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Friday, 14 October 2011

(9.30 am)

(Proceedings delayed)

(9.403 am)

THE CHAIRMAN: Good morning. Yes, Ms Dunlop.

MS DUNLOP: Thank you, sir. I'm obliged to you for allowing a little bit of time for the resolution of one or two minor issues. There remains, however, a matter which I need to draw to your attention.

Professor Ludlam is not yet in the room because there is an issue about what questions are going to be put to him by counsel for the patients' families and the Haemophilia Society. A set of questions was intimated timeously and indeed, I have tried to include a number of them in my own questioning but some of them are very specific to two particular individuals.

You have the list, sir, and the questions I'm referring to are questions 18 to 23 and then also questions 51 and 52, which relate to a second individual.

Normally, when counsel for one of the core participants intimates questions in advance, it's possible for the lists to be discussed between counsel and a common position reached, but on this occasion I have taken the view that whether these particular

1 questions may be posed should be a matter for you, sir.
2 I would therefore suggest that it might be best to
3 invite counsel for the core participants to address you
4 on whether these questions are appropriate.

5 THE CHAIRMAN: Right. As a formal matter, can I be sure
6 that I understand the scope of the potential dispute.
7 Gentlemen, do you agree that these two groups of
8 questions, 18 to 23 and 51 to 52, are the contentious
9 areas?

10 MR ANDERSON: Sir, those are the questions and the only
11 questions to which I would object in this list.

12 THE CHAIRMAN: And you are content that that is the position
13 also?

14 I should say, gentlemen, that in the case of the
15 questions 18 to 23, the list of questions that I have
16 seen name an individual and I'm not anxious that the
17 name should appear as an aspect of any debate that takes
18 place here today. On the other hand, does the
19 individual in question, or do the individuals in
20 question, know that they are being discussed in this
21 way?

22 MR DI ROLLO: Yes, they do. I don't think it's necessary for
23 my purposes that they should be named or identified in
24 any way.

25 THE CHAIRMAN: They have to be identified in some way to

1 make sense of the discussion.

2 Application by MR DI ROLLO

3 Submissions by MR DI ROLLO

4 MR DI ROLLO: I suppose so. But there are two specific
5 instances which require some examination, in my
6 respectful submission. It is not necessary to identify
7 or to name the individuals.

8 THE CHAIRMAN: Is there a protocol that we can adopt that
9 will make it sensible, distinguish between the two and
10 make sure that the transcript can be read?

11 MR DI ROLLO: I believe they are already called A and B, I'm
12 being told.

13 THE CHAIRMAN: They are in some contexts being called A and
14 B, but I have to know here in public that that's the way
15 we are going to do it. Is the individual in questions
16 18 to 23 to be called "A"?

17 MR DI ROLLO: Very well, yes.

18 THE CHAIRMAN: And the individual in questions 51 to 52,
19 "B"?

20 MR DI ROLLO: Very well, indeed.

21 THE CHAIRMAN: I think that I can go about this in a number
22 of ways but in order to keep matters within reasonable
23 bounds, it might be best, Mr Di Rollo, if you would make
24 a positive application to have these heard.

25 As you know, you are departing from my protocol as

1 to how these applications should be made but since the
2 questions were intimated, I understand in good time, and
3 Ms Dunlop has had a chance to look at them, I'm not
4 going to take any procedural point in this case, but
5 please don't take that as an indication that I will
6 relax the strictures that I have sought to lay down in
7 any other case.

8 Would you like to take them, I think, group by
9 group, Mr Di Rollo? So deal with questions 18 to 23
10 first, and you can tell me how these fit into my terms
11 of reference and why I should explore them in the way
12 they are put.

13 MR DI ROLLO: 18 to 23 concern the circumstances in which
14 patient A became infected with Hepatitis C as a result
15 of the administration of a concentrate in May 1986.

16 THE CHAIRMAN: Yes. Okay.

17 MR DI ROLLO: And your terms of reference, of course, do
18 encompass the circumstances generally in which patients
19 became infected as a result of the administration of
20 concentrates.

21 THE CHAIRMAN: Yes, well, I think I should say that the
22 generalities on that seem to me to have been very widely
23 explored already and, as at May 1986, I would incline to
24 the view at the moment that the evidence probably
25 establishes that by that date, everyone getting

1 Factor VIII concentrate already was, if they had been
2 treated in the past, or would immediately become
3 infected. Is that not so?

4 MR DI ROLLO: Yes, it does.

5 THE CHAIRMAN: What is particular to this person, patient A,
6 that affects the generality of that view?

7 MR DI ROLLO: The circumstances are whether or not he, as
8 a previously untreated patient --

9 THE CHAIRMAN: Whether he, as a previously untreated
10 patient?

11 MR DI ROLLO: Yes.

12 THE CHAIRMAN: Yes, okay.

13 MR DI ROLLO: Should have received a Factor VIII concentrate
14 at that time.

15 THE CHAIRMAN: That appears to me immediately to be
16 a question of clinical practice and not a question of
17 the infectivity of the product or the general issue of
18 vulnerability of patients to infection if they got it,
19 Mr Di Rollo.

20 That's as far as I'm going at the moment,
21 Mr Di Rollo. I want you to be alert to that as
22 a problem. I would like this to focus on my terms of
23 reference, not on what might be the subject of
24 proceedings elsewhere. Are these issues the subject of
25 proceedings elsewhere?

1 MR DI ROLLO: They are the subject of proceedings elsewhere.

2 THE CHAIRMAN: Then you will be conscious of the question as
3 to whether any power of mine should be exercised in
4 a way that is ancillary to the pursuit of litigation
5 outside of this room, rather than in pursuit of my terms
6 of reference.

7 MR DI ROLLO: I can assure you that I'm well aware of the
8 need not to use this as a vehicle for pursuing in
9 litigation, and it's not my intention --

10 THE CHAIRMAN: Mr Di Rollo, it's not you I'm concerned with
11 here, with the greatest respect. I understand you are
12 carrying out your instructions and I'm not suggesting
13 the matter shouldn't have been drawn to my attention.
14 I accept that it should. But I think I have to be aware
15 that I have powers that have been prescribed to enable
16 the recovery of documents, the citation of witnesses and
17 so on, to instruct this Inquiry as to matters of fact
18 relevant to the disposal of the terms of reference.

19 If I can't be sure that that's why I'm being asked
20 to do something, that becomes a factor in itself.

21 Anyway, I'm going to let you get on and tell me what
22 it is. You know I have been thinking about this and I
23 have been looking at it, but I want you to tell me, in
24 a way I can write down and be sure that I understand,
25 just exactly what it is that makes this relevant to the

1 Inquiry.

2 MR DI ROLLO: What makes it relevant to the Inquiry is an
3 examination of the systemic issue of the decision-making
4 relative to whether previously untreated patients should
5 or should not receive factor concentrates during the
6 relevant period, ie the period between the end of 1985
7 and the middle of 1987.

