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Wednesday, 16 November 2011

(9.30 am)

(Proceedings delayed)

DR BRIAN McCLELLAND (continued)

Questions by MR MACKENZIE (continued)

(10.04 am)

THE CHAIRMAN: Good morning. Yes, Mr Mackenzie?

MR MACKENZIE: Thank you, sir. I apologise for the delay in starting. It has allowed me to discuss Dr McClelland's supplementary statement with him. I do apologise for keeping everyone waiting.

Dr McClelland, could we return, please, to your main statement, which is [\[PEN0170754\]](#), and we got to page 16, I think, 0769. We had reached question 8, where we had asked:

"The steps taken by the SNBTS, and when, to prepare for the introduction of surrogate testing, including the evaluation of any surrogate tests and the preparation of guidance on testing and counselling donors."

You explain in 8.1 the different studies undertaken and the matters considered, and you then set them out individually in 8.1:

"The clinical features associated with elevated ALT levels and positive Hepatitis B core anti-body in Scottish blood donors."

1 You refer to the study by Dr Gillon and colleagues
2 published in 1988 in Vox Sanguinis, [\[LIT0011857\]](#). We
3 don't have to go to that, the study in donors testing
4 for ALT and anti-HBc.

5 Over the page, a few lines down:

6 "It was predicted that using both the screening
7 tests would exclude 4.4 per cent of donations and the
8 authors concluded that the findings did not justify
9 initiating surrogate testing until a prospective
10 controlled trial had been done."

11 8.2:

12 "The extent to which ALT levels fluctuate when
13 donors are tested during the course of several donor
14 attendances."

15 You refer to Dr Susan Lumley studying a group of
16 donors:

17 "... who were donating plasma regularly by
18 plasmapheresis."

19 Just to pause and ask, doctor, why was there a group
20 of donors donating plasma regularly by plasmapheresis?

21 A. This was to increase the supply of plasma for the
22 production primarily of Factor VIII. This is a method,
23 which I'm sure the Inquiry has already heard about,
24 which allows an individual donor to donate substantially
25 greater quantities of plasma than can be obtained by the

1 use of conventional whole blood donation. The relevance
2 here was that these are people who attend quite
3 frequently and, therefore, there was an opportunity to
4 test routinely obtained blood samples at relatively
5 frequent intervals and thus to see the temporal
6 fluctuation of the levels of any parameter in the blood.

7 Q. Yes. How frequently did the donors attend
8 approximately?

9 A. I can't say in relation to this particular group of
10 donors, but possibly monthly. The limit for donation by
11 plasma in the UK is roughly equivalent to a monthly
12 donation.

13 Q. I think the study was undertaken in 1987. Where was
14 this practice taking place of plasmapheresis? Was it
15 just Edinburgh? Was it elsewhere in Scotland or what?

16 A. It was a fairly standard practice in many countries.
17 I'm sure that -- it had been done for quite a long
18 period primarily to collect plasma from particular
19 donors who had high levels of antibody to, for example,
20 tetanus or the rhesus antigen. It was used for
21 production of immunoglobulins that had high levels of
22 that particular antibody, and the reason for using
23 plasma collection, plasmapheresis, in these donors was
24 that they are small in number and their own plasma was
25 of particular special utility.

1 Q. We should perhaps just go to the paper. I think the
2 reference is [\[PEN0170776\]](#). We will see this is a letter
3 dated 30 April 1991 from Dr Gillon to Professor Cash.

4 Dr Gillon is digging out the results of the study
5 Susan Lumley undertook in 1987. Could we go to the next
6 page, please?

7 We can see a retrospective survey was carried out of
8 all Edinburgh plasmapheresis donors past and present.
9 I'm just wondering, doctor, plasmapheresis was being
10 carried out at Edinburgh obviously in 1987. I'm just
11 wondering what was the purpose of that? Was it for the
12 production of immunoglobulin for particular patients or
13 was the purpose of plasmapheresis at Edinburgh in 1987
14 to generally produce more plasma to send for
15 fractionation generally?

16 A. Oh, I think in 1987 it probably was primarily for
17 hyperimmunoglobulin.

18 Q. If we just scroll through the paper it might tell us.
19 Perhaps just carry on going through. The next page,
20 please. Just carry on going until we see the word
21 "immunoglobulin". Hopefully it might appear but equally
22 it may not.

23 Perhaps if we go to the end of the paper to see the
24 conclusion.

25 THE CHAIRMAN: Can we stop there? On "possible aetiological

1 features".

2 MR MACKENZIE: Yes.

3 THE CHAIRMAN: We seem to have quite a variety of factors.

4 I would like to go back to paragraph 8.1, when this
5 paragraph is finished, but it's fairly clear that quite
6 a lot of people had aetiological features for ALT
7 variations that wouldn't have been terribly helpful in
8 forming a conclusion about NANBH.

9 A. I think we may need to actually take a look at -- I have
10 a feeling that I may have forgotten some relevant
11 information preparing this statement. I think that
12 Dr Gillon in the paper that you have recently referred
13 to, the paper in Vox Sanguinis, may also have included
14 data on platelet donors.

15 But just sticking with this, can you just take me
16 back to the first page for a moment? I don't wish to
17 mislead the Inquiry and I'm just beginning to wonder if
18 these are patients who underwent therapeutic
19 plasmapheresis or were they -- no, they were donors.

20 Sorry, plasmapheresis is also used as a treatment
21 procedure, and just looking at that table made me think,
22 have I misread this and confused donors with patients?
23 But, no, these are donors.

24 Q. Yes. The point simply interested me, doctor, because my
25 understanding, rightly or wrongly, was that

1 plasmapheresis was not generally carried out in
2 Scotland, at least in the 1980s, with a view to
3 collecting --

4 A. That's correct.

5 Q. I think we can leave that paper. But, sir, I think
6 there was something --

7 THE CHAIRMAN: Yes, I'm slightly concerned about the general
8 validity of findings that depend on a very small
9 population, obviously not selected on a particular
10 basis, almost casual, on this presentation of it, and
11 how one can extrapolate from that to any general
12 proposition, Dr McClelland?

13 A. This was a group of individuals -- let's just call them
14 that -- who were selected on the basis that they were
15 there donating -- undergoing this procedure and blood
16 samples were available, and they were patients whom we
17 had very close -- donors with whom we had very close
18 contact. So consent and so on was not an issue. They
19 could be informed of what was being done. It's not
20 representative of the general population.

21 THE CHAIRMAN: Indeed, my immediate concern --

22 A. It's not claiming to be representative of the general
23 population.

24 THE CHAIRMAN: That's right.

25 A. It's simply stating in this group of people the ALT

1 levels fluctuated. It's not saying anymore than that.

2 THE CHAIRMAN: It's almost like asking whether one could
3 determine the driving characteristics of the general
4 population by focusing on those who use Rolls Royces.
5 The method of transport in that case and the method of
6 extraction in this case are the things that distinguish
7 people, but one would be very slow generalise on the
8 results.

9 A. Well, absolutely, and this is precisely an example of
10 the sort of confounding factor that I was referring to
11 yesterday, when we were talking about prospective
12 randomised controlled trials.

13 THE CHAIRMAN: I understand you are going back to
14 Dr Gillon's paper.

15 MR MACKENZIE: Yes, sir.

16 THE CHAIRMAN: Because I think on paragraph 8.1 there are
17 some very interesting question that arise. There we
18 have got 82 per cent of donors with alternative
19 explanations for raised ALT, which suggests that only
20 18 per cent of the small number of 2.4 per cent are
21 going to give rise to data that bear upon the prevalence
22 of NANBH. Is that right?

23 A. I'm not a statistician, as I will have occasion to say
24 later on this morning again. I think in very simple
25 response to that, I would say that there are, of course,

1 many factors that will produce a transient or prolonged
2 elevation of a particular liver derived enzyme in the
3 blood. Some of them are very common factors. So the
4 fact that an individual has an ALT and has an
5 explanation for it that can be divined by a clinical
6 assessment tells you absolutely nothing about whether
7 they may or may not have Hepatitis C in their blood.

8 Perhaps I should qualify that. It's probably not
9 true to say it tells you absolutely nothing, but the
10 correlation between having Hepatitis C and having an
11 elevated ALT is totally not a simple one.

12 THE CHAIRMAN: I think that's the point. There is another
13 putative explanation, which makes it difficult to
14 generalise. Thank you, Mr Mackenzie.

15 MR MACKENZIE: Thank you, sir. Sir, I don't propose going
16 back to Dr Gillon's paper further. We have got him
17 coming tomorrow so we could perhaps put it to him again
18 tomorrow.

19 Doctor, paragraph 8.2, sticking with the statement
20 that:

21 "Dr Lumley found that donors' ALT levels fluctuated
22 from one attendance to the next," is that true as
23 a general propositions in relation to healthy donors who
24 are not infected with Hepatitis C?

25 A. I think this is perhaps the point that Lord Penrose was

1 alluding to.

2 Q. But from other studies. This can't be the only study
3 carried out.

4 A. From other studies -- and I'm not, I have to say,
5 familiar, I have not researched all the studies that may
6 have looked at serial measurements of ALT in healthy
7 individuals representative of the public or
8 representative of blood donors, there probably are very
9 few because these are awkward things to do. But my
10 understanding is that if one were to do such a study,
11 one would find fluctuating -- a proportion of people who
12 had ALT levels which would flicker in and out of the
13 range that would be deemed to be a positive test in
14 terms of a surrogate test --

15 Q. If one drinks alcohol, if I have a drink the night
16 before or today --

17 A. If you were to measure the ALT levels of the Scottish
18 male population on 2 January, you would find a very high
19 proportion with elevated ALTs.

20 THE CHAIRMAN: Do they have to be able to stand up to be
21 measured?

22 A. No, you can take blood samples in the horizontal
23 position.

24 MR MACKENZIE: Exercise and other perhaps transitory reasons
25 for elevated ALT --

1 A. Absolutely.

2 Q. -- so it does seem consistent with what else we know
3 that healthy donors' levels of ALT may fluctuate and
4 that is perhaps a factor which may create a problem in
5 using ALT as a surrogate test for Hepatitis C?

6 A. It's one of many reasons why the use of this generic
7 type of test can at best be a partial solution to the
8 problem, because the fact that you sample an individual
9 at 6 o'clock on a Thursday evening and their ALT level
10 is comfortably within the normal range does not tell you
11 that if you sampled them a week later, at 2 o'clock in
12 the morning, their ALT level may not be elevated. In
13 contrast to testing them for the presence of, let's say,
14 Hepatitis B surface antigen, which if they have it on
15 Monday, they will have it on Friday and they will have
16 it three months down the line.

17 Q. Another difficulty, perhaps, just developing that
18 a little is that for a donor who in the late 1980s did
19 have Hepatitis C that infected donor's ALT levels may
20 fluctuate as well?

21 A. Unquestionably they did.

22 Q. Even for infected donors, their ALT level would not
23 always be elevated?

24 A. That's very well established.

25 Q. Yes, thank you.

1 THE CHAIRMAN: Dr McClelland, we have seen graphs, of
2 course, that trace the peaks in ALT and the trough in
3 ALT. If one looks at that and simply measures ALT at
4 a given point, the relationship between peak, trough and
5 the date of measurement must be purely casual unless
6 some factor has been introduced into the definition of
7 your group at the outset, such as after a heavy weekend
8 or whatever.

9 If it is purely casual like that, aren't the ranges
10 of variation such that generally inferences are very
11 difficult to draw?

12 A. I'm not entirely sure that I understand what you mean by
13 "the casual relationship" --

14 THE CHAIRMAN: Not planned. The relationship between the
15 date on which the particular individual peaks and the
16 date on which his ALT is measured --

17 A. Right.

18 THE CHAIRMAN: -- is not something that is predictable from
19 generalities. It must be built in to the selection of
20 the class.

21 A. I think that's probably a very complex question, but
22 I think there are two factors that come to my mind. One
23 is that -- assuming one had a continuous readout of the
24 ALT level, it would be seen to fluctuate with
25 a periodicity, which could be related to -- for example,

1 could show diurnal variation, as many biological
2 variables do. It could show seasonal variation. It
3 should show variation of the menstrual cycle or
4 whatever. Or it could be completely random, which means
5 we don't know what are the factors that are triggering
6 it. Or it could be episodic relating to identifiable
7 causes or factors like having a good drink.

8 The second factor is the periodicity of the sample
9 because we almost never have, only in very specific
10 samples would you have a continuous readout or even
11 hourly or daily samples to work on.

12 So actually the practicalities of obtaining the data
13 make it exceptionally difficult to develop a good
14 understanding of, first of all, the pattern of
15 variation, regular or irregular and, secondly, the
16 association of those different levels with any other
17 identifiable factor. And this is not just true of ALT
18 levels, this is true are almost every biological
19 variable that you choose, that our understanding what is
20 the normal value is almost always, in my experience,
21 when I have tried to scrutinise carefully and understand
22 what a so-called normal range meant, I have become less
23 and less confident that it was really very soundly based
24 or could be seen to be truly representative of the
25 population.

1 PROFESSOR JAMES: Could I just add for most of those
2 biological variables, for example, ALT, this is
3 a statistical concept, so a normal range for ALT is plus
4 or minus two standard deviations from the level which is
5 found in a population, which is thought by the lab or by
6 the inventors of the test to be the most reliable
7 "normal" where they have said nobody has got a cold on
8 that day, nobody has had a heavy drink on that day et
9 cetera, et cetera, but "normal", nonetheless, is
10 a statistical concept, plus or minus two standard
11 deviations. So people do accept that "normal people",
12 a few normal people, might "normally" have an ALT, for
13 the sake of this argument, that is marginally above the
14 "upper limit of normal".

15 A. Absolutely. This is a big topic.

16 PROFESSOR JAMES: It's very, very boring but many, many
17 people have spent many happy hours trying to define
18 these things.

19 THE CHAIRMAN: Yes, I quite enjoy boring things,
20 Dr McClelland. But I don't think I want to pursue this
21 too far. It is quite clear that there is a generally
22 accepted standard based on quite a changing but
23 ever-increasing population, whose data feeds into it.
24 That's all right.

25 My concern in asking the question was not about the

1 base data from which one would measure variation, but
2 the chances of finding on the day, as it were, one
3 carries out a more limited test consistency of data that
4 could reliably be used as a measure perhaps. And
5 "casual" simply means there is not a finite defined
6 relationship or set of circumstances; it depends on all
7 sorts of factors, many of which you have listed, that
8 would undermine the exercise. I think that's enough
9 boring material from me.

10 MR MACKENZIE: Thank you, sir. Could I move on, please,
11 doctor, to question 78.3, the question of:

12 "Evaluations of a system designed for testing large
13 numbers of samples. Laboratory testing of ALT levels
14 and the establishment of reference ranges for the
15 Scottish blood donor population. Age and sex
16 distribution of ALT levels in the donor population."

17 You refer, doctor, to:

18 "An evaluation of a commercial analyser (an
19 Eppendorf EPOS) was conducted by the SNBTS
20 West of Scotland and reported in 1987."

21 The reference, without going to it, is [\[PEN0170841\]](#).

22 Is that essentially, doctor, the evaluation of test
23 equipment with which to undertake surrogate testing?

24 A. It was. That was the primary purpose, but it also,
25 because there was quite a substantial sample of donors

1 covering a span -- both sexes and a span of age, it also
2 was quite a substantial source of, as it were, baseline
3 data, addressing the questions we have just been
4 discussing, on the actual observed ALT levels in the
5 population of donors. So it had a second utility, which
6 was to allow a more confident prediction, I think, than
7 we could have made before as to the probable loss of
8 donations from testing, and also the point that
9 Professor James raised with me yesterday, the number of
10 donors who actually would be identified and would
11 require counselling and care related to the observation
12 of the positive result.

13 Q. Yes. We can see that samples from 5,000 donors were
14 taken, and you say:

15 "Because ALT level is a continuous variable, the
16 definition of a positive result must be based on
17 a judgment essentially arbitrary as to how an
18 individual's test result relates to the results from the
19 representative population and for any practical
20 large-scale application such as blood donor screening,
21 a threshold value must be set, above which a sample is
22 considered to be positive and the West of Scotland study
23 showed that if the threshold level was, for example, set
24 as the population mean plus 2.25 standard deviations,
25 giving an ALT value of 55, then about 2.3 per cent of

1 donations would be considered positive and would require
2 to be discarded."

3 Over the page, please. You tell us:

4 "The West of Scotland study mentioned above also
5 analysed the effect of age and gender on ALT levels,
6 providing data that indicated that the threshold ALT
7 levels may well require to be adjusted to be age group
8 specific for males and for females."

9 I think that's because, in short, men were found to
10 have higher ALT levels than women. Is that correct?

11 A. That's a consistent observation and also there is
12 a trend -- you know, an age-related difference, which
13 actually from the point of view of a donor screening
14 test was making this whole thing begin to look really
15 quite complicated. It's not just a yes or a no, you
16 need a sort of statistical algorithm to decide what
17 is -- if you are going to relate this to the biology of
18 the population, you actually need to select a threshold
19 level of ALT which is appropriate for that person's age
20 and gender, touching again on the points that
21 Lord Penrose was referring to.

22 Q. What is the age relation to ALT --

23 A. I can't remember whether it goes up or down with older
24 age. It probably goes up.

25 Q. With older age?

1 A. I can't remember.

2 Q. I think we do know that ALT levels are higher in males
3 than females. Why is that?

4 A. Many things are different between males and females.
5 Whether, if you did this study now with the changing
6 pattern of drinking in females, you might well find
7 a rather different result.

8 THE CHAIRMAN: Drink is a factor, isn't it?

9 A. Yes, of course.

10 THE CHAIRMAN: It did occur to me that there ought to be
11 a higher level tolerated in Scotland than in some other
12 parts of the world simply because of the reputation
13 Scots have, as males get older for drinking excessively.
14 So, you know, you can almost imagine the patients saying
15 to the doctor, "No, no, doctor, it's not disease, it's
16 the drink that has contributed to my condition".

17 A. Absolutely.

18 MR MACKENZIE: Thank you. Then again:

19 "In 1988 the SNBTS undertook a multi-centre
20 evaluation of the same equipment for ALT determination
21 and concluded that results were consistent between the
22 centres, taking a threshold value of the population mean
23 plus 2SD would lead to about 5 per cent of donors being
24 excluded, whereas a slightly higher threshold of mean
25 plus 2.5SD would exclude about 1.5 per cent of donors."

1 So to pause, there, if surrogate testing had been
2 given the green light, then SNBTS would have been in
3 a position, at least in terms of identifying suitable
4 equipment, to introduce such testing?

5 A. Yes. I mean, this was an important assessment because
6 something we haven't really touched on is the
7 technology, the methodology, for measuring these enzymes
8 is actually quite tricky. I think we saw a document
9 yesterday from an evaluation carried out in three
10 centres in England, which expressed concerns that in one
11 of the three centres the ALT values were systematically
12 different from in the other two, and that was why the
13 approach that we would have had to have plan to adopt,
14 if we were going to start testing, was to use the same
15 equipment throughout, control it carefully and be
16 confident that a positive result in Inverness, the same
17 sample would also be a positive result in Glasgow or
18 Edinburgh.

19 Q. Yes, thank you. Then in your statement you say:

20 "I have no recollection of being involved in or
21 being aware of work on the preparation of guidance on
22 testing and counselling donors. However, I'm sure that
23 there was concern about how we would manage donors
24 rejected on the basis of a surrogate test, since we
25 suspected that in most cases the test would not indicate

1 the presence of infective non-A non-B Hepatitis."

2 I think you indicated yesterday really that little
3 or no thought had been given to that stage of
4 counselling donors and what to tell them and what to do
5 with them in terms of recommended treatment. Is that
6 essentially correct?

7 A. It's probably not quite fair to say little or no thought
8 had been given, but what Professor James asked me was
9 when we really sort of bottomed this out, and we
10 certainly hadn't. We hadn't got to the stage whether we
11 should have been doing this at this stage or not is an
12 arguable point. We knew that we would have something of
13 the order of 4,000, probably about 4,000 individuals who
14 would fall into the category of having had a donation
15 deferred for an elevated ALT level, and we were aware
16 that that was going to be a very significant burden of
17 work. But we certainly had not sort of prepared
18 a systematic sort of management plan and costed out the
19 stuff involved, looked at the implications for the other
20 hospital departments and GPs and all that stuff we had
21 not done.

22 Q. Hypothetically speaking, if you had been given the green
23 light to introduce surrogate testing, so the service did
24 then have to bottom that out and start drafting
25 guidelines and protocols for counselling and recommended

1 treatment for donors, do you think that is a matter
2 which could have been properly addressed or would that
3 have been an insurmountable obstacle?

4 A. I'm absolutely confident it could and would have been
5 addressed and that, you know, there were a lot of
6 strategies that could have been adopted to allow testing
7 to begin while some of that work was being done. It
8 wouldn't have all had to be fully in place before one
9 started testing.

10 At the simplest level you could commence testing
11 setting the cut-off level somewhat higher, which
12 actually probably in retrospect, with what we know now,
13 would have been exactly the right thing to do, because
14 the higher ALT level was probably more strongly -- well,
15 we now know it was almost certainly more strongly
16 predictive of Hepatitis C being present and that would,
17 as you can see from these figures, have dramatically
18 reduced the number of donors. So there are many way
19 I ways this could have been handled.

20 So I think my answer to your question is, if there
21 would have been a decision that testing would start, we
22 would have clearly needed a few months, probably, to get
23 all the equipment and everything in place and operating
24 and staff trained. We would certainly have had to take
25 some measures in terms of training donor staff,

1 preparing information for them and so on, but we had
2 quite bit of experience of sort of working through that
3 sort of thing some years previously with the
4 introduction of HIV testing. I think we would have
5 found our way through that fairly effectively.

6 Q. You mentioned the setting of ALT levels. Am I right in
7 thinking that the higher the ALT level one chooses, the
8 specificity of the test is increased? One is more
9 likely to find a true positive, whereas the sensitivity
10 is decreased?

11 A. The sensitivity is certainly decreased. I'm on fragile
12 ground here because I haven't reviewed this, but I think
13 that there are later data, which does indicate --
14 I think it's probably evident in the Canadian study by
15 Blajchman and colleagues, which I mentioned later on,
16 that the higher ALT levels were more strongly predictive
17 of Hepatitis C being present. I would have to go back
18 and look at the paper.

19 Q. So we would have to be cautious with that. So why did
20 you say that you would perhaps have started with
21 a higher ALT level?

22 A. I simply threw that out as one of the strategies that we
23 could have adopted, because we would have reduced the
24 number of donors and donations that had to be managed in
25 the first six months while we were getting our feet

1 under the table with this new technique. I'm not saying
2 that we would have done that but there was that and
3 other things that we could have done.

