of the beginning
2 of this, how this all came about, and it was not unusual
3 that Bob should go down to Richard Tedder and try and
4 find out just what was going on.

5 I think other people were doing the same thing but
6 naturally Richard was a bit reluctant to say too much
7 about it having had difficulties with Dr Gallo and the
8 question of rights of access. It is difficult to share
9 information in that kind of climate.

10 Q. Certainly, Dr Mitchell, we have heard tales of people
11 bringing virus in a flask from Paris and leaving it at
12 Waterloo Station and I have also seen a reference to
13 somebody flying across the Atlantic with virus packed in
14 dry ice. So I can imagine that people travelled around
15 at this point with their samples of virus, but you have
16 a memory of Dr Gallo being in Glasgow?

17 A. I tried to think back to these days and I have a feeling
18 that he did come to Glasgow, and the professor that went
19 to get some of the material and bring it back, he was
20 interested in possibly producing a vaccine to the virus
21 at that time. We actually invited him to speak at one
22 of our first Scotblood meetings, which is the annual
23 meeting of the Scottish National Blood Transfusion
24 Service in those days, of which I was the originator of
25 the scientific meetings. And it's interesting just

1 looking back over many, many years that that's the sort
2 of position we were in at that time.

3 We knew about this, we knew it was going on, we knew
4 that people were interested, mainly in the States,
5 because they had a bigger -- a huge problem, as far as
6 the literature would indicate, so perhaps -- I don't
7 know if that answers your question?

8 Q. Actually I think we are slightly off the track but it's
9 interesting, so if you don't mind, I'll pursue it
10 a little bit. Which professor in Glasgow are you
11 talking it?

12 A. Jennett, Professor Jennett.

13 Q. Brian Jennett?

14 A. Yes. He is unfortunately not still with us.

15 THE CHAIRMAN: Just get it into the notes what his
16 discipline was.

17 MS DUNLOP: Actually he was a neurosurgeon.

18 A. It was his brother. I think he was the veterinary
19 professor in Glasgow. Brian was the chap who did the
20 head injury studies, yes.

21 Q. So he was at the vet school in Glasgow?

22 A. That's right, yes, as I remember it.

23 THE CHAIRMAN: How much did you have to do with the vet
24 school? I'm interested in their knowledge of
25 retroviruses.

1 A. Not a lot.

2 THE CHAIRMAN: Not a lot?

3 A. Not a lot because as I say, in Scotblood it was in its
4 early days at that time. We had only started just
5 briefly before that, and we knew that Professor Jennett
6 had a interest in other oncogenic viruses, and he had
7 written about this, mainly in cattle.

8 So in just general terms for the interest of the
9 audience and people in blood transfusion, it was
10 interesting just to talk about viruses and the activity
11 in general terms. We had other people who spoke. We
12 had one lady who spoke about cervical cancer and the
13 papillomavirus and so on. It was a scientific meeting
14 but also a meeting of colleagues --

15 Q. Yes.

16 A. -- from various disciplines.

17 Q. I understand. Thank you.

18 So in that light you weren't at all surprised to be
19 reminded that Dr Crawford had made a visit to see
20 Dr Tedder to find out exactly what was happening at the
21 Middlesex Hospital?

22 A. Yes, yes.

23 Q. And just to look at the letter, Dr Crawford is setting
24 out some information about the two different tests,
25 first of all Dr Tedder's test, and he is saying that in

1 the Tedder test, if we just call it that for the moment:

2 "Unknown serum and labelled antibody compete."

3 A. Yes.

4 Q. Actually it does look as though it's still
5 a radioimmunoassay he is describing at this point.

6 A. That's right.

7 Q. I think that must be right with the reference to counts
8 per minute?

9 A. That's right.

10 Q. Then the American test, which we understand is not the
11 same kind of format, solid phase purified antigen,
12 unknown specimen, presumably, and then an enzyme
13 labelled anti-immunoglobulin. It can be made sensitive
14 or specific but not both.

15 A. Yes, there are all different ways of doing it.

16 Q. Yes, and then a reference in the section headed "Source
17 of Antigen" to the growing of the Gallo isolate in the
18 cell line, H9?

19 A. Yes.

20 Q. We understand that in due course that actually led to
21 some problems with false positives?

22 A. Yes.

23 Q. Yes. I don't need you to explain that to us because
24 we have had some explanations of it but you were aware
25 of that, were you?

1 A. Yes, I think the American literature was absolutely
2 clear on that. All the technical information from the
3 various companies in the States who had been looking at
4 it, always were reporting large amounts of false
5 positive information. And what was more worrying was
6 the false negatives.

7 Q. Yes. I think we understand that for a transfusion
8 service, both cause problems; both false positives and
9 false negatives, obviously.

10 A. Oh yes.

11 Q. Then we can see Dr Crawford reciting the names of the
12 five firms -- four firms actually -- who are working to
13 develop tests and that Dr Tedder had asked American
14 companies for antigen with which he could work and that
15 he wasn't able to do that, and he explained to us that
16 he thought that was really to do with the legal
17 position.

18 A. Yes.

19 Q. Then mention of industrial culture facilities. That's
20 CAMR Porton?

21 A. Yes. Certainly I knew this bit of information, yes.

22 Q. This material is all quite familiar information?

23 A. Oh, yes.

24 Q. Then the reference on the second page in that second
25 paragraph to the possibility that given cells and virus

1 and support from Middlesex, Scotland might go it alone.

2 A. Yes, that's right.

3 Q. What do you think he was meaning by "go it alone", do
4 what alone?

5 A. I think we could have helped considerably with the
6 development of a test.

7 Q. Right.

8 A. I think that's the important aspect of this. There is
9 no use having a test that would work in a test tube --

10 Q. Yes.

11 A. -- with half a dozen specimens. We have got 100,000
12 specimens to do.

13 Q. Yes. Then Dr Crawford, maybe with that in mind, has
14 turned his attention to talking about safety for those
15 working with the virus.

16 A. Hm-mm. That's right, that's very important.

17 Q. Yes. Then on the final page we can see that he has also
18 addressed what I think was a live topic around this
19 time, which is trying to ascertain from laboratory
20 testing if the heat treatment that PFC were carrying out
21 was being effective.

22 A. Yes. That's correct.

23 Q. Right.

24 THE CHAIRMAN: Dr Mitchell, what would have been the basis
25 for confidence at that time that Scotland might go it

1 alone? Was there some relevant experience or a body of
2 skill or whatever, that would instruct that view?

3 A. Well, we certainly had a lot of experience from mass
4 screening in terms of the Hepatitis B virus. We had
5 done a lot of work on that. We had a lot of knowledge
6 and experience of doing those kind of work-ups for these
7 tests, and so if conjugate had been available, then I'm
8 pretty sure that the West of Scotland would have played
9 a very considerable part in developing a suitable test.

10 It was important to have a test which would be
11 reliable and would answer the question of: did it have
12 specificity and sensitivity? You wouldn't buy a car
13 from someone without doing a test drive. That's my
14 answer really.

15 MS DUNLOP: Yes, indeed.

16 A. We would have been most interested in doing it. Again,
17 for many reasons but mainly because we had a staff who
18 were particularly good at doing these kind of
19 evaluations.

20 As you probably saw from the hepatitis studies,
21 Glasgow was very instrumental in making sure that many
22 of these tests that were being used were in fact up to
23 speed and up to standard. That was the case in the
24 States. I mean, many of the tests developed there were
25 miles out. I mean, 1986, I think it was, that I read,

1 they were still talking about 90 odd per cent false
2 positives.

3 THE CHAIRMAN: That's a sidetrack.

4 A. I'm sorry, that doesn't answer your question.

5 THE CHAIRMAN: I wonder if I could ask my second question
6 and let you decide where you are going to go.

7 I probably should have known but wasn't aware until
8 now that Gallo was one of the Glasgow mafia.

9 A. I don't think that's true.

10 THE CHAIRMAN: Do you know when he graduated?

11 A. No, I think he was doing a PhD at the time.

12 THE CHAIRMAN: You don't know who his contemporaries might
13 have been?

14 A. I think the professor in virology was Scharpey Schaffer.

15 THE CHAIRMAN: Not someone who figures in --

16 A. No, Scharpey Schaffer is dead now. That's how
17 I remember it, but it's a long, long time ago.

18 MS DUNLOP: Just before we leave Dr Gallo, are we talking
19 about Gallo actually being a student in Glasgow?

20 A. No, I think he was doing part of his PhD. I wasn't
21 involved with that department. So I really couldn't
22 answer that question.

23 Q. Right.

24 A. As far as I know -- it was said at the time that one of
25 the reasons he came back to say hello to Glasgow was

1 because he was coming back to thank his mentor, ie the
2 professor of virology. That was what was said at the
3 time.

4 Q. I see.

5 A. Because as I said to you, I think at the time there were
6 only about eight people in the world who knew anything
7 about retroviruses.

8 Q. And one of them was in Glasgow?

9 A. Well, one of them was a professor of virology in
10 Glasgow, yes.

11 Q. Yes. Right.

12 THE CHAIRMAN: Was he in the vet school --

13 A. No, no, no. He was in the university department of
14 virology, which is a separate organisation.

15 THE CHAIRMAN: I'm just conscious, you see, that I have
16 heard already that information tended to be exchanged
17 rather readily between people who had historic contacts
18 with each other.

19 A. That's right.

20 THE CHAIRMAN: And I was wondering whether there was any
21 significance in Gallo's association here.

22 A. I don't think -- as I say, I was only an observer at
23 that time. I wasn't involved.

24 MS DUNLOP: Do you remember Dr Forbes --

25 A. Charles Forbes?

1 Q. Yes. Having contacts in America as well?

2 A. Not personally. I didn't know of that. I had a feeling
3 that perhaps he did have information from again,
4 haemophilia colleagues in the States. That would not be
5 at all unusual because reports had been received in his
6 speciality as well. And of course he had worked over in
7 the States.

8 Q. Yes.

9 A. So he was aware of people who were there, and no doubt
10 kept in touch with them.

11 Q. Just going back, if we could, to the idea of what might
12 have been possible in Scotland in early 1985, can we go
13 back to the statement, please? We are still on the
14 first page, [\[PEN0171002\]](#)? You say that you were aware
15 of the refusal of Dr Gallo to agree that the DHSS would
16 have access to his isolate and then you have told us
17 that in fact there was a British isolate anyway. So
18 that gap was plugged by the research work, I think,
19 mainly of Professor Weiss, whose forte this was?

20 A. But it didn't go simultaneously. The Weiss isolate was
21 really in desperation not being able to get the American
22 one.