8 THE CHAIRMAN: Just pause on that so far. It's systemic
9 issue of the decision-making. Now, these are clinical
10 decisions, are they?

11 MR DI ROLLO: There are decisions to be made in relation to
12 the ordering or not ordering of the 8Y concentrate from
13 England and then there are, beyond that, on guidance to
14 be given in relation to the circumstances in which
15 previously untreated patients should receive
16 concentrates.

17 THE CHAIRMAN: Mr Di Rollo, I can see some general questions
18 implicit in that, for example, whether there were
19 established protocols for addressing the question.
20 That's not what you are asking. But there are other
21 points, you see: the ordering of 8Y. Maybe I should
22 draw to your attention right away, because it occurred
23 to me when I saw this, that in the UK Haemophilia
24 Reference Centre Directors' analysis of possible forms
25 of treatment, [SNB0015606](#) of 16 May 1988,

1 paragraph 5.2.3:

2 "For patients in Scotland and Northern Ireland with
3 Haemophilia A, NHS 8Y is not available and we recommend
4 either Z8 or [something else]."

5 That's when 8Y was in production. The period we are
6 concerned with now is the period when it was being
7 tested and there are records as to what the CTX was for,
8 and if you are going to raise questions about the
9 availability of 8Y in Scotland, it seems to me that
10 perhaps a necessary prior step is to establish that
11 there was indeed an availability of the product other
12 than on the casual basis, perhaps, that we have heard
13 about from Professor Ludlam already. There is no use in
14 asking about protocols for the use of a product if it's
15 not available.

16 Could you just tell me then what your researches
17 have shown as to the availability of 8Y for general use
18 in Scotland at this time?

19 MR DI ROLLO: As far as I'm aware, the only way in which
20 this item could be obtained would be in the way in which
21 it was dealt with in the middle of 1986, after this
22 particular event.

23 THE CHAIRMAN: Then the answer, I am afraid, is that you do
24 not know, Mr Di Rollo. With great respect, where is the
25 factual substratum if you have not researched the actual

1 availability of the products? I know this is extremely
2 important to patient A in another context, and I know
3 that it's something that patient A wants to be
4 ventilated.

5 MR DI ROLLO: And this is the only opportunity that he will
6 have for it to be ventilated.

7 THE CHAIRMAN: So what? The fact that I am here does not
8 create an opportunity. That is a quite inappropriate
9 way to approach it. My question is how, within my terms
10 of reference, I can deal with this, where the substrate
11 of fact is not set up?

12 So, Mr Di Rollo, I'm not here to exercise sympathy
13 and this is a matter of strict competence from my point
14 of view. I'm not trying to be too hard on you but
15 I think I really must know the basis, and with the
16 greatest respect, to tell me that this is the only time
17 is not part of the answer.

18 MR DI ROLLO: Well --

19 THE CHAIRMAN: If it were, it would apply to every single
20 individual in Scotland who thinks that they have
21 something that they want to find out.

22 MR DI ROLLO: The circumstances in which this occurred were
23 mentioned yesterday in a letter which the -- it was
24 mentioned in the preliminary report as -- the critical
25 letter, I think, is the letter which -- just give me

1 a moment --

2 THE CHAIRMAN: Where is the preliminary report reference,
3 Mr Di Rollo? I'll look that up.

4 MR DI ROLLO: The preliminary report references are
5 paragraphs 10.197 and also at paragraph 11.318.

6 THE CHAIRMAN: Thank you. And the letter?

7 MR DI ROLLO: The particular letter that I'm interested in
8 is the letter dated 27 June. It's [SNB0075871](#).

9 THE CHAIRMAN: Where do you want to go first?

10 MR DI ROLLO: If we could go to the letter and just look at
11 the paragraph:

12 "A young haemophiliac --"

13 THE CHAIRMAN: Can we wait until it's brought up, please.
14 (Pause)

15 MR DI ROLLO: "A young haemophiliac, who previously had
16 minimal therapy with Factor VIII, received an infusion
17 of the current heat-treated product a month ago. He now
18 shows signs of liver enzyme rises indicating non-A non-B
19 Hepatitis. Christopher is a bit ruthless with his own
20 staff about this because he feels that this patient
21 should have received 8Y or an equivalent product."

22 THE CHAIRMAN: Right. You have looked up in the dictionary,
23 I hope, about "ruthful"?

24 MR DI ROLLO: I have, I have a copy of it.

25 THE CHAIRMAN: I was hoping for some hope in understanding

1 its general application.

2 MR DI ROLLO: I don't, having looked it up in the
3 dictionary, know what "ruthful" is meant in the context
4 it is used in this particular passage, I have to say.

5 THE CHAIRMAN: You do not know?

6 MR DI ROLLO: I don't know what was meant by Dr Boulton, and
7 I don't know whether Dr Boulton is using his own word or
8 using Christopher Ludlam's word.

9 THE CHAIRMAN: I can see the problem; I don't see the
10 solution.

11 MR DI ROLLO: I have to say the word "ruthful" wasn't one
12 that I had ever seen or used.

13 THE CHAIRMAN: "Ruthless" is one that occurs more often in a
14 judicial context.

15 MR DI ROLLO: Indeed, and it seems to be the opposite of
16 that. But the use of the word, I think, when it was
17 explained yesterday in evidence by Professor Ludlam --
18 he said:

19 "I think I felt a bit sad that we did not have 8Y to
20 give the patient."

21 Is what he said. And that use of the word "sad" in
22 that context would seem to be one meaning of "ruthful".

23 THE CHAIRMAN: It might suggest that the word should have
24 been different and be "rueful", or something like that.

25 MR DI ROLLO: It might be, or it might not. I don't know.

1 It's one of the things I would like to explore, and what
2 I would like to know is whether or not Professor Ludlam
3 was upset with his staff because this patient got
4 Factor VIII on that occasion, or whether he was
5 defensive of his staff because he felt his staff had no
6 opportunity to avoid infecting him because the 8Y wasn't
7 provided.

8 THE CHAIRMAN: Well, now, Mr Di Rollo, could you, please,
9 tell me where that aspect of clinical practice and
10 Professor Ludlam's response to it fits into my terms of
11 reference?

12 MR DI ROLLO: Well, in terms of reference 8, you are
13 required:

14 "To investigate the steps taken by those involved
15 in, and those responsible for, the NHS in Scotland
16 including NHS boards and SNBTS, their officers and
17 employees and associated agencies, to prevent the
18 provision of infected blood and blood products."