4 Q. So it could have been set at a higher level initially
5 for practical reasons?

6 A. Yes.

7 Q. I see. Thank you.

8 Then question 9, please, moving on. We then ask:
9 "Estimates made at the time of the likely cost of
10 introducing surrogate testing in Scotland."

11 I'll come later with Professor Cash to look at the
12 bids for funding, but you do say in your written
13 response that:

14 " ... providing a reliable cost estimate of
15 a surrogate testing programme would have been
16 a difficult exercise. While the cost of equipment,
17 reagents and personnel would have been relatively
18 straightforward to determine, the costs that could be
19 created in a blood donor programme would have been more
20 difficult to predict. In addition to the costs
21 associated with obtaining perhaps 5 per cent more
22 donations to replace those discarded because of
23 surrogate test results, there would have been the costs
24 of care and management for a large number of donors who
25 would find themselves deemed unacceptable to donate."

1 We are back, then, to the 4,000 approximately
2 rejected donors.

3 A. Yes.

4 Q. Then over the page, please, page 19, question 10, we
5 asked:

6 "In surrogate testing of blood donors for NANBH was
7 not introduced in Scotland."

8 You explain:

9 "I think there are many connected reasons."

10 You attempt to summarise them. Firstly:

11 "There was a persisting belief among most SNBTS (and
12 NBTS) transfusion professionals that NANB hepatitis was
13 a much less common consequence of transfusion than it
14 appeared to be in the USA, and that it was generally not
15 a particularly serious condition. I have dealt with
16 this more fully above."

17 In terms of when these beliefs were held, doctor,
18 what sort of time period do you have in mind?

19 A. Well, I was really relating this statement, which is an
20 expression of opinion, I have to say, to the period, let
21 us say, between 1980 and 1988, when Hepatitis C testing
22 began to emerge. I do think that that coloured quite
23 a number of the decisions or perhaps non-decisions.

24 Q. Thank you. Paragraph 10.2 you say:

25 "Medical advisers in the SHHD appeared to have

1 shared this view."

2 Do you say that just from reading the documents
3 produced as part of the Inquiry or is that a perception
4 you held at the time?

5 A. That statement is based essentially on reading the
6 documents because I honestly can't remember to what
7 extent I had any understanding of the views held in the
8 department at that time.

9 Q. Thank you. 10.3, you say:

10 "This belief undoubtedly prevented serious
11 consideration being given to undertaking a robust
12 prospective clinical assessment of the effects of
13 surrogate testing at a time when it should in my opinion
14 have been undertaken."

15 When you say "at a time when it should have been
16 undertaken," what time period do you refer to there?

17 A. I think we have covered this pretty fully yesterday but
18 I think that was the very early 1980s because, as we
19 said, it would have taken probably three years with
20 a fair wind to get complete -- or have preliminary data
21 from a study of adequate size and power. If it had been
22 started much later than 1984 or 1985, its results would
23 have converged with the emergence of Hepatitis C testing
24 which, as the Blajchman paper shows very clearly, makes
25 surrogate testing irrelevant.

1 Q. Even as at July 1987, the time of the letter to The
2 Lancet "Surrogate testing irrational perhaps but
3 inescapable", even at that time, so before Chiron had
4 announced discovery of the Hepatitis C genome in
5 March 1988-ish -- even in July 1987 at that time I think
6 you thought it was too late to start a prospective
7 study.

8 A. Yes, as I've said, I think any time probably after 1985,
9 it would not have impact -- it would not have actually
10 provided any gain in patient safety, unless there was
11 some fairly spectacular preliminary results earlier than
12 one would have planned or expected that would have
13 motivated a decision to introduce surrogate testing.
14 The point is, would any patients have been spared
15 getting hepatitis? That's my judgment.

16 Q. I suppose that's looking back at things now with the
17 benefit of hindsight, given we know the Hepatitis C test
18 became available roughly in 1989, looking back one can
19 say, well, it would have been pointless to start
20 a prospective study after a certain date. But I'm just
21 really trying to clarify your thinking at the time.

22 In the 1980s it appears there came a time where you
23 thought, well, we should simply introduce testing rather
24 than start a prospective study, and certainly by the
25 time of the letter in July 1987 that appears to have

1 been the view.

2 A. Yes, I mean, my thinking about this fell into two epochs
3 with, as we discussed yesterday, a gap in the middle
4 when we were all fully exercised with AIDS and non-A
5 non-B Hepatitis. From my perspective, it rather fell
6 off the agenda.

7 I think by the time we came back to it, which was
8 towards the end of 1986, by that time I think my feeling
9 was that we actually just needed to get on with it.
10 Obviously I had no knowledge at all at that time of
11 whether or when some more definitive test procedure
12 would be available. I had no inside track about what
13 was going on in Chiron.

14 Q. Just to pick up on that, was the AIDS experience
15 a factor in coming to the view that by late 1986/1987
16 surrogate testing for NANBH should be introduced, or was
17 the AIDS experience and surrogate testing four NANBH two
18 completely separate matters?

19 A. I don't know to what extent I consciously would have
20 related the two at that time. I can't remember. But
21 there is absolutely no doubt that the sort of learning
22 through the AIDS experience and the realisation that
23 something could be there in our donor population for
24 years before we even realised that there was a problem,
25 you know, the whole of that, I think, was a very

1 powerful factor, in my own thinking, that we would have
2 to be more proactive in being able to do things. And in
3 the case of non-A non-B Hepatitis, it was arguably more
4 pressing because we knew there was something there, we
5 had known for quite a long time that something bad was
6 happening.

7 Q. Then in paragraph 10.4 you say:

8 "SNBTS and NBTS medical professionals were
9 unconvinced that surrogate testing would offer material
10 safety gains and were concerned that it would lead to
11 the loss of donors and donations and difficult problems
12 in the subsequent care and management of donors rejected
13 on the basis of a surrogate test result.

14 10.5:

15 "Requests to the SHHD for funding to undertake
16 surrogate testing were repeatedly turned down by the
17 SHHD."

18 I'll go over that with other witnesses:

19 10.6:

20 "The 1988 multi-centre study of surrogate markers in
21 blood donors was in my opinion essentially an
22 irrelevance, yet it appears to have distracted a great
23 deal of effort that could have been better directed to
24 a dispassionate re-evaluation of information that was
25 already available and that strongly challenged the

1 belief that non-A non-B Hepatitis was a non-serious
2 condition that was rarely transmitted by transfusion.

3 "10.7. Perhaps most importantly SNBTS was not
4 supported by SHHD in its expressed desire to adopt what
5 Justice Krever would go on to describe as the
6 'precautionary principle' by introducing surrogate
7 testing for non-A non-B Hepatitis."

8 Over the page, please, doctor, we asked:

9 "If surrogate testing for NANBH had been introduced
10 in Scotland, the extent to which the incidence of
11 post-transfusion NANBH/hepatitis C is likely to have
12 been reduced."

13 You do go on to develop your answer, doctor, in
14 a supplementary statement, which we will come to
15 shortly, but just, firstly, if I may finish your first
16 and main statement, you explain in paragraph 11.1:

17 "A number of studies provide some suggestions as to
18 the possible impact that surrogate testing might have
19 made to the risk of transmission of hepatitis by
20 transfusion."

21 You deal first with the risk for recipients of blood
22 components, and then for recipients of coagulation
23 factors:

24 "For patients transfused with blood components."

25 You refer to a Canadian paper, which we should

1 perhaps go to, it's [\[LIT0013223\]](#).

2 We can see this is a paper published in 1995 by part
3 of the Canadian post-transfusion hepatitis prevention
4 study group. I think if one takes things
5 chronologically, if we start in the right-hand column
6 under "Introduction" we see:

7 "A prospective study of post-transfusion hepatitis
8 in Canada in 1984-85 showed an overall post-transfusion
9 hepatitis frequency of 92 per 1,000 allogeneic blood
10 recipients, with a post-transfusion frequency of
11 Hepatitis C of 31 per 1,000 recipients. Since 1985 many
12 measures were introduced by blood collection agencies
13 worldwide to try to improve the safety of the blood
14 supply. These included the introduction of screening
15 for HIV ... and direct questioning of blood donors about
16 relevant medical information and lifestyle."

17 Reference in 1986 to the USA agencies introducing
18 surrogate screening.

19 And then at the start of the next paragraph -- or
20 rather the end of the last paragraph the decision in
21 America was made:

22 "... without the benefit of data from prospective
23 intervention studies showing efficacy ..."

24 Of surrogate testing.

25 Then:

1 "Because of the lack of such evidence, the Canadian
2 Red Cross Society and some blood transfusion services in
3 western Europe did not screen blood donors for NANB
4 surrogate markers. We thought a randomised double-blind
5 trial was needed in Canada to assess the frequency of
6 post-transfusion hepatitis and to see whether the
7 withholding of donor blood positive for the NANB
8 surrogate markers would reduce the frequency of
9 post-transfusion hepatitis.

10 "While our study was in progress, the genome of HCV
11 was elucidated. Testing blood donors for antibodies to
12 HCV was introduced in Canada in May 1990. Subjects were
13 involved in our study before and after the introduction
14 of HCV testing."

15 That's by way of introduction.

16 If we go to the left-hand column, please, we will
17 see a summary of the results of this study which is
18 being reported.

19 In the second paragraph down, in the left-hand
20 column, we see:

21 "From 1988 to 1992 4,588 subjects were enrolled into
22 two study groups that received allogeneic blood from
23 which units positive for NANB surrogate markers were
24 either withheld or not withheld. We also assessed
25 a simultaneous non-randomised cohort (650) of subjects

1 who received only syngeneic."

2 What's the pronunciation?

3 A. Syngeneic, it's their own blood. "Autologous" is
4 another word.

5 Q. I see:

6 "All subjects were followed up for six months and
7 assessed for the presence of post-transfusion Hepatitis
8 due to Hepatitis A, B, C non-A, B, C, Epstein-Barr virus
9 and cytomegalovirus. Withholding of blood containing
10 NANB surrogate positive units reduced the overall
11 post-transfusion hepatitis rate by 40 per cent and the
12 Hepatitis C rate by 70 per cent. Most of the benefit of
13 NANB surrogate testing was due to reduced frequency of
14 Hepatitis C virus after transfusion before all donor
15 blood was screened for anti-HCV."

16 The bottom left-hand column:

17 "Our study indicates that screening of blood donors
18 with the NANB surrogate markers was of value in reducing
19 HCV infection before HCV screening began but
20 subsequently the value of screening cannot be clearly
21 established."

22 It's not an entirely easy paper, I don't think,
23 doctor.

24 If we can then, please, go to the discussion at
25 page 24, which is 3226, the second last page. We see

1 the bottom of the right-hand column "Discussion". In
2 the second paragraph:

3 "During our study ..."

4 There is some repetition here:

5 "... withholding of NANB surrogate marker positive
6 units reduced the overall post-transfusion hepatitis
7 rate by 40 per cent ... the introduction of HCV
8 screening ..."

9 The second line from the bottom:

10 "Nonetheless our data suggest that NANB surrogate
11 testing in Canada before May 1990 would have reduced the
12 frequency of NANB hepatitis, especially that caused by
13 HCV."

14 The next paragraph:

15 "The drop in the HCV hepatitis rate from 31.3 per
16 1,000 to 12.6 per 1,000 between 1984-85 and 1988-90
17 appears to have been associated with improved methods
18 for the screening of blood donors, since the drop
19 occurred without NANB surrogate markers. In the USA
20 a similar reduction in HCV hepatitis was reported over
21 the same period in association with the introduction of
22 NANB surrogate marker testing."

23 That's the paper, doctor.

24 What points do you take from it, and feel free to do
25 that with reference to your written answer or simply to

1 do it orally?

2 A. I'm not quite sure how you want to do this because this
3 will come up when you move on to my second statement.
4 It might be more economical of the time if we did it in
5 a oner. This is a complicated paper and the more I look
6 at it, the more I have realised there are some issues in
7 interpreting the data.

8 Q. I think we will perhaps leave it. That's our first
9 taster of it. We will leave it and put it to one side
10 and come back to it when we look at your supplementary
11 statement. I'm grateful. That may be the better way to
12 do it. Thank you.

13 Just reverting to your main statement at page 20,
14 I think we have covered most of what you say in page 20.

15 Over the page, please, paragraph 11.5. We come back
16 to Scotland and the Crawford and others paper published
17 in 1994.

18 You say, paragraph 11.5:

19 "During the first six months of donor screening for
20 Hepatitis C antibody in Scotland, 181,000 donors were
21 tested and 0.088 per cent were confirmed to have
22 Hepatitis C antibody. Among the Hepatitis C-positive
23 donors, 59 per cent had ALT levels above the upper limit
24 of normal. Although this study did not determine ALT
25 levels in donors who were Hepatitis C negative, the

1 findings suggest that the use of ALT screening would
2 have allowed the detection of a substantial proportion
3 of HCV-positive units."

4 I don't think we have to go to the paper. We have
5 looked at it before but I'll give the number. It's
6 [\[PEN0020582\]](#).

7 We are going to come on shortly, doctor, to your
8 supplementary statement, but are you still of the view
9 that the findings of the Crawford paper suggest that the
10 use of ALT screening would have allowed the detection of
11 a substantial proportion of HCV-positive units?

12 A. I think one has to take that in conjunction with the
13 Canadian paper really, and I was aware obviously of the
14 Canadian paper when I wrote this. In the absence of
15 that one sort of genuinely prospective study, accepting
16 its limitations, I think one would be somewhat less
17 confident in making that prediction. However, that is
18 precisely the type of data on which the American
19 authorities made the decision to start surrogate
20 testing, if you like.

21 Q. Okay, I think we will come on to develop your view on
22 this a little when we come to your supplementary
23 statement. Maybe I could just finish your main
24 statement in the time we have left before 11 o'clock.

25 In paragraph 11.6 you look at patients treated with

1 plasma-derived coagulation factor products, and you say:

2 "It is generally accepted that surrogate testing
3 would have offered little or more likely no safety
4 benefit to patients treated with these products. This
5 is a consequence of the large number of donations
6 included in each manufacturing batch of product and the
7 introduction of heat treatment."

8 You refer to a SNBTS document, the number is
9 [\[PEN0130220\]](#). We don't have to go to it.

10 Doctor, we have heard discussion of the question of
11 viral load. Would surrogate testing have offered any
12 benefit to pooled plasma-derived products by resulting
13 in a reduced viral load?

14 A. I'm really not competent to answer that question.
15 I don't know.

16 Q. Okay. Then in question 12, finally in this session, we
17 asked:

18 "If surrogate testing for NANBH had been introduced
19 in Scotland, the percentage of donations that are likely
20 to have been rejected and the extent to which, if at
21 all, that is likely to have caused difficulties in
22 maintaining a sufficient blood supply..."

23 In respect of ALT testing you say:

24 "If the level of ALT that had been set as the
25 threshold for a 'positive' result was the population

1 mean plus 2.5 SD (about 45 IU), the loss of donors would
2 have been of the order of 2.5 per cent. If anti-HBc had
3 been used in addition, losses would, according to
4 Dr Gillon's study, have been about 4.5 per cent."

5 Finally you say:

6 "It is worth noting that a German report ..."

7 I will give the reference but not go to it, it's

8 [\[PEN0170869\]](#):

9 "... describes much higher ALT threshold levels of
10 134 IU for males and 89 IU for females. Using these
11 higher threshold levels, only 0.25 per cent of the
12 donors exceeded the threshold. Information is being
13 sought about the ALT thresholds in use for donor
14 screening elsewhere in Germany."

15 Have you had any success, doctor, in obtaining any
16 further useful information from Germany?

17 A. Yes, the short exchange of emails I gave you yesterday
18 was as far as I got with this. What I did ascertain
19 from the medical doctor who is in charge of donor
20 testing in the Frankfurt Red Cross centre, in North
21 Rhine-Wesphalia, which is the biggest German centre, was
22 that these ALT levels were indeed applied across the
23 German blood services. From the start of ALT testing,
24 which I believe to have been round about 1990s, although
25 he did not give me that information, I think it will

1 appear somewhere in evidence available to the Inquiry,
2 the ALT testing was terminated across Germany in 2006.

3 I did seek further information, first of all, about
4 the levels of deferral, because this is only a brief
5 reference to 0.25 of donors being deferred, and also
6 about any evidence that they might have comparable to
7 the Canadian study to look at the association of ALT
8 levels with the presence or absence of Hepatitis C,
9 because they continued ALT testing for quite a number of
10 years after Hepatitis C testing was introduced.

11 So the data exists in Germany, but after a very
12 encouraging initial response to my first questions,
13 subsequent attempts to get the supplementary information
14 met with a resounding silence. But what is interesting,
15 and it relates to our earlier brief conversation, is
16 that the higher ALT levels you can see clearly here a
17 much, much smaller proportion of donors that were
18 excluded.

19 So one could say that the German in a sense voted
20 with their feet, or on the basis of the evidence which
21 I don't know, to choose these high levels, either
22 because they believed those would be more predictive,
23 they would be more, as it were, specific for infectious
24 units, or because they were being pragmatic and not
25 wanting to get too big a problem with donor deferral as

1 a result of ALT testing.

2 Q. Yes. I think you mention that had ALT testing had been
3 introduced in Germany some time in the 1990s. Is that
4 correct?

5 A. Yes, I have on a feeling -- I glanced through the other
6 statements around this block and I think in
7 Professor Leikola's statement, he actually gives
8 information about the time -- the starting of testing.

9 Q. I had understood, and I may be wrong, that at least some
10 parts of Germany were ALT testing since the 1960s.

11 A. That's entirely possible because the system is actually
12 quite heterogeneous in Germany, particularly in earlier
13 years there were university-based -- university hospital
14 based blood collection centres, Red Cross centres. So
15 I think it's only relatively recently that there has
16 been a much more sort of standardised regulatory regime
17 for the transfusion services.

18 Q. I see. So when you talk of ALT testing in Germany in
19 the 1990s, is that a reference to across all of Germany?

20 A. That may just be wrong actually. I don't know.
21 I vaguely recall seeing a document in the last few days
22 which gave a date, and I think it might have been one of
23 Professor Leikola's papers.

24 Q. So in short we should perhaps look to other sources?

25 A. Please. I can't answer that at the moment.

1 Q. Thank you, sir. That may be an appropriate point to
2 break.

3 THE CHAIRMAN: Yes, thank you.

4 (11.02 am)

5 (Short break)

6 (11.26 am)

7 MR MACKENZIE: Thank you, sir. Dr McClelland, I would like
8 to turn now, please, to a supplementary statement you
9 produced for us. It's [\[PEN0172651\]](#). I should perhaps
10 explain that we initially sent out a set of routine
11 questions for our various witnesses and then, having
12 considered the responses we sent out a set of
13 supplementary questions to try and focus on particular
14 papers.

15 Question 1 we asked:

16 "Should a large-scale prospective study, as
17 originally proposed by Dr McClelland in 1981 (ie along
18 the lines of the US ... studies ... including the
19 follow-up of recipients), have been carried out in the
20 UK in the early 1980s (or at some point thereafter) with
21 the following aims:

22 "(a) to assess the prevalence of post-transfusion
23 NANBH in the UK.

24 "(b) to evaluate surrogate markers for the disease.

25 "(c) to investigate the natural progression and

1 seriousness of the disease.

2 "(d) to produce a library of 'known' infected sera
3 with which to evaluate any future assays which became
4 available?"

5 Your reply at 1 you say you I have not changed your
6 view in the years since this was originally proposed
7 such a study.

8 You still believe that:

9 "... such a study should have been carried out in
10 the UK. A true prospective study was carried out in
11 Canada recruiting patients between 1988 and
12 January 1992."

13 You explain:

14 "This study probably provides the best available
15 evidence on which a judgment of the value of surrogate
16 testing might be (or have been) made."

17 We will come back to that paper.

18 Question 2 we asked:

19 "If such a study had been carried out to what extent
20 is it likely to have met the objective set out in 1
21 above? To what extent would such a study have provided
22 more information on which to base a decision on whether
23 surrogate testing should be introduced?"

24 I think really the second part of that question,
25 what we were seeking to ask, was whether such a study

1 could have led to more informed decision-making.

2 In your reply 2 you say:

3 "The outcomes of a study of this nature would have
4 depended entirely on the quality of the design and
5 research protocol ..."

6 Et cetera:

7 "These in turn would have been in large part a
8 function of the resources both intellectual and
9 financial -- that were devoted to the study and of the
10 extent to which government and influential figures in
11 the health service communicated the importance of the
12 study to participants ..."

13 You go on to say:

14 "I think it is clear from the documents held by the
15 Inquiry that the proposals that I submitted in the early
16 80s were at most outlines -- intended to illustrate the
17 kind of study that was required. A successful study
18 would have required the engagement of people with the
19 knowledge and skills to design an effective study with
20 adequate statistical power, cost it, obtain funding and
21 carry it to completion."

22 Just to pause there, doctor, would a study of that
23 type have been required to have been carried out at a UK
24 level rather than a purely Scottish level?

25 A. It certainly would have needed to be a multi-centre

1 study, just because of the size of enrollment that would
2 be required, I think, to achieve a study of adequate
3 power and statistical power. As I think we already said
4 yesterday, it would have been an expensive, difficult
5 and long study to do. It could not have been
6 accomplished by one or two individuals based in one
7 regional transfusion centre with small financial inputs.

8 Q. I think you explained yesterday that such a study would
9 really have required support at the highest level, at
10 government level.

11 A. Yes, both to fund it and as I tried to imply in this
12 statement -- I mean, this is wisdom, this is knowledge
13 that I have now that I did not have in 1981 but, you
14 know, I have in the latter part of my career in various
15 capacities in a number of large clinical studies and
16 learned to understand just how much resource is needed.
17 I did not have that understanding at the time that I put
18 these proposals forward.

19 Q. I see. With the understanding you have now about the
20 complexities of designing and effectively implementing
21 such studies, with the benefit of hindsight, do you
22 think it would have been practical to carry out such
23 a study in the early 80s?

24 A. Well, I think, there is kind of two answers to that.
25 I think if -- and that's why I included quite a long

1 paragraph about this here. I think if the study had
2 been done to a high standard, it could have, as I have
3 said to you, produced useful answers in terms of three
4 of the four objectives but probably would not have been
5 informative about the long-term health effects of
6 Hepatitis C infection, simply because that requires
7 a very long follow-up of a large population and would
8 have been very difficult to do. However, I think it's
9 quite possible that if there had been a moderate degree
10 of interest in the study, a study would have been done
11 that was too small and underpowered and might not have
12 yielded conclusive results.

13 Q. I understand.

14 And question 3, doctor, we refer to the conclusions
15 of the work of Drs Dow and Follett, and we refer to
16 certain documents in footnote 1 on page 2 of your
17 statement. I'll go on to look at some of these
18 documents with Dr Dow next week.