23 Q. But perhaps focusing on little more closely on what was
24 happening in the West of Scotland, we do have some
25 information about the idea that there could be

1 evaluation of commercial kits in the West of Scotland,
2 and can we just look at a pair of letters on that topic?
3 The first is [\[SNB0059715\]](#). This is a letter from you to
4 Dr Cash.

5 A. Hm-mm, yes.

6 Q. And you are thinking that you and he have had a process
7 of thought transfer?

8 A. Hm-mm.

9 Q. And you have already had a visit from Abbott
10 Laboratories.

11 A. Yes.

12 Q. This is as at 21 January 1985. You had had a visit from
13 somebody at Abbott. Did you have contacts within
14 Abbott?

15 A. Only with the representatives who came from time to
16 time.

17 Q. Yes.

18 A. Because we were using Abbott technology for the
19 Hepatitis B virus.

20 Q. Right. I think Abbott had a base in England, didn't
21 they?

22 A. They probably did, yes. I'm not sure where their base
23 was.

24 Q. Right. So they had come and asked if you might be
25 interested in a --

1 A. I think I had asked them.

2 Q. Oh, you had asked them?

3 A. I had asked them if they had access to any suitable
4 materials that we might test.

5 Q. Do you actually remember this? As you sit here today,
6 do you have a mental picture of any of these contacts
7 with Abbott or any discussion about evaluating their
8 kit?

9 A. Well, all I can tell you is that Abbott did come, not
10 infrequently, but fairly frequently to the laboratory to
11 see how things were going with the other testing, and if
12 they were developing another test, then clearly they
13 might have come and said, "Would you be interested in
14 this test?" I would have said, "Yes, of course."

15 I think that's probably how it arose. It was
16 probably them coming and saying they have a test.

17 I knew very well that they had a test in America but
18 whether it was available in the UK or not, I don't know.

19 Q. Right. You seem in this letter to be raising some
20 practical issues in connection with this proposed
21 evaluation.

22 A. Hm-mm.

23 Q. You are actually trying to speak to Dr Cash on the phone
24 and you were hoping to speak to him at a meeting,
25 I think, last week, but hadn't managed. You go on to

1 refer him to a copy of the MMWR. In particular you are
2 referring to the content of that publication on the
3 topic of screening?

4 A. Hm-mm.

5 Q. Abbott have asked you to write a letter to satisfy the
6 FDA requirement. I am afraid we haven't been able to
7 find the enclosed draft, and you are making some
8 enquiries of Dr Cash in connection with ethical matters.
9 If we just look at the second page of the letter, we can
10 see that.

11 A. Yes. Do you want me to comment on that?

12 Q. By all means.

13 A. I would imagine that the reason that Abbott would be
14 interested in a method of making sure that no
15 information was released to competitors, for example,
16 would be a prerequisite of their coming into the market,
17 as far as we were concerned.

18 I think that was -- and I think the other problem,
19 if I could recall at that time, would be the whole
20 question of blinding the samples. Quite clearly it
21 would be a bit unusual to test samples without looking
22 at the consequences of the result.

23 Q. Right.

24 A. You might find yourself holding a very delicate and
25 important piece of information from a person who could

1 be named and identified.

2 Q. Yes.

3 A. With a test which was really, as far as we were
4 concerned, in its infancy. So that's the reason that
5 one would look at blinding samples.

6 Q. Yes.

7 A. It was a question of trying to find out what was the
8 frequency of positivity, how well did it perform in the
9 field, as against what would you do with the answers if
10 you got them.

11 Q. Yes. Just to be 100 per cent clear, by "blinding" you
12 mean anonymising samples?

13 A. Anonymising them, yes.

14 We had a system in the service in Glasgow that
15 Bob Crawford, whom you mentioned -- we had
16 an arrangement that Bob was the only man in the
17 department that knew anything about any particular
18 positive individual, and these were all very
19 confidentially marked and kept by Bob. No one got
20 access to it. I didn't have access to it. No one else
21 had access to it. It was a 100 per cent lock-up of
22 information. That's how it came about initially; but so
23 far as Abbott were concerned, I think their interest
24 would really be in blinding and secondly in the
25 commercial secrecy.

1 Q. Right. The other letter, which goes with this one, is
2 [\[SNB0059713\]](#).

3 A. Can I go back to the ethics committee, because that
4 was --

5 Q. I'm sorry?

6 A. I'm just noticing there, it was Ronnie Girdwood, who of
7 course was in fact the chairman of the Scottish National
8 Blood Transfusion Association, which was set up to look
9 after the interests of donors. That's what it really
10 was all about. And he did a very good job in that sense
11 and he had this ethics committee, rightly so, which
12 said, if you are going to be doing work with donor
13 samples, you have got to clear it with us, and that was
14 the reason that I was referring it to the ethics
15 committee. What did they think about how we should
16 handle the specimens.

17 Q. I understand.

18 THE CHAIRMAN: This is an association ethics committee, not
19 a hospital ethics committee?

20 A. No, no. When the SNBTS was set up -- that is the
21 service was set up at the time of the founding of the
22 National Health Service, the old SNBTA, which was an
23 association, a kind of voluntary organisation, which ran
24 blood transfusion, it was disbanded or stood down. But
25 in Edinburgh the SNBTA continued because it had this

1 link with donors, and Professor Girdwood, when he was
2 a member of the working parties and coordinating group
3 of the National Blood Transfusion Service, he still kept
4 his chairmanship of the SNBTA, which of course, was
5 a very valuable thing because it was the way in which
6 the Blood Transfusion Service could still get into what
7 the donors thought about this, what did they feel about
8 having the samples tested, anonymously or otherwise.

9 Q. Yes. So the role of the SNBTA was to stand up for
10 donors, as it were?

11 A. That's right.

12 Q. And to promote the interests of donors.

13 A. Yes, that's exactly what they did. They had
14 a considerable interest in donor care and management.

15 THE CHAIRMAN: I think the general interest, I do
16 understand, is the particular indication you have given
17 that included in that was an ethics committee because
18 that might imply a structure for application,
19 consideration, assessment, adjudication and so on. Is
20 that what one should understand?

21 A. Yes, yes. I can't remember all the people who were on
22 the ethics committee but I think it's true to say that
23 they were not active blood transfusion directors or
24 active individuals in blood transfusion.

25 I remember one was an eminent haematologist in

1 Glasgow, Dr Robert Cumming, who was a haematologist at
2 Stobhill Hospital in Glasgow. I remember he was
3 a member of it but there were others and Girdwood was
4 the chairman. But I think it was interesting that they
5 did not disband it. It was originally ran from an
6 Edinburgh legal office, in Edinburgh, it was Neil Milne
7 who was Writer to the Signet in Edinburgh, who was the
8 first, if you like, secretary general of the SNBTA,
9 being legally -- he being a lawyer, had an great
10 interest in making sure that the service ran very
11 smoothly, so far as donors were concerned.

12 MS DUNLOP: I think lawyers are good at that.

13 A. I would imagine so. That's their job.

14 Q. I think we are happy to accept the compliment,
15 Dr Mitchell.

16 THE CHAIRMAN: Only if we accept the responsibility that
17 goes with it, Dr Mitchell.

18 A. Sometimes I become the director, you see, that's not
19 uncommon.

20 MS DUNLOP: But when you say it was run from an Edinburgh
21 legal office, that's the whole SNBTA, not the ethics --

22 A. Yes, the early SNBTA, the association, was an
23 association of the five regional transfusion centres,
24 right, and they met as an association of directors.

25 Q. Do you want just to go back to the previous letter so

1 that we can see in its context the reference to
2 Professor Girdwood, if we could, please. That's
3 [\[SNB0059715\]](#).

4 A. I saw it at the bottom of the letter. It is approved by
5 the ethics review board.

6 Q. He is on the next page.

7 A. Yes, just when I saw that, I remembered Ronnie Girdwood
8 being the committee chairman.

9 Q. Yes.

10 A. But it was an ethics committee of the SNBTA, but SNBTS
11 clearly recognised that as a very important standing
12 group.

13 Q. Right.

14 A. That would give us advice.

15 Q. So when somebody within SNBTS was contemplating some
16 form of research, involving work on donor samples, would
17 they have felt it proper to consult Professor Girdwood's
18 committee?

19 A. Yes, I think it would be very valuable to do that.

20 Q. Right. Can we go back to the other letter, please.

21 We can see that there have been discussions
22 involving, obviously, yourself, Dr Brookes from Dundee.
23 Now, Bill, is he --

24 A. Bill Wagstaff?

25 Q. You think it might have been Bill Wagstaff?

1 A. Bill from Inverness.

2 Q. Bill Whitrow?

3 A. Yes.

4 Q. And then Brian would be Brian McClelland at
5 Trinity Park House.

6 A. That's right.

7 Q. Dr Cash is going on to say that:

8 "The blood transfusion in the West should undertake
9 initially evaluation studies of commercial kits."

10 Dr Cash doesn't restrict this to Abbott. So were
11 there kits from other manufacturers in mind?

12 A. Well, there were people -- other manufacturers, yes.

13 Q. Right.

14 A. I think John had more contact with individuals than
15 I did.

16 Q. I see. Then in paragraph 2 he sets out a proposal to
17 use retrospective studies to donor samples currently in
18 store, and then we can see the point you make about
19 anonymising the samples.

20 A. Hm-mm. I think that's fairly clear, what John says in
21 his letter.

22 Q. Yes. If we look on to the next page, we can see the
23 third paragraph: sufficient volume to enable certain
24 particular steps.

25 A. I think that's no problem. That's exactly how it would

1 be done. I think it's important to look at point number
2 4. It's very important to keep residual aliquots of
3 what I would call all the interesting samples. That's
4 where the ideas of these Tricky Dicky stuff comes in.
5 You are always looking for the unusual. You are looking
6 for the needle in the haystack, because that's the one
7 that will come back and jab you.

8 So we have to keep samples of these things and they
9 were often exchanged between individual labs. You will
10 know that many of the Glasgow samples from donations
11 eventually found their way into national quality control
12 standards.

13 Q. Right. And then the question of ethics is dealt with in
14 paragraph 4 and actually Dr Cash is anticipating that
15 Professor Girdwood may give ethical approval himself,
16 without calling a meeting of his committee.

17 A. Yes. I think that's true, and it's true to say that
18 John's penultimate paragraph, or ultimate penultimate
19 one, saying that we certainly didn't want to be
20 pressurised by any particular company. They obviously
21 had an very considerable financial interest in having
22 a test which would be rapidly introduced.