19 In terms of reference 5:

20 "To examine the circumstances generally in which
21 patients treated by the NHS in Scotland became infected
22 with Hepatitis C, HIV or through the use of blood
23 products in the course of their treatment."

24 THE CHAIRMAN: I have five specific individual deaths
25 specifically referred to me. Do you say that that

1 requires me to investigate specific instances other than
2 those deaths?

3 MR DI ROLLO: No, it doesn't require you to investigate
4 specific instances, but you are required to investigate
5 the circumstances that a number of specific instances
6 potentially gave rise to and may have been avoided.

7 THE CHAIRMAN: I'm not sure I understand that.

8 MR DI ROLLO: I will try and explain myself.

9 THE CHAIRMAN: "Required to investigate the circumstances
10 that a number of specific instances potentially gave
11 rise to and may have been avoided."

12 Please, you have to break that up a bit and help me.

13 MR DI ROLLO: Well, we are here concerned, in this
14 particular section of the Inquiry, with a particular
15 problem. We are here concerned with the problem that
16 arose in a period during which it was known that there
17 was a severe danger, or serious danger, that if someone
18 received a concentrate for the first time, they would be
19 infected with non-A non-B Hepatitis.

20 THE CHAIRMAN: But this is not that sort of case in the
21 light of the clinician; this is someone who has had
22 minimal therapy with Factor VIII but has had some.

23 MR DI ROLLO: Precisely, and there may well be patients,
24 that we don't know who they are exactly, but there may
25 well be patients out there somewhere who are going to

1 present to their GP or at Accident & Emergency during
2 this period, who have lower than normal levels of
3 Factor VIII or potentially IX, or some other problem,
4 which means that when they present to casualty, those
5 treating them may well take a decision to administer
6 a concentrate to them. If they were to do that during
7 this period, that would result in infecting them with
8 non-A non-B Hepatitis.

9 THE CHAIRMAN: Not necessarily. This is a person who has
10 had Factor VIII, in the understanding of the writer.
11 Now, we are talking about clinical practice. That's
12 absolutely clear, and therefore the fact that must be
13 assumed to be in the mind of the person writing this
14 letter was that the individual had had Factor VIII.

15 MR DI ROLLO: Well, that's an error.

16 THE CHAIRMAN: With the greatest respect, that simply draws
17 attention to the particularity of this, that has got
18 nothing to do with generality.

19 Let's take a hypothetical case in which the
20 clinician is confronted with a young man like this, who
21 is believed to have had Factor VIII. The information at
22 the time would be that, really, almost inevitably --
23 unless he is in a very special category, such as the
24 hyperimmune -- he is going to get hepatitis. So if he
25 is a hyperimmune person, he is not going to get

1 hepatitis this time. If he is not hyperimmune, he has
2 already got it.

3 Mr Di Rollo, we must be more precise about this. If
4 this is clinical, the hypothesis is set out in the
5 letter, and it is the hypothesis of a person who has
6 been treated with Factor VIII.

7 MR DI ROLLO: I see that that's what the letter says. The
8 systemic issue I want to look into is the circumstances
9 as to what should happen in relation to someone who had
10 never previously received Factor VIII, Factor IX before
11 their presentation at Accident & Emergency.

12 THE CHAIRMAN: That's not this case.

13 MR DI ROLLO: It is this case.

14 THE CHAIRMAN: No, with respect, it is not this case. This
15 case is one that is defined by the contemporary
16 correspondence, and what you are saying is that the
17 hypothesis on which the correspondence proceeded is
18 wrong, but that's not an issue for me. And I don't
19 think it can be an issue for me. If this is wrong, it's
20 just irrelevant. The issue that you have outlined, the
21 systemic issue as to what one does with PUPs, is
22 something that can be asked without reference to this
23 case at all.

24 MR DI ROLLO: This whole section arose as a result of me
25 putting a hypothesis to Professor Ludlam last time

1 round.

2 THE CHAIRMAN: If it was with this in mind, perhaps the
3 hypothesis was not sufficiently clear for me to
4 understand what you were about.

5 MR DI ROLLO: I don't know the answer to that. I would have
6 thought it was pretty obvious what I was about at the
7 time then, and it's also pretty obvious what I'm trying
8 to do now.

9 THE CHAIRMAN: Yes, it is pretty obvious, and it is becoming
10 obvious, that what you are instructed to try to do is to
11 obtain information that will be of primary significance
12 in a litigation which is not my affair.

13 MR DI ROLLO: With respect, you should give me more credit
14 for understanding what I do. That's not what I'm trying
15 to do. I'm actually trying to explore something of real
16 significance here.

17 THE CHAIRMAN: Well, please, is it in relation to previously
18 untreated patients?

19 MR DI ROLLO: Yes.

20 THE CHAIRMAN: Is it of a general nature?

21 MR DI ROLLO: Yes.

22 THE CHAIRMAN: Then it has got nothing to do with the facts
23 understood by the medical profession at the time in
24 relation to patient A, and it can be asked without
25 reference to patient A.

1 At least it seems to me at the moment, you would be
2 perfectly entitled to say to Professor Ludlam,
3 "Professor Ludlam, were there, as at this date in" --
4 1987, is it, or 1986? -- "between 1986 and 1988, were
5 there in position within your area, protocols for the
6 treatment of persons presenting for the first time with
7 indications of haemophilia, which ought to have been
8 enforced" -- or however you care to put it -- "in order
9 to protect PUPs from risk of infection?" Something
10 perfectly general. And the answer to that will either
11 be, "Yes, there were protocols," or, "No, there weren't
12 protocols," and I can't see why you shouldn't explore
13 whether there should have been protocols if there
14 weren't. It has nothing to do with patient A. It's
15 a general issue.

16 The problem here is that, with respect, these
17 questions are focused in such a way as effectively to
18 avoid the generality and concentrate it on the
19 particular, when they could easily be asked -- and
20 perhaps there would be no objection; Mr Anderson might
21 object but he might fail. Perhaps there would be no
22 problem about getting an answer to the generality.

23 MR DI ROLLO: I think it goes beyond simply the issue of
24 protocols available to staff because what I'm also
25 interested in is what could and should have been done to

1 protect the previously untreated patients during this
2 period.

3 Some questions were asked yesterday about when it
4 occurred to Professor Ludlam to order the 8Y or to try
5 and get a supply of 8Y for this very purpose, and we had
6 some limited answers in relation to that.

7 It respectfully seems to me, a possible situation is
8 that it only occurred to him to order 8Y after this
9 particular incident in May 1986, and it is worthwhile,
10 it seems to me, exploring the issue as to whether or not
11 it could have occurred to him before that event.