19 But we asked:

20 "Did the conclusions of Drs Dow and Follett place
21 sufficient emphasis on the likely prevalence and
22 seriousness of post-transfusion NANBH? In particular,
23 as well as having regard to reported cases of the
24 disease, did the work of Drs Dow and Follett have
25 sufficient regard to the fact that most cases of NANBH

1 were subclinical and were unlikely to be detected
2 without prospective follow-up (by biochemical testing)
3 of recipients?"

4 You say in your reply:

5 "I cannot recall the extent to which I was aware of
6 these findings before Dr Dow's May 1986 report to the
7 SNBTS directors. However, I am confident that I would
8 have realised then that the studies were not designed in
9 a way that could determine the prevalence of clinically
10 silent post-transfusion hepatitis or obtain a reliable
11 epidemiological picture of the severity of the
12 condition."

13 Obviously, doctor, you would have seen Dr Dow's
14 May 1986 report to the directors. Is that correct?

15 A. Yes.

16 Q. Do you remember seeing that report at the time?

17 A. I don't have any recollection now, but I think I was
18 present at a meeting at which it was presented.

19 Q. We refer to three documents in the footnote, a final
20 report of 1984, a thesis of 1985 and the special report
21 of May 1986. Have you looked at these reports recently?

22 A. I don't claim to have read them all in great detail but
23 I'm fairly familiar with the principal findings.

24 Q. Thank you. Over the page, please on to question 4 we
25 asked:

1 "In the second half of the 1980s, did SHHD medical
2 officers place sufficient weight on the likely
3 prevalence and seriousness of post-transfusion NANBH?"

4 In footnote 2 on this page we refer to particular
5 documents:

6 "To what extent did their views in that regard
7 influence their opinion on whether surrogate testing of
8 blood donors should be introduced?"

9 You reply that:

10 "In responding to this question I would like to
11 refer to my previous witness statement."

12 In that you stated your:

13 "... personal opinion that professional staff in the
14 transfusion services did not fully appreciate the scale
15 and importance of NANBH before the advent of the HCV
16 test."

17 When you refer to 'professional staff in the
18 transfusion services", is that in both England and
19 Scotland?

20 A. I think that applies to both, yes.

21 Q. A general comment.

22 You have also described your:

23 "... views as to why the problem may have been
24 under-recognised. Medical officers in the SHHD would
25 have had no reason to be expert in hepatitis and

1 I imagine that they would have depended on information
2 from those considered to be experts. It seems clear
3 from a number of documents included in the detailed
4 chronology ..."

5 That's the chronology compiled and sent by the
6 Inquiry to yourself and other witnesses:

7 "... that officials in SHHD and some of the
8 professional advisers felt that the Dow and Follett work
9 provided evidence that NANBH following transfusion was
10 not a serious issue in Scotland at the time. Advice
11 from other sources in the UK may also have tended to
12 underestimate the prevalence and seriousness of NANBH."

13 What did you mean by "other sources"? Anything in
14 particular?

15 A. Well, there was a fairly small group of experts,
16 virologists mainly, who were members of all the relevant
17 committees and some of whom were quite frequently party
18 to decisions or non-decisions around the infection
19 testing. So I think advice and opinion was coming
20 centre from, if you like, a professional community
21 defined by having an interest in this particular topic.

22 Q. You then say:

23 "I have not seen documents that suggest that
24 importance was attached to obtaining information from
25 the USA, Canada or elsewhere that may have challenged

1 the reassuring received view from the UK."

2 When you say "information from the USA, Canada or
3 elsewhere", can you give an indication of the sort of
4 information that you mean?

5 A. Well, I think the Inquiry has already seen a huge amount
6 of information that had been built up, for example, from
7 the TTV study and similar activities, pointing to the
8 importance of non-A non-B Hepatitis in terms of both how
9 common and how serious. I'm merely trying to respond to
10 question 4, perhaps slightly overpolitely, and I say
11 I think it's entirely reasonable that the rather small
12 cadre of medical staff in the Scottish Home and Health
13 Department at that time couldn't be expected to be
14 experts in hepatitis.

15 It does seem, you know, looking with the wisdom of
16 the retrospectoscope that they were guided very much by
17 one single piece of work, which was the Dow and Follett
18 research, and didn't show -- there wasn't much to see in
19 the documentation that they had actually seriously tried
20 to take a more independent look at the literature and
21 the information that was available. That's all I was
22 trying to say.

23 Q. I see.

24 THE CHAIRMAN: It's a difficult area, this, because

25 I suppose it's not just the availability of information

1 but one's approach to it and the understanding of it
2 that would instruct a view on how serious NANBH was at
3 any one time. How do you resolve this? It's not an
4 easy equation to define.

5 A. It's not, and that's why I'm not intending to be
6 overly-critical here. I think you just have to be
7 prepared (a) to -- as with anything like this, to take
8 a look at what has been written and to look at the
9 literature. It wasn't a difficult thing to do, even in
10 1986, shall we say, before the internet was available
11 and so on. It was quite easy to go to the library and
12 look at a few current journals, and at that time there
13 was masses of stuff being written and published about
14 this, and then pick up the telephone and ask a few other
15 people what they thought about it. It's not rocket
16 science really.

17 I think this is the way one tends to form a judgment
18 about a complicated technical issue that is not bang
19 centre in one's own field of expertise. I'm not sure
20 whether that's answering your point or not, sir.

21 THE CHAIRMAN: I think at some stage I'm going to have to
22 take a view about what was realistic and what might
23 realistically have been expected of those who had
24 administrative and advisory roles round about this
25 period, and I suspect that there will be many factors

1 that enter into that. I'm not sure actually that it's
2 all that easy to say you can just wander along to the
3 library and pick up the relevant material. I'm not sure
4 that the library would necessarily have been arranged in
5 such a way at this time to enable one to pick up the
6 material. Nowadays I wouldn't expect to see many of the
7 publications on the shelves, it would all be computer
8 terminals.

9 A. I would say so. In some ways it was possibly easier in
10 the early to mid-80s because you could go to a library
11 and it had journals on racks and you could go and pick
12 up one called "T for transfusion", or "N for New England
13 Journal of Medicine". Now you have to grapple with the
14 knowledge network or Ovid or something.

15 THE CHAIRMAN: I don't think I can take it very far at the
16 moment. I can't get you to take the decisions for me.

17 MR MACKENZIE: Thank you.

18 Dr McClelland, in question 5a we asked:

19 "If surrogate testing of blood donors, (ie testing
20 for elevated ALT and/or able-HBc) had been introduced in
21 Scotland what percentage of donors are likely to have
22 been deferred."

23 You reply:

24 "This would have depended entirely on the rules
25 adopted for the performance and interpretation of both

1 ALT and Hepatitis B core antibody ... tests. Perhaps
2 the best data on ALT for Scotland is the report on the
3 evaluation of ALT testing ..."

4 You give a reference. We don't have to go to it.
5 It is [\[SNB0024423\]](#). This was a report by Drs Robertson
6 and Cuthbertson, evaluating the Eppendorf EPOS system we
7 referred to earlier:

8 "This reported a threshold ALT level of 2.5SD above
9 the mean value would lead to a loss of 1.5 per cent of
10 donations and at a lower cut of 2SD above the mean the
11 loss to be about 5 per cent. Gillon et al in their 1988
12 Vox Sanguinis article [\[SNB0083536\]](#) reported that
13 2.4 per cent of 1,742 donors had ALT levels above 45
14 units and anti-HBc was detected in 2 per cent. There
15 was no overlap between donors with raised ALT and those
16 with anti-HBc.

17 "A reasonable estimate would be that the combined
18 application of ALT testing at the 2.5SD level and
19 anti-HBc testing would have led to the loss of
20 3-4 per cent of donations in the mid-1980s. These
21 numbers may have underestimated the longer-term effect
22 on donor attendances because later research has shown --
23 perhaps not surprisingly -- that donors who are rejected
24 on one occasion are unlikely to return to volunteer
25 again and this tends to have a cumulative effect that is

1 not measured by the initial rate of deferral."

2 We then asked:

3 "Could a sufficient blood supply have been
4 maintained?"

5 Your view was that for the Southeast Scotland region
6 at least a sufficient blood supply could have been
7 maintained to meet clinical requirements.

8 I think I'm right, doctor, that at least at some
9 points in the 1980s, your region were transferring red
10 cells to London to help them?

11 A. Yes.

12 Q. It's against the background perhaps, am I right in
13 thinking, that a lot of plasma was required to produce
14 blood products but perhaps less components were required
15 for routine transfusion purposes? It's a very inelegant
16 question but ...?

17 A. So long as one is depending or was depending primarily
18 on the collection of whole blood and not depending on
19 the plasmapheresis procedure that we were discussing
20 this morning, then with the rising requirements for
21 Factor VIII, if you collected enough bags of whole blood
22 to meet the targets that we had been set for plasma,
23 then we had too much red cells.

24 Q. Yes.

25 A. Well, we had more red cells that were needed for

1 sensible transfusion of the patients in the population
2 that our region served.

3 Q. Yes. The next question is more difficult and it's
4 a longer answer. We then asked:

5 "To what extent are cases of post-transfusion
6 Hepatitis C likely to have been prevented (having
7 regard, for example, to the finding that in the first
8 six months of HCV screening the prevalence of HCV and
9 Scottish blood donors was 0.088 per cent and that
10 elevated ALT levels were found in 59 per cent of
11 HCV-positive donors)?"

12 That's, of course, a reference to the Crawford paper
13 of 1994, [\[PEN0020582\]](#).

14 Page 5 you begin your answer. You say:

15 "My response to this relates to patients who were
16 transfused with blood components."

17 You then in the next paragraph say:

18 "The question breaks into two main parts: (a) how
19 many individuals were infected with Hepatitis C as
20 a result of transfusion of a blood component and (b)
21 what proportion of Hepatitis C transmissions could be
22 avoided by the use of surrogate testing with ALT and
23 anti-HBc."

24 So you then look at the first part of that question:

25 "What was potentially preventible -- ie how many

1 patients were being infected with Hepatitis C by
2 transfusion each year before HCV testing began? In the
3 UK we have no direct knowledge of the number of
4 transfusion recipients who became infected with HCV in
5 any year before the start of HCV testing.

6 "We do know that when routine HCV testing began in
7 September 1991 a positive HCV test was found in about
8 one in 1,000 (0.09 per cent) of attending blood donors.
9 This figure reflects the true prevalence of HCV in SNBTS
10 donors in 1991-2 and is, to my knowledge, the only
11 reliable prevalence data that we have. For any earlier
12 years, an estimate of the number of HCV-positive donors
13 would have to be made, in turn necessitating estimates
14 of the factors that are believed to influence
15 prevalence."

16 One factor is information from
17 Health Protection Scotland:

18 "Because of the increasing incidence of injecting
19 drug misuse, the prevalence of HCV in the Scottish
20 population is believed to have risen substantially over
21 the period 1970-1991 and that this is believed to have
22 accounted for an increasing prevalence of Hepatitis C
23 infection in the Scottish population."

24 Just pausing to look at other factors which may play
25 a part in trying to estimate the likely HCV prevalence

1 in blood donors prior to September 1991, we know that in
2 roughly 1983 there were the beginning of steps to try
3 and exclude donors at a higher risk of transmitting HIV
4 and presumably those steps became increasingly effective
5 or stronger as time went on. Does that seem reasonable?
6 A. They may well have had a cumulative effect, as it were,
7 within the community. I mean, certainly, as the Inquiry
8 has already seen, there were progressive modifications
9 and refinements and some extensions of the donor
10 exclusion criteria in relation to HIV. Unfortunately,
11 of course, we don't have any direct evidence of the
12 effect that that had on either the prevalence of
13 Hepatitis C in the donations that were collected or on
14 the rate of non-A non-B Hepatitis in recipients. But
15 I have later on referred to a letter written to the New
16 England Journal by Professor Blajchman and his
17 colleagues comparing information from the United States
18 and Canada over a similar period, and his interpretation
19 of the data are that in the United States there was
20 a substantial fall in the rate of non-A non-B Hepatitis
21 in recipients, which was attributed to the introduction
22 of surrogate testing. But over a comparable period in
23 Canada there was a comparable reduction in the rate of
24 non-A non-B Hepatitis in the recipients. In the absence
25 of surrogate testing, those were -- is attributed to the

1 effect of the AIDS-related donor selection measures.

2 That's about the best data I could find to address
3 the question, but I can't map that directly on to what
4 happened in Scotland or the rest of the UK.

5 Q. No.

6 THE CHAIRMAN: Can I just ask for some clarification about
7 this paragraph that we have just ended on? You say that
8 the increased incidence of injecting drug misuse is
9 related to increasing prevalence of HCV. I think I can
10 understand that. The drug users are part of the
11 population and so you increase one element, you increase
12 the overall position. But does this read through to the
13 donor population?

14 A. I have to be very clear that this statement, starting
15 from "My understanding" to the end of that paragraph, is
16 really based on discussions that Dr Gillon and I had
17 with Professor David Goldberg and his colleagues in the
18 course of preparing a document, which has been
19 separately submitted to the Inquiry at your request,
20 sir. And two points: first of all, they have
21 a publication which I haven't cited because I felt it
22 was more appropriate to Professor Goldberg's evidence,
23 based on statistical modelling and it is on the basis of
24 that they have made the statement that the number of
25 injecting drug users has increased sharply from the

1 early 1980s.

2 Secondly, if I understand correctly
3 Professor Goldberg's thesis, the main driver of the
4 prevalence of Hepatitis C infection in the community in
5 Scotland is injecting drug misuse.

6 THE CHAIRMAN: I think I understand that, but I think you
7 will be aware of Professor Simmonds' analysis of the
8 phylogenetic trees related to the transmission of HIV in
9 Scotland.

10 A. Yes.

11 THE CHAIRMAN: And as I recollect it, the drug abusing
12 population did not contribute to the infection of
13 haemophilia patients and indeed only had one single
14 original source. I'm speaking from memory and not from
15 having the article in front of me. But if that were so
16 and they were not contributing to the transmission of
17 HIV, that would only be because they were not part of
18 the blood donor population contributing to the sources
19 of blood products, would it not?

20 A. Well, I would obviously very much like to think that the
21 drug injecting community were not part of the donor
22 population. And in earlier evidence to the Inquiry
23 I did make the point that although it was only in 1983
24 or 1984 that we formally introduced an exclusion for
25 drug users, in fact the practice in the Southeast of

1 Scotland centre -- and I am sure it was the case in
2 other transfusion centres -- had been based on
3 a recognition of evidence of drug injection was
4 a disqualification, it was just less formal.

5 THE CHAIRMAN: Really it's only this last sentence or two
6 that worries me, because as presented it might give rise
7 to the inference that one could read through to
8 a relationship between drug abuse and the spread of
9 Hepatitis C among blood donors -- sorry, in blood
10 donations and that worries me just a little on the whole
11 information I have, including your earlier evidence
12 about the extent to which these people had been
13 excluded.

14 A. I entirely accept that, sir, and, yes, I don't wish to
15 add anything to that.

16 PROFESSOR JAMES: Can I just pursue this a fraction? The
17 evidence from the States and Canada that you have
18 alluded to suggests that improved screening of donors
19 did actually very significantly reduce the incidence of
20 post-transfusion non-A non-B Hep C in roughly the decade
21 between 1981-1982 and 1991, when HCV screening came in.
22 While I accept what the chairman says, as a matter of
23 fact from my understanding, your screening of donors and
24 indeed in the UK as a whole but particularly here in
25 Edinburgh and in Scotland really did get tighter in

1 a progressive fashion over that period of time. It
2 wasn't just one step, and it was perfect sort of thing.

3 So would you like to hazard an estimate of whether
4 a similar sort of -- I mean, for the figures for 1991
5 that, you know, we have got the famous 0.0088 per cent
6 (sic) from Dr Gillon's original survey, the implication
7 might be that actually the prevalence among donors in
8 the early 1980s might have been two or three times as
9 great as that, or do you think that's just too
10 speculative or a reasonable inference to draw?

11 A. I'm not sure I have understood you. Are you asking
12 whether I think it's possible that the prevalence ten
13 years -- say 1980 would have been substantially higher
14 than it was in 1991.

15 PROFESSOR JAMES: Yes, in the general population and in
16 particular in the donor population.

17 A. I think it would be pure speculation. I made the
18 statement here that I think the only modestly reliable
19 prevalence data we have is the 1991 figure. I did
20 write, you know, before the Inquiry hearings started,
21 when we were just beginning preparation -- I did spend
22 some time with Peter Simmonds to try and get his take on
23 what one could or could not say about essentially two
24 questions. One was when Hepatitis C might have appeared
25 in the community in Scotland. And, secondly, what one

1 might deduce from the sort of phylogenetic evidence
2 about how the population of Hepatitis C carriers might
3 have increased and as a result of what factors. And
4 I have to say that the only conclusion that I was able
5 to draw from that discussion and reading what are
6 actually for me quite difficult scientific papers was
7 that one could be reasonably confident that Hepatitis C
8 has been present in the community for a long time.

9 As to quantitating it or producing any confident
10 assertion as to what may have influenced its prevalence,
11 I wasn't very much the wiser having had that discussion.

12 PROFESSOR JAMES: Quite a lot of people are not much the
13 wiser after technical discussions with
14 Professor Simmonds.

15 THE CHAIRMAN: That's not a reflection of
16 Professor Simmonds.

17 PROFESSOR JAMES: No, no. Speaking for myself, it's my own
18 inadequacies over a number of years.

19 THE CHAIRMAN: Having looked add his phylogenetic trees as
20 best I could over quite a considerable period of time,
21 I'm not sure that I understood more than the few
22 sentences in which he actually indicated his
23 conclusions. So it's not a criticism but it is
24 difficult.

25 PROFESSOR JAMES: In summary, you can't make any estimation

1 as an analogy with the sort of estimations that they
2 were making in Canada and the United States?

3 A. Unfortunately we can't because we don't have any of the
4 data because we didn't do the studies.

5 PROFESSOR JAMES: Yes. I agree with you that that's
6 a matter of regret.

7 THE CHAIRMAN: Let's wait and see. Yes, Mr Mackenzie.

8 MR MACKENZIE: Thank you, sir.

9 I think one point of clarification for the record,
10 I think Professor James referred to the incidence of HCV
11 in donors as being 0.0088 per cent and, of course, it's
12 0.088 per cent. I should clarify that.

13 Just the point in short perhaps, doctor, that
14 looking at that paragraph on page 5 we have just
15 discussed that one certainly can't exclude increasing
16 injecting drug misuse as a possible factor in an
17 increased prevalence of Hep C in the Scottish donor
18 population?

19 A. I think that's undoubtedly true.

20 Q. So it may be a factor what weight we place on it is
21 perhaps very difficult to say?

22 A. Yes.

23 THE CHAIRMAN: I suppose we do have to bear in mind that
24 it's not just the drug abuser who may be the source of
25 a donation that transmits, it can further down the line.

1 A. Absolutely, and this is part of Professor Goldberg's
2 hypothesis, I think.

3 MR MACKENZIE: Thank you.

4 Then at the bottom of the page, doctor, you say:

5 "However, Ebeling and Leikola (1991) cite a number
6 of studies that show that the overall incidence of
7 post-transfusion hepatitis has declined in the 1980s ...
8 this is partly due to changes in transfusion practice
9 towards fewer units per patient and also to a reduced
10 infection risk per unit.'."

11 I should perhaps pause and explain, sir, that
12 Dr McClelland has a number of additional references at
13 page 10 of his supplementary statements, which we will
14 find reference numbers and put into court in due course.
15 We hope to do that on Friday to the extent that we can
16 find them.

17 To return to the top of page 6:

18 "This trend is demonstrated by the rates of PTHC in
19 Canada that were observed in two studies in 1984-5 and
20 in 1988-92 (HCV antibody was measured using archived
21 samples for years before HCV testing began in May 1990).
22 Feinman et al (1988) reported that the rate of PTHC in
23 Toronto was 31.3/1,000 blood recipients in patients
24 recruited to the study in the period 1984-5. Blajchman
25 et al (1995) in a multi-centre study in Canada found

1 a PTHC rate of 12.6/1,000 in the recipients of blood in
2 the absence of surrogate testing."

3 Is table 1 a reference to Blajchman's table 1 or
4 your table 1?

5 A. That's a reference to the table 1 in the Blajchman
6 publication. I apologise for the confusion.

7 Q. Not at all.

8 Then:

9 "Donohue et al (1992) reported a falling rate of
10 PTHC in the USA (from 38/1,000 to 4.5/per 1,000) and
11 attributed this to the effect of surrogate testing.
12 However, this conclusion was challenged by Blajchman et
13 al (1993) who suggested that the observed fall was due
14 to changes in donor selection related to AIDS, since
15 Canada had seen a similar decline but had not introduced
16 surrogate testing."

17 I think really, doctor, all of that discussion
18 perhaps indicates the difficulties in trying to come to
19 any firm views about this period and whether a surrogate
20 testing had been introduced to the extent to which
21 things may have been affected?

22 A. I think absolutely, and I think it's extremely important
23 to be aware that there is this evidence that actually
24 prevalence -- sorry, the effect on patients might have
25 been very considerable without the introduction of

1 surrogate testing. I have gone into some detail on that
2 because of the question that was asked. I think it has
3 to be answered with that background.

4 Q. Thank you.

5 Then you say:

6 "How many donations with HCV could have been
7 detected by the use of ALT testing and HBcAb testing?"

8 The study that is probably most informative is that
9 of Blajchman in Canada.

10 I think we can then take the rest of that as read
11 because I think we have looked at this study now.

12 I think over the page you reproduce a table from
13 Blajchman --

14 A. May I just clarify, this is not a reproduction of the
15 table, this is my table 1, and I have extracted what
16 I thought was relevant data from a much more complicated
17 table in the Blajchman paper. And I have to say also I
18 think I may have made a typo because I can't quite
19 square the arithmetic in the 0.0 Hepatitis C rate.
20 There may be a typo there, for which I apologise.
21 I need to cross-check this for the record with the table
22 in the full paper to --

23 Q. I'm not sure you have made an error, doctor. If we go
24 to the paper, please, it's [\[LIT0013223\]](#).

25 A. Thank you.

1 Q. It's at page 3225 we see the table at the top of the
2 page.

3 A. That's the one.

4 Q. If we go to the second column from the right -- second
5 entry, we do see 0.0. Read across to the left, we will
6 see other figures.

7 A. Yes, I can explain this. It's the distinction between
8 the overall post-transfusion hepatitis events and those
9 which were specifically Hepatitis C related.

10 Q. Right. So --

11 A. So what this table is saying is in the withhold group,
12 which means the group of patients who received blood
13 that had had an ALT and core test done and all units
14 which were positive for ALT or core had been removed, ie
15 patients who received, let's say, ALT and core negative
16 blood, the rate of Hepatitis C transmission was zero
17 with confidence in intervals of 0.7 -- 0 to 7.4 per
18 1,000.