23 Q. Yes.

24 A. At considerable cost.

25 Q. Yes.

1 A. But that was never the name of the game. Never.

2 Q. Because?

3 A. Because we wouldn't want to put ourselves into all the
4 difficulties of sorting out all the problems that we
5 knew would arise, that had arisen in other testing
6 systems that we had investigated in the past. We
7 wouldn't go ahead with a test which was not fit for its
8 purpose.

9 Q. I see. So if great speed had been used, quality might
10 have suffered. Is that the point you make?

11 A. I'm sorry.

12 Q. If great speed was used, quality would suffer. Is that
13 the point you are making?

14 A. Oh, yes.

15 Q. Right.

16 A. I think hasten slowly would be the answer.

17 Q. Right. Dr Mitchell, I'm wondering, have you had a look
18 at the transcripts of some of the evidence this week?

19 A. Very briefly. I think they are still coming in.
20 I think yesterday I saw a fax or an email, yesterday and
21 I think the day before. Things have been coming in at
22 that speed. Tedder's I hadn't seen until yesterday
23 afternoon.

24 Q. I see. I just wanted to ask you what happened to this
25 initiative? I think before you answer, we would be

1 primarily interested in your own personal recollection.

2 So anything you can remember, unprompted by whatever you
3 may have read recently.

4 A. I think the difficulty would have been to pursue this
5 idea would be -- firstly, the availability of samples,
6 availability of commercial tests. I think there would
7 be a difficulty in any manufacturer at that level, at
8 this time, supplying sufficient tests for us to have
9 a look at and -- I think they were busy as it were, in
10 their own backyard, trying to develop the tests.

11 I think what Abbott might have been saying was, "In the
12 event that we were willing to do this, we would ask you
13 to do the following things", or insist on the following
14 things.

15 I always said all companies that ever approached us
16 about any test, "We will look at your test, we will
17 analyse it, quite unknown to you, we will look at the
18 results, we will publish the results, fear or favour."
19 We believe in telling what exactly we find. We will not
20 be stampeded into making allowances for this, making
21 allowances for that. We had to be sure that the test
22 was fit for purpose. That was for mass screening, day
23 in, day out. Same test today, same test tomorrow, the
24 same expected results, the same expected performance.

25 Q. What sort of --

1 A. I think the reason that we couldn't pursue this was just
2 because the materials were not available, weren't
3 readily available.

4 Q. Is that how you remember it?

5 A. Yes. I think John has made that point very clear. Even
6 with Bob going down to London, Tedder wouldn't be
7 prepared to let Glasgow or anywhere else, outside the
8 little group in London, have access to his material.

9 Q. What sort of number of kits would you have needed for it
10 to be a meaningful exercise?

11 A. That's a difficult question because clearly you don't
12 know. If you are getting false positives of 90 per cent
13 and they give you 1,000 kits, then it's not much use.
14 A lot depends on what you expect. You do a preliminary
15 study first and then you start scaling it up. There
16 would come a time when you were scaling it up to maybe
17 being able to do a week or a day's complete turn with no
18 problems. Then you might say the time has now come to
19 think of a bigger introduction.

20 Q. Right. When you say "90 per cent false positives",
21 I think we can understand that what that must mean is
22 that nine of every ten samples which have reached
23 a certain point turn out, on confirmatory testing, not
24 to be positive, is that right?

25 A. No, no -- well, yes, when you do the confirmatory test,

1 yes.

2 Q. What I'm wondering is, what is, as it were, the
3 denominator? Nine out of every ten samples that ...

4 Is it initial screening or is it repeat reactive?

5 A. That would be the initial screening.

6 Q. Right.

7 A. But many of them would just repeat again and again and
8 again.

9 Q. So if you repeat the initial screening, you must get rid
10 of some of them?

11 A. You might get rid of some of them.

12 Remember, these samples that were giving false
13 positives, they were folk walking about who were
14 perfectly normal healthy people. You had no reason to
15 believe that they were suffering from some related
16 condition like HIV. They weren't suffering from slim
17 disease or any other lymphoma or any other problem that
18 you were aware of. These were healthy people. That's
19 what the donor's information says: the donor shall be
20 healthy.

21 Q. You didn't actually give me a figure and I don't want to
22 press you if you don't want to give me one, but I think
23 just a ballpark would be interesting for us. When this
24 exercise is being discussed, would you have wanted to
25 get your hands on 100 kits or 500 kits or a thousand or

1 5,000? What sort of number of kits would you have
2 wanted?

3 A. It's difficult to answer that. Certainly five kits
4 would be useless, ten would be useless. 1,000 might be
5 doable.

6 Q. Right.

7 A. I don't think you would get a manufacturer to give you
8 a large number of kits. Because you might find
9 something that he didn't like.

10 Q. Okay. But if you had been able to get something of the
11 order of 1,000 kits, the exercise would have been worth
12 doing. Is that what you are saying?

13 A. I think we would have been prepared to have a go at it,
14 to look at it, but whether it would have revealed
15 anything in particular that would promise to go on and
16 accept large numbers, that would be a different thing.
17 Much would depend on the results of the first run, the
18 first analysis.

19 Q. You have covered in your answer to my question the whole
20 topic of availability of kits. We understand that. You
21 can't do any sort of experiment with kits if you haven't
22 got the kit, but was there any other reason why this
23 initiative didn't bear fruit? Did something else bring
24 it to a halt?

25 A. I think -- as far as I understood it at the time, around

1 about that time anyway, there was that group in London
2 that were doing evaluations or starting to do
3 evaluations of the Tedder kit or the development of that
4 kit, and I think that -- what's his name? -- the
5 virology department had looked at the various kits that
6 were available.

7 Q. Philip Mortimer?

8 A. Philip Mortimer. He had been able to get information
9 from -- small numbers of kits from various -- I don't
10 know how he did it but he got some. Clearly Gallo
11 wasn't prepared to do that but he got them from the
12 various manufacturers and they did an analysis, but
13 their testing didn't do much except -- I think the
14 number was 360 samples they examined.

15 Q. Right.

16 A. Was it five or six individual kits?

17 Q. Yes.

18 A. And on the basis of that they had advised the Department
19 of Health, or others, that two kits came out as being
20 the most likely kits that might be useful to examine.

21 Q. Yes, Dr Mitchell --

22 A. One of those was not Abbott.

23 Q. I don't want to interrupt you and you are absolutely
24 right about that but you are taking us a bit further
25 forward, because that exercise was completed by the end

1 of July.

2 I am just interested in whether in January in 1985,
3 something choked off this plan to do an assessment in
4 the West of Scotland?

5 A. I think it stood on that basis that, "If you have a kit,
6 please come, offer it to us and we will have a look at
7 it for you". You see, the one thing that -- why Glasgow
8 is chosen to do many of these tests or evaluations was
9 because of two things: we had a very excellent technical
10 staff. Secondly, we had an almost inexhaustible supply
11 of test samples, being the largest region.

12 Q. I see.

13 A. And that's one of the reasons -- there would be no point
14 putting this into Dundee or Aberdeen or perhaps
15 Inverness. They just didn't have the throughput. So it
16 was natural that Glasgow should be asked to do that.

17 Q. I'm going to prompt you a little bit. Can you have
18 a look at the transcript for Tuesday, please? It's
19 going to come up on the screen at page 83. Can you see
20 that question that starts about line 7, where it says:

21 "We have established, I hope, the position
22 in January, what the concerns were, and that you were
23 initiating some evaluations in Scotland, principally or
24 perhaps exclusively in the West. But then you ..."

25 And the "you" is Professor Cash because this is me

1 questioning Professor Cash:

2 "... you say that you were invited to discuss the
3 situation with Dr McIntyre and that he made it clear
4 that SHHD was strongly opposed to the prospect of SNBTS
5 undertaking its own kit evaluation."

6 There is then a quote from Professor Cash's current
7 statement, so a statement he has recently written.

8 A. "SHHD have given assurance to the department that they
9 were content ..."

10 Yes, that's true, I think that's right, yes.

11 Q. The next bit. Professor Cash has said in his 2011
12 statement:

13 "As I recall, I thereafter consulted with
14 Dr Mitchell and Dr McClelland and we agreed that in view
15 of the hostile reaction of SHHD, this SNBTS initiative
16 should be stood down."

17 A. Yes.

18 Q. Do you have a recollection of that?

19 A. Yes.

20 Q. You do?

21 A. Oh, yes.

22 Q. All right. Can you tell us about it then, please?

23 A. As I say, this was the whole argument that went on
24 about -- the Gallo stuff was not available in the UK.
25 Someone in London had developed a similar system.

1 Q. Yes.

2 A. I think there was a general feeling that it might be
3 a good idea to promote the British system, the British
4 test, and it might be available more readily than
5 something which was considered to be confidential and
6 patented and so on elsewhere. And I think that was the
7 reason that the department set up -- that is the
8 Department of Health -- did set up an evaluation group,
9 to look at the Tedder isolates and Tedder materials.

10 Clearly, if such an evaluation was going on and the
11 SHHD had agreed that they would go along with it, then
12 we were dependent on them for funding and all sorts of
13 things, and if they said, "No, we don't want you to do
14 that," there is nothing else we could do.

15 Q. Right. Everything you say makes sense, Dr Mitchell, but
16 I just want to press you on whether you have an actual
17 memory of an occasion when Dr Cash is confiding to you
18 that he has had a difficult meeting with Dr McIntyre.
19 Do you remember that or do you not?

20 A. I often think about why did we not start the testing and
21 clearly we would not have abandoned it except if
22 John Cash, being national director, had agreed it with
23 us. I think that's all I can tell you. When you say to
24 me do I remember a meeting on 5 December, or whatever it
25 was, I don't remember --

1 Q. I know, that's really hopeless actually. We can all
2 think back to the 1980, it's very difficult.

3 A. I can remember it being said, "Look, we are not going to
4 do this test, we are not going to do the evaluations
5 because we understand there may well be a British test
6 on the horizon, albeit a little bit behind the field".

7 Q. I see. Thank you.

8 A. It may take a little longer to get a British test up and
9 running but if and when it came, we would be delighted
10 to look at it.

11 Q. Right. Thank you, Dr Mitchell.

12 Can we go back to Dr Mitchell's statement then,
13 please, page 2 of [\[PEN0171000\]](#).

14 Over the page. Some of this we have covered
15 already. If we just look at the questions, we can see
16 what's being asked.

17 A. Yes. I think in my answer there -- I think that's again
18 just what I have said.

19 Q. Yes.

20 A. That clearly the confirmatory testing was being set up
21 by Dr Follett and Dr Peutherer in Edinburgh, and to us
22 that was a very important development.

23 Q. Yes.

24 A. Because, if we had a test that we were using, we would
25 have no way of doing any confirmatory work in my

1 laboratory.