12 THE CHAIRMAN: It didn't occur to people in Glasgow at all,
13 Mr Di Rollo.

14 MR DI ROLLO: Well, I'm not sure how that makes any
15 difference. That makes it even worse for the people in
16 Glasgow, perhaps.

17 There is material which we have which indicates
18 fairly, in my submission clearly, so far so good as far
19 as the English 8Y product was concerned, and that it
20 would not have been unreasonable to have anticipated,
21 I would suggest, that and steps could have been taken to
22 prevent by having such a supply available at an earlier
23 stage. So the issue then arises as to what it was that
24 caused Professor Ludlam to order the 8Y. Was it this
25 particular event or was it simply an appreciation at

1 some point during the course of 1986 that there had been
2 a change of situation or a -- there was a better
3 development in terms of the information that was
4 available.

5 THE CHAIRMAN: You say Professor Ludlam ordered the 8Y, did
6 he?

7 MR DI ROLLO: He didn't order it but I think there is
8 a letter -- that he asked Brian to see if it was
9 possible for it to be obtained and then there was then
10 a -- put into -- he went through the PFC in order for it
11 to be ordered.

12 THE CHAIRMAN: And he gave an undertaking about applying
13 a protocol if it were used? Or Dr Perry did?

14 MR DI ROLLO: I think Dr Perry --

15 THE CHAIRMAN: Because it was part of ...? Or was made to
16 appear to be part of the CTX process?

17 MR DI ROLLO: Trial.

18 THE CHAIRMAN: Yes.

19 MR DI ROLLO: If the point is not obvious to you or if it's
20 something which you don't think that it requires to be
21 looked into, then there we are.

22 THE CHAIRMAN: I can see that there are points here that can
23 be made the subject of general questions that could be
24 relevant, Mr Di Rollo. What I can't see is how the
25 particular issues that you have focused on actually bear

1 upon the generality, and if we look, for example, at
2 question 21, that's an attempt to recover something
3 that's of no real significance in this Inquiry at all.
4 That's my problem. I'm looking at the questions you
5 have posed to get the flavour of what's happening, and
6 really, as you have tried skilfully to expand it and
7 make it general, you seem to me to be taking it further
8 and further away from these questions without
9 formulating issues or questions that I might be able to
10 deal with more sympathetically.

11 MR DI ROLLO: Well --

12 THE CHAIRMAN: Anyway --

13 MR DI ROLLO: The difficulty that one has is I don't know
14 what Professor Ludlam's answers are going to be in
15 relation to a lot of the questions. The point is
16 that --

17 THE CHAIRMAN: None of us know that.

18 MR DI ROLLO: Well, exactly, and I have to give notice of
19 specific questions that I may want to ask in advance and
20 the issue as to -- first of all, the circumstances
21 surrounding this event, one would have thought, may well
22 be in the forefront of his mind, and one wants to test
23 the extent to which he was influenced by this event in
24 relation to the decision to have available the 8Y
25 product.

1 That is why I feel that it is necessary to give
2 notice that one would want to know whether or not there
3 was an Inquiry made by him into the circumstances
4 surrounding this particular incident and whether he was
5 satisfied by the explanation that he was given in
6 relation to that. If he felt that he had not provided
7 his staff what they should have had available to them,
8 then that seems to me to provide a background to what he
9 then does next, which is to seek the provision of this
10 material, whether it's just for Edinburgh or for the
11 whole of Scotland. That leads us on to the next issue,
12 which is whether or not, even when more information
13 becomes available, and when it becomes obvious that the
14 English are prepared to make the material available,
15 more should have been done to make this material
16 available for the rest of the potential population,
17 ranging from the very severe haemophiliac to the person
18 with a very slightly lower than normal Factor VIII or IX
19 level, all of whom may be required to be treated for the
20 first time before the Z8 comes in. That's where we are
21 going with this.

22 THE CHAIRMAN: Who is the very severe haemophiliac, patient
23 A or patient B?

24 MR DI ROLLO: B.

25 THE CHAIRMAN: B? I see.

1 MR DI ROLLO: We know that the administration of Factor VIII
2 is potentially lethal and therefore there has to be
3 a system in place --

4 THE CHAIRMAN: Do we know it's potentially lethal in that
5 language, rather than being liable to transmit a disease
6 that could, in the long run, involve a higher degree of
7 morbidity. "Potentially lethal" is a very harsh
8 expression to use unless are going to give me examples
9 of it.

10 MR DI ROLLO: They knew it was progressive liver disease
11 leading to cirrhosis of the liver.

12 THE CHAIRMAN: I would have thought that "potentially
13 lethal" would be a better description of the two young
14 people who tried to cross the railway track yesterday
15 and were killed. What you mean is: capable of
16 transmitting a disease that might, in some cases in the
17 long term, give an increased morbidity and mortality to
18 the patient.

19 MR DI ROLLO: I think I would put it a bit stronger than
20 that and maybe somewhere between "potentially lethal" in
21 your language.

22 We know that it was known in 1986 that the product
23 was potentially harmful to a patient and therefore there
24 would require to be systems in place so that only those
25 patients who strictly required that item would be given

1 it, and it respectfully seems to me that the system, if
2 there was a system -- and I'm not sure we do know there
3 was a system -- broke down in this particular case and
4 if a system breaks down, then that, in my submission, is
5 something which this Inquiry is entitled to look into.

6 THE CHAIRMAN: Every system can break down. You know? No
7 system is infallible. You know, I don't need evidence
8 to tell me that systems can break down.

9 I think this system, if there was a system, as you
10 say -- and you have not explored that yet -- may have
11 broken down in thousands of cases throughout the
12 United Kingdom, millions of cases throughout the world.

13 We are talking about human beings. You see, this is
14 where one reaches the cusp, as it were. The generality
15 is that the product can transmit infection. There are
16 a few exceptions to that, and therefore one might infer
17 that unless a person falls within the scope of an
18 exception, administration of the product for the first
19 time is going to infect him.

20 There may be, then, a question whether, knowing
21 that, one should have in place what I have called,
22 "protocols", but basically a series of systemic rules
23 that have to be applied by any clinician confronted with
24 the need to deal with a patient who is showing signs of
25 damage related to a blood disorder.

1 The answer to that may be, "There is a need for
2 those", "There is no need for those", "There was a need
3 but we didn't have them". That's a real systemic issue.
4 "There was a need; we did have them". But, from time to
5 time, problems are going to arise that are not dealt
6 with. When you reach that stage, apart from the
7 generality that problems are going to arise, exploration
8 of the particular doesn't increase one's knowledge of
9 the systematic points. It becomes personal to the
10 person who is going to allege a deviation from the
11 system that may or may not be negligent, give rise to
12 claims and so on, which are properly the business of
13 a different tribunal from this.