19 Q. I'm not sure, doctor, I understand everything in the
20 table, but I think it would take quite a lot of time to
21 go through it in detail, but what in short do you take
22 from the table, doctor? What's the point you seek to
23 tell us from the table?

24 A. I think the important -- there are a couple of points,
25 and this is why I tried to condense this into the

1 smaller table in my answer. There are two epochs in
2 this study. There is the period before Hepatitis C
3 screening was introduced, and then there is a period
4 after hepatitis screening was introduced, during which
5 the researchers continued to apply the protocol for
6 their trial, ie to randomise patients to receive blood
7 that had been ALT tested and positive units withheld and
8 blood that had not been influenced by the effect of ALT
9 or core testing.

10 So they started a randomised study to compare tested
11 and untested blood, and then about a sixth of the way
12 through the recruitment to that study Hepatitis C
13 testing came in, but they continued with the protocol
14 and, as it were, superimposed the Hepatitis C testing on
15 that.

16 This is where my statistical skills become woefully
17 inadequate, but I felt it was only safe to look at the
18 data for the period before Hepatitis C testing had been
19 started, and the number of patients there is relatively
20 small. However, there were nicely matched numbers and,
21 as far as I can tell, quite well-matched groups of
22 recipients in this period. So 397 patients received
23 blood that was not subject to the effect of surrogate
24 testing. 402 received blood that was subject to the
25 effect of surrogate testing. There were eight events as

1 defined by elevations of liver enzymes in the recipients
2 in the no test group, and only two events in the test
3 group.

4 The important figures, though, in relation to the
5 question, which is specifically about Hepatitis C, is in
6 the penultimate column on the right, which is that the
7 rate of Hepatitis C in the recipients of the untested
8 blood was 12.6 per 1,000 with a wide range of 4 to 29.
9 Whereas in the 400 recipients of untested blood there
10 were no transmissions of Hepatitis C.

11 I'm not at all confident to comment on the
12 statistical power of that observation because the number
13 of patients in that group are quite small, and I'm not
14 really, certainly at the moment, prepared to comment on
15 the significance of any results that were found in the
16 period after Hepatitis C screening had started because
17 I haven't got my head around that.

18 But what you can say is that the -- what this data
19 appears to show is that once you have started
20 Hepatitis C screening, then the surrogate testing had no
21 statistically detectable effect on the rate of
22 post-transfusion Hepatitis C. Whereas, before you had
23 Hepatitis C testing, surrogate testing has an effect, an
24 apparent effect, on the rate of Hepatitis C in the
25 recipients. However, I always thought that if you see

1 the 95 per cent confidence intervals overlapping, as
2 they do here, the statistical confidence in the finding
3 was not that high, and I feel that is reflected in the
4 discussion or the final conclusions of the paper, which
5 says:

6 "Our results suggest that ... surrogate testing
7 would have reduced the rate of Hepatitis C in the
8 patients."

9 I would stress that this is not a simple paper and
10 the more I looked at it, the more I felt less confident
11 in the conclusions I can draw from it. And I would hope
12 that if the Inquiry feels it is important, they would
13 seek the input of someone with greater skills in this --
14 more competent than me to evaluate it.

15 Q. In particular, in the question of statistics, it is
16 a statistician, I think, is the area that you are
17 talking about?

18 A. Yes.

19 THE CHAIRMAN: Can I just say that I think there was an
20 error in your answer and that the 400 you refer to are
21 the 400 where there was testing. You use the two groups
22 as untested -- in your answer here, you won't see it on
23 the screen.

24 A. Okay.

25 THE CHAIRMAN: But the distinction in the first two lines is

1 between those where no testing was applied and those
2 where testing was applied. Is that right?

3 A. It's entirely possible that I have --

4 PROFESSOR JAMES: It's the ambiguity there in the word
5 "testing". What you meant by "testing" was that they
6 were screened for ALT and for antibody.

7 A. Screened and withheld.

8 PROFESSOR JAMES: Correct, yes.

9 THE CHAIRMAN: It's just in the answers recorded. I simply
10 want to make sure that you are not recorded as saying
11 something that didn't work.

12 A. Thank you.

13 MR MACKENZIE: Thank you, sir, I think that's correct.

14 Then returning to your statement, doctor, you then
15 look to apply that to Scotland, if we believe the
16 conclusions of the Canadian authors are correct.

17 Sir, there are a few pages still to go and it gets
18 quite complicated again. I wonder if I may seek a very
19 short break of five minutes, if that wouldn't be too
20 inconvenient.

21 THE CHAIRMAN: No, a recovery period is quite in order.

22 (12.14 pm)

23 (Short break)

24 (12.22 pm)

25 MR MACKENZIE: Thank you, sir.

1 We reached page 7, Dr McClelland, and you set out
2 there that in the months of September 1991
3 to February 1992, following the commencement of HCV
4 screening in Scotland, 0.088 per cent of 159 donations
5 were designated positive and 95 per cent of the donors
6 of these units returned for further information and
7 tests:

8 "More than half (59 per cent) of the donors in whom
9 HCV antibodies were detected had elevated ALT levels,
10 suggesting indirectly that as many as half of
11 HCV-positive donors might be directed and excluded by
12 detection of a specified elevated level of ALT. If the
13 findings of the Canadian study were simply applied to
14 the Scottish donor HCV prevalence of 0.088 per cent,
15 then up to 70 per cent of the HCV-positive units would
16 have been removed. For the estimate below I have used
17 the assumption that surrogate testing would have allowed
18 50 per cent of HCV-positive units to be withdrawn."

19 Do you think that's a reasonable assumption, or is
20 it one one should be extremely cautious about, or what?

21 A. I think one should be very cautious about all of these
22 numbers. Primarily because, as I said just before the
23 break, there are wide confidence intervals around these
24 numbers. So I mean, the figures from the Canadian
25 study, if you applied the confidence intervals, it could

1 be 0 to 100 per cent, rather than 70 per cent. That's
2 why you need a statistician.

3 THE CHAIRMAN: The 50 per cent is just a working hypothesis?

4 A. It's to allow me to do what I think is an illustrative
5 calculation. It's nothing more than that.

6 MR MACKENZIE: Thank you.

7 You say:

8 "To gain an idea of the impact of this partial
9 removal of infective units in terms of the numbers of
10 infections in transfusion recipients, I have used data
11 from a SNBTS account for blood database. Since AFB is
12 a recent development ..."

13 Approximately, doctor, when was that brought in?

14 A. Well, this has been in evolution for about ten years,
15 but it's only actually for the years 2010/11 that the
16 thing has matured to the point where we can be confident
17 that we actually know the number of patients. We know
18 accurately the number of patients who actually received
19 a transfusion of one or more blood components.

20 As with the 1 in 1,000 figure for prevalence, which
21 I feel is solid, this is the only number that I feel is,
22 in terms of the number of recipients, solid and we
23 clearly have to consider then, if one is trying to look
24 at other years, when the true figure for other years
25 might be.

1 Q. Okay. You then say:

2 "Table 2 lists number of assumptions that have been

3 made to provide an illustrative example. Errors in

4 these assumptions may lead to over or underestimates of

5 the number of infections."

6 So table 2 "Blood components transfused to patients

7 in Scotland":

8 "Data from account for blood 2010-11.

9 "Number of brood component units."

10 Does that include or exclude plasma products such as

11 albumin?

12 A. That's blood components as we define them, ie including

13 any fractionated plasma product. It's red cells,

14 platelets, plasma and cryoprecipitate. And any one of

15 those products counts as one in these data.

16 Q. Yes.

17 A. And the basis of that -- the logic behind that is that

18 we assume that the even if -- you know, the probability

19 of any component of the blood containing Hepatitis C is

20 the same as the probability of the parent donation

21 containing it.

22 Q. Each of these type of components you have mentioned

23 would be capable of transmitting Hepatitis C?

24 A. Yes. Equally -- I think we would say equally capable of

25 transmitting.

1 Q. You then look at -- so number of blood components, all
2 types transfused. So we are not looking at number of
3 donations or units collected, we are looking at the
4 number of blood component units actually transfused?

5 A. Yes. If I could just explain, the Blood Transfusion
6 Service obviously has data about the number of units
7 that are placed into stock, that are shipped to
8 hospitals, but it is dependent on the hospital blood
9 banks for information about what is transfused to
10 patients and what isn't. So this part of the -- the
11 reason it has taken so long to build this database is it
12 involves setting up systems which each of the hospital
13 blood banks in Scotland, with one small exception, which
14 is not material, daily or twice daily send an automated
15 report to the central data warehouse, which is based on
16 units of blood -- of each component that are confirmed
17 to have been transfused.

18 Q. Thank you.

19 A. The data that we did not have accurately or reliably
20 before.

21 Q. We see the number of blood component units transfused as
22 207,439.

23 We then see the number of patients who received one
24 or more blood component units as 36,875.

25 If one were to have asked that question as in the

1 late 1980s, how many patients received one or more blood
2 component units? I appreciate there isn't data
3 available, but do you have a feel for an approximate
4 number?

5 A. This is a number that has been obviously very important
6 for a long time, and the estimate that I have tended to
7 use over that period, up to about the early 2000s,
8 I tend to work with an estimate of about 50,000
9 recipients, based on piecing together various types of
10 information that we had.

11 In 2005 -- and I think this is in a document which
12 is probably in the Inquiry's papers -- I produced an
13 estimate for the Crown Office, Procurator Fiscal
14 Services, and at that time I used a figure of 40,000
15 recipients, which was based on slightly more
16 information, because by that time we had done the first
17 two pilot iterative projects that led to the account of
18 blood database. So we were a bit more confident of the
19 figure then and it actually came down.

20 THE CHAIRMAN: Dr McClelland, it has got off screen. Could
21 you just remind me what component units comprised, red
22 cells, platelets?

23 A. Yes, the terminology basically from one whole blood unit
24 one can produce red cells, platelets, plasma, or
25 cryoprecipitate, and the convention we have used here is

1 that any one of those would be a component unit.

2 THE CHAIRMAN: I understand that for your first line. You

3 then have the number of patients who received one or

4 more blood component units.

5 A. Yes.

6 THE CHAIRMAN: Is that the same definition?

7 A. Yes.

8 THE CHAIRMAN: You have got a problem for me.

9 A. Just to be clear, if I was the patient and I received

10 one bag of plasma, the plasma obtained from one blood

11 donation, I would count that as one unit in this table.

12 THE CHAIRMAN: Yes, but in reality, is that the way life

13 operates or are the components, as you have defined

14 them, not processed in many cases before they get back

15 to the patient?

16 A. They are always processed. The unit of -- the bag --

17 THE CHAIRMAN: But think of the cryoprecipitate.

18 A. Right.

19 THE CHAIRMAN: What happens to the cryoprecipitate in number

20 terms to get the number of patients who receive one or

21 more components of cryoprecipitate?

22 A. Well --

23 THE CHAIRMAN: I find that difficult to imagine.

24 A. Cryoprecipitate is usually supplied for the patient in

25 that sort of standard dose of six donation units. The

1 cryoprecipitate of six donations will either be --
2 I think the current practice now is actually that that
3 is mixed into one bag before it's supplied to the
4 patient. In earlier years they were supplied as
5 separate bags. It's immaterial for the purpose of this
6 table, this would be counted as six because it contains
7 some of the blood from six separate blood donations.

8 THE CHAIRMAN: Here we are dealing only with components that
9 actually get into patients as such?

10 A. Yes, we are excluding from these numbers components that
11 might have -- outdated in the hospital blood bank or
12 been damaged or discarded or something. We are not
13 counting those at all.

14 THE CHAIRMAN: Right. I think I understand that so far.
15 I think we will look over the page in due course, no
16 doubt, to your table, to see how the spread comes.

17 A. Yes.

18 MR MACKENZIE: Thank you, sir.

19 Doctor, 207,439 blood component units are
20 transfused. Number of patients who received one or more
21 blood component units, 36,875. In terms of looking at
22 the average number of blood component units received by
23 each patient, do we simply divide the 207,439 by 36,875?

24 A. That's correct.

25 Q. We can see, I think, your handwritten calculations

1 suggesting a figure of about five?

2 A. It's about five.

3 Q. Then in the next line down:

4 "Possible outcome of surrogate testing for NANBH,
5 assuming 50 per cent reduction of transmission of HCV."
6 Looking at the number exposed with no surrogate
7 testing, 36,875 -- we can see where that comes from --
8 times 0.00088, which is the prevalence of HCV upon the
9 start of donor screening in Scotland in September 1991,
10 results in a figure of 32?

11 A. May I just interject for clarity?

12 Q. Yes.

13 A. I think I should have -- that heading should have been
14 assuming 50 per cent reduction of transmission, but also
15 assuming a recipient of one blood component, I think for
16 clarity, if you think of this as being the risk
17 calculation for a patient who received a single blood
18 component, be it a red cell or platelet, or a
19 (inaudible) or plasma, because we can then dissect out
20 the effect of multiple components.

21 Q. Yes.

22 THE CHAIRMAN: So this is the risk per unit, if one can use
23 that rather crude way of looking at it?

24 A. Yes, what we are doing is taking the risk per unit and
25 applying it to the risk per patient, and to make it

1 simple, assuming the patient only gets one unit.

2 THE CHAIRMAN: But if one looks at the reality, we'll come

3 to the effect of your table --

4 A. We will come to the effect of multiple units.

5 MR MACKENZIE: So the calculation, 36,875 times 0.00088 is

6 the risk per unit. Presumably the more units one

7 receives, the higher the risk of a particular patient

8 receiving HCV?

9 A. I think we should be very careful about terminology.

10 The risk per unit is 0.088. It's one in 1,000

11 essentially. This calculation here tells you something

12 different; it's the risk -- it's the product of that

13 risk per unit and the number of patients who actually

14 get transfused and, therefore, it gives you an estimate

15 of the number of patients who actually got infected, who

16 actually received a Hepatitis C-positive unit.

17 Q. Yes. And in simple terms, the more units one receives,

18 the more likely one will receive an infected unit?

19 A. Yes. My understanding -- and I did consult about this

20 but not with the most authoritative people because find

21 them in the time available -- my understanding of this

22 is that the risk of a patient receiving a positive unit

23 is essentially additive; it is the sum of the -- it

24 is -- the risk is additive. So if you get one unit, the

25 risk of getting a positive unit is one in 1,000. If the

1 get two units, the risk of getting a positive unit is
2 two in 1,000. If you get ten units, the risk of
3 a getting a positive unit is 10 in 1,000. That's what
4 intuition would tell you. But intuition and statistics
5 don't always go too well together. But I did check that
6 out and I believe that to be correct.

7 THE CHAIRMAN: I think it's consistent with evidence we've
8 had before --

9 A. I'm relieved to hear it, sir.

10 THE CHAIRMAN: -- about the progressive risk being additive.

11 A. I would stress, because we will come back to this in
12 a minute, that is the risk of a patient receiving
13 a Hepatitis C-positive unit.

14 PROFESSOR JAMES: I think these terms here in this table 2
15 are -- you have explained them but they are actually as
16 they stand quite misleading. I have just done some
17 quick sums, and as a matter of fact the total number
18 exposed is -- you multiply 32.4 by 5.6 approximately and
19 that comes out to around about 340 individuals exposed
20 no surrogate testing.

21 A. That, sir, is why I suggested that I think we needed to
22 amend the heading here, to -- I was trying to separate
23 out the risk of exposure due to a single unit. And
24 I think you are right, I think I have missed a step in
25 the logic here. I have jumped a step in the logic here.

1 PROFESSOR JAMES: For the records here, it is rather
2 important that we don't go away with the impression
3 that, for example, the number exposed with surrogate
4 testing using the assumptions you have made is 16, as
5 a matter of fact the number exposed with surrogate
6 testing, making the assumptions that you have, is around
7 about 170 actually.

8 A. Yes. It may be a little bit more complicated than that
9 but that's probably closer to the mark. I'm not sure
10 that the average is the right multiplier to use here, as
11 you will see when you look at the table.

12 PROFESSOR JAMES: You have just said that this is additive.
13 So if you get five units for the sake of this argument,
14 you are five times more likely.

15 A. Correct.

16 PROFESSOR JAMES: So the calculations that I have just made,
17 which I'm not suggesting are more than plus or minus 2
18 or 3 -- the calculations I have made are on that
19 assumption. There is nothing more complicated in those
20 calculations?

21 A. Absolutely. What you have done is take the average and
22 assuming that the average is the correct -- five units
23 per patient approximately is the right number to take,
24 it may not be the right number to take.

25 PROFESSOR JAMES: Okay.

1 A. But, yes, in principle I agree.

2 PROFESSOR JAMES: That's the best we can do, though, isn't
3 it?

4 A. Yes. Yes. Well, no, it's not the best we can do --

5 PROFESSOR JAMES: Oh good.

6 A. -- if we carry on, we can do better.

7 PROFESSOR JAMES: Thank you.

8 MR MACKENZIE: Thank you.

9 So, doctor, I think Professor James was putting to
10 you that in terms of the number of patients exposed
11 without surrogate testing, the total number exposed, one
12 would make a calculation something along the lines of
13 32.45 times 56, I think it was.

14 A. I think --

15 Q. Times five --

16 A. -- for clarity in --

17 Q. 5.6 I think it was, yes.

18 A. For clarity in the evidence, I think it might be safer
19 to actually split this up, as I suggested, and to say
20 this -- which will require this table to be modified,
21 but to be quite clear that this calculation is based on
22 the assumption that each patient only gets a single
23 unit, which would allow us then to go, as it were, over
24 the page and say: but what about the real numbers of
25 units that patients get? It's simply that if we

1 conflate two parts of the calculation, it might actually
2 be very difficult to interpret later on. That's my
3 suggestion.

4 Q. We will come over the page shortly, doctor. What I'm
5 particularly interested in is the figure, even if it's
6 simply an approximate figure, for the total number of
7 patients exposed, and I think you did agree that
8 Professor James' approach of 32.45 multiplied by
9 approximately --

10 A. The average number of units. It's a perfectly
11 reasonable starting point.

12 Q. Yes. Reverting to your table, we can then, I think,
13 understand the number exposed with surrogate testing on
14 the 50 per cent hypothesis. We can see how you reach
15 a figure of 16 on the assumption --

16 A. It's simply halving it.

17 Q. On the assumption a patient received one unit. And
18 equally we can understand Professor James' calculation,
19 looking at the total numbers of patients, it would be
20 50 per cent of about 340.

21 A. I'm less confident in the second one because to
22 calculate the effect of the surrogate testing in the
23 recipient of multiple units, bearing in mind the partial
24 effect, I'm not certain whether that calculation is
25 straightforward or not. I'm sorry, I'm out of my depth

1 for this.

2 Q. Me too.

3 PROFESSOR JAMES: Me too.

4 MR MACKENZIE: I'm sure this won't be the final word on the

5 question of statistics.

6 We then see the assumptions you have made in

7 carrying out that working example. We can simply read

8 them all for ourselves, I think.

9 Over the page we come to an interesting table at

10 page 9, the effect of the amounts of blood received by

11 an individual patient.

12 You say:

13 "A proportion of patients receive very large numbers

14 of blood component units. For these individuals, the

15 risk may be materially increased, and the impact of

16 testing may have been greater."

17 We can see the table you have produced is again from

18 the account for blood in 2010 to 2011.

19 A. Correct.

20 Q. And --

21 A. That's a direct printout from the database.

22 Q. Looking at each column, we can see the left-hand column

23 "Units per patient per year". So, again, we are looking

24 units of blood actually received by patients. And then

25 we can see the number of patients transfused. And,

1 finally, the total number of units transfused, which is
2 essentially, I think, a multiplication of the figures in
3 columns 1 and 2.

4 A. It is the multiplication.

5 Q. One can see, for example, 12,603 patients received two
6 units, and one can see the spread. One can see between
7 2,199 patients received 11 to 20 units. I think we can
8 just let the figures perhaps speak for themselves.

9 Is there anything else you wanted to draw attention
10 to from the table, doctor?

11 A. Not at the moment.

12 THE CHAIRMAN: I find it quite difficult that there are no
13 figures at the bottom end of the table for number of
14 units transfused. The number down to ten comes
15 somewhere under 100,000, which would mean 107,000 are
16 thereby for the remaining sections, and averaging it out
17 down to 50 you get another 65/66,000 or thereby. It
18 rather suggests that an awful lot of units were
19 transfused into the 293 who got over 50.

20 A. That is correct. I mean, there is -- it's one of these
21 sort of --

22 THE CHAIRMAN: The sort of exponential --

23 A. It's one of these 20/80 situations where a small
24 proportion of patients get a very large proportion of
25 the blood components and that actually, when you think

1 about it clinically, is kind of what you would expect
2 but it is -- this is why I was guarded about the use of
3 the average.

4 THE CHAIRMAN: That's what I was --

5 A. It's highly skewed population -- distribution, I should
6 say.

7 THE CHAIRMAN: A purely arithmetical average is not terribly
8 reliable here.

9 A. We can produce these data for the other columns. It was
10 just going to make the table very long and unwieldy.
11 The purpose of this was just to sort of offer the
12 Inquiry an approach to the question, which is
13 a difficult question.

14 MR MACKENZIE: And by the 20/80 rule, you mean that just
15 very simply and unscientifically about 20 per cent of
16 patients receive about 80 per cent of the blood.

17 A. Yes, it's a fairly well recognised distribution.

18 Q. Yes. Under "Conclusion" you say:

19 "I am very much aware of the risks of making
20 a simplistic attempt in the absence of sufficient data,
21 to estimate the possible effect of something that was
22 not done 10, 20 or 30 years ago. I suppose the essence
23 of question 5c is how one would interpret the evidence
24 if I or one of my family was the patient likely to
25 require a transfusion. This is a test that I have often

1 resorted to over the years in trying to make a judgment
2 on difficult questions like this one. Using that test,
3 I have little doubt that if I needed a transfusion today
4 in a situation where there was no Hepatitis C tested
5 blood available, then I would, on the basis of the
6 evidence that we have, prefer to receive blood that was
7 negative in one or both of the surrogate tests for NANBH
8 than to receive blood that was positive in one or both
9 of the tests."

10 You asked that question, doctor, if you needed
11 a transfusion today in a situation where no Hepatitis C
12 tested blood was available, but how about if you needed
13 a transfusion in 1987 and with the knowledge of non-A
14 non-B Hepatitis at that time, would you still have
15 preferred to have received blood that had been screened
16 negative for surrogate markers?

17 A. I think unquestionably, yes. I didn't ask myself the
18 question at that time, I don't think, but I think the
19 answer would have been the same.

20 Q. Yes. I suppose the additional question, doctor, you say
21 you would have preferred to have received blood that was
22 negative than to receive blood that was positive. How
23 about a choice between a blood that had been screened
24 and was negative for the surrogate tests and blood which
25 was unscreened?

1 A. Yes.

2 Q. The same answer to the question?

3 A. It's a variant of the same question.

4 Q. Yes, thank you. We are not done with the statistics
5 yet, doctor. Over the page, please. We can see this is
6 an extract from a paper prepared by the SNBTS in
7 response to questions from the Crown Office and
8 Procurator Fiscal Service in 2005. Who was the author
9 of this response?