2 Q. You are referring in your answer, Dr Mitchell, to some
3 difficulty in obtaining test materials from England.

4 A. Yes.

5 Q. You remember this, do you?

6 A. Yes, hm-mm. Yes, that's right.

7 Q. And this was -- are you remembering the --

8 A. This is because technical staff do talk to one another
9 on a regular basis. We had many other things to be
10 going on with. So they do tend to keep in touch, and
11 when you hear someone else is doing something, you say
12 "That's interesting, could we do that, please?" And we
13 tried to get materials from the evaluation team in the
14 south but unsuccessfully, again, because, as I think
15 I have said there, DOH had funded the thing and why
16 would they give us free materials when they had funded
17 it, albeit that we were not part of the evaluation team.

18 Q. Yes.

19 A. We would only be given limited access to samples and
20 test systems. It was really a question of, "Could we
21 have a flying start on this? Could we have a quick look
22 at it, please?" The answer was, "No, wait until the
23 evaluation is complete and then we will tell you what
24 the results are".

25 Q. As the director of a regional transfusion service and

1 a big one, the biggest one in Scotland, what was your
2 mood when you knew there were going to be HTLV-III tests
3 on the market, that they were coming? What was your
4 personal feeling about that? Were you relieved or were
5 you apprehensive because of the problems, or was it
6 a mixture? What were your sentiments?

7 A. You mean the test on the horizon was the English test?

8 Q. Just any test. When you realised in 1984 that there was
9 going to be testing.

10 A. Just general disappointment that we weren't looking at
11 things that other people were looking at. I think that
12 was the general feeling, a feeling of disappointment,
13 not so much relief. We certainly would be relieved in
14 the sense that we didn't have to do all that extra work.
15 Remember, we weren't in any way funded to do this.

16 Q. Yes.

17 A. We were doing it because we were interested.

18 Q. Yes.

19 A. You may think interest is not all that relevant but it
20 is. If you are actually working in a field, it's very
21 important to keep up-to-date with what's going on.

22 Q. I appreciate that, Dr Mitchell.

23 A. So that's why we were talking to the English all the
24 time.

25 Q. I think I'm just trying to capture the mood of the

1 transfusion service when you learned that the AIDS risk
2 would, one hoped, be alleviated by the arrival of
3 testing.

4 A. Yes, I think you have got to consider that the American
5 set-up was quite different from what it is in the UK:
6 different population of donors, different availability
7 of kits, different manufacturers, some manufacturers who
8 couldn't meet the deadlines. If you read the American
9 literature, you will see that some couldn't even -- even
10 Abbott, for example, couldn't supply all of America,
11 although they were -- I think, I believe they were
12 licensed -- not licensed but given an undertaking to
13 take this on as a contract. But even they were unable
14 to supply the whole of the market. And even then, the
15 number of positives expected in the UK would be much
16 less than you would expect in America.

17 Q. Right.

18 A. So we were disappointed not to be involved in the
19 evaluation in the United Kingdom.

20 THE CHAIRMAN: You are still concentrating at this stage on
21 the initial evaluation exercise?

22 A. Yes; yes.

23 THE CHAIRMAN: And that's what you have been talking about?

24 A. Yes. I think --

25 MS DUNLOP: Did you regard it as a given that screening

1 would be introduced?

2 A. Yes, I'm pretty sure it would be, yes, when a suitable

3 test was available, yes.

4 Q. How did you feel about that?

5 A. Excellent, great idea, no problem. We would be very

6 pleased at such an event.

7 Q. Right.

8 A. Yes.

9 Q. So what we are, I think, appreciating from your account,

10 Dr Mitchell, is a sense of frustration that you weren't

11 more directly involved.

12 A. Yes.

13 Q. That you weren't evaluating kits yourselves and --

14 A. Yes.

15 Q. And you couldn't get your hands on any sort of supply?

16 A. There were many other things going on at the time, but

17 we would like to have been a bit busier.

18 THE CHAIRMAN: Quite apart from that, this surely must have

19 been one of the big challenges facing your profession at

20 that stage.

21 A. I think that's right. I think Robin Weiss wrote a paper

22 in 1996, I think it was, I read it, saying that it was

23 the major thing in blood transfusion; the most important

24 event was that one, because here we were looking at

25 a lethal disease in those days.

1 MS DUNLOP: Yes.

2 A. "Lethal" meaning pretty quick.

3 THE CHAIRMAN: And you weren't getting in on the act.

4 A. We weren't seeking to give people bad news.

5 THE CHAIRMAN: No, no.

6 A. But at the same time we would have liked to have

7 introduced the test as soon as possible in the Blood

8 Transfusion Service in Scotland.

9 THE CHAIRMAN: There is a pride. When I refer to the

10 "Glasgow mafia", it's not a pejorative expression.

11 I reckon to be part of it. But --

12 A. We have a certain pride --

13 THE CHAIRMAN: You had a pride.

14 A. -- in our job, and anything in blood transfusion that

15 was going on, even if on the purely physical side,

16 I wanted to be involved. I wasn't a bystander. It

17 would be very easy for us to just have said, "Oh, just

18 leave it alone, don't bother with it. You know, it will

19 unfold in its normal way and one day we will all waken

20 up and there will be a test system and we will have

21 a turnkey system, all we do is turn the key and it will

22 work." That wasn't the way we looked at it.

23 MS DUNLOP: Yes. And this sense of positive anticipation

24 that the testing was going to be introduced, that must

25 have been something that you realised when the virus was

1 isolated or when the news broke that the virus, the
2 cause of AIDS, had been found. That must have been your
3 response, that a test would come and that donated blood
4 would be capable of being tested.

5 A. The feeling then was, "Thank God --

6 Q. Yes.

7 A. -- we have a handle on this thing."

8 Q. Just looking again at your statement and trying to get
9 as much information as we can about the availability of
10 kits, you have been asking Dr Dow -- we have been asking
11 Dr Dow as well -- as somebody who might have information
12 about that, but I think really the only picture we are
13 able to build up is that around July 1985 SNBTS was able
14 to do mini evaluations of the two selected kits. That
15 must have been July/August, so the Organon kit and the
16 Wellcome kit, which had made it through the phase 1 of
17 the evaluation. There were supplies of those kits to
18 permit the different areas in Scotland to do their own
19 mini evaluation.

20 Of course, then, based on the results of their mini
21 evaluations, they would make the choice between the two.

22 So obviously in the summer there were kits available.

23 Do you remember that mini evaluation process?

24 A. I have a good idea I remember it, yes.

25 Q. Right.

1 A. I think a number of labs were asked to do a mini
2 evaluation, a look at it, when it became clear from the
3 PHLS group what tests were going to be recommended.

4 I think was at Organon, and the Wellcome one.

5 Q. Yes.

6 A. And at that time I think a number of people were saying,
7 "Look, hallelujah, let's get on, we have got something,
8 let's look at it." But remember what I said to you
9 earlier, that the Mortimer study looked at 360-odd
10 samples, which were selected. Some of them were pretty
11 obviously going to be positive, they were known cases of
12 the disease, whereas when you had to scale that up to
13 the point of technical know-how -- Mortimer's group was
14 a group of very eminent virologists, who didn't run
15 a blood transfusion centre, didn't run anything to do
16 with blood transfusion.

17 What they said was good, their evaluation was very
18 thorough, and I don't think we could have done it at
19 that level of virology, molecular virology. But at the
20 same time 300-odd samples did really add up to mass
21 screening.

22 Q. Yes.

23 A. And we had to evaluate -- they were telling us what to
24 do but we knew how to do it, if you know what I mean.

25 Q. Yes.

1 A. But, in the knowing how to do it, there was
2 a considerable amount of work still needed to be done.
3 We had to do all sorts of things about sample
4 identification, computerisation, all sorts of things.
5 My centre was the first one in the world to have
6 a computer on line to the test the system.

7 Q. Right. We do know, Dr Mitchell, that, as originally
8 envisaged, the evaluation exercise was supposed to have
9 two phases: the Mortimer phase, if we can call it that,
10 and then the second face, where, according to our paper,
11 to which Dr McClelland contributed, there would have
12 been 10,000 samples looked at.

13 A. That's right, yes.

14 Q. As far as we can tell, however, because of pressure of
15 time, the whole of that exercise was not carried out
16 before October 1985, when screening was introduced.

17 A. Yes.

18 Q. But that sort of phase 2 exercise is what you are
19 describing, I think --

20 A. No, the mini evaluation started -- (inaudible) start
21 with the phase 2.

22 Q. But it's on a very much smaller scale?

23 A. A much smaller scale because they weren't available, the
24 test materials were not available.

25 Q. And so what we can take, I think, from what you are

1 telling us and what's in your statement is that kits
2 were available in the summer of 1985 for the West of
3 Scotland to do its mini evaluation and choose between
4 the two, but before that you think that you had also
5 made an unsuccessful attempt to get some test kits from
6 Wellcome earlier in the year?

7 A. No, I don't think --

8 Q. Well --

9 A. -- that's right.

10 Q. -- it's this sentence:

11 "Professor Cash had asked Harold Gunson to release
12 some of the English test materials from Wellcome."

13 A. But that wasn't successful.

14 Q. That wasn't successful?

15 A. No, no.

16 Q. Right.

17 A. But I think -- did Brian McClelland not write to
18 Wellcome?

19 Q. He did, yes.

20 A. Asking for a small amount of material and was not really
21 terribly successful with that?

22 Q. Yes.

23 A. When you said the middle of July, I'm sorry, I can't
24 remember the exact date when it was we received a number
25 of kits from Wellcome. Whether Wellcome are in

1 a position to scale up and go 100 per cent overnight,
2 I doubt that very much. I think, if I remember rightly,
3 the early samples that we got were good, they were fine,
4 and we could detect known positives and known negatives
5 and so on with the small amount we got, but when that
6 was scaled up, then we ran into all sorts of
7 difficulties.

8 Q. Yes, Dr Dow has indeed given us some further detail on
9 that.

10 A. Yes, that's an example of where what looks good suddenly
11 goes bad in your hand when you scale it up. You see,
12 a virology department has all the time in the world --
13 I don't mean that literally, but lots of time to look at
14 a thing: Two hours, two days, four days, next week ...
15 That's fine.

16 Q. Right.

17 A. Blood transfusion has to get this stuff on the shelves
18 this afternoon.

19 Q. Yes. I think you are telling us exactly that at the
20 bottom of page 2, talking about the difficulties --

21 A. When you start scaling it up and you discover that you
22 have got to repeat your tests over and over and over
23 again on the same day to get any sense out of it -- that
24 is that the manufacturer's own controls are working okay
25 as against the samples, to be sure the results are

1 genuine -- then you begin to see, "My goodness gracious,
2 this isn't really fit for purpose at the moment."