14 This is my worry, that, so far, I can see loads of
15 good grounds for pursuing the general. I see lots of
16 grounds for acknowledging human fallibility. Goodness,
17 I have probably displayed plenty of it in the course of
18 this Inquiry myself; perhaps most of us have. But if
19 you look at your questions, they are not of a level of
20 generality. You are actually looking for a report into
21 the particular case.

22 What has that got to do with my terms of reference?
23 That's the reason I'm pressing you on this.

24 MR DI ROLLO: Well, I can see that questions number 18 and
25 19 are specific in a way which is perhaps unnecessary to

1 explore the sort of issue -- I have tried to explain to
2 you what it is that I'm trying to do in relation to
3 this. It is quite difficult in advance of a piece of
4 examination to know exactly what one would want to ask
5 in relation to answers where one doesn't know what one
6 is going to get.

7 THE CHAIRMAN: Yes.

8 MR DI ROLLO: What I have done in the questions, I suppose,
9 is put the questions in as extreme a form as one would
10 hope to be able to ask, so that everyone knows the
11 extent to which I'm seeking latitude.

12 What I am seeking to do is to be able to examine
13 Professor Ludlam with a view to trying to get an
14 understanding of what it was that those who were on the
15 front line in May would be expected to do with such
16 a patient, and what they were instructed to do and
17 whether or not those instructions could be expected to
18 be complied with.

19 If there was a failure, which I think there may have
20 been, why did it fail?

21 THE CHAIRMAN: You see, again we come near -- as I have
22 tried to say, I have very little concern at the moment,
23 subject to what Mr Anderson has to tell me, about the
24 generalities, about the need for instructions and so on,
25 as questions that can be asked. But one should step

1 across the boundary from the general into the
2 particular. You are not using the particular to
3 instruct the generality in this case; you are using it
4 to explore something quite different.

5 Anyway, I have heard what you have to say.
6 Mr Anderson has no doubt heard it all too. Is there
7 anything else you want to say about the first class of
8 case, the questions 18 to 23? I think I would like to
9 deal with them in stages so that I get a proper feeling
10 for each group of questions.

11 MR DI ROLLO: I would say that it is reasonable for me to be
12 allowed to ask why it was that letters were written to
13 Dr Ludlam about what happened in --

14 THE CHAIRMAN: What letters are these?

15 MR DI ROLLO: Both the houseman and the registrar wrote
16 letters to Dr Ludlam about what had happened. They were
17 asked for an explanation, as I understand it, from
18 Professor Ludlam.

19 THE CHAIRMAN: This is of general importance, rather than
20 relating to the particular case?

21 MR DI ROLLO: It is of general importance because again it
22 is a question of exploring the system that was in place.
23 Was there a system and did it break down and why did it
24 break down? If somebody goes to casualty and is given
25 Factor VIII and they don't need it at all and if that

1 was happening on a regular basis, is that not something
2 that should be looked into?

3 THE CHAIRMAN: Was it happening on a regular basis? Are you
4 alleging it was happening on a regular basis?

5 MR DI ROLLO: I don't know.

6 THE CHAIRMAN: Well, with the greatest respect, that will
7 not do, Mr Di Rollo. You are introducing pure
8 speculation in support of this. Now, the reality is, if
9 you had known about a number of cases, these questions
10 wouldn't have been asked in this case. These questions
11 are asked with reference to a specific case.

12 MR DI ROLLO: All I know is what's contained in the
13 preliminary report in relation to numbers, which is
14 that, as we explored with Professor Lowe, there are
15 31 people that were previously untreated patients who
16 received concentrates for the first time during this
17 period.

18 THE CHAIRMAN: Yes.

19 MR DI ROLLO: I actually don't know whether in fact
20 patient A is the person referred to in the documents
21 that we have.

22 THE CHAIRMAN: Nor should you because we are trying hard to
23 protect individuals' identities.

24 MR DI ROLLO: Even I don't know the answer to that.

25 THE CHAIRMAN: I know. Again this is because of my concern

1 that what we are doing now is moving to the particular
2 as the focus of attention, not as an illustration of
3 a wider problem.

4 MR DI ROLLO: I can quite see there are a large number of
5 questions that you do not need to know the answer to in
6 order to conduct or to fulfil the terms of reference
7 arising out of this specific case, but there are some
8 questions arising out of this specific case that do
9 inform those terms of reference and those questions
10 relate to the explanation that was given to -- whether
11 an explanation was required, what the explanation was
12 and whether he was satisfied with that explanation as
13 against the system that was in place or not, as the case
14 may be, in relation to dealing with this particular
15 problem. I hope that makes it clear what I'm trying --

16 THE CHAIRMAN: That's your submission.

17 MR DI ROLLO: -- to explain.

18 Question 21 obviously deals with the conclusion of
19 that investigation. I'm prepared to depart from
20 questions 22 and 23. I don't require those questions to
21 be answered in the specific sense. But I would perhaps
22 want to ask some general questions about the volume of
23 product that might be required and also the levels of
24 Factor VIII in a person's bloodstream.

25 THE CHAIRMAN: Well, I'm not going to deal with issues of

1 that kind casually, Mr Di Rollo. I think the discussion
2 already is developing to the point at which the wisdom
3 of requiring proper formal applications with support is
4 becoming clearer and the departure from questions is
5 just as bad as the proposing of them in the first place.

6 Anyway, should I hear what Mr Anderson has to say
7 about questions 18 to 23 at this stage or do you think
8 it would be better from your point of view to cover the
9 questions at the end, 51 and 52 as well?

10 MR DI ROLLO: Questions 51 and 52 -- I'm content just to
11 deal with that -- are really to explore in general terms
12 how one would look into or how one would deal with
13 preventing someone being infected with concentrate at
14 a later time. It's 1986 to 1987. It's obviously after
15 patient A. There is other material available in
16 relation to that I will submit makes it clear that it
17 was even more important by that stage to cater for the
18 previously untreated patient as time went on.

19 THE CHAIRMAN: This again is focused on a particular
20 individual, is it not?

21 MR DI ROLLO: When we say we were focused on a particular
22 individual, I can't proceed on the basis of things in
23 the abstract; I have to have something in mind. As
24 I understand it, two core participants were selected as
25 examples, as I understand it, of a large number of

1 potential individuals, and one has to have in mind
2 specific circumstances in order to make meaningful any
3 general questions that one has.

4 THE CHAIRMAN: In some cases that's undoubtedly so.

5 MR DI ROLLO: The questions I'm asking are general questions
6 and I would submit that there is nothing specific --
7 I have someone specifically in mind, of course, but
8 there is nothing specific about questions 51 and 52.