10 A. I wrote this.

11 Q. Thank you. We can see that the Deputy Crown Agent in
12 a letter of 21 June 2005 raised a number of questions.

13 One question, 3, was this:

14 "An estimate of the prevalence of the virus in
15 donated blood in the UK until such times as a screening
16 test was successfully introduced in 1991 ... information
17 regarding the process of selection of donors to minimise
18 any such risk."

19 You then in your response said:

20 "Prevalence of HCV in donated blood before the start
21 of HCV testing."

22 There is a reference to the first four months of
23 Hep C testing. We have seen that before. The
24 prevalence of 0.09 per cent.

25 Then you give three estimates. Estimate 1 is this:

1 "Patients exposed to HCV by transfusion."

2 You say:

3 "From work currently being carried out and still
4 subject to verification, we have estimates based on data
5 for 2002 that currently covers 77 per cent of the blood
6 supplied to Scottish hospitals."

7 Is this essentially the start of the account for
8 blood exercise?

9 A. Yes, this was the early, first or second, step in that,
10 yes.

11 Q. "... and this shows that blood components were
12 transfused to about 31,000 patients. On this basis, for
13 the whole of Scotland in that year about 4,000 patients
14 would have received a blood component transfusion. If
15 we assume first that the figures were similar in 1990
16 and second that very few patients would receive more
17 than a single unit of HCV-positive blood component, then
18 the number of patients exposed by blood component
19 transfusion in one year can be estimated as
20 0.09 per cent of 40,000, ie about 40 individuals."

21 That, again, was dependent upon that important
22 assumption that very few patients would receive more
23 than a single unit --

24 A. I think in retrospect -- I may just say by way of
25 explanation, this was -- I hadn't actually intended to

1 include this with the statement. It was because of the
2 glitch that I handed you this yesterday, and it was my
3 own copy that I had stuck this on the back.

4 I included this merely because of the question that
5 was asked earlier on about how would we estimate the
6 transfused population, the number of recipients, to
7 just -- because this was the only other documented thing
8 I could find of an earlier estimate of the transfusion
9 population, which at that time was 40,000. So it has
10 found its way into the evidence, but it was actually
11 unintentional.

12 I had intended to make reference to that, as I have
13 done in my oral statement. I'm not sure that the rest
14 of the other estimates are particularly relevant to
15 the -- that's entirely up to you, sir.

16 Q. Estimate 1, is that essentially similar to the working
17 example --

18 A. It is.

19 Q. -- we have just looked at?

20 A. And it's subject to Professor James' comment.

21 Q. Just one final point as regards estimate 1, the final
22 sentence:

23 "The study mentioned below suggests that around 50
24 to 60 per cent of these would have become infected with
25 Hepatitis C."

1 Why isn't that about 100 per cent? Why is it 50 to
2 60 per cent?

3 A. That was the -- gosh, I think that is based on the very
4 extensive work done by Dr Kate Soldan, which has been
5 published a number of years, which -- and I honestly
6 can't remember what -- where that figure -- how that
7 figure emerges from her work.

8 Q. Is your position -- I have to say that I hadn't realised
9 until now that these two pages were included in error
10 essentially. Is your position we should be a little
11 cautious in relying upon these estimates?

12 A. Yes. I'm not sure that they're terrifically helpful to
13 the Inquiry, they are rather old, and the only reason
14 I had initially thought of including it was because
15 of -- anticipating the question of how would we have
16 estimated the population of transfused patients in
17 earlier years, and this was the only previous -- the
18 only earlier estimate that I was able to lay hands on.
19 I just would be concerned that the other paragraphs may
20 actually be non-contributory and waste rather a lot of
21 time.

22 I'm sure the Inquiry has already heard extensively
23 about the Soldan work.

24 THE CHAIRMAN: We have heard a lot about Soldan in the past.
25 I think perhaps the best way to approach it is that you

1 are not relying on the information in these two
2 sheets --

3 A. Absolutely not.

4 THE CHAIRMAN: -- to support any proposition at this stage.

5 A. No, absolutely not.

6 THE CHAIRMAN: If you are not supporting it, I don't think
7 we need to be overconcerned about it.

8 A. Thank you, sir.

9 MR MACKENZIE: I am grateful, sir.

10 THE CHAIRMAN: There is no need to analyse the degree to
11 which they might be reliable.

12 A. Thank you. I did just want to -- reverting to the
13 previous page, if we could for one moment, to the last
14 page -- yes, this one.

15 I had been deliberately vague in the statement at
16 the top of the page, and I referred to the impact of
17 testing because what we are actually concerned about is
18 the number of patients who get Hepatitis C and the
19 severity of their disease, and while we have clarified
20 with Professor James' help the -- a view of the risk of
21 a patient receiving a Hepatitis C-positive unit, the
22 relationship between receiving more than one
23 Hepatitis C-positive unit and the risk of contracting
24 Hepatitis C and the severity of the subsequent disease
25 is not simple, and it would be for the Inquiry to

1 paragraph you are talking about:

2 "Patients treated with plasma derived coagulation
3 factor products."

4 You say:

5 "It is generally accepted that surrogate testing
6 would offer little or more likely no safety benefit to
7 patients treated with these products. This was
8 a consequence of the large number of donations including
9 in each manufacturing batch of product and the
10 introduction of heat treatment."

11 And you make a reference to a further SNBTS
12 document.

13 Just to ease that out a little bit more. I assume
14 you are talking about concentrate treatment there. Is
15 that right?

16 A. Plasma derived coagulation factor products.

17 Q. Concentrates.

18 A. Concentrates. Yes.

19 Q. Am I right in thinking that your reference, first of
20 all, to heat treatment would mean after heat treatment
21 came in in 1987 it afforded such a protection to
22 haemophiliacs that surrogate testing would have been of
23 no additional benefit?

24 A. I think once it became clear that non-A non-B Hepatitis
25 was effectively not occurring, though it was a product

1 that did not transmit, then surrogate testing would
2 probably have been of little relevance.

3 Q. If one were to look at the period before heat treatment
4 against non-A non-B were effective, because we have
5 looked at that period during this evidence as well,
6 would I be correct in understanding your position that
7 due to the large number of donations that would go into
8 each pool, your position would broadly be the same, ie
9 that surrogate testing with its obvious limitations
10 would not have offered any benefit in reality to the
11 those receiving concentrate?

12 A. Broadly, yes. I think -- again, there may be some
13 statistics involved in this because it might depend
14 a lot on pool size, and I suppose it is conceivable --
15 it's conceivable that with -- let us assume the
16 prevalence of Hepatitis C was one in 1,000 and you found
17 half of them, and the pool size was 1,000 -- it's
18 probably bigger actually, I can't remember the pool
19 sizes at the moment. So it's -- on a probabilistic
20 basis there might have been an occasional batch that
21 would have been protected from containing Hepatitis C.
22 I'm really not sure that I'm competent to answer that.
23 Again probably not a simple calculation. But I don't
24 think -- what I think one can say with confidence is
25 that it would not have afforded any reliable degree of

1 protection to recipients of, say, Factor VIII
2 concentrate.

3 THE CHAIRMAN: We will stop at that, Mr Dawson. I think it
4 is necessary.

5 (1.01 pm)

6 (The short adjournment)

7 (1.45 pm)

8 MR DAWSON: Thank you, sir.

9 Dr McClelland, I was just asking you before lunch
10 a couple of questions about the possibility that
11 surrogate testing would have had an impact upon safety
12 for those being treated with concentrates.

13 I would like to ask you whether you think that
14 surrogate testing would have had any such advantages for
15 haemophiliacs being treated with cryoprecipitates over
16 the relevant period, on the basis that those patients,
17 of course, wouldn't have had the advantages of heat
18 treatment that we have discussed?

19 A. I think that the same -- broadly the same arithmetical
20 arguments apply. Severe haemophilia patients receive --
21 requiring a lot of treatment would receive an awful lot
22 of donations worth of cryo. I think -- you know, it all
23 depends on one's estimate of the effectiveness of
24 surrogate testing on, as it were, interdicting
25 Hepatitis C-positive units. And as I think we discussed

1 this morning, the evidence for that is not particularly
2 solid.

3 So I would have thought that very much, as I said
4 before lunch about non-heat-treated concentrates, it
5 might have had a marginal effect but, as it were, over
6 a long-ish period in which a patient -- certainly
7 a patient with severe haemophilia would get either
8 repeated doses of concentrate or repeated doses of --
9 you know, 20, 30, 50, donations in cryo. I suspect that
10 it wouldn't really have made very much difference.

11 Q. In one of the earlier sections, the C3A section, we
12 heard evidence about a particular kind of patient. This
13 patient was someone who, say, in the mid-1980s, had not
14 received treatment with concentrates before, and we had
15 contemplated with Professor Ludlam the possibility that
16 such a patient might be treated with cryoprecipitate.

17 A. Yes.

18 Q. He told us that there would be a point at which such
19 a patient, if receiving a lot of cryoprecipitate would
20 lose the benefit of the small pool on the basis that
21 they would be exposed it to an accumulating number of
22 donors.

23 Do you think it would be logical to say that such
24 a patient -- I should say, first of all, do you agree
25 with that proposition that there would be a point at

1 which such a patient being treated with cryoprecipitate
2 would lose the benefit of the small pool in the way that
3 I have described?

4 A. I think it's arithmetic. It's not necessarily totally
5 simple arithmetic, but if you accept the sort of numbers
6 we were discussing this morning, say, about 1 in 1,000
7 donations would have the capability of transmitting
8 Hepatitis C, then your probability of getting a positive
9 donation will be a product of the number of donations
10 you get.

11 Q. Does it follow from that, that that patient, whom I have
12 described, if one had surrogate testing, which would
13 have, I think you said, had some impact on the number of
14 positive donations getting through, if you like, that
15 patient would be able to receive more treatment before
16 they reached the point where statistically they would be
17 likely to be infected?

18 A. I would have put it slightly differently, but it
19 probably amounts to about the same thing, that if we
20 accept with all the reservations that surrogate testing
21 had some effectiveness in reducing the risk of receiving
22 positive donation, then -- let's say it was, you know,
23 as I said this morning, 50 per cent effective, then you
24 would reduce the probability of getting a positive
25 donation at any given dose level by a factor of about

1 50 per cent.

2 Q. Okay.

3 A. That's a very simplistic view but that's what I could
4 come up with.

5 THE CHAIRMAN: Mr Dawson, you should remember that there is
6 a problem about statistics that while they may be valid
7 for a general picture, you cannot extrapolate back to
8 the individual example.

9 MR DAWSON: Indeed, sir.

10 THE CHAIRMAN: I wouldn't like to see a lot of time taken
11 up --

12 MR DAWSON: I'm moving on from that. I think that's
13 something that we may wish to explore elsewhere, sir.
14 I'll move on from this series of questions.

15 I think it would be fair to say, from your evidence
16 so far Dr McClelland, that the patient that you really
17 had in mind when thinking about surrogate testing was
18 predominantly the blood transfusion patient. Is that
19 right?

20 A. Yes.

21 Q. Could you tell me -- you may have given evidence to this
22 effect before, but say around about 1986 to 1988, how
23 much of the blood that was being collected ended up
24 being used at the PFC and being made into concentrates?

25 A. Sorry, what year?

1 Q. Say around about 1986 to 1988. I don't want anything
2 specific --

3 A. A very large majority of the plasma -- a large majority
4 of the plasma derived from the whole blood collections
5 would have ended up at PFC, because back as far as 1975
6 Professor Cash had introduced a policy initially in
7 Edinburgh of essentially converting from whole blood
8 being transfused to red cell concentrates, and that
9 spread over the whole service. I can't tell you now
10 from cold precisely what proportion of whole blood and
11 red cell concentrates were used in other parts of
12 Scotland but I would say a majority -- probably quite
13 a large majority of the blood that was collected had its
14 plasma separated and that was sent for fractionation.
15 As we have heard many times before, that was a driver
16 for the whole of the Scottish Blood Transfusion Service.

17 Q. Would it be correct to say that a proportion of the
18 total blood that was collected would effectively go down
19 the PFC route and a proportion of the total blood that
20 was collected eventually ended up being transfused into
21 blood transfusion patients?

22 A. That might -- that could be seen as quite an ambiguous
23 statement. The blood that was -- the majority of the
24 blood was separated into red cells and plasma. A large
25 proportion of that plasma went to the PFC. Some of it

1 was used as direct, clinically transfused plasma, some
2 of it was made into cryoprecipitate. But the red cells
3 and the platelets from those donations would be
4 transfused.

5 Q. There is a degree of overlap, if you like, then, between
6 the two categories. Is that right?

7 A. I'm not sure that's a very helpful description.

8 Q. What --

9 A. I don't know quite where you are driving with it.

10 Q. What I'm trying to explore is there appears to be an
11 argument that one of the reasons that surrogate testing
12 was not introduced would be that it would be a very
13 large-scale operation and it would cost a lot of money.
14 What I'm trying to investigate is whether it might have
15 been possible to introduce surrogate testing on
16 a smaller scale --

17 A. I see.

18 Q. -- for the blood that had been collected for those for
19 whom there would be the greatest benefit, ie the blood
20 transfusion patients?

21 A. No, that wouldn't have been a runner. It would have
22 been actually operationally much easier to introduce it
23 for every donation than to introduce it for a subset.
24 No question about that.

25 Q. Thank you. Can I just ask you some questions about

1 material that was covered yesterday, in particular the
2 thought process behind the recommendation in the
3 3 March 1987 SNBTS directors' meeting that surrogate
4 testing be introduced. You remember, we looked at that
5 minute in particular, and then we looked at The Lancet
6 article of 4 July 1987 in some detail.

7 In your evidence yesterday, you suggested that
8 ultimately there required to be some persuasion of those
9 within the government that this was a good idea and in
10 particular you suggested that there required to be
11 well-argued and rational advice for the government to
12 take that course. Is that accurate?

13 A. I can't remember precisely what I said yesterday but
14 that to me is common sense. I would not expect the
15 government -- either the minister or his or her advisers
16 to take a decision other than on the basis of
17 well-argued and rational advice.

18 Q. Would it be correct to say that between the beginning of
19 the 1980s, where we have looked at the efforts that you
20 were making to try and institute a large-scale
21 prospective study and the meeting that I referred to in
22 1986, that you had changed your view about whether
23 surrogate testing should be introduced without that type
24 of study?

25 A. I think if you put it slightly differently, as I said

1 yesterday, I had been very keen that we should do
2 a proper evaluation of the effectiveness of this in the
3 early 1980s, and although in, say, 1986 or 1987 I had no
4 prescient foreknowledge of the emergence of the Chiron
5 discovery, I felt that what had happened to change my
6 view since perhaps the 1980/81 sort of era was that,
7 first of all, more evidence had accumulated from more
8 studies, most of them broadly analogous to the TTV
9 studies. And, secondly, that the Americans had, having
10 argued the toss about the pros and cons of doing this
11 testing for a long time both very publicly in the
12 literature and obviously behind closed doors and on the
13 Blood Products Advisory Committee, had decided that they
14 had no option but to go ahead and do it without the
15 benefit of a proper trial.

16 I think those were the two factors that, you know,
17 made me feel there was little point in pursuing the --
18 what appeared to be a fairly thoroughly lost cause of
19 the clinical trial and that the evidence had built to
20 a point where we really had a duty to start.

21 Q. I actually wanted to ask you a little bit about the
22 factors that were influencing your choice at that stage.
23 Can we look at that in a bit more detail. Just to be
24 clear, can we perhaps look at the transcript for
25 yesterday, in particular page 143?

1 I just wanted to refer, first of all, to the
2 question and answer at the bottom of that page.

3 Mr Mackenzie asked you:

4 "At this time in July 1987 ..."

5 This is the passage we you are talking about The
6 Lancet article which came out on 4 July:

7 "At this time in July 1987 to what extent was
8 patient safety a factor in your consideration?"

9 And I think your answer was:

10 "Answer: It was the factor in my consideration."

11 Was that a correct recollection of the emphasis that
12 you put on -- which one doesn't quite get from the page?

13 A. Yes, I think so.

14 Q. Okay. I also just want to refer you --

15 A. If I said it was the factor -- that's not strictly true
16 because obviously there were other factors which were
17 specifically mentioned in that letter.

18 Q. Indeed. I just wanted to refer you -- indeed. I just
19 want to refer to you another couple of things you have
20 mentioned already.

21 The first is one can see there on page 141, going
22 over to 142 you gave some evidence to the effect that:

23 "... even in the absence of a proper -- you know a
24 definitive prospect of randomised controlled study to
25 provide a real answer, that there was sufficient

1 evidence -- the evidence which had convinced the Blood
2 Products Advisory Committee of the FDA that surrogate
3 testing needed to be introduced and led to the decision
4 in the United States was, while not complete and not
5 definitive, very, very difficult to ignore and I had no
6 conviction that the epidemiological situation, the sort
7 of prevalence, the amount of Hepatitis C -- or non-A
8 non-B Hepatitis infection in the UK was really that much
9 less than it was in America, in 1986, because, you know,
10 commercial paid donors had stopped. They had introduced
11 similar changes in donor selection in relation to AIDS
12 that we had, and I felt if, in the light of, you know,
13 those two major changes, the United States felt it had
14 to introduce this testing, we were in a very, very poor
15 position to not follow suit in the UK, unless we had
16 convincing evidence that it really genuinely wasn't a
17 problem."

18 I referred, first of all, to the emphasis upon
19 patient safety. This might be deemed as a second prong
20 to your rationale that by this stage you had become
21 convinced that the American position and the American
22 conclusions were in fact relevant to the position in
23 Scotland. Is that correct?

24 A. Well, yes, I mean, I think it would have been --
25 I couldn't see then and I can't see now any reason for

1 not taking very serious note of what was emerging in
2 another part of the world with, okay, probably a rather
3 different epidemiology, a history of paid blood donation
4 and so on. But, yes, I thought it was relevant
5 information.

6 Q. If I could turn to what seemed to me to be perhaps the
7 third prong to your rationale. This is on page 147. At
8 the top of the page, going from line 2. You say there:

9 "As I recall, the only studies that looked at
10 surrogate testing and concluded that it didn't have any
11 effect, if you look carefully at them actually, the
12 number of patients enrolled was very small and probably
13 not sufficient to draw any conclusions from at all as a
14 statistical basis."

15 I think the third -- as I have described it as the
16 third prong, what you are saying there -- and please
17 correct me if I am wrong -- is that any of the small
18 studied which tended towards the conclusion that
19 surrogate testing wouldn't be a good idea, you didn't
20 think were as important as the US studies that we have
21 just referred to. Is that right?

22 A. I think that's broadly true. I mean, there is a huge
23 literature -- and I may have missed some studies out but
24 I would probably stand by what I said yesterday, yes.

25 Q. I have described it as a three-pronged rationale:

1 safety, the increased importance of the US studies and
2 the limited significance of the smaller studies.

3 What I would like to ask you about those three
4 prongs is to what extent did you communicate to the
5 Scottish Government through the SHHD the fact that your
6 view in 1986 was based on these three prongs, if you
7 like?

8 A. I honestly can't recall whether I personally was
9 communicating as an individual to the
10 Scottish Government about the -- to the SHHD about this.
11 I think 1986 was a period when we still had fairly
12 regular representation, participation, from the
13 department in the directors' meetings of the SNBTS, and
14 I think I would have assumed really that my channels of
15 communication with the department, as one of five
16 regional directors, was either through the national
17 director, Dr Cash, and/or through the discussions that
18 took place in the documents around the directors'
19 meeting and the coordinating group, to which the
20 department was party. I don't think I would have seen
21 it as my role, unless it was an issue to which -- for
22 which I had been sort of specifically delegated a job on
23 behalf of the SNBTS, to go and make direct
24 representations to the department.

25 Q. What about generally speaking? Obviously that's your

1 individual position. What about as a part of the SNBTS
2 directors group? Do you feel that this rationale and
3 this three-pronged logic was something that was
4 communicated to the SHHD at that time?

5 A. Well, as I say, I can only answer that in terms of, you
6 know, what is documented, you know, what was minuted as
7 discussions that took place at the directors' meetings
8 in the presence of department officials, which obviously
9 they would have been aware of, and what was
10 documented -- what is documented in terms of
11 communications on behalf of the directors to the
12 department through our national director.

13 Q. Could I just take you to a document that we didn't look
14 at yesterday, as far as I recall. This is [\[SGH0028127\]](#).

15 If we could flip over to the second page, we can see
16 that this is a memo by Dr McIntyre, dated 6 April 1986,
17 and one can see from the first full paragraph there,
18 just to orientate this in time, where it says:

19 "The directors of SNBTS are unanimous and are now
20 pressing fairly strongly that this screening should be
21 instituted, we are perfectly aware that it would be
22 costly and could not abolish transmission completely,
23 they would then claim to have taken all steps open to
24 them to reduce transmission. Before embarking on such
25 an expensive programme, it would seem logical to

1 participate in the proposed research and to delay any
2 further action until the results of this were known."

3 So just to orientate that in time, this is the month
4 after the meeting during which you had made the
5 recommendation or you had decided upon making the
6 recommendation.

7 A. Yes, I'm familiar with this.

8 Q. Could I just go back to the first page, please? One can
9 see that this is a document which was circulated by
10 Dr McIntyre to a number of people with whom you will be
11 familiar within SHHD at that time, Dr Scott et cetera,
12 et cetera.

13 One can see from the third paragraph that there is
14 an attempt to summarise really what the background to
15 this argument is. In particular it says:

16 "In USA, largely one suspects because of the fear of
17 litigation, there has been a great deal of pressure to
18 introduce this indirect screening for non-A non-B
19 Hepatitis and we understand this is likely to happen
20 soon. A similar situation is said to exist in Germany.

21 "SHHD was asked last year to meet the expenditure of
22 £810,000 annually to establish screening of all blood
23 donations with the intention of reducing transmission of
24 non-A non-B Hepatitis by blood and blood products.

25 Approval was not given as the research already conducted

1 in the West of Scotland with CSO funding indicated the
2 impact there of transfusion associated non-A non-B
3 Hepatitis was not great; also that the indirect
4 screening proposed would be expensive, could not in any
5 event abolish the transmission of this hepatitis by
6 blood and blood products and would lead to a loss of
7 a perceptible amount of innocent blood by which
8 nevertheless failed to pass the screen. We also wished
9 to await DHSS thinking on this subject.

10 "DHSS have now invited their Transfusion-Associated
11 Hepatitis Working Party, which includes two Scottish
12 members and an SHHD observer, to consider this issue.
13 The Working Party noted the research already conducted
14 in the West of Scotland and advised that instead of
15 embarking at once on expenditure amounting the UK to
16 perhaps £6-8m, research should be commissioned to expand
17 the previous Scottish research; it is agreed that the
18 impact of this 'Hepatitis' differs considerably in
19 different countries. The research is planned to take
20 place in three English centres and one Scottish centre
21 (Edinburgh)."