3 Q. Can we move on to the next page of the statement,
4 please, and look at your passage under the heading
5 "Introduction of HTLV-III screening in Scotland?" Now,
6 we know from a number of sources -- and you are
7 obviously particularly well placed to tell us -- that
8 the West also went for the Wellcome test.

9 A. That's right.

10 Q. And we asked some questions about short-term contracts.

11 A. Yes.

12 Q. And you have answered that. You think it would have
13 been unwise to introduce an interim, unvalidated test
14 whilst validation was being carried out?

15 A. I think I have just explained that to you.

16 Q. Yes. And you say no decision had been made to override
17 any evaluation, and you also say:

18 "Funding for such a venture would not have been
19 agreed for any one region, so as to avoid premature
20 regional variation within donor and patient anxiety."

21 Were you in favour of a uniform date for the
22 introduction of screening for the whole of the UK?

23 A. Yes.

24 Q. Right.

25 A. I think if you consider Scotland as part of the UK.

1 Q. I think it was -- and is.

2 A. You could have people coming from Carlisle up to
3 Dumfries.

4 Q. Yes.

5 A. That was known. Donors in Carlisle give in Dumfries.

6 Q. I take your point. But one area did go it alone.
7 I don't know if you remember that. There was an area in
8 England that started testing.

9 A. That was Hepatitis C.

10 Q. Oh, well, let's look at [\[DHF0019468\]](#). Do you see this?

11 A. Newcastle.

12 Q. This is 19 March 1985, and this is the DHSS writing to
13 the PHLs and talking about the need to put resources
14 aside in 1985 to 1986 to fund the introduction of
15 screening tests, but the regional general manager of the
16 northern region had replied to say that:

17 "Antibody screening is already being undertaken by
18 the PHLs in Newcastle."

19 And that money had been allocated by the region to
20 a consultant at PHLs to develop tests for the Blood
21 Transfusion Service.

22 A. That's PHLs. That's not the blood transfusion
23 department.

24 Q. Right.

25 A. That's not the regional centre. Dr Sherlock was not

1 doing screening of donors.

2 Q. He wasn't screening donors?

3 A. No, no.

4 Q. Right.

5 A. This might well have been somebody trying to do what

6 Eddie Follett was doing. They are trying to set up

7 a regional reference lab. I think that's what -- sorry,

8 I haven't seen that letter.

9 Q. No, indeed.

10 A. But that's what it would reveal to me. The general

11 manager was trying -- as John Cash and David McIntosh

12 and others have done -- to get reference centres in

13 various regions. This was to stop -- if the tests came

14 in, why should Newcastle send all its material, its

15 doubtful specimens, down to London. They might get the

16 answer back next week, whereas when we had somebody like

17 Eddie Follett on the doorstep. And no doubt Peutherer,

18 you were able to get an answer pretty quickly. Each

19 region would have its own reference centre.

20 Q. It was just this reference to antibody screening already

21 being undertaken by the PHLS in Newcastle.

22 A. Sorry, again, I'm only reading the letter as you give it

23 to me. The PHLS in Newcastle may well have been

24 offering an service to --

25 Q. To clinicians?

1 A. -- the clinicians for the urinary medical clinics or the
2 haemophilia centres down there, I really don't know, but
3 I think that would be what they were doing. They might
4 well have been offering a clinical service, which was --
5 remember what Scotland had said: in order to avoid
6 donors, or bogus donors, as I call them, attending to
7 get a free test, it was very important that the area
8 health boards should set up a reference laboratory which
9 could handle the clinical samples.

10 Q. Yes. We can see the sort of reasoning that the DHSS are
11 employing.

12 A. Yes.

13 Q. If we look down in the letter, they say:

14 "In the first place the introduction by one region
15 of a test to screen blood donations could severely
16 embarrass other blood transfusion centres."

17 A. That's right.

18 Q. And then:

19 "Secondly, we are concerned at the possible
20 emergence of different standards of positive results
21 ..."

22 A. Yes.

23 Q. And then:

24 "Lastly and most importantly, as was made apparent
25 at the recent meeting at PHLS, the Gallo isolate was

1 being used to provide the antigen for the test in
2 Newcastle. You should know that the department, some
3 nine months ago, wrote to the United States government
4 asking for their permission to use the isolate sent by
5 ..."

6 I suppose that will be Gallo to Professor Weiss:

7 "... in order to provide antigen for development of
8 tests in the NHS. Permission was not given and in the
9 knowledge of this the department cannot but look askance
10 at the entrepreneurial exercises that are being carried
11 out by ..."

12 A. I'm sorry, I have no knowledge of that. I didn't see
13 that letter at all.

14 Q. It was just an opportunity, Dr Mitchell, to refer to the
15 fact --

16 A. I'm very, very surprised at that actually.

17 Q. There seems to have been, at least to some extent,
18 a slight breaking of ranks?

19 A. I hope it wasn't within the blood transfusion ranks.

20 Q. I take your point.

21 A. It was quite clear that we were all to sing from the
22 same hymn sheet.

23 Q. And you agreed with that?

24 A. Absolutely.

25 Q. Can we just scroll right down to the bottom? Thank you.

1 Yes, there we are.

2 A. Sorry, I hadn't seen that before at all until now.

3 Q. Can we go back to the statement, please, and just move
4 over on to the next page, so we are talking about
5 [\[PEN0171002\]](#), now at 1005. In this section we were
6 focusing on the letter which was sent to the Lancet. It
7 actually appeared in the Lancet in March 1985 and it
8 registered the concern of transfusion directors at the
9 likely incidence of false positives with the commercial
10 kits then coming on stream.

11 But, of course, we know too that by the end of May
12 Professor Bloom was becoming very anxious about the lack
13 of screening and we know about his letter to the BMJ, to
14 which Dr Rizza and Dr Forbes were also signatories.

15 A. Yes.

16 Q. And we asked about your sources of information
17 underpinning the belief that there was a high rate of
18 false positive results with the commercial kits. We
19 asked what SNBTS had done to try to obtain information
20 from other blood transfusion services abroad and we
21 asked about various measures that might have been taken
22 to lessen the effect on donors or transfusion recipients
23 and you drew our attention to the letter from
24 Dr McClelland to Mr Madden. We have already looked at
25 that this week.

1 I think you actually went on to say that you
2 wouldn't have been in favour of introducing tests by the
3 back door. I suppose there would be two different
4 possibilities. I think maybe what the question was
5 getting at -- and I didn't put this well yesterday, but
6 the question was really getting at introducing donor
7 testing perhaps with information to donors when they
8 were in the centre but without public announcements, so
9 you wouldn't have this problem of people turning up to
10 get a test. The information would have been, I suppose,
11 discreet and within the transfusion centre but wouldn't
12 have been in the newspapers or in the public arena, no?
13 A. Maybe that's what wishful thinking would reveal but in
14 the real world I think you would find that that sort of
15 information would get out pretty quickly.
16 Q. Yes, I take your point.
17 A. Remember the number of people who were actually handling
18 all this material. The same thing happened with
19 hepatitis, if you remember. All the information --
20 stuff was being leaked to the press like mad and one
21 couldn't determine how it was leaked but at the same
22 time that kind of information, as I think I did say,
23 that getting out into the public domain would have been
24 devastating on the public. They would have lost all
25 credibility, blood transfusion would have lost it, and

1 people would have lost all interest in becoming blood
2 donors. They would say to themselves, "Well, if that's
3 what you think of me, don't bother calling me. Don't
4 bother telling me anything more. I don't want to know
5 if you are going to do that." You test one lot and not
6 another lot and the guy in Carlisle says, "Maybe if
7 I had been working in Dumfries, I would have had
8 a test," and the chap -- you can't have people crossing
9 boundaries and going around to find out if they are
10 positive or negative. There was an element of that --

11 Q. Yes.

12 A. -- early on.

13 Q. We know that from a very early stage the need for
14 alternative testing facilities was identified, so people
15 whose only purpose was to get an AIDS test were not
16 wanted as potential donors. We have some information
17 about the alternative testing facilities in Edinburgh
18 and I just wondered what the alternative testing
19 facilities were in the West.

20 A. As far as I know, the area health board in Glasgow did
21 set up access testing through the regional virus lab.
22 That was through Eddie Follett and that group. I think
23 they were well up and running about the time that we
24 were talking about Eddie Follett setting up the
25 screening test and the confirmatory testing. I think

1 they were a little bit running in parallel with blood
2 transfusion.

3 Q. Do you remember as at autumn 1985 what avenues would
4 have been open to a member of the public in Glasgow who
5 just wanted an AIDS test. Where would they have gone?
6 Where could they have gone?

7 A. I think some people did approach us.

8 Q. Right.

9 A. And we would have had to say to them, "I'm sorry, we are
10 not offering it to general public; what we are doing is
11 trying to get a test for donors. Please go and see your
12 own doctor." Their own GP might well have said,
13 "I don't know if I can have a test done but I'll find
14 out if the regional virus lab are doing it." I think
15 that's --

16 Q. So was there anything in the West of Scotland where
17 people could just walk in off the street and say to
18 somebody, "I would like to be tested for AIDS," and that
19 would happen?

20 A. No, not that I am aware of that. No, I don't think so.

21 Q. So a self-referral facility? You don't think so?

22 A. No, I think they would either have to go through their
23 GP or go through one of the clinics.

24 Q. Right.

25 A. You know, the drug abuse clinics or the other clinics or

1 genitourinary infection.

2 Q. Right. And then I think the other point that you are
3 making, Dr Mitchell, in your response, if we look at the
4 final page, 1006, relates to information from other
5 countries.

6 A. Hm-mm.

7 Q. Is it your position that it wouldn't have been safe to
8 introduce tests straight away in the UK on the strength
9 of evaluations that might have been carried out in other
10 countries. Is that what you are saying?

11 A. Yes.

12 Q. Right. So you couldn't just say, "This test has been
13 tried out in America, we can introduce it immediately in
14 the West of Scotland"?

15 A. No.

16 Q. Why would you not say that?

17 A. You know from the American literature the number of
18 false positives that they were finding.

19 Q. Right.

20 A. A tremendous number of false positives. As I say, even
21 as I read, I think it was in that Crewdson or that paper
22 that was sent to us. I think, if I remember rightly,
23 there was one saying in 1986 they were still trying to
24 improve the test so as to detect false negatives.

25 Q. Yes.

1 A. And I think in the States it was perhaps easy to say to
2 someone, "Well, you are a donor, we pay you for this but
3 just don't bother coming back. We don't quite know
4 what's wrong with you." You know? But I think the
5 position in the UK would be, "We have got to get
6 something done about this." Your donor has now become
7 a patient and you then have a duty to say, "Well, I'm
8 going to get you the best information I can get for
9 you."