9 THE CHAIRMAN: No, 52 is a question of such generality that
10 I'm not sure I understand what it's all about:

11 "Why should an infant from outwith the central belt
12 given Scottish Factor VIII in 1987?"

13 What? Why should the infant what?

14 MR DI ROLLO: I think it's, "should be given".

15 THE CHAIRMAN: "Why would an infant from outside the central
16 belt then be given Scottish Factor VIII
17 in January 1987?"

18 I suppose one answer is because he was here.

19 MR DI ROLLO: The purpose of this exercise, I think, is to
20 try to give notice to other parties as to the sort of
21 issue that may be raised. My understanding is that if
22 there is a problem, it's because it's too specific.
23 You, sir, have just indicated clearly that if the
24 question has a problem, it's not because it's too
25 specific and therefore I don't think it requires much

1 more input from me.

2 I think I would be in a position to ask general
3 questions about this particular matter and I don't
4 think --

5 THE CHAIRMAN: Without identifying patient B?

6 MR DI ROLLO: Of course not.

7 THE CHAIRMAN: Yes, and without going to circumstances so
8 particular to patient B that they cease to be
9 illustrative of the general point and really came to
10 focus on patient B, because that's my worry.

11 MR DI ROLLO: The only witnesses I can deal with for this
12 particular matter are Professor Ludlam and Dr Colvin and
13 of course I have to put some sort of general hypothesis
14 to them.

15 THE CHAIRMAN: Right.

16 MR DI ROLLO: The essence of it, in relation to both
17 patients, is to do exactly the same thing. The problem
18 that arises with Professor Ludlam is that one of the
19 patients happens to be potentially -- or could be --
20 I don't know, in fact, as a matter of fact -- could be
21 one of his own patients, and why I'm constrained to
22 putting specific questions is because I don't know what
23 he is going to say in answer to questions about systems.
24 That's the reason why the questions have been put in the
25 specific way that they have in relation to patient A.

1 THE CHAIRMAN: Mr Anderson?

2 Submissions by MR ANDERSON

3 MR ANDERSON: I'm much obliged, sir.

4 Sir, the existence of these questions was brought to
5 my attention by Ms Dunlop on Sunday. There had been no
6 prior information, either to myself or those instructing
7 me, and consequently there has been no investigation
8 into the questions in dispute.

9 As I said earlier, I have no objection to the vast
10 majority of the questions, which seem to fall to
11 a greater or lesser extent cleanly under the topic C3A
12 and indeed some have already been answered, but I have
13 concern about the particular questions. But I should
14 make clear that my objection is not based simply because
15 of the fact that they have come somewhat late in the
16 day, although there is an element of that.

17 THE CHAIRMAN: I wouldn't rely on that, Mr Anderson. The
18 procedure is flexible and if it's time that's a cause of
19 concern, I'll make sure that you are given the time to
20 prepare properly to deal with any issue that arises.
21 I'm not concerned to listen to purported problems of
22 that kind.

23 MR ANDERSON: I was seeking to make clear that I was not
24 relying upon that but there is an element of the fact
25 that the individual cases have not been investigated;

1 rather, I object as a matter of principle and I simply
2 seek to make that clear. In my submission there are
3 good reasons for this.

4 Sir, these two individual cases, or at least one of
5 them, involve named doctors and one can see that,
6 I think, in question 19. These doctors may be impliedly
7 or explicitly criticised. Neither of these doctors
8 knows anything about these questions or indeed this
9 inquiry, neither being still within the employment --

10 THE CHAIRMAN: Could you just pause a moment? Douglas, have
11 you got the regulations with you? You have just raised
12 something which I would like to be clear about. I may
13 be using one of my own witnesses for this purpose.

14 (Handed)

15 Why I'm raising this question is that, of course, if
16 indeed lack of notice were to become important, rule 12
17 of the Inquiry Scotland Rules provides that:

18 "The chairman may send a warning letter to any
19 person where the chairman considers that (a) the person
20 might be or has been criticised during the proceedings
21 at the Inquiry."

22 Now, at the moment my concern is "might be". If you
23 are right that there is a risk of criticism, direct or
24 indirect, being directed towards the individual named
25 doctors, it is just possible that I don't have the

1 flexibility to deal with this at my own hand and relax
2 the rules, as I might otherwise be inclined to do,
3 because I would be obliged to send a letter to any of
4 the doctors. If indeed they are being sued, as appears
5 likely to be the case, it would be wholly inappropriate
6 to allow questions to be asked without their getting
7 service of a formal notice under rule 12.

8 MR ANDERSON: Indeed, I did not have in mind, I confess, the
9 rule itself but simply as a matter of principle --

10 THE CHAIRMAN: We are dealing with a statutory construct,
11 where principle is perhaps less obvious from time to
12 time.

13 MR ANDERSON: One might like to think that the regulations
14 have their provenance in a good and sensible principle,
15 sir. But, as I say, although neither remain in the
16 employment of -- at least as far as we know -- health
17 boards -- one is thought to be working in the south of
18 England and the other one's present whereabouts are
19 unknown -- I have a grave concern about former employees
20 being directed to a discussion about their clinical
21 judgment in individual cases in a situation in which
22 they are not represented, they know nothing about it and
23 they have no ability to have any input into the matter,
24 and this is a discussion about them and about their
25 professional judgment, their clinical judgment, which

1 will apparently be disseminated on the World Wide Web.

2 THE CHAIRMAN: Yes.

3 MR ANDERSON: The second reason, sir, is that, as you have
4 suspected, there are extant civil actions in respect of
5 these two questions, albeit they have been sisted for
6 some considerable period of time. I think the position
7 was that they were raised in order to defeat the time
8 bar.

9 THE CHAIRMAN: A perfectly proper course of action,
10 Mr Anderson.

11 MR ANDERSON: Perfectly proper. I don't suggest otherwise.

12 THE CHAIRMAN: But again, because it's on the World Wide
13 Web, I would not for one moment anyone to get the
14 impression that it was inappropriate to raise an action
15 to stop a time bar running.

16 MR ANDERSON: I think everyone is at one on that, sir.

17 I simply, by way of background, the summons were served
18 and then sisted and, as I understand it, there has been
19 no further procedure. The point is that there are civil
20 actions extant and I'm very unhappy about a witness, in
21 particular Professor Ludlam, who is likely to be
22 a material witness in one of the litigations, being
23 questioned in this forum, particularly when he has not
24 investigated the matter, and I have grave concerns about
25 the appropriateness of using this forum in this way.