22 Then over the page:

23 "The English component has been presented to the
24 research management division of DHSS, a formal
25 application has been encouraged and is now being

1 prepared with a view to a start in September 1987."

2 Then we have the paragraph I have read already.

3 And then in the final paragraph:

4 "If recipients of this minute are agreeable that
5 this is the correct line to adopt, then the Edinburgh
6 SNBTS will be asked to prepare a detailed proposal along
7 similar lines to that of their English counterparts.
8 Consideration will require to be given as to how the
9 cost of the research estimated to be in the order of
10 £25,000 can be met. If this line of approach is
11 considered to be inappropriate, the
12 transfusion-associated working party at DHSS would
13 require to be advised as soon as possible since the
14 working party would presumably then recommend expanding
15 the English component. This would leave Scotland
16 without locally derived fresh information to illuminate
17 decision on the proposed screening."

18 So does it appear from this, which is the SHHD
19 position, if you like, or an expression of that in the
20 aftermath of your recommendation in March 1987, that
21 those at SHHD had understood the three prongs to your
22 argument, as I have described it?

23 A. I don't think this really enlightens -- or enlightened
24 me very much on that question.

25 Q. There doesn't seem to be any suggestion here, certainly

1 as I read it, that the US research, which was
2 influencing you at this time, was something which the
3 SHHD thought should be influential to the extent that
4 surrogate testing should be introduced?

5 A. I think the paragraph on the previous page is rather
6 dismissive to be honest. One suspects largely for
7 medical/legal reasons and so on.

8 Q. Indeed. What I'm trying to investigate here,
9 Dr McClelland, is the extent to which the thinking which
10 had driven you to come to the recommendation you did
11 in March had been communicated to SHHD to the extent
12 that they understood why it was you had made that
13 recommendation?

14 A. I think the -- not entirely but I think the second
15 complete paragraph -- first complete paragraph on this
16 page we have on the screen at the moment is reasonably
17 clear. I mean, what Dr McIntyre is saying is that the
18 directors were saying, as they were, "We wanted to feel
19 confident that we had taken" -- I don't think it's so
20 much claim, "I think we wanted to feel that we had taken
21 all possible steps to reduce transmission". And that's
22 basically what I said yesterday.

23 Q. Given that you said yesterday that there were a number
24 of conflicting view points at this point and there was
25 a requirement that a full and rational view be put

1 forward to the SHHD, does it look from this document as
2 if the full reasoning that you had based your
3 recommendation on had got through to them?

4 A. I really can't answer that.

5 Q. Could I just ask you -- I don't think we need to go to
6 the document but obviously when I refer to The Lancet
7 letter of 4 July you know which document I'm talking
8 about?

9 A. Yes.

10 Q. Why did you feel it necessary to write a letter to The
11 Lancet at that time in those terms?

12 A. I think, as I said -- I think I said yesterday it was
13 the sort of -- I think I was getting quite frustrated
14 actually, to be honest, and I felt that it was not
15 something that I had done a lot in my career but that it
16 was appropriate for something that I felt quite strongly
17 about to try and stir the pot a bit, and in the hope
18 that perhaps by putting the particular set of arguments
19 that were contained in it -- because there were several
20 quite materially different points in that letter --
21 putting that into the public domain might in some way
22 stimulate a reconsideration of the importance of getting
23 on with this. I think that was probably extremely naive
24 in retrospect but I think that was probably what was in
25 my mind in drafting that letter.

1 Q. In whom were you trying to stimulate a reconsideration?

2 A. I'm not sure how, as it were, targeted I would have been
3 in my thinking about that because, you know, if I tried
4 to answer that question from now, I would say, well, the
5 potential targets would have been, you know, opinion
6 formers and the people to whom those opinions have to be
7 relayed to get a decision to make a change in health
8 policy.

9 Q. So presumably that would include the SHHD people and
10 also -- I think at that time there were perhaps some
11 people, although perhaps not directors, people within
12 SNBTS that didn't hold the same view as you?

13 A. Well, yes, and there were a number of people who were
14 advising, as you are very familiar with, people who were
15 advising the department in London and there would be
16 some advice coming to the department in Scotland, and
17 clearly there was liaison between the departments. So
18 I thought, putting these arguments as clearly and
19 strongly as we could into a national, large circulation
20 general medical journal might provoke some thought which
21 might in turn provoke some action. It was probably
22 rather naive but that, I think, was probably what was in
23 my mind.

24 Q. Thank you. Could I just move on to a related but
25 slightly different topic, something that we covered to

1 a certain extent this morning, and that's to do with the
2 practical arrangements for surrogate testing and the
3 extent to which those had been throughout through at the
4 time of your recommendation. I think we covered this to
5 a stern extent this morning, and you have mentioned in
6 your evidence a number of things which decisions would
7 have had to have been taken about and practical measures
8 would have had to have been put in place for surrogate
9 testing to get up and running, for example a decision
10 about the cut-off for the ALT, there would have to have
11 been provision for counselling. You have mentioned
12 training of staff and equipment. Are these the kinds of
13 things --

14 A. Yes, absolutely.

15 Q. -- which practically one would have had to be thinking
16 about?

17 A. Absolutely.

18 Q. In one of the previous sections relating to the
19 introduction of HTLV-III antibody testing, you gave some
20 evidence about an algorithm that had been created in
21 order to lay down a template for how the testing would
22 work.

23 A. Yes.

24 Q. Was any similar plan of action, if you like, thought
25 through for surrogate testing?

1 A. It was certainly thought about. It didn't reach the
2 stage of formal debate at the level of the directors
3 meeting and so on, but certainly those of us who were
4 interested in this had -- we were aware of the --
5 I mean, having been through the process of developing
6 a sort of decision chart for HIV -- which, of course, we
7 subsequently had to do for Hepatitis C -- we were fairly
8 aware of all the directions, all the questions that
9 started to arise and became -- compelled one to address
10 them when you started to explore this decision process.
11 So you, know, we were in a position to hit the ground
12 running with developing that. That's not to say it
13 would have been easy, and it would undoubtedly, had we
14 had to do it, would have gone through many iterations.
15 But, as I said this morning, I think we were actually
16 quite well equipped in terms of past experience and so
17 on, to get on and deliver this relatively quickly.

18 Q. So that would tend to suggest that you were aware of
19 what questions needed to be asked and what issues would
20 need to be dealt with because of your previous
21 experience of doing this kind of thing. What I'm more
22 interested in is the extent to which you had formulated
23 what the answers would be to those question, by the time
24 that you made the recommendation in March 1987.

25 A. I don't think I can add very much to what I said this

1 morning. We had not done a great deal of formal work on
2 it.

3 Q. Okay. Can I take it from the fact that you hadn't done
4 a great deal of formal work that not a great deal about
5 this type of thing, the practical arrangement, had been
6 communicated to SHHD?

7 A. I think that the department were clearly very well aware
8 of the main elements of the -- the issues that would be
9 problematical about the loss of donors and the creation
10 of a population of individuals who would have suddenly
11 got an abnormal screen test.

12 This is not revolutionary stuff. It's exactly what
13 happens when you initiate a new screening programme.
14 And medical folks in the department would have been
15 perfectly familiar with those issues.

16 You start -- you have many identical issues arise.
17 So I think they were probably perfectly well informed --
18 informed with a level of sort of detail that was
19 appropriate at the time to make a judgment on those
20 issues.

21 Q. Okay. Thank you very much.

22 There is just a couple of other areas I would like
23 to cover with you quickly. The first is in relation to
24 a passage which you produced in your original statement,
25 which one can see at page 11 of [\[PEN0170754\]](#). This is

1 something that we looked at yesterday.

2 Am I correct in my understanding that this is you
3 reproducing a note that was drafted by Harold Gunson and
4 which had been made available to people who had attended
5 the working party on transmission associated hepatitis
6 in November 1986?

7 A. Yes, this is -- it's a scan or a -- an image, facsimile
8 of the one -- probably, the second, page of a four or
9 five-page document that was produced by Dr Gunson as the
10 working paper for that document, which I think is -- I'm
11 sure it's in the court book.

12 Q. I'm right about the authorship?

13 A. Yes, I just was too lazy to type it all out again.

14 Q. No, it's helpful to have it there.

15 I think in your evidence yesterday you said that
16 this document in particular was one which had been
17 persuasive as regards the development of your thinking
18 towards recommending introducing surrogate testing. In
19 particular, I think you said that the numbers that were
20 being used in this document had been influential. Is
21 that correct?

22 A. That is correct, yes.

23 Q. And do you I take it that the similarity in the numbers
24 here and in the numbers which one might find in The
25 Lancet article is not coincidental and that this is the

1 source of the information in The Lancet article?

2 A. It may well be. I honestly can't remember. But if they
3 are the same numbers, then I'm sure that's where I got
4 it. But I can't remember the answer to that.

5 Q. I just wanted to ask you if you could be a bit more
6 specific about precisely what it was within this that
7 had been so influential on your thinking, other than the
8 author of it, of course, but the actual detail?

9 A. Well, I think it may well be the first time that I had
10 seen a calculation of the number of infections that
11 could be occurring based on what we then knew. I'm not
12 sure -- I certainly should have done that calculation
13 myself before but I'm not sure that I did, and I think
14 the scale -- I think I probably would have seen this in
15 the context of what we'd seen with HIV, where actually,
16 although it was a terrible problem, the numbers of
17 infections were very, very small. Compared to this they
18 were tiny. But I cannot honestly say I remember the
19 eureka moment when I read this and thought, "My God,
20 these are big numbers". I think seeing those number, as
21 it were, in cold blood probably was a factor in my
22 trying to push on a bit more.

23 Q. Can you help me with what Dr Gunson's position was when
24 this paper was presented about the attractiveness or
25 otherwise of introducing surrogate testing?

1 A. Well, only insofar as there is an illegible scribbled
2 note of mine from the meeting, which I haven't yet tried
3 to decipher fully, and there is that interesting note
4 that we were reminded of yesterday in which I think it
5 was Dr Forrester asked the chairman, Dr Gunson, if he
6 would introduce testing if it was free of charge and he
7 said, "No, I wouldn't".

8 Q. That's really what I'm asking about, Dr McClelland. I'm
9 trying reconcile how it is that you could be presented
10 with this material and that have apparently
11 a significant influence on your thinking towards
12 favouring surrogate testing and the reference that you
13 have made to the note made by Dr Forrester, which would
14 tend to suggest that Dr Gunson was not in favour of
15 surrogate testing to the point where he said he wouldn't
16 introduce it, even if it were at no coast?

17 A. Looking back at this while I was preparing these
18 reports, I found this very hard to square. I would not
19 wish to conceal that at all. I think I have said it in
20 my statement. I find it very difficult looking back
21 with the wisdom of hindsight to understand how a group,
22 of which I was a member, could have this very
23 well-prepared, well-argued, well-sourced, well-informed
24 paper presented to us with these quite disturbing
25 numbers and then proceed to agree to do yet another

1 study of prevalence in donors.

2 I think I probably -- I cannot now say why I didn't
3 make more of a fuss. I know I arrived very late for the
4 meeting and possibly felt it was inappropriate for me to
5 make a fuss at the meeting, but it was following -- you
6 know, it was after this, I think, that we began to push
7 again for some action.

8 But if you are asking me to tell you precisely what
9 was the relationship between seeing this document and
10 the action that I -- that was -- the decision taken by
11 the BTS directors, it would be pure speculation because
12 I don't have a clear -- I don't have any memory of my
13 thought processes over that period.

14 Q. Thank you. Could I just clarify one final matter with
15 you, Dr McClelland? Am I right in saying that
16 throughout the period when one was considering surrogate
17 testing with all its inevitable disadvantages on the
18 basis that it wasn't a true test but was a surrogate
19 test, that it was only ever being considered as an
20 interim measure until something better might come along?

21 A. No, I don't think one can really say that. I think that
22 might have been a hope. I don't think I ever considered
23 it as an interim measure because I didn't know it was --
24 you know, I had no -- I mean, what I knew about the
25 development of specific tests at that time was gleaned

1 from the work that one of my own staff had been doing,
2 which was proving that it was incredibly difficult, and
3 through him the knowledge of a lot of other groups
4 around the country, some of whose work -- around the
5 world, some of whose work I had read, some of whom I had
6 met, who were all finding it incredibly difficult. So
7 my own knowledge at the time was not such to make me
8 expect an early resolution to this problem.

9 And I think that would have been the position of
10 most people because actually the breakthrough, if I can
11 use that term, that led to Houghton and his group
12 discovering the Hepatitis C test was dependent entirely
13 on what was very novel technology, which I and most of
14 my colleagues didn't know anything about at the time.
15 You know, the sort of reverse engineering of a virus
16 from -- starting off with an antibody was science
17 fiction, as far as I was concerned.

18 Q. Okay. And would it be --

19 A. So I don't think I had an expectation that there was
20 going to be an early emergence of a super-duper specific
21 test.

22 Q. I think it has occurred to me that I may have made an
23 assumption, that I should probably ask you about, in my
24 earlier question, which is, it is, is it not, inherent
25 in the nature of surrogate testing that there is going

1 to be a degree of unreliability about it?

2 A. Well, the use of something like the ALT test, it's
3 absolutely inherent.

4 Q. But the fact it's a surrogate test means it is never
5 going to be the test you would really want in an ideal
6 world?

7 A. I think the sense in which the term is used means you
8 are measuring something which you hope is associated
9 with the presence or absence of something else.

10 Q. Which adds in an extra layer of complication, if you
11 like, in terms of its accuracy?

12 A. Yes.

13 Q. So if someone were to say that, "I don't like surrogate
14 testing because of the fact it's not going to eradicate
15 all of the non-A non-B Hepatitis in the donor
16 population", that would probably misunderstand the
17 parameters within which one should be discussing a test
18 of that nature?

19 A. Sorry, could you repeat the statement again? I missed
20 a bit. The hypothetical statement that you made.

21 Q. If someone were to say, "I don't like surrogate testing
22 because of the fact it's not going to eradicate all of
23 the non-A non-B Hepatitis in the donor population," that
24 would probably misunderstand the parameters within which
25 one should be discussing a test of that nature. What I

1 mean by that is a surrogate test is always going to have
2 a degree of inaccuracy?

3 A. Yes, I think the question is a much more general one:
4 would you use a treatment that does not guarantee to
5 cure 100 per cent of the disease? Would you reject it
6 because it only cures 50 per cent?

7 Q. Thank you. There is one final area I would like to
8 explore with you, and to do that I would like to return
9 again to the statement -- sorry, the transcript from
10 yesterday.

11 I would just like to refer you to two particular
12 answers that you gave. The first is on page 144.

13 This is the question which comes immediately after
14 the one which I referred you to earlier and it's in the
15 context of the way in which you had presented the
16 argument along with the other centre directors in the
17 July 1987 Lancet article.

18 You said there, in your answer in line 2:

19 "The objective was to try and get testing started."

20 If I could just refer you to another passage from
21 page 106 towards the bottom of that page, in line 18.

22 This was in the context of you answering some questions
23 about the multi-centre trial, you will recall that no
24 doubt, and you refer there to the fact that:

25 "It did seem rather like a way of buying time

1 actually."

2 What I wanted to ask you was you seem there to be
3 presenting two schools of thought, if you like. One is
4 the objective that we have to get on with things and the
5 other is the school of buying time.

6 What I wanted to ask you was, would it be fair to
7 say that around this issue there were really two camps;
8 one was the we have to get on with it camp and the other
9 was the buying time camp?

10 A. I don't know that that really -- that makes it sound
11 very polarised. I don't recall it being like that.
12 There was a certain amount of perhaps inertia.

13 I think if I was to criticise the -- you know, the
14 sort of -- with the wisdom of hindsight, there was
15 perhaps a very large preoccupation on all the problems,
16 which maybe was more influential in people's thinking
17 than perhaps thinking about the potential safety gains
18 that could be gained.

19 I don't think it was polarised. I don't think
20 anybody was -- perhaps I shouldn't have said that.
21 I certainly didn't feel anybody was explicitly trying to
22 buy time, trying to prevaricate. But I did feel, as
23 I was trying to say here, that this was a study that was
24 actually quite -- you know, relatively easy for the
25 transfusion services to do because in a sense the

1 clientele was entirely under their control. But I
2 didn't see that it was actually going to help us with
3 making a decision about what to do. It might at most
4 have told us a bit more about the magnitude of some of
5 the problems but it wasn't going to tell us anything
6 about the magnitude of the some of the benefits.

7 MR DAWSON: Okay, thank you very much, Dr McClelland. Thank
8 you, sir.

9 THE CHAIRMAN: Mr Anderson?

10 Questions by MR ANDERSON

11 MR ANDERSON: Thank you, sir. Dr McClelland, could we look
12 together, please, at a document that you haven't been
13 shown thus far? It's [\[SNB0059240\]](#).

14 MR JOHNSTON: Sir, I wonder if I could interrupted for
15 a moment. As I think it may have been made clear by the
16 Inquiry team, I do have an objection to the line that
17 I think Mr Anderson is going to pursue resting on this
18 document and the reply to it.

19 THE CHAIRMAN: It has not been made clear, since I would
20 have resisted any attempt to make anything clear before
21 hearing you. Mr Johnston, it has been made clear that
22 you have an objection but I have not read the letter and
23 I don't know what it is yet. So help me, please, to
24 understand what it is.

25 MR JOHNSTON: Yes, I'm grateful. We can see, looking at the

1 letter, and I should say, as I understand Dr McClelland
2 has seen the letter and I don't think there is any need
3 for him to disappear in the course of what I hope will
4 just be a brief discussion, but we can see from looking
5 at the letter that there is a suggestion that the
6 individual officer should be removed from duties which
7 include interface with the Scottish Transfusion Service.
8 That seems to be supported by reference to a position he
9 took at the last BTS subcommittee meeting in relation to
10 a particular project, namely a collaborative research
11 agreement, and exception is taken to the way in which he
12 approached that.

13 That's a very short summary of the large second
14 paragraph on that page.

15 THE CHAIRMAN: Yes.

16 MR JOHNSTON: Perhaps it's enough simply to note that the
17 entire issue, so far as one can see, has no bearing
18 whatsoever on topic C2 or indeed, so far as I can see,
19 anything else with which this Inquiry is concerned.

20 The remaining short paragraph on the page mentions
21 another event that happened earlier, which relates to
22 a delay in the AIDS validation studies of plasma-derived
23 blood products and, again, it's suggested that the
24 approach taken by the particular officer led the
25 directors to have little or no confidence in him.

1 That clearly, one could say, is something that falls
2 within the scope of the Inquiry in general, albeit not
3 topic C2.

4 Then moving over the page to page 9241, we can see
5 that Dr Cash points out that not all the fault lies on
6 one side, and he accepts that others may perhaps have to
7 share in this. And he points out there has never been
8 such a difficulty with predecessors, which I think must
9 be a reference to Dr Bell.

10 The reason I object to this -- I should say there is
11 a reply to it, sir, and I'm not sure, in order to
12 address the issue you would prefer to see that also.

13 THE CHAIRMAN: I think you are probably giving me the
14 flavour of the correspondence without going into the
15 detail.

16 MR JOHNSTON: In that case, the reason I object to it, sir,
17 is quite straightforward, it is simply that without any
18 prior warning, as I understand the line that is sought
19 to be pursued, we are going to end up in a position
20 where an individual is subject to criticism. No prior
21 warning of any such issue was given to me before about
22 11 o'clock this morning.

23 Equally, it is not clear how it has any bearing on
24 the C2 topic, as I have already said. There are, of
25 course, as we know, various memos in relation to C2, of

1 which this particular person was the author and, of
2 course, if there are specific complaints about advice he
3 gave in relation to C2, then those memos, of course, can
4 be discussed with him, and indeed with others who have
5 a view on them. But in my submission it's simply
6 inappropriate to single him out for criticism in
7 a rather abstract way and not in a way that has any
8 connection with the topic that's actually before the
9 Inquiry in this phase of the hearing.

10 THE CHAIRMAN: Yes.

11 MR JOHNSTON: Those are the reasons for which I object, sir.

12 THE CHAIRMAN: Mr Anderson, what do you say in response to
13 that.

14 MR ANDERSON: Yes, I'm obliged, sir. Perhaps I should
15 explain that this letter from Dr Cash to Mr Morison and
16 its reply were, I think, stumbled upon by an Inquiry
17 team some time last week. They were intimated some time
18 after 5 o'clock on Friday and discovered by those
19 instructing me on Monday. I saw them and I suspect my
20 learned friend Mr Johnston only saw them for the first
21 time yesterday.

22 I think it's important to make clear that it's not
23 my desire that this matter be ventilated, nor is it the
24 desire of Professor Cash or indeed Dr McClelland. It's
25 a decision taken by the Inquiry team, and I make no

1 comment upon that, but I think it's important to
2 understand that it's the Inquiry team that sees these
3 letters as relevant and wishes to explore the contents
4 of these letters with Professor Cash and, I'm sure, with
5 Dr Forrester, who is due to give evidence, I think, on
6 Monday of next week.

7 My purpose in seeking to put this to Dr McClelland
8 is that, of course, he is mentioned in this letter, both
9 implicitly as being one of the SNBTS directors, and also
10 expressly in about the fourth line of the second
11 paragraph.

12 THE CHAIRMAN: Can we go back to that, please, so that I can
13 see what the reference is?

14 MR ANDERSON: If one returns to page 1 -- that's 9240 --
15 what is said in the second paragraph is:

16 "I cannot begin to understand the problem but the
17 quality of Dr Forrester's remarks at the last BTS
18 subcommittee meeting in the context of the Sandoz
19 Collaborative Research Agreement were regarded by my
20 colleagues, particularly Dr McClelland and myself as
21 bordering on insulting."

22 Then, sir, you will see just about three lines from
23 the foot of the first page, it says:

24 "Taken together along with other episodes of only
25 minor importance, I must, with regret, conclude that the

1 SNBTS directors have little or no confidence in the
2 person who currently provides the vital medical link
3 between the operational part of the blood transfusion
4 service and SHHD."

5 Now, as I say, I'm not responsible for these letters
6 coming before the Inquiry but since they are before the
7 Inquiry, it does seem to me with respect, to be helpful
8 that the matter is investigated to some degree, and
9 rather than have perhaps the unedifying prospect of
10 Professor Cash saying one thing and Dr Forrester saying
11 another -- and I have no idea what he will say, of
12 course -- it seems to me that it would be helpful to
13 have Dr McClelland's comments on this.

14 THE CHAIRMAN: So that on one view we might have two saying
15 one thing and one saying the other? It's very strange,
16 Mr Anderson, that you should have introduced a letter
17 with a view to attracting an objection which you are
18 then in effect asking me to sustain. I'm not quite sure
19 where I am. Perhaps I should ask the Inquiry team for
20 their observations on this, unless you have got much
21 else to say.