10 Q. Well --

11 A. And that's where our beloved Dr Crawford took over.

12 Q. I understand that, Dr Mitchell, but I suppose I'm really
13 just wondering whether, if there had been a very good
14 commercial test from another country -- let's say the
15 United States -- a test that had very positive research
16 underpinning it and the field evaluations had all been
17 carried out in some part of the United States, that
18 would have been good enough to justify its introduction
19 without evaluation in the UK, or would some sort of
20 evaluation still have been needed?

21 A. We would certainly want to have a look at it first, to
22 see if it was compatible with our testing systems.
23 I mean, there may have been bits like, gearing up your
24 lab, having to buy extra equipment, extra staff, as
25 I said, computing, all the -- all the paraphernalia of

1 doing it on a large-scale.

2 Q. But is information about how a test performs on American
3 donors a reliable guide to how it will perform on
4 British donors?

5 A. No, they had a different population, you see.

6 Q. Right.

7 A. Many of their donors, as I understand it, were recruited
8 from penitentiaries and places like that, where clearly
9 there was a large degree of drug addiction and other
10 hazardous occupations or things. So I don't think we
11 would necessarily have just immediately willy nilly have
12 accepted the American tests.

13 I think even the American, if you read, they had
14 difficulty deciding among themselves what would be the
15 most superior test. As far as I read, there were
16 perhaps five or six individual tests all being used
17 throughout the States. None of which were compared with
18 one another. Nobody was exchanging samples to say,
19 "Look at this tricky one. Can you detect that? Or can
20 you detect it?" There was no correspondence between
21 individual centres.

22 Q. Yes.

23 A. You know, what's positive with me has to be positive in
24 Edinburgh --

25 Q. Yes, I think we can --

1 A. -- and London.

2 Q. We can understand that a proper comparison is really
3 dependent on different test kits looking at the same
4 samples. I think we can understand that, Dr Mitchell.

5 A. I think one of the difficulties was that many of these
6 people in their confirmatory testing were testing the
7 confirmatory test against the original virus, the
8 isolate, whereas in actual fact they should have been
9 using two separate tests, at least two separate ones.
10 It's like comparing cheese and chalk.

11 Q. Yes.

12 A. That was the difference.

13 Q. Right. Excuse me a moment, Dr Mitchell.

14 Thank you very much.

15 THE CHAIRMAN: Should we have a break or ...? I'll just
16 find out whether there are questions.

17 Do you have any questions?

18 MR DI ROLLO: Not for me.

19 MR ANDERSON: Nor I, sir.

20 MR JOHNSTON: Nor me. Thank you, sir.

21 THE CHAIRMAN: I don't think we need a break for
22 Dr Mitchell's purpose.

23 What's your general position?

24 MS DUNLOP: I have no further witnesses for today, sir, but
25 I do have a number of other statements, as perhaps is

1 common towards the conclusion of any one topic. There
2 are a number of other statements and I would like to
3 tender them.

4 THE CHAIRMAN: Then we should have a break and come back.

5 MS DUNLOP: I think a break would be sensible, yes.

6 THE CHAIRMAN: Thank you very much, Dr Mitchell.

7 (11.03 am)

8 (Short break)

9 (11.30 am)

10 THE CHAIRMAN: Yes?

11 Tendering of other witness statements by MS DUNLOP

12 MS DUNLOP: Yes, sir. I simply wanted to mention some of
13 the statements from witnesses who have not attended to
14 give evidence in person, and the first such statement is
15 from Dr McIntyre, [\[PEN0170552\]](#).

16 If we look at that ourselves, Dr McIntyre is
17 entirely, naturally, not able to remember very much and
18 has difficulty in answering most of the questions, and
19 we also have to bear in mind this is an omnibus schedule
20 of questions and much of it relates to happenings within
21 the DHSS, which one would perhaps not ever have expected
22 him to know a great deal about.

23 If we just perhaps look at the second page, one
24 point which does come across is his strong support for
25 the idea of an evaluation of test kits before they are

1 introduced. We can see that particularly in
2 paragraph 8.

3 THE CHAIRMAN: Is this generally or with reference to the
4 particular examples?

5 MS DUNLOP: He does say "generally". He says:
6 "It is normal practice to evaluate a new test."
7 THE CHAIRMAN: That can be a surprise really, can it?

8 MS DUNLOP: No, it's common sense but I think it's as well
9 for us to educate ourselves on these points.

10 THE CHAIRMAN: It is better to have evidence to rely on than
11 common sense, which is a variable element in any
12 assessment of a position.

13 MS DUNLOP: In paragraph 9 he makes reference to a briefing
14 minute to the Scottish health minister. That's the
15 Mr Macpherson minute, that one. 0027226 Mr Macpherson's
16 minute of 21 March 1985.

17 Then on to the next page. He also goes back to the
18 topic of evaluation, this time more specifically in
19 relation to the HIV test kits and that's looking at 11.

20 Then on to the next page. He perhaps encapsulates
21 the difficulty for people being asked these sort of
22 questions when he says:
23 "This all feels logical but is no more than my
24 attempt to elucidate the thinking of DHSS colleagues
25 after a lapse of 25 years, and my comments should be

1 read in light of this caveat."

2 Perhaps a caveat that should apply to most people
3 asked and would, I suspect, apply to us as well if asked
4 about events in the 1980s.

5 THE CHAIRMAN: Yes.

6 MS DUNLOP: Then going on to the next page as well, he talks
7 about personnel. He talks about Dr Bell in particular
8 in paragraph 23, and Dr Bell's various minutes.
9 Dr Alison Smithies and then Dr Ed Harris and
10 Dr Mike Abrams, and then Dr Diana Walford initially
11 before handing over to Dr Smithies.

12 Then his initial response to the idea of the SNBTS
13 evaluations is set out in paragraph 26. He did actually
14 say:

15 "I cannot recall being involved in any discussions
16 between SHHD and SNBTS regarding this matter. It was
17 also agreed at this meeting ..."

18 That's the coordinating group:

19 "... that no transfusion centre in Scotland would
20 commence routine HTLV-III antibody testing
21 unilaterally."

22 To try to be a little bit more specific, we did put
23 Professor Cash's version of events to Dr McIntyre. We
24 asked the Scottish Government to do so and we have an
25 email response, which is [\[PEN0171836\]](#). I think perhaps

1 I should just let everyone read it. (Pause)

2 THE CHAIRMAN: Yes. The last paragraph, which of course we
3 have seen before, actually misses the point. I don't
4 think Dr Cash's complaint is as to the tone of the
5 intervention but as to its effect. When I read this
6 first, I didn't really think that worrying about the
7 hostile character of it and so on mattered, nor is it
8 necessary to say that they treated colleagues in
9 a professional manner. You can treat people in
10 a professional manner and still fail to give them the
11 comfort they are looking for, I suppose.

12 MS DUNLOP: I suppose the question is perhaps whether it was
13 an offering of advice or opinion or an instruction.

14 THE CHAIRMAN: Yes.

15 MS DUNLOP: I'm not sure we are going to get to the bottom
16 of that.

17 THE CHAIRMAN: No. Well, the one thing that seems to be
18 reasonably clear -- and I will be interested in other
19 people's comments -- is that however it came about,
20 there was an acceptance as between the two major centres
21 in Scotland, who might have been involved, that the
22 process that was taking place in England was the right
23 way to go about it, properly funded, and that it
24 shouldn't be replicated here.

25 MS DUNLOP: Yes. I think there does come across an anxiety

1 immediately after the New Year in 1985 about whether
2 anything very much was happening.

3 THE CHAIRMAN: Yes. That's bound to be if people aren't as
4 involved, as clearly Dr Mitchell would have liked them
5 to be, even on an informal basis.

6 MS DUNLOP: Yes. When you look at material from the DHSS,
7 it is plain that steps were being taken to put together
8 a panel of experts to oversee the evaluation, to draft
9 protocols and so on.

10 THE CHAIRMAN: Yes.

11 MS DUNLOP: The next individual who has provided a statement
12 is Dr Macdonald, Dr Iain Macdonald. And his statement
13 is [\[PEN0170559\]](#).

14 He was the other deputy chief medical officer but he
15 points out that Dr Graham Scott, as deputy chief medical
16 officer, had responsibility for blood transfusion
17 matters.

18 I have to say, without intending any criticism,
19 a number of his answers do begin with "I do not know",
20 and given those circumstances and the lapse of time,
21 that would seem to be understandable.

22 THE CHAIRMAN: Certainly when the alternative is "I imagine
23 ..."

24 MS DUNLOP: Well ...

25 If we look at the second page, we can see, however,

1 a reference to DHSS as a Whitehall department taking the
2 lead. This is an expression that does crop up from time
3 to time. He makes a general point about DHSS:

4 "... having significantly larger numbers of both
5 administrative and medical staff who could give their
6 attention to health matters than SHHD. Individual
7 members of staff in DHSS could handle in greater depth
8 a smaller number of issues than their opposite numbers
9 in SHHD".

10 THE CHAIRMAN: I can see that in fact. I'm not sure it
11 answers what might be a question in the long-term, which
12 is whether DHSS had a role that subordinated thinking in
13 SHHD, or whether SHHD had a continuing responsibility to
14 assess issues for itself; no doubt with the assistance
15 that was derived from SHHD work.

16 I'm not sure that I know where this should end up.

17 MS DUNLOP: Well, we certainly have another big topic to
18 look at, which is analogous in relation to the
19 introduction of Hepatitis C screening.

20 On the topic of evaluation, he goes on to say in 8
21 that:

22 "The government would have been criticised had there
23 not been an assessment of the available tests."

24 THE CHAIRMAN: That's clearly correct, isn't it?

25 MS DUNLOP: Well, it would certainly seem to be supported by

1 the evidence, and I don't think actually anyone suggests
2 the contrary.

3 THE CHAIRMAN: There has been no suggestion otherwise?

4 MS DUNLOP: No.

5 THE CHAIRMAN: I don't think that is really challenged in
6 any way by Dr Mitchell, whose department was the one
7 that would have been doing something different.

8 MS DUNLOP: Then if we go on through the next pages, perhaps
9 particularly 24 is worth noticing, he says --

10 THE CHAIRMAN: Paragraph 24?

11 MS DUNLOP: Yes.

12 THE CHAIRMAN: That's skipping a lot that I have not read.

13 MS DUNLOP: There is a lot of "I don't knows".

14 THE CHAIRMAN: Okay.

15 MS DUNLOP: It's actually only one page. If we go to the
16 next page, 562.

17 THE CHAIRMAN: Right, it's quite compressed through that.

18 MS DUNLOP: Yes. 24, he does say he has some sympathy for
19 SNBTS in wishing to do things on their own account
20 without waiting for NBTS.