1 I don't for one moment, of course, question my
2 learned friend Mr Di Rollo's probity in this matter and
3 it may very well be, as he says, that this is not the
4 purpose of his asking these questions, but the result of
5 asking these questions is almost certainly to influence
6 in one way or another the litigation which is currently
7 sisted and in my submission that's simply not
8 appropriate.

9 It may be said that those individuals are simply
10 looking for answers and I heard my learned friend use
11 the phrase "the only opportunity". I have two things to
12 say about that, sir. The first is, of course, that
13 those instructing my learned friend, if they are looking
14 for information, can simply write to the relevant health
15 boards with questions of fact, which those health boards
16 will be happy to answer and indeed, as I understand it,
17 would be obliged to answer. That is something which has
18 not been done hitherto, as I understand it.

19 Secondly, I have a suspicion that this is an attempt
20 essentially to extract some sort of opinion evidence
21 from Professor Ludlam and again I have very grave
22 concerns about that, and one can see in question 21
23 where that concern arises from.

24 In brief, sir, it's a matter for you but I would
25 suggest that these mini inquiries, which is essentially

1 what they are, will be of no assistance to you. They
2 are unnecessary, inappropriate and this is simply not
3 the apt forum to discuss questions of clinical decision
4 in individual cases. That, sir, is not part of your
5 remit, I would suggest, and it is particularly
6 inappropriate to discuss questions of clinical decision
7 in individual cases, when the matter has not been
8 properly investigated and the whole background facts are
9 not known.

10 The final thing I would like to say is this: if, as
11 a general proposition, it is accepted that the treatment
12 of choice for a particular class of persons is X and the
13 treatment in one particular case is Y, then in my
14 submission no significant inference can be drawn from
15 that fact and in particular no adverse inference can be
16 drawn from that fact, especially when we don't know all
17 the facts, we don't know the background and, as
18 Professors Lowe and Ludlam said yesterday, matters of
19 choice of treatment require you to assess the patient
20 individually.

21 Until one knows everything one needs to know about
22 the individual patient, it is quite wrong to embark upon
23 a discussion as to the rights or wrongs of treatment in
24 any particular case. But in any event, as a matter of
25 principle, I suggest to you, sir, that it is not within

1 your remit and for that reason alone these questions
2 should be disallowed.

3 Now, much of what I said, I think, relates to
4 questions 18 to 23 but, when one turns to 51 and 52, the
5 difficulty there -- if one looks at 52, there is
6 a problem with that, firstly, that it clearly is
7 a reference to patient B, but at the same time the
8 question is posed in such general terms as to give rise
9 to a question as to its usefulness in any event.

10 It's a matter for you, sir, but I would suggest to
11 you that whatever answer were to be given to that will
12 take this Inquiry no further at all. So for those
13 reasons, sir, I object to those questions.

14 THE CHAIRMAN: Mr Di Rollo, do you have anything to say
15 about the application of regulation 12?

16 MR DI ROLLO: The questions, if one looks at them, are not
17 intended to lead to any criticism of anyone. What's
18 being asked in relation to question 18 is who gave the
19 instruction to administer, so there is no criticism in
20 relation to that. Was there a misunderstanding --

21 THE CHAIRMAN: Mr Di Rollo, I think that you have already
22 gone far enough for me to give you my decision. I think
23 that the discussion has made it abundantly clear that
24 the formal procedure for intimating issues that are to
25 be investigated should be followed, that you should set

1 out afresh, looking at these questions in the light of
2 the discussion we have had, some way of presenting them
3 as a matter of generality that seeks to avoid some of
4 the inherent difficulties that we have discussed, that
5 that is intimated to Mr Anderson's present clients, that
6 I will then consider it on its terms and explore whether
7 regulation 12 has to be applied.

8 So in hoc statu I'm going to refuse permission to
9 examine Professor Ludlam today. I have got an interest
10 in completing this Inquiry. I have got no interest in
11 excluding matters of substance. But I am determined now
12 to ensure that if matters of substance are to be
13 explored that are arising afresh, as it were, proper
14 steps are taken to ensure that everyone who could be
15 affected by the material is properly apprised of what is
16 involved.

17 Now, I really do think that your attempts,
18 successful attempts in many ways, to tell me what the
19 generality is point the way to how you might do this.
20 At the moment I'm left with the concern, focused by
21 Mr Anderson, this is far too particular to individual
22 cases and it's far too open to the representations that
23 we have discussed that at times focused on them to the
24 exclusion really of the generality, and I think also you
25 should be aware that I have got a real concern, not just

1 for this Inquiry but for any others that might, if
2 anyone is ever minded to instruct such an inquiry again,
3 follow as to the risk of intentional or accidental abuse
4 of the powers by exploring matters in relation to civil
5 litigation.

6 I think I might well recommend to the cabinet
7 secretary that there be a specific instruction to any
8 other reporter ever instructed to ensure that where
9 a generality is focused, individual cases are not
10 explored.

11 Anyway in the meantime I'm refusing the questions in
12 hoc statu but I want to you consider very carefully what
13 it is that you are interested in obtaining. Put it in
14 an application. We will have it intimated and
15 circulated and I will consider the need to apply
16 regulation 12 in relation to the circumstances as they
17 emerge.

18 I think regulation 12 is very important in the
19 context that Mr Anderson has focused. If you just look
20 at the structure of the questions, the risk of criticism
21 emerging is so great that I don't think it can be
22 ignored, whatever intentions one has. Therefore, this
23 has to be thought through and I give you the opportunity
24 to do that.

25 I suggest that you make the application within

1 four weeks, which is the date I gave yesterday for all
2 such applications, but that we then take matters forward
3 as best we can.

4 Now, I think as far as I'm concerned, it's time for
5 a break.

6 (10.50 am)

7 (Short break)

8 (11.42 am)

9 THE CHAIRMAN: Yes, Ms Dunlop?

10 MS DUNLOP: Thank you, sir. This morning's discussion has
11 made me realise that there are some further questions
12 which I ought to ask and I wonder if I might be allowed
13 to pose some further questions to Professor Ludlam.

14 THE CHAIRMAN: Is that acceptable to others?

15 Yes, certainly.

16 MS DUNLOP: Perhaps Professor Ludlam should return.

17 THE CHAIRMAN: Yes.

18 PROFESSOR CHRISTOPHER LUDLAM (continued)

19 Questions by MS DUNLOP (continued)

20 THE CHAIRMAN: Good morning, Professor Ludlam. I hope you
21 have found the accommodation acceptable during --

22 A. Thank you, and the coffee's particularly good.

23 THE CHAIRMAN: Yes, Ms Dunlop?

24 MS DUNLOP: Thank you, sir.

25 Professor Ludlam, I'm going to ask you one or two

1 more general questions about the period from the end of
2 1984 to the middle of 1987.