22 MR ANDERSON: The only thing I would say, sir, is I'm
23 seeking to emphasise that I did not introduce the
24 letter.

25 THE CHAIRMAN: This is the first time I have seen it and it

1 came to me as a result of you asking a question. So, so
2 far as I'm concerned, you have introduced it.

3 There is a mass of material at this Inquiry that
4 I have been spared due to the diligent work of the
5 Inquiry team in making sure that I only get to see what
6 they think is important, and this is the first time
7 I have seen this one, Mr Anderson. But I get lots of
8 surprises. So I'm not too worried about that.

9 MR ANDERSON: We have all been spared, I have no doubt, sir.
10 But, as I say, I'm not producing this. It's the Inquiry
11 team that is producing it and I'm quite happy if the
12 matter is not investigated, but if it is to be
13 investigated --

14 THE CHAIRMAN: I think now that I have seen it, it's so
15 intriguing that I can't see it being left out of account
16 altogether. This sounds very much like something up the
17 hill I would be saying I repel the objections, subject
18 to irrelevancy and competency, Mr Anderson.

19 MR ANDERSON: Ultimately, that would have been my position,
20 sir, but if you remain undecided, that would be an
21 option, that you simply allow it under reservations.

22 THE CHAIRMAN: I'm not sure that the reservation is strictly
23 accurate in these circumstances but, of course, I'm open
24 to submissions at the end of the day that some
25 particular topics should not be referred to in a final

1 report for particular reasons. If I may, I think
2 I would rather we get on with it but preserve every
3 person's interest in arguing that it's not material at
4 the end of the day.

5 Internecine battles, I would have expected to hear
6 about. I can't imagine any major public department
7 operating for a long time without generating them, and
8 if this turns out just to be something like that,
9 perhaps it will disappear off the dyke with a lot of
10 other snow. But let's wait and see. I think you should
11 ask your questions now and, Mr Johnston, you will not be
12 prejudiced in the ultimate analysis if this proves to be
13 totally irrelevant.

14 MR JOHNSTON: Thank you, sir.

15 MR ANDERSON: I'm much obliged, sir. I don't intend to take
16 up much time on this.

17 Dr McClelland, we see this is a letter of
18 21 August 1986. It's addressed to Dr Morison of the
19 Scottish Home and Health Department and it's addressed
20 "Dear Hugh ..."

21 Can you help us first of all with this. Do you know
22 who Hugh Morison was?

23 A. Not perhaps with a degree of precision which you would
24 wish, but he was a very senior civil servant in the
25 Scottish Home and Health Department whose

1 responsibilities portfolio included the SNBTS.

2 Q. All right. Can you tell us who Dr Forrester was and
3 what his duties were?

4 A. Dr Forrester is a medical doctor who was -- again, I'm
5 not sure what his precise -- he was a medical officer.
6 I don't mean any disrespect if he was of higher status
7 than that but he was one of the medical professional
8 team in the Scottish Home and Health Department.
9 I honestly don't remember what his grading, what his
10 precise position was, but he did have -- my recollection
11 is that Dr Forrester had the retirement or illness --
12 I can't remember whether Dr Bell left his post because
13 of illness or retired but following Dr Bell,
14 Dr Forrester became the medical sort of liaison person
15 between the department and the Scottish Home and Health
16 Department.

17 Q. I'm obliged.

18 A. That's my recollection of his relationship to BTS.

19 Q. You will see that the letter starts off:

20 "I must once again request that consideration be
21 given by appropriate colleagues in SHHD to give
22 Dr Forrester duties which do not include an interface
23 with the Scottish Transfusion Service."

24 In the second paragraph it goes on:

25 "I cannot begin to understand the problems but the

1 quality of Dr Forrester's remarks at the last BTS
2 subcommittee meeting in the context of the Sandoz
3 collaborative research agreement were regarded by my
4 colleague, particularly Dr McClelland and myself, as
5 bordering on the insulting. They also revealed
6 the depth of the scientific/medical understanding that
7 was remarkably and disturbingly shallow."

8 Before getting to what may or may not have been said
9 at the beginning, could you help us with this, please,
10 doctor: what was the Sandoz Collaborative Research
11 Agreement and who were Sandoz?

12 A. Sandoz was a large Swiss-based multinational
13 pharmaceutical company, who had a longstanding interest
14 and commercial and research and development activity in
15 the field of immunoglobulin; that is antibody therapy
16 for a variety of disorders. So they were a very large
17 pharmaceutical company but had an major division which
18 specialised in an area which was very -- of very great
19 interest to the SNBTS because we also had
20 a manufacturing activity in that field.

21 Q. What was the Sandoz Collaborative Research Agreement?

22 A. This was an agreement which was established and endured
23 for four or five years, quite substantial sums of money
24 were involved, and the purpose was to develop monoclonal
25 antibodies; that is antibodies made by manipulation of

1 cells outside the body, directed at bacterial -- parts
2 of the chemistry of bacteria which cause a condition
3 called endotoxemia. This is part of the bacterial wall
4 of a particular class of bacteria, which was known -- is
5 known to be an extremely -- cause profound disruption to
6 the physiology of the body, which, in its most severe
7 form, produces, you know, rapidly lethal shock, and in
8 a less severe form is an ongoing problem in critically
9 ill patients such as occupy many intensive care unit
10 beds.

11 It's a manifestation of bacterial infection, which
12 is not amenable to antibiotic therapy, not simply
13 maintainable to antibiotic therapy. Therefore some form
14 of biological-based therapy designed to interrupt the
15 effect of this fragment of the bacteria was a very
16 important therapeutic target.

17 Q. All right. I'm not sure we need to know much about the
18 science. In fact, Dr McClelland, but we see in capital
19 letters, the Collaborative Research Agreement. Who was
20 the agreement between?

21 A. It was between the -- the players were the Sandoz
22 company and a research team in the
23 Scottish National Blood Transfusion Service. The actual
24 signatories to the agreement was probably the
25 Common Services Agency, but I can't honestly remember

1 the contractual details.

2 Q. I think that's all we need to know for present purposes.

3 What is referred to here are comments by

4 Dr Forrester at a meeting. Do you remember this

5 meeting?

6 A. I do actually.

7 Q. Can you help us with what the comments were and why they

8 may have provoked this response from Dr Cash?

9 A. Yes, I do remember quite clearly because it was -- I was

10 actually quite upset at the time. We were endeavouring

11 to explain to the committee, which had to approve this

12 agreement, the nature of the science, probably along the

13 lines I have just summarised for you, and I certainly

14 can't remember the exact words but the recollection that

15 I have is that Dr Forrester was actually very, very

16 dismissive of this and said it was completely irrelevant

17 and I think, you know, the implication was that we were

18 completely out of date in terms of even thinking that

19 this was a problem worth addressing.

20 The committee of obviously non-scientific people was

21 clearly a bit nonplussed by this and, yes, I was very

22 disturbed because he was wrong. And he was not only

23 wrong but was -- I felt, as John Cash said in his

24 letter, what he said was actually very insulting to both

25 our ability and our integrity that we should be putting

1 forward a serious agreement on something that apparently
2 was valueless.

3 Q. The next sentence is that:

4 "They [\[the remarks\]](#) also revealed the depth of
5 scientific/medical understanding that was remarkably and
6 disturbingly shallow."

7 Would you associate yourself with that comment?

8 A. Well, I think -- my recollection is that what actually
9 emerged when there was some discussion of this after the
10 meeting, was that Dr Forrester was actually talking
11 about a different condition.

12 THE CHAIRMAN: I'm sorry, I didn't hear that.

13 A. I'm sorry, I think my recollection is that what emerged
14 when there was some discussion after the formal part of
15 the meeting was that Dr Forrester had actually
16 misinterpreted what we were proposing and was referring
17 to a completely different condition, to which his
18 remarks probably were apposite.

19 THE CHAIRMAN: A different medical condition?

20 A. Yes.

21 THE CHAIRMAN: Yes.

22 MR ANDERSON: It goes on to say:

23 "Dr Forrester made identical comments at the
24 commercial interface steering group on 6 August and when
25 challenged made it quite plain that his view that the

1 clinical importance of endotoxic shock/overwhelming
2 coliform septicemia was of historical interest only and
3 was nowadays quantitatively a trivial matter, had been
4 formed after appropriate consultation and was 'the
5 official SHH view' on the matter."

6 Do you remember that incident?

7 A. I honestly don't remember those precise words being
8 said.

9 Q. If we go to the final paragraph on that page, please,
10 doctor, it says:

11 "Taken together along with other episodes of only
12 minor importance I must with regret conclude that the
13 SNBTS directors have little or no confidence in the
14 person who currently provides the vital medical link
15 between the operational part of the Blood Transfusion
16 Service and the SHHD."

17 You were one of the SNBTS directors at the time.
18 Was it right to say that you had little or no confidence
19 in Dr Forrester?

20 A. I'm not sure that I would express it in those words.
21 I think, looking back, what I was probably aware of --
22 and this is -- I say this because it is verifiable, my
23 recollection was that in the -- if I can say the era of
24 Dr Bell, he was a regular -- and I think I said this
25 morning -- a contributing participant to the SNBTS

1 directors meetings and there was regular and easy
2 contact. I do not recall that being the case during the
3 period that Dr Forrester occupied the same role.

4 Q. Why was it different?

5 A. I don't think Dr Forrester attended -- this is why
6 I feel it's perhaps -- it may be worth looking at some
7 minutes to check, but my recollection was that he was
8 less regularly present at our meetings and, as it were,
9 there was this less sense of easy communication with the
10 department during his period in that office.

11 THE CHAIRMAN: Mr Anderson, we are going to have to have
12 a break for the benefit of the stenographer unless
13 perhaps another second or two would do you.

14 MR ANDERSON: A minute or two.

15 I take it you would not have seen a draft of this
16 letter or the letter itself before it went out?

17 A. I'm sure I didn't, sir. I think I first saw it in the
18 course of looking at papers for the purpose of this
19 Inquiry.

20 Q. What Dr Cash is effectively asking is that Dr Forrester
21 be moved sideways, as it were, and be removed from
22 duties in relation to the Scottish Transfusion Service.
23 If you had seen this letter before it had gone out,
24 would you have supported it?

25 A. I might well have done. Probably -- whether my reasons

1 would have been entirely dispassionate or not -- but
2 I had been quite disturbed by this incident that's
3 referred to in the first paragraph of the letter or two
4 incidents actually.

5 Q. No doubt there is one specific reason for this incident
6 which gave birth to this letter, but in it Dr Cash says
7 that the comments of Dr Forrester "reveal the depth of
8 the scientific/medical understanding was remarkably and
9 disturbingly shallow". Had Dr Forrester ever manifested
10 that problem previously? Was that a concern in other
11 words from the point of view of the SNBTS?

12 A. I cannot say, sir, that I have any recollection of that.

13 THE CHAIRMAN: I don't want to stop you inappropriately.

14 MR ANDERSON: We will leave it there.

15 THE CHAIRMAN: Do you have further questions on this to ask,
16 Mr Johnston.

17 MR ANDERSON: No, I'm content to leave it at that.

18 THE CHAIRMAN: No, no, Mr Johnston, do you have questions to
19 ask about it?

20 MR JOHNSTON: I think just a couple of very short ones.

21 THE CHAIRMAN: I think we will break because I would like
22 just a little bit of information whether the research
23 into monoclonal antibodies that you have described had
24 any direct or indirect connection with the raising of
25 antibodies to any of the conditions that I'm concerned

1 with and the same would apply to any other aspects of
2 this work.

3 Incidentally, did you have contacts with
4 Professor Charlie Brown at Heriot-Watt at this time?

5 A. Yes.

6 THE CHAIRMAN: Perhaps you might like to tell me whether
7 there was a relationship there too.

8 (3.03 pm)

9 (Short break)

10 (3.19 pm)

11 THE CHAIRMAN: Dr McClelland, I have had the benefit of
12 a little tutorial on just how serious a condition
13 endotoxic shock was. So, Professor James will come back
14 to that later and we needn't take time on it at the
15 moment.

16 Sandoz would be interested, given the nature of that
17 condition and the problem that it caused, in finding a
18 monoclonal antibody that could be exploited commercially
19 if they could get it.

20 A. Yes, absolutely.

21 THE CHAIRMAN: Did they approach you or did you approach
22 them?

23 A. I think they originally approached us.

24 THE CHAIRMAN: Would that be to try to get access to some
25 material that perhaps was derived from a patient or

1 patients who had had endotoxic shock and recovered from
2 it?

3 A. No, I don't think it was. I think it was because one of
4 my colleagues, Dr Robin Barclay, had developed an
5 interest in -- purely for the reasons of SNBTS work --
6 I may be factually incorrect. My recollection is that
7 Robin had developed some quite nice techniques for
8 studying human blood donor plasma to detect plasmas with
9 high levels of antibody to various endotoxin components,
10 because our original thought, which had emerged from
11 a previous idea that Professor Cash and I had worked on
12 before, was that we might find donors with naturally
13 high levels of endotoxin -- anti-endotoxins IGG
14 specifically, which might provide -- we might be able to
15 make sufficient quantities of intravenous immunoglobulin
16 to allow a pilot clinical trial with a product which was
17 in essence already licensed and that that would be
18 a bridging step towards -- sort of proof a principle
19 test that didn't involve all the huge regulatory
20 problems of using an artificial antibody.

21 THE CHAIRMAN: So yours didn't involve the artificial
22 antibody?

23 A. It did, because we went on -- we had in parallel been
24 pursuing them on -- because we had already done a lot of
25 work on monoclonal antibodies for a whole variety of

1 other applications. So we had --

2 THE CHAIRMAN: And some of that, I think, I have read about
3 in PhD theses and so on --

4 A. Quite possibly.

5 THE CHAIRMAN: -- because Charlie Brown was interested on
6 this.

7 A. I think he may have actually supervised one of -- we
8 certainly did have --

9 THE CHAIRMAN: Dr Horsley(?).

10 A. Yes, that's right. We did have discussions I'm sure
11 with Professor Brown about manufacturing aspects of this
12 as well.

13 THE CHAIRMAN: But having gone through that, I think it's
14 fairly clear that it has got nothing to do with
15 monoclonal antibodies to any of the infections and other
16 things that I'm concerned with in this Inquiry.

17 A. No, we did give some thought, as did others, to the
18 possibility that monoclonal antibodies against HIV might
19 have some relevance, but rapidly concluded that it was
20 probably a non-starter. I think that's probably
21 correct.

22 THE CHAIRMAN: And that was in common with other people?

23 A. In common with other people.

24 THE CHAIRMAN: Now, Mr Johnston, I don't know if that helps
25 you at all.

1 Questions by MR JOHNSTON

2 MR JOHNSTON: Thank you, sir, that removes the main question
3 I wanted to ask. And the only one other in fact, if
4 this is the right time to ask it, whether Dr McClelland
5 recalls whether the Collaborative Research Agreement
6 actually went ahead?

7 A. Oh yes, it did, it operated for quite a number of years
8 and in fact produced some very promising products but
9 eventually was terminated very amicably, as was Sandoz
10 made a commercial decision not to pursue the line of
11 investigation. There had been a huge fanfare about
12 another monoclonal antibody produced in the
13 United States with the same objective, which we actually
14 were confident wouldn't work because it was directed
15 against the wrong thing, and it failed very
16 spectacularly and blew the market away for quite number
17 of years. So Sandoz -- it was a very civilised divorce
18 actually.

19 THE CHAIRMAN: Scots and Swiss it had to be reasonably
20 civilised, I suppose. You don't want to ask.

21 MR JOHNSTON: I have no further questions, sir.

22 THE CHAIRMAN: Thank you very much.

23 MR MACKENZIE: Thank you, sir, the next witness is
24 Professor Cash. We won't finish him today but I think
25 we can make a useful start.

1 THE CHAIRMAN: Yes.

2 PROFESSOR JOHN CASH (continued)

3 Questions by MR MACKENZIE

4 THE CHAIRMAN: Good afternoon, Dr Cash?

5 A. Good afternoon.

6 MR MACKENZIE: Good appear, professor, I apologise you have
7 been kept waiting today.

8 Now, professor, we have asked you to attend to speak
9 to topic C2, the question of surrogate testing for non-A
10 non-B Hepatitis in the 1980s. You have provided us,
11 professor, with some statements but before we go to
12 them, what I would like to do, please, is to take you in
13 chronological order to one or two documents where
14 I think you can assist us.

15 I would like to start, please, by taking you back to
16 1981, to the advisory group on testing for Hepatitis B,
17 of which I think you were a member. Could we, please,
18 look at [\[DHF0030037\]](#)?

19 I think we can faintly see this, professor, is
20 a third report of this group. It's dated 1981. If we
21 can then go to page 0041, please, we can see the members
22 of this group and we can see, professor, that you were,
23 of course, a member of this group and no doubt you will
24 recall that?

25 A. Yes, I do, yes, thank you.

1 Q. I think this report is relevant to us for one reason.
2 Can we then, please, go to page 5, which is -- rather
3 page 4 to start with, 0045, and we can see in
4 paragraph 22 under the subheading "Tests for non-A non-B
5 Hepatitis viruses", it states:

6 "Non-A non-B Hepatitis viruses are a common cause of
7 PTH in the United States and are thought to have been
8 responsible for cases of PTH in the UK. Hepatitis due
9 to these viruses is common among haemophiliacs and
10 follows the administration of imported and occasionally
11 of British Factor VIII and Factor IX. There is evidence
12 for the occurrence of sporadic cases of non-A non-B
13 Hepatitis in the general adult population and in
14 association with cryoprecipitate therapy in the UK."

15 Over the page, please, paragraph 23 states:

16 "There are at the present time no screening tests
17 for detecting non-A non-B Hepatitis viruses in blood
18 donations."

19 Then paragraph 24:

20 "We recommend that research is undertaken in the UK
21 to determine the extent and severity of PTH due to non-A
22 non-B Hepatitis viruses. Unless this is done, we will
23 not have the knowledge on which to base any possible
24 future recommendations about screening blood donations
25 for these viruses."

1 Do you recall that sort of discussion, professor, as
2 part of the workings of this group?

3 A. I don't honestly but I would take the view that that's
4 a pretty accurate minute. I don't recall.

5 Q. Indeed, it's not a minute, it's an official report of
6 the group.

7 A. I beg your pardon, yes.

8 Q. So presumably the members --

9 A. Some pretty distinguished people there, Sheila Sherlock.

10 Q. Yes. And then finally and for completeness, can we go,
11 please, to page 8 of the report, which is 0049, the
12 summary of principle recommendations are set out.

13 Number 9, towards the bottom of the page, we can see
14 one principle recommendation of the group was that:

15 "Research should be undertaken in the UK to
16 determine the extent and severity of post-transfusion
17 hepatitis due to non-A non-B Hepatitis viruses."

18 Professor, we heard from Dr McClelland yesterday
19 about his membership firstly of a Medical Research
20 Council group, a working group on post-transfusion
21 hepatitis, which met in 1980 and 1981, and Dr McClelland
22 had submitted a study proposal to this working group to
23 undertake essentially a study in the UK of the sort that
24 was undertaken in America.

25 Do you remember, professor, whether Dr McClelland

1 discussed these proposals with you at the time?

2 A. Oh, yes, indeed. I was on the main committee, and

3 Harold Gunson set up a subcommittee, post-transfusion

4 hepatitis, and Brian was asked to serve on that. We

5 also had another committee, a subcommittee, that I was

6 chairman of, so, yes --

7 Q. And when you say were a member of the main committee --

8 A. Yes.

9 Q. -- that would have been the MRC blood transfusion

10 research committee?

11 A. That was the resurrected committee. It had been

12 disbanded several years before and then had been

13 resurrected under the chairmanship of Harold Gunson.

14 Previously, Pat Mollison, Professor Pat Mollison, was

15 the chairman.

16 Q. So you were certainly well aware of Dr McClelland's

17 study proposal to the MRC working group in 1980/1981?

18 A. He discussed it with me and then I saw it when it came

19 up to the parent committee.

20 Q. What was your view on the proposal?

21 A. I was strongly -- I was leaving it to them to get on

22 with it but at the main committee I was strongly in

23 support. I mean, I believe we couldn't even think

24 seriously about surrogate testing until we had done some

25 important research, and much of that needed to be

1 a replication in the UK context of the TTV study in the
2 States. So I was very supportive.

3 Q. Do you remember the views of the other members of the
4 blood transfusion research committee, the main
5 committee --

6 A. I can't remember. To be absolutely honest with you, no,
7 I can't. I think they would have taken the view -- but
8 this is again conjecture -- that as the subcommittee was
9 packed full of people who were pretty well expert in
10 this area, they would, I'm sure -- certainly I know,
11 Harold Gunson, who was chairing the parent committee and
12 the subcommittee could have expected them to say, "Yeah,
13 it seems a great idea".

14 Q. We know that the MRC blood transfusion research
15 committee was disbanded. And if we could, please, go to
16 a letter in that regard, [\[SNB0025864\]](#), we can see,
17 professor, this is a letter from Helen Duke of MRC to
18 yourself, dated 19 July 1982, stating that:

19 "The committee had fulfilled its remit and should be
20 disbanded."

21 What was your reaction to receipt of that letter?

22 A. I was exceedingly angry, for very good reasons, which if
23 you are interested, I will come to, and I hotfoot down
24 to Manchester to speak to Harold Gunson, who was the
25 chairman, to find out -- because I couldn't believe what

1 I was hearing. My first intimation that it had been
2 disbanded was not from Helen Duke, it was a call from
3 Harold Gunson and I was extremely angry.

4 Q. Do you know why the committee was disbanded?

5 A. Well, there is Helen Duke's reason, and we can easily
6 discuss that. But I went down to Manchester and spoke
7 to Harold and he insisted that I didn't speak to my
8 colleagues about it, but he made it absolutely clear to
9 me there were two reasons. First, my own personal
10 interest. I was heading a research group in that MRC
11 unit that was looking at the use of albumin in the acute
12 intensive care area and the acute bleeding area which we
13 use in vascular surgery. We had set up a major,
14 multi-randomised double-blind trial for the use of
15 albumin versus -- which cost millions of pounds
16 worldwide -- versus salt solutions which cost 4p
17 a patient. And the answer we wanted to know, was it
18 more effective the albumin or was it less and was it
19 dangerous? Because there was enough information to know
20 that that was a real issue.

21 That was a study which is eventually done in
22 Australia and New Zealand 20-odd years later and it
23 demonstrated that albumin, as Professor James is
24 nodding, is a complete waste of money and it initially
25 suggested -- or it came back on that that it actually

1 was dangerous in some clinical situations.