21 THE CHAIRMAN: But he really doesn't remember or know
22 anything about the background.

23 MS DUNLOP: No, I think that's really right, sir.

24 He does make general comment in 27 about this idea
25 of one service introducing testing in advance of the

1 other. Then he also remembers the need for alternative
2 testing facilities. That's covered in 29. He makes the
3 practical point, that perhaps no one else has said in
4 terms, that the sheer numbers of people who might have
5 turned up would have caused a logistical problem.

6 THE CHAIRMAN: I think I might have been more concerned with
7 the possibility that with an inefficient test system,
8 there would be false negatives that would expose
9 patients to greater risk.

10 MS DUNLOP: Well, indeed, and that would certainly dwarf any
11 point about running out of kits.

12 Then there is really nothing on the last page.

13 We then have a statement from Alexander Murray --
14 Sandy Murray, I think he was -- which is [\[PEN0121899\]](#).
15 He was a branch head. He says in (iii):

16 "My job title in SHHD was head of branch 3 of
17 division IVD."

18 I'm not sure if that's 4D or IVD? Four, thank you.

19 It's 4D. He explains a bit about the set-up.

20 THE CHAIRMAN: I will just read that paragraph more
21 carefully, if I may? (Pause)

22 How should one understand the relationship, if any,
23 between A and B?:

24 "... to carry out the administrative and executive
25 functions in relation to the CSA as such."

1 And:

2 "... a number of divisions of the CSA, including the
3 SNBTS."

4 Should one understand a hierarchical structure with
5 the SNBTS functions being subsumed under the CSA, or is
6 the care of the SNBTS separate from care of the
7 Common Services Agency so that there is a direct
8 relationship between branch 3 and the SNBTS, or what?

9 MS DUNLOP: Well, I understand it to have been pyramidal,
10 sir. I'm not sure about the hierarchy but certainly the
11 Common Services Agency appears to have had resourcing
12 and staffing of its own and then underneath it would be
13 the divisions of the Common Services Agency, and he
14 instances the SNBTS, the Scottish Ambulance Service and
15 the Scottish Antibody Production Unit, and as I think we
16 have said before, the Central Legal Office too.

17 And branch 3 has had duties in relation to both
18 levels. So the level higher up the pyramid, which
19 oversaw all of these divisions, and --

20 THE CHAIRMAN: Would the exercise of a function relating to
21 SNBTS have been channeled through the CSA or would it
22 have impact directly on the SNBTS? I don't think he
23 tells us that.

24 MS DUNLOP: No, but I think we can see from the documents
25 that sometimes Mr Murray is considering directly such

1 matters as funding of the introduction of screening,
2 without there having been some kind of intermediary from
3 the Common Services Agency getting the message from
4 SNBTS and transmitting it to SHHD. So there seems to
5 have been some issues where there was direct liaison.

6 THE CHAIRMAN: But the question is what the inferences might
7 be that one could draw from that, as to whether there
8 was a properly structured hierarchy or something much
9 more casual, which I think I may have to look at in due
10 course.

11 MS DUNLOP: Well, I suppose, sir, it really depends on the
12 issue, doesn't it? It's impossible to prescribe in
13 advance how any structure will respond to any issue
14 which might arise, and there seems to have been a degree
15 of flexibility, which no doubt was advantageous in some
16 circumstances.

17 THE CHAIRMAN: Well, may have been advantageous in some
18 circumstances.

19 PROFESSOR JAMES: You could perhaps put that the other way
20 round and say there was a degree of vagueness which
21 could have been disadvantageous in certain
22 circumstances.

23 MS DUNLOP: If it's necessary for the Inquiry to express
24 value judgments on these management structures in the
25 early 1980s, I'm sure we can ask some further questions

1 about them, but it's no doubt difficult for people to
2 give an overall impression at this juncture.

3 Mr Murray points out on the second page that he has
4 no medical or scientific qualifications and he says he
5 is unable to answer many of the questions put to him.
6 And there are again a number of questions to which his
7 response has to be that he doesn't know.

8 Then on to the next page, please. He mentions the
9 ministerial involvement in decision-making, which we
10 have seen in the minutes and indeed telexes
11 from February and March 1985.

12 On to the next page. He sets out circumstances in
13 which an issue would be brought to ministers' attention.
14 Then he talks about submissions going first to a junior
15 minister and then to the Secretary of State.

16 Then not really much else on the final page, 1903.

17 Immediately above Mr Murray was Mr Davies and we
18 have a statement from him, [\[PEN0171007\]](#).

19 THE CHAIRMAN: You say, all right, he moved across from
20 science then to become a principal administrator?

21 MS DUNLOP: Yes.

22 THE CHAIRMAN: A principal of the general division, right.

23 MS DUNLOP: So he is head of IVD, and then IVD had a number
24 of branches and Mr Murray was head of one of the
25 branches.

1 THE CHAIRMAN: It is interesting that Mr Davies came into
2 the service as a scientist.

3 MS DUNLOP: Yes. With a background in computing, in fact.

4 THE CHAIRMAN: Computing, oh, all right. I see that. Well,
5 it doesn't necessarily mean that was his background. He
6 became involved in computerisation, but I think --

7 MS DUNLOP: It's just that sentence:
8 "I had a background in computing ..."
9 That makes me think that must have been his
10 background.

11 THE CHAIRMAN: Yes.

12 MS DUNLOP: But I suppose quite early in the process, so the
13 division which he headed between 1983 and 1985 had
14 overall responsibility for SNBTS-related matters, and
15 then Mr Macpherson headed another division, which had
16 responsibility for inter alia, misuse of drugs and
17 communicable disease. So I suppose we have had some
18 examples of the crossover.

19 THE CHAIRMAN: In Civil Service terms, Mr Davies had a very
20 interesting career path, didn't he?

21 MS DUNLOP: Yes. I think some members of our team --
22 certainly one member of our team is able to remember
23 Mr Davies.
24 We can see in paragraph 5 he is mentioning
25 discussion of donor screening, but again I think really

1 reconstructing events rather than speaking of any direct
2 recollection. And predictably perhaps quite a lot of
3 "don't knows" or "I am unable to answer this question."

4 Go on to 3, please.

5 THE CHAIRMAN: Paragraph 22 indicates that even though he
6 wasn't directly involved in the scientific side of this,
7 the message has got through to him that everywhere was
8 extremely reluctant to use tests that ran the risk of
9 giving high numbers of false positives.

10 MS DUNLOP: Indeed, yes.

11 THE CHAIRMAN: And an equal concern about false negatives --
12 well, not equal. It's different. He doesn't remember
13 that as much.

14 MS DUNLOP: Hm-mm.

15 THE CHAIRMAN: We should remember that the tabloid press at
16 the time were hysterical. Does this period stand out
17 particularly for that?

18 MS DUNLOP: Then on the next page, he doesn't really again
19 remember anything of substance, although from the
20 paragraph at the bottom of the page he, and indeed his
21 wife, remember this as an anxious period.

22 THE CHAIRMAN: Yes.

23 MS DUNLOP: Then on to the final page, if we could, please.

24 It's just a small section.

25 So that's Mr Davies.

1 The next document is [\[PEN0170504\]](#). That relates to
2 Dr Alison Smithies. We did see if we could get
3 a statement from Dr Smithies and this is the response.
4 THE CHAIRMAN: It rather misses the point, does it -- or two
5 points? It's not really for Dr Smithies to decide
6 whether she should be helpful or not and the comment
7 that a person can make on a contemporary document may be
8 of great assistance even though that person doesn't
9 fully appreciate the total context in which the answer
10 is to be considered. There you are.

11 MS DUNLOP: We also, sir, mindful of the suggestion made by
12 Professor Cash and indeed Dr Mitchell too, that Dr Dow
13 might have useful information, contacted Dr Dow and he
14 provided at the same time a statement very swiftly.
15 [\[PEN0171680\]](#).

16 This is the one that we looked at earlier, and we at
17 least can see the different colours, but I know that
18 anybody who is reading it later will be able to or not?
19 They will? Yes, if they look at the PDF version, they
20 will be able to see the black, blue and red.

21 At the bottom of the page Dr Dow is setting out his
22 recollection of events in January 1985 and beyond. I'm
23 not completely sure about the meaning of that sentence,
24 that he knows that there was an Abbott system being used
25 in Ruchill. I'm not entirely sure why this is.

1 THE CHAIRMAN: That was the question I raised, prompted by
2 Professor James, about what was happening in Ruchill.

3 MS DUNLOP: Maybe it's worth looking. Leave Dr Dow's
4 statement open. It's worth looking at the mention of
5 Ruchill to which I alluded when I replied, sir, which is
6 in [\[DHF0019169\]](#).

7 So on February 11th, 1985, Abbott -- and can we just
8 look at their letterhead, please. They are actually
9 writing from Delkenheim. That's the factory we saw
10 mentioned as supposedly coming on-stream in 1985 to
11 supply Europe. They are writing to talk about the
12 Abbott HTLV-III EIA diagnostic test kit.

13 They say that they have already contacted three
14 British evaluators. If we look over the page, there we
15 have it.

16 THE CHAIRMAN: There is Ruchill.

17 MS DUNLOP: Yes.

18 THE CHAIRMAN: Yes, the question is: what was the population
19 that Ruchill was dealing with at that stage? I think
20 the suggestion is that it may have been people who had
21 problems of HIV/AIDS infection, not related to
22 haemophilia.

23 MS DUNLOP: I suppose one can speculate that in practice
24 there are likely to have been problems with any kind of
25 planned evaluation at Ruchill of a similar sort,

1 particularly if it was in March and April 1985, that the
2 availability of the kits seems to have been so limited
3 that in spite of what may have been intended by Abbott,
4 any evaluation exercise on anything approaching
5 a large-scale may have had to have been postponed or may
6 not have proceeded. But I take your point, sir, that
7 there is another aspect to this, which is simply that
8 the kits could have been being used for diagnostic
9 purposes in Ruchill at this time.

10 PROFESSOR JAMES: I would think that would be extremely
11 likely.

12 MS DUNLOP: Yes.

13 So can we go back to Dr Dow's statement then,
14 please? He refers to the West of Scotland mini
15 evaluation and that's at the bottom of the page. Can we
16 just go up a little bit. He says:

17 "Around July 1985, SNBTS were in the position to
18 perform a mini evaluation of these two proposed
19 commercial anti HTLV-III tests."

20 Then he says on the next page:

21 "... there were insufficient supplies of any (other
22 than the Abbott test) commercial HTLV-III test kit in
23 early 1985 for a significant evaluation for blood donor
24 screening purposes."

25 THE CHAIRMAN: Interesting expression:

1 "I realised that a national evaluation had been
2 performed."

3 There is nothing to indicate that he knew in advance
4 of the arrangements being proposed or put into effect.

5 MS DUNLOP: No.

6 THE CHAIRMAN: Of course, he has already said that he wasn't
7 involved in procurement, which I imagine was general and
8 not just specific to the example he gave.

9 MS DUNLOP: But he was at Ruchill because he said at the
10 start that he was on a part-time secondment to Ruchill
11 in 1985. I don't think he actually says what month he
12 began at Ruchill.

13 Then at the point when we framed our questions, we
14 were more interested in the deference between RIA and
15 ELISA than in the difference between a competitive
16 format and another type of format, and I think that we
17 have been on a bit of a learning curve on that topic.
18 So we did ask quite lot of questions about RIA versus
19 ELISA and he gives some interesting information about
20 the supply issue. He says that:

21 "Today, kits sometimes have expiry dates over a year
22 in advance but that wasn't the position in the 1980s."

23 Then the point made by almost everybody that the use
24 of isotopes for radioimmunoassay tests were also under
25 strict control, with laboratory staff having to wear

1 monitoring badges:

2 "So it was necessary for transfusion services to
3 accept the use of ELISA techniques that resulted in
4 completely new equipment being used."

5 Another practical consideration which one should
6 bear in mind in assessing the timing of all of this
7 process. He has given us a photograph of the equipment
8 necessary for performing the anti HTLV-III ELISA test
9 made by Wellcome.

10 Further down then, please, we asked about the
11 working party -- that is the regional transfusion
12 directors' working party amending its report, and about
13 various practical arrangements that had to be made. He
14 says on the next page that he is unaware of a second
15 stage to the evaluation but, of course, we have seen the
16 draft report of the second stage. Then he goes back to
17 the mini evaluation.

18 Again, a now familiar point about the initial
19 problems with plate validation failures and the test kit
20 being less sensitive than the developmental batch tested
21 in July. Of course, Wellcome, in one sense, had been
22 almost too successful because, despite there being two
23 tests approved, Wellcome seemed to have attracted custom
24 from almost the entire United Kingdom blood transfusion
25 services.

1 THE CHAIRMAN: Possibly the three factors identified by
2 Dr Dow were generally appreciated.

3 MS DUNLOP: Yes.

4 PROFESSOR JAMES: They were probably also supplying the
5 routine public health labs throughout the UK, when it
6 became clear that that was a better test at the same
7 time.

8 MS DUNLOP: Yes.

9 THE CHAIRMAN: It certainly must have put them under
10 tremendous stress to have to gear up to cover
11 everything.

12 MS DUNLOP: Yes. Then there is another --

13 THE CHAIRMAN: The plates would come from somewhere else,
14 I take it, or would they be Wellcome too?

15 MS DUNLOP: I don't know about the plates, I am afraid, sir.
16 Perhaps one could speculate that in that he says that
17 equipment was delivered; it may have been that Wellcome
18 subcontracted some aspects of that and delivered
19 a package, but we don't actually know.

20 THE CHAIRMAN: It would be Wellcome who would treat the
21 plates in the first instance, so that they would come --

22 MS DUNLOP: I expect so, yes.

23 THE CHAIRMAN: -- with their antigen and so on --

24 PROFESSOR JAMES: I think that's where the failures will
25 have lain. It's the displacement. We know what sort of

1 assay it is. So it will be the fact that these plates,
2 with multiple little sort of dips in them, as it were,
3 you know, just weren't properly coated to a really high
4 standard when they began to really, really mass produce
5 them. That would be my guess as to why some plates as
6 a whole, worked and others, you know, just didn't.

7 THE CHAIRMAN: So plate validation is much more likely to
8 deal with the plate ready for a test.

9 PROFESSOR JAMES: Exactly, yes, yes.

10 THE CHAIRMAN: Yes.

11 MS DUNLOP: Then he actually gives us some more interesting
12 information slightly further down about the
13 practicalities of storage. He says:

14 "Three months' supply would have filled several
15 shelves of our laboratory refrigerators."

16 THE CHAIRMAN: Yes.

17 MS DUNLOP: Perhaps on to the next page as well, please.

18 This is talking about confirmatory testing. Then
19 this table, which we have seen before. Statistics for
20 the first 176,149 donations tested. Actually it looks,
21 looks, as though the positive predictive value is only
22 about 20 per cent. But then he goes on to say that
23 Abbott was tried and proved even less specific.

24 THE CHAIRMAN: Yes. All the information about Abbott that
25 has been adduced tends to suggest that there were great

1 difficulties with their test.

2 MS DUNLOP: Yes. And of course, Dr McClelland made the
3 point that the Abbott explanation for the less
4 successful performance of their kit in the evaluation
5 doesn't work once you get into the field and you are --

6 THE CHAIRMAN: That's right. It certainly doesn't work for
7 the American experience.

8 MS DUNLOP: No.

9 THE CHAIRMAN: But it does suggest that, had the Abbott rep
10 succeeded, when the fly was cast, over Dr Mitchell
11 in January 1985, in attracting sufficient attention,
12 things could have been bad in Glasgow if a supply had
13 become available in April/May.

14 MS DUNLOP: It's perhaps fair to point out, though, sir,
15 that there is almost no information available about the
16 Electronucleonics test, which was approved very close to
17 the time when the Abbott test was approved in the
18 United States.

19 THE CHAIRMAN: No. They are the people who complained very
20 bitterly about discrimination, in effect, in America?

21 MS DUNLOP: Electronucleonics?

22 THE CHAIRMAN: Yes.

23 MS DUNLOP: I'm not sure that I can remember that.

24 PROFESSOR JAMES: Are they the ones that were seen by the
25 chief executive of Abbott coming out of the door --

1 MS DUNLOP: Yes, and assumed them to have won, yes. But
2 then I think sent away with the explanation that the
3 approvals were granted in alphabetical order.

4 THE CHAIRMAN: Which I have to say is not a terribly
5 persuasive explanation.

6 MS DUNLOP: Then on to the further page. It gets rather
7 more technical. I suppose Sheffield, having chosen the
8 Organon test, was useful.

9 If we go a little bit further down in Dr Dow's
10 response, we can see that there was what seems to have
11 been some kind of standardisation exercise required of
12 regional centres.

13 THE CHAIRMAN: Can we go up just a little, please, to see
14 the sentence introducing that?

15 MS DUNLOP: Yes.

16 THE CHAIRMAN: All right. Do you understand what the panel
17 2, panel 3, panel 4 and panel 5 differentiation is? We
18 have got a low positive one, a high positive one and
19 then panels 2, 3, 4 and 5.

20 MS DUNLOP: No, I don't know what the difference between
21 these panels would be, sir.

22 THE CHAIRMAN: And the other thing we don't know, as far as
23 this is concerned, is what the result of retesting of
24 the Ruchill weak positive was. But does it come? Yes.

25 MS DUNLOP: I should say, sir, that the view I have taken is

1 that both this information and the information which
2 Dr Dow has given on the following page, about practical
3 problems in the conduct of testing, has not been further
4 investigated because this topic is really meant to
5 relate to the introduction of testing and not to go
6 further into what happened once testing had been
7 introduced.

8 THE CHAIRMAN: Yes, indeed. And in any event, if it gives
9 us a general conclusion, it is probably much more
10 valuable than the analysis of the technical detail.

11 MS DUNLOP: Yes.

12 THE CHAIRMAN: And he does say here that the testing staff
13 of all UK RTCs got confidence that their testing
14 procedures would identify known positives day-to-day.

15 Yes, but I appreciate what you say, that you aren't
16 really focused at this stage on the effectiveness of it.

17 MS DUNLOP: No. Then if we go on to the last page, we can
18 see that Dr Dow has provided a number of references. He
19 says:

20 "Problems associated with the introductory use of
21 the Wellcome HTLV-III kit with regard to sensitivity and
22 address the problems of false positive tests
23 (specificity)."

24 So these references are there.

25 THE CHAIRMAN: But that again --

1 MS DUNLOP: Yes, we are going perhaps rather further than we
2 need to. So that is Dr Dow's contribution.

3 Could we go next, please, to [\[PEN0171000\]](#)? This is
4 Dr Mortimer's response. Well, it's the letter to
5 Dr Mortimer and then we have his response. So perhaps
6 if we just take a moment to look at the letter to
7 Dr Mortimer. (Pause)

8 THE CHAIRMAN: Can we go on down the page, please? I think
9 you can go on to the second page.

10 MS DUNLOP: Yes, we are still on the topic of ELISA versus
11 RIA.

12 THE CHAIRMAN: Yes.

13 MS DUNLOP: Then he replied, [\[PEN0171761\]](#), giving very
14 similar information about the change to ELISA from RIA.

15 THE CHAIRMAN: Another new expression "sandwich ELISA".

16 MS DUNLOP: Yes, I am afraid I can't explain that.

17 Then he talks about the other precautions which were
18 taken, if we go a little bit further down. Then perhaps
19 we could turn over. He suggests another enquiry we
20 could make, but we obviously have tried to look at the
21 whole question of statistics and we do have information
22 which we looked at in March.

23 Then next, if we could look at [\[PEN0131396\]](#), please.
24 This is from Professor Leikola and the only purpose in
25 looking at this in this particular topic is just to

1 note -- I think it's paragraph 7 -- that he gives
2 information about when screening began in Finland. Yes,
3 there we are:

4 "Testing of blood donors ..."

5 Well, in the Helsinki area, he says,
6 was September 1985. I'm not sure whether that would
7 cover the whole of Finland but obviously very similar to
8 the timing in Scotland and England. And that's the only
9 thing in the statement I wanted to look at in this
10 context.

11 Just finally, sir, in relation to our enquiries, we
12 do have an email -- well, a short statement, in fact,
13 which has been sent to us from Dr Perry, about the
14 letter -- I think it's [\[SNB0074920\]](#) -- that mentions an
15 evaluation of French testing kits at the end, which
16 seemed interesting and we did follow it up. It's not in
17 court book yet but perhaps I can just distribute hard
18 copies of it. Thank you.

19 We have a very short response from Dr Perry and yet
20 again, I think we have caused some meticulous research
21 of old files and no one has been able to find anything.

22 (Handed)

23 THE CHAIRMAN: Yes.

24 MS DUNLOP: So if I can just simply tender that as an answer
25 to what was an interesting question earlier in the week.