2 As a consequence of that, 25 years later, the
3 albumin market and the fractionators collapsed, and
4 Harold Gunson told me I have no -- just listening to
5 him, the DHSS was heavily lobbied by the pharmaceutical
6 industry that are interested in making -- the albumin
7 market and were -- forcibly made the point that they did
8 not wish to see this research take place. That's what
9 Harold told me.

10 The other thing he told me that DHSS was strongly
11 opposed, for whatever reason -- he didn't explain -- to
12 his hepatitis working group and so the notion that
13 Helen Duke is saying this is being reproduced elsewhere,
14 the albumin was certainly not. And if you ask: what
15 about the hepatitis? All I can say is that, as in the
16 papers here, before the MRC research committee got into
17 the hepatitis group, with Harold Gunson in the chair,
18 there was an ad hoc meeting that took place in 1979 and
19 out of that ad hoc meeting emerged four major project
20 grants. It's in the papers. You need to ask who got
21 them, which -- you know, did Harry Zuckerman get them.
22 Did Sheila Sherlock? So in other words the MRC as
23 a result of this ad hoc thing, before Harold Gunson was
24 allowed to take over, had already committed resources
25 for other people to be doing research.

1 So that may have been the reasons for the hepatitis
2 going down. But Harold was sure DHSS did not want to
3 get into surrogate testing.

4 Q. Okay. Looking on then to what your reaction to the
5 disbanding of the committee was, if we can go to another
6 letter, please, [\[SGH0010087\]](#) we can see this is a letter
7 dated 23 July 1982 from yourself, professor, to the
8 other SNBTS directors and Mr Watt advising that:

9 " ... the MRC has disbanded their Blood Transfusion
10 Research Committee."

11 You deeply regretted this development but stated
12 that the time was now:

13 " ... opportune to consider the establishment of a
14 UK transfusion Services' Research Committee."

15 Am I right in thinking professor that, in short,
16 that didn't happen?

17 A. No.

18 Q. And I think we have heard evidence -- you shook your
19 head at that question.

20 A. Absolutely.

21 Q. I think we do know that the CBLA had an research
22 committee in blood transfusion but that wasn't a true
23 UK-wide research committee?

24 A. No. If you had asked me would Dr Lane, who was an old
25 friend of mine, support the notion of an albumin

1 multi-centre randomised trial, the answer was certainly
2 not.

3 Q. Okay. So there are these matters in the background
4 perhaps. What we do know is that in 1982 the UK Blood
5 Transfusion Services, I think again partly or largely
6 through your prompting, set up a working party on
7 transfusion-associated hepatitis and you recall that?

8 A. I do. I'm sure that Harold Gunson was just as positive
9 as I was.

10 Q. Yes.

11 A. I can't take all the credit.

12 Q. And certainly one feature of the documentation does seem
13 to be -- and correct me if I am wrong -- that you seem
14 to have had a good working relationship with Dr Gunson?

15 A. Yes, on the whole I did. We had some fundamental
16 differences, which may, for instance, come out when we
17 talk about Hepatitis C donation testing but, yes, we
18 wine and dined together, he slept over at our house and
19 so on, and I did at his house. So, yes, I would say we
20 were good friends.

21 Q. Now, Dr McClelland was a member of the UK Blood
22 Transfusion Services working party on
23 transfusion-associated hepatitis and we have heard from
24 Dr McClelland how again he put forward a study proposal
25 suggesting a prospective study in the UK, looking at

1 donors and recipients with a view to looking at the
2 prevalence of post-transfusion hepatitis and the
3 question of surrogate testing. And I think that
4 proposal was drafted by Dr McClelland in 1983. Do you
5 remember that, professor?

6 A. I don't know him drafting it. I do recall vividly -- we
7 were in regular contact, Brian and I -- that he was
8 going to have another crack because this, he thought,
9 might be a different environment outside the MRC.
10 Little did he know, however ...

11 Q. Is that something you would have supported at the time?

12 A. Oh, absolutely. I supported this notion right from the
13 1979/1980.

14 Q. Now, I would like, then, please, to go forward to 1985,
15 if I may, and refer you to a document [\[SGH0018259\]](#).
16 These are minutes of an advisory committee on the
17 National Blood Transfusion Service, so I think it's the
18 NBTS in England and Wales, not Scotland.

19 A. Yes, indeed.

20 Q. We can see that you were a member of this advisory
21 committee --

22 A. Yes.

23 Q. -- professor. Can you help us just a little, what was
24 this advisory committee? What did it do? What was its
25 purpose, just very briefly?

1 A. You may remember that there was this immense shemozzle.
2 You've had the DVD that we have looked at,
3 self-sufficiency and so on in the 75s -- in 1975. And
4 then in 1980, the minister, who is now part of the
5 current government, stood up in Parliament in December
6 to talk about self-sufficiency and so on and so forth.

7 It was very clear, because I was really quite close
8 to Ed Harris, he came up here on several occasions on
9 the invitation of Graham Scott, I think, and we had
10 a number of discussions, and there is quite a lot of
11 correspondence between Ed and myself. He's the deputy
12 chief medical officer.

13 And it became very clear, and Ed was very clear,
14 that the problem -- there were some very severe problems
15 in England and Wales. There was the BPL rebuild, and
16 they just didn't have the plasma that we all felt was
17 needed. So they set up an advisory committee of the
18 national blood transfusion in England and Wales to look
19 at these issues. And what emerged over the months and
20 months and months was that this committee was going
21 nowhere.

22 There was really -- the fundamental problem,
23 I believe, there was no political will to actually
24 resolve the issues that they had down there. And if you
25 chase the database, you will discover eventually it was

1 just disbanded, it disappeared. And just before it
2 disbanded, I resigned. It was a complete waste of a day
3 going down there. And I wrote to Ed and apologised.
4 Q. Thank you, professor. A particular item I would like to
5 look at is on page 3. It's 8261. Item 14, the bottom
6 of the page we will see is headed "European Community
7 Directive on product liability". I think this is
8 a reference to a council directive dated 25 July 1985,
9 which was going to bring in strict liability in the UK,
10 and I think the UK are three years from July 1985 within
11 which to implement the Directive.

12 We can see the entry in the minute states that:

13 "It was reported that this Directive would be
14 binding upon the United Kingdom, imposing a legal
15 liability upon the 'producer' of defective products;
16 this liability was not believed to extend to the donor
17 but advice on this point was being sought."

18 We know, professor, that this Directive was
19 implemented in the UK by the Consumer Protection Act
20 1987, which came into force, I think, in March 1988, at
21 least in respect of the strict liability provisions.
22 But my question, professor: was this the first occasion
23 on which this European Directive on product liability
24 came to your attention? Was that something you had been
25 aware of before?

1 A. I really would be speculating a little. One of the
2 problems I have constantly is I was buzzing all the time
3 with European colleagues, Jussi Leikola, who I know
4 is -- Pim van Aken and so on and others, Alfred Hassig
5 in Switzerland. And these guys, unlike myself or indeed
6 Harold Gunson, were heavily involved in
7 Council of Europe business and deliberations. And very
8 often they would tell me, "Oh, by the way, John, this is
9 coming along, this is coming along". So the question,
10 is this the first time? I honestly, genuinely don't
11 know. I doubt it. But clearly here it's recognised,
12 it's in a minute of a DHSS meeting.

13 Q. So certainly by this date, November 1985, obviously you
14 were aware of this Directive, which was on its way?

15 A. Yes, indeed, and you will recall, sir, previous
16 discussions about the whole question of Crown immunity,
17 the whole question of John Watt getting very worried and
18 the directors getting worried as to whose going to be
19 legally liable in this context. We saw ultimately it
20 was going to be taken out, we assumed, of our
21 government's hands and would become part of a European
22 initiative.

23 THE CHAIRMAN: Could we just pause on the terms of this item
24 because I find them rather strange. It says that:

25 "Liability was not believed to extend to the donor

1 but advice on this point was being sought."

2 What was the focus of discussion here?

3 A. I don't remember, sir, but there is the very famous
4 Scottish -- I was about to say "trial", but it was
5 a Scottish case in which I was heavily involved,
6 High Court, in which relatives sought to get the names
7 and address of a donor that they believed had lied or
8 whatever in giving information to us that was HIV
9 positive. It was very famous, and I had an amazing day
10 in the High Court up there, and the judge eventually
11 ruled that they would not give the name and address of
12 the donor.

13 So the notion that somehow the donor would be
14 protected in case of liability, as I have always
15 understood, sir, had in the event, as lawyers are always
16 telling me, to go -- there needed to be a case and
17 a judgment made, and certainly I was heavily involved in
18 that. I got a lot of ribbing from his Lordship.

19 MR MACKENZIE: I think --

20 A. He is quite famous actually. Sorry.

21 THE CHAIRMAN: I don't think I want to pursue someone who
22 has give you a ribbing. But at this stage was it just
23 accepted that people like yourselves, the SNBTS, would
24 be liable --

25 A. Yes.

1 THE CHAIRMAN: -- and this is considering the extension of
2 liability to the donor?

3 A. And the donor was protected. We were to be --
4 discovered that the donor might not be protected but the
5 judge eventually said they are.

6 MR MACKENZIE: And the point perhaps is, who is the producer
7 of a unit of blood? Is it the donor who donates it
8 and/or the SNBTS? It may have been the short point,
9 yes.

10 Moving on, please, professor, to [\[SNF0010135\]](#), this
11 is a minute of the meeting of the SNBTS directors on
12 25 March 1986, if we can please go to the last page,
13 it's 0142. We can see under item 5 "Surrogate testing
14 for non-A non-B". We can see reference to the FDA
15 advisory panel's recommendation in the US in February,
16 recommending surrogate testing in the United States.

17 It appears to be, professor, that it's that which
18 brought the question of surrogate testing towards the
19 front of the agenda for the SNBTS. Does that seem fair?
20 Is that how you remember it?

21 A. Yes, I would only go -- you have heard the word
22 "Lieutenant Colonel Tom Zuck" in this Inquiry.
23 Bill Bayer(?), Kansas City, a remarkable man in San
24 Francisco. Also we were buzzing very closely together.
25 And, again, I must have been aware that the FDA were

1 moving in this direction. So we didn't sit there
2 waiting for the FDA. We were beginning to think we were
3 going to have to think about this.

4 Q. We can see after a full discussion, which I think
5 somebody may have mentioned earlier, that the secretary
6 of --

7 A. Miss Curry, yes.

8 Q. Shorthand perhaps for strong opposing views held.

9 A. Yes.

10 Q. I'm not sure if that would necessarily apply here?

11 A. I can't remember. It wouldn't surprise me, sir. It
12 wouldn't surprise me. That's a Morag Corrie code, or
13 lively discussion.

14 Q. "So after a full discussion the directors agreed to give
15 consideration to funding someone to undertake research.
16 Dr Cash would think about the possibilities in
17 association with Dr Fraser and make some proposals to
18 the directors."

19 I think the next document of interest, professor, is
20 to go down to England and look at the set of minutes of
21 the English directors in April 1986. This is
22 [\[DHF0021290\]](#).

23 We can see the names of those present have been
24 blanked out, but there was representation from the
25 SNBTS. I take it that would have been you, professor?

1 A. Almost certainly. I can't be sure. What we know is the
2 chairman was certainly Ian Fraser.

3 Q. If we go to page 7, which is 1296.

4 A. I should say, I notice that somebody was welcomed as the
5 first RTD to represent Scotland. I just saw that. So
6 the odds are on it wasn't me. Just one of my
7 colleagues. But it doesn't matter, we would have been
8 fully briefed.

9 Q. Thank you, professor, for pointing that out, of course.

10 Under item 16:

11 "Should the N BTS carry out a study on NANB
12 hepatitis.

13 "The chairman reported that this had been discussed
14 by the Scottish directors and that he had agreed to
15 raise it with RTDs [blank]. Reminded directors of two
16 previous attempts, one by the MRC and one by the
17 transfusion-associated hepatitis working party, to study
18 this problem. After discussion it was agreed that this
19 should not be pursued because of lack of time and
20 resources."

21 Is that consistent with your understanding of the
22 feeling, the opinions of the English directors towards
23 the question of carrying out a study into non-A non-B
24 Hepatitis?

25 A. Yes, in fact Ian Fraser wrote to me and virtually the

1 same wording applies.

2 Q. And if we could then, please, come back to Scotland and
3 look at the Scottish directors meeting of 25 June 1986,
4 which is [\[SGH0016286\]](#). If we may go to page 5, please,
5 6290, under topic (i) "Surrogate testing" at the bottom
6 of that underlined:

7 "It was greed to await the outcome of
8 Dr Fraser/Dr Contreras' joint deliberations and to
9 discuss the matter again at that time."

10 Under (k) "Product liability" we see:

11 "Following recent discussions and the attendance of
12 a legal office representative at the coordinating group
13 to advise directors on the implications of this
14 legislation, Dr Cash advised colleagues he had taken up
15 the matter with the general manager."

16 Can I pause there, please, professor, and ask: what
17 advice did you seek or receive in relation to how the
18 Consumer Protection Act may impact upon the SNBTS?

19 A. What I was keen to know is that if we hadn't, for
20 instance -- there were other things as well --
21 incorporated surrogate testing into a programme, was
22 this going to be a matter that would be a cause of
23 concern in the event of the patients and relatives
24 taking the service to court? That was a fundamental --
25 and in that context, if they did, who would be

1 responsible, held responsible, for this, in the event
2 that we, as operational managers, had said we need to be
3 doing X and we were not allowed to do that? It was to
4 try and begin to get some clarification. And the
5 general manager of the CSA at that time was Jim Donald
6 and he was very supportive to getting that sort of
7 ventilated and discussed.

8 Q. Do you remember ever receiving any legal advice on the
9 implications of the Act?

10 A. No. Well, I need to be -- we got two opinions -- I need
11 to be very careful -- from the CLO. One related to --
12 I think they both actually related to (a) the directors
13 in general, but then John Watt saying, "Are we legally
14 liable in terms of product liability?" We did and
15 I know the Inquiry archives have got both these
16 opinions. If you haven't, I can certainly make them
17 available to you.

18 Q. When you say the question was "Are we liable?", does
19 that mean the opinion was on the personal liability?

20 A. Yes, it was, I think.

21 Q. Rather than --

22 A. I think you may be -- yes.

23 Q. There is perhaps also a question: would the SNBTS as an
24 organisation be liable as the producer of a donation
25 which caused infection? Is that an issue on which legal

1 advice was ever sought or obtained, can you remember?

2 A. I'm not sure. It may have been about -- I can't recall,
3 I'm sorry, sir. Certainly in 1988 there was this
4 extraordinary meeting in the Scottish Office in
5 September of that year, in which the Scottish Office
6 convened a meeting of interested parties to discuss the
7 potential of litigation in relation to HIV.

8 Chris Ludlam was there, as I recall, the general
9 manager of the CSA was there, I was there, in which
10 people were giving their opinions as to where then if
11 that arose there would be weaknesses in what we had done
12 and not done and so on and so forth. And the whole
13 question of -- and I think I have raised it on a number
14 of occasions -- who was actually responsible for the
15 safety of blood was not discussed. It was raised by me
16 but we didn't get it clear answer, even to the extent of
17 all of us are responsible and we need then to work
18 closely together. It was a difficult meeting, I recall.

19 Q. In the second half of the 80s, what was the procedure or
20 mechanism for the SNBTS obtaining legal advice? We see
21 reference here, the general manager of the CSA. Would
22 you contact, firstly, the CSA, who would then pass the
23 request on?

24 A. Yes, we would do that, sir, and I can't remember for
25 sure but I could well understand -- and I'm fairly sure

1 this was -- it was made pretty clear to me, the notion
2 of John Cash directly writing to the CLO was not
3 appropriate; it was the CSA that should be the route,
4 and I accepted that.

5 Q. Okay. Then over the page, please, of the minute, at
6 page 6, we can see at the top of the page:

7 "The question of whether or not BTS would be liable
8 in terms of paragraph 56C if the Directive had been
9 raised wherein it is stated that the producer has
10 a defence if he can show that he 'did not manufacture
11 the product for an economic purpose, nor distributed it
12 in the course of his business' and Mr Murray of the SHHD
13 believed that this statement would not exclude BTS was
14 liability in the event of litigation. This and other
15 questions would hopefully be answered when the draft
16 statutory instrument became available for comment. It
17 was noted that much depended also on the result of early
18 court cases."

19 Et cetera.

20 The underlined part:

21 "As had been previously agreed at a coordinating
22 group meeting, Dr Cash would take this matter up at the
23 NBTS advisory committee, which included DHSS
24 representation."

25 Two questions, professor, one small, one larger.

1 The small question is, what does the underlining in
2 the minutes represent? Simply that that was a matter
3 which somebody was to take forward or to action? Or did
4 the underlining represent a matter of significance or
5 importance?

6 A. No, I suspect it's my secretary underlining, "do
7 something".

8 Q. Yes. The slightly larger question: you were to take the
9 matter of product liability up at the NBTS advisory
10 committee. Can you remember doing that?

11 A. I can't honestly remember, sir.

12 Q. We may come to some minutes which may assist in that
13 regard.

14 A. Yes.

15 Q. Thank you. We know that in America surrogate testing
16 was commenced by the various blood bank organisations in
17 1986.

18 A. Yes.

19 Q. Could we then, please, look at a letter from yourself to
20 Dr Fraser of 28 August 1986. It's [\[SGH0016269\]](#). We
21 will see it's a letter from yourself, professor, on the
22 question of surrogate testing for non-A non-B and you
23 say:

24 "I have a feeling that as the drums are beating
25 louder and louder in other parts of the world on this

1 topic the Brits remain fast asleep. I may be wrong but
2 I would like to be better briefed on the matter."

3 Presumably the reference to the beating drums
4 elsewhere is a reference to America having introduced
5 surrogate testing?

6 A. Yes. We knew the French -- you know, it was all
7 happening and people are bubbling around and thinking
8 about it. Yes. Yes. I think the Australians got off
9 and they had a bad sticky start but, yes.

10 Q. And you go on to say that you raised the issue:

11 "... at a SNBTS directors' meeting some months ago
12 and it was agreed that Dr Fraser would explore the idea
13 of setting up a UK prospective trial. I recall you
14 saying to me that you pursued this at the NBTS
15 directors' meeting (I am afraid I wasn't there) and it
16 went down like the proverbial led balloon."

17 A. Sorry about the language.

18 Q. Then:

19 "I'm bound to conclude that I feel we cannot leave
20 the matter as it is and would value your comments on the
21 suggestion that we (you and I) get down in the near
22 future to plan a 'consensus meetings' designed to look
23 at the issues associated with NANB donation testing."

24 Et cetera:

25 "The purpose of the meeting to which all UK BTS

1 directors would be invited, would be to see whether we
2 can reach conclusions which would enable us to make some
3 clear operational decision and that these would be
4 transmitted to the various departments of health."

5 Can you remember, professor, was your position at
6 this stage that you supported the introduction of
7 surrogate testing or that you wanted more information
8 upon which to make a decision?

9 A. (Inaudible). Can I just enlarge a little on that, sir.

10 Q. Please.

11 A. The surrogate testing issue, as I'm sure
12 Brian McClelland has told you, it was a hugely important
13 and very difficult position -- situation. First of all,
14 we had no benefit -- no notion, of the real benefit it
15 would bring to the patients in the United Kingdom.

16 We knew at that time that in the United States' big
17 study there were very substantial variations,
18 geographical variations in the nature of the beast. And
19 the question was: where did the UK sit in this big
20 variation? And when I tell you that that was a key
21 element of data that we were short of, there was the
22 other side, there was the cost, there was the sheer
23 money, and I and a lot of my colleagues were very
24 concerned if we spent £800,000, that wouldn't be extra
25 from the Treasury, that would be taken from somebody

1 else's pocket in the NHS and somebody would have to pay
2 for that.

3 So we needed to be able to -- there was a cost
4 related to the whole exercise. There was also a cost,
5 as I'm sure Brian has said, in terms of donors. You
6 know, a vast numbers of donors a knock on -- Jack Gillon
7 knocks on my door and says, "I am afraid I have some bad
8 news", you know, and the fact of the matter was we knew
9 then that a large number of these people -- had either
10 been out having a good bevy in the pub the night before
11 or overweight or been on treadmills and goodness knows
12 what, but the message from Jack would have been "It's
13 bad news". And exposing vast numbers of our donors and
14 relatives and families to this misinformation when we
15 didn't even know if there was serious benefit to what we
16 were going to do was a great cause.

17 The second think that was worrying me, in 1987 we
18 discovered for real when the Scottish Office announced
19 it was going on open a private hospital, in Clydebank of
20 all places, to treat wealthy folks from the Middle East.
21 When that happened there was an absolute explosion and
22 for a moment we got into very serious trouble with our
23 donor people in the West of Scotland, such that our
24 blood collection went down. And I recognised that our
25 donor panel, although in Scotland was very strong

1 numerically, I sensed that it was messed about with by
2 aspiring politicians and civil servants, we could get
3 into quite serious trouble.

4 So the other cost was our donor panels. If the word
5 got out, "If you become a donor, you may be labelled",
6 and the guys saying, "We are not sure -- you may be
7 labelled," that will have impact on your dental care,
8 your GP and everything else, and that was absolutely
9 nonsensical, we would be in serious difficulty.

10 So this was a big decision. It wasn't like HIV
11 donation tests in a sense. This was making a major
12 tactical moral position and we needed the data. So
13 I supported that getting the data very strongly.

14 Q. Yes. I think the transcript has missed -- you said "Can
15 I just enlarge on that very much the latter". So
16 I think when I had originally asked you -- I think your
17 answer, after I asked the question -- your answer was:

18 "Very much the latter. Can I just enlarge upon
19 that?"

20 A. Absolutely, we needed the data desperately. But as we
21 all discovered, it became eventually evident, largely
22 due to the leadership of Brian McClelland, that the tide
23 was going out, that we were going to lose, if we
24 couldn't get engaged, generating the data, it was going
25 to be too late.

1 THE CHAIRMAN: Mr Mackenzie, the stenographer really needs
2 to stop now.

3 MR MACKENZIE: We can stop there, sir.

4 A. Sorry, I do apologise.

5 THE CHAIRMAN: The stenographer is not terribly well.

6 MR MACKENZIE: Sir, Professor Cash unfortunately isn't
7 available tomorrow but I think we will be able to
8 accommodate him another day within our forthcoming
9 timetable.

10 THE CHAIRMAN: We are getting slightly out of time and
11 order.

12 MR MACKENZIE: We are.

13 THE CHAIRMAN: I think we will just simply have to make the
14 best of it.

15 MR MACKENZIE: Yes.

16 THE CHAIRMAN: Professor Cash has got a little tutorial on
17 toxic shock -- sorry, Professor James has and I don't
18 think this needs to be taken down. So I wouldn't worry
19 about it. It's just for people's information.

20 (Off the record discussion)

21 THE CHAIRMAN: I hope that provides some context for the
22 issues which might arise.

23 (4.12 pm)

24 (The Inquiry adjourned until 9.30 am the following day)

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