3 Can we start by going back to the December 1984
4 document from the reference centre directors. That's
5 [SGF0012388](#).

6 Can we go to page 2 of that, please?

7 We remember actually that the structure of the
8 document is that at the foot of page 2 it outlines
9 firstly a list of options, options in probable
10 decreasing order of safety from AIDS for Haemophilia A,
11 and we see that option number 1 is shown as "heated UK
12 concentrate", but with the caveat that there is still
13 an NANB hepatitis risk. And then number 2:

14 "Single donor cryo or fresh-frozen plasma."

15 Number 3:

16 "Heated imported concentrate. Note: still NANB
17 hepatitis risk."

18 Then there are recommendations. Number 1, the need
19 to continue to use concentrate because of the risk of
20 bleeding causing disability or death; number 2, DDAVP.
21 Then on to the next page, please.

22 Number 3:

23 "For Haemophilia A needing blood products."

24 We have a divide between virgin patients, those not
25 previously exposed to concentrate, and children:

1 "use cryo or heated NHS Factor VIII (if available)."

2 And then severe and moderate patients are discussed
3 also. Haemophilia B is section 4.

4 Perhaps a similar sort of ethos as between
5 haemophilia A and Haemophilia B, which seems to be being
6 particularly careful with patients who are "virgin",
7 those not previously exposed to concentrate, and
8 children are mentioned specifically in 3(a).

9 Now, this is December 1984, so the factual position
10 is that screening of blood donations has not yet been
11 introduced and I think we have established that that
12 does make a difference in one's assessment.

13 Next I would like, if I could, please, to go back to
14 the transcript for yesterday, and towards the beginning,
15 can we look, firstly, please, at page 59 from
16 yesterday's transcript?

17 This is a part, Professor Ludlam, where you and
18 I are still discussing generalities at the outset of
19 your evidence. As far as the number for the page with
20 the four pages, it's 15, if that helps. If that makes
21 sense. Thank you.

22 Do you see there, at line 8 on page 59, I'm saying
23 to you that:

24 "The concern that one has, obviously, in relation to
25 this matter is that treating someone for the first time

1 with a blood product during this period means that you
2 are exposing them to the risk of hepatitis -- non-A
3 non-B, as it was then known ... "

4 THE CHAIRMAN: I'm slightly concerned, is this
5 Professor Ludlam's evidence or is this Mr Di Rollo's
6 questions directed to Professor Lowe?

7 MS DUNLOP: Sorry, I may be in the wrong bit.

8 THE CHAIRMAN: I think this is Mr Di Rollo's questions to
9 Professor Lowe that started around about 56.

10 MS DUNLOP: Sorry, I'm in the wrong bit. Yes, I can see
11 that. If you will allow me a minute, sir, we will find
12 the right bit.

13 THE CHAIRMAN: It is probably exactly the same point.

14 MS DUNLOP: It is the same point but it's the wrong witness.

15 THE CHAIRMAN: The summary starts around about page 72,
16 I think. Look at [TRN0010054](#) at page 74.

17 MS DUNLOP: Yes, thank you. Sorry about that. Yes, there
18 we are, 74:

19 "I wonder if it would be fair to say however, that
20 the therapeutic policy generally over this period would
21 be guided by a desire to avoid the use of blood products
22 unless there was no alternative.

23 "Answer: That, I think, is fair, yes."

24 We will just look at the top of 75 to make sure
25 there is nothing else we need to look at. Right.

1 Now, Professor Ludlam, the guidance, I suppose,
2 might be described as being deceptively simple in its
3 terms, in that the sorts of choices between individual
4 products that may fall to be made with any one patient
5 could be very difficult. So I suppose the thinking
6 behind providing the guidance is that it will be
7 a starting point for clinicians, but the finishing point
8 will obviously have to involve an assessment of the
9 circumstances of the individual patient. But you
10 personally, as a director at that time, and a reference
11 centre director at that, presumably saw the provision of
12 guidance as helpful?

13 A. Yes.

14 Q. Yes. Can we then start with you as a centre director at
15 that time. You had been at the meeting, which had
16 discussed the issues, and you will have received the
17 document too. So, yes, it will have been in Edinburgh
18 Royal Infirmary?

19 A. Yes.

20 Q. Yes. I just wondered what steps were taken in Edinburgh
21 Royal Infirmary to ensure what I might term "vertical
22 dissemination", so you are at the top but obviously you
23 are not always there. So what steps were taken to
24 communicate the thrust of the guidance to other staff
25 who might be encountering patients with haemophilia?

1 A. Well, I think the guidance given in this document,
2 leaving aside, if I can, the heat treatment, is what our
3 therapeutic practice was.

4 Q. Right.

5 A. In other words, it was standard practice to use DDAVP if
6 that was suitable. Very much so. Because we were aware
7 of the risks that we have all been discussing here.

8 Q. Yes.

9 A. If DDAVP or desmopressin was not suitable for whatever
10 reason, then it was a question of considering
11 cryoprecipitate or heat-treated concentrate, and we were
12 particularly fortunate in Scotland in having
13 heat-treated concentrate. We didn't have to make some
14 of the awful decisions that some of the clinicians had
15 to make early in 1985 in England.

16 So there was still the policy, depending on the
17 circumstances -- and every patient is different -- we
18 were still using cryoprecipitate for small children and
19 babies around that time and moving on to the
20 concentrate, as I hinted yesterday or stated yesterday,
21 often when they came to go on to home treatment. That
22 was the way we arranged things.

23 Q. Yes. What actually happened in the department? Was
24 there a folder with guidance documents in it? Were
25 there charts on the wall? Was it all done with verbal

1 instruction? How was guidance disseminated?

2 A. We had a small team of people: myself, a lecturer,
3 a registrar and a haemophilia sister, and our policy
4 was -- policies for all sorts of things were, I think,
5 generally accepted and well-known within the team.

6 Q. There has to be something that leads to their being
7 generally accepted?

8 A. Yes. I am afraid I can't remember at the moment. Now
9 we have large numbers of written policies. I can't
10 remember at this time. I know two or three years after
11 this we certainly had written policies. I can't
12 remember at this stage whether there were written
13 policies for -- guidance policies in general, locally
14 produced. I'm sorry, I can't remember.

15 Q. Right. The most difficult decision, it seems to me as
16 a layperson, is the choice between heat-treated
17 concentrate, NHS heat-treated concentrate, certainly,
18 and cryoprecipitate. Now, I suppose the sense of risk
19 that attached to cryoprecipitate must have been
20 different before October 1985, from what it was after
21 1985. Am I right about that?

22 A. Yes.

23 Q. Right. So the introduction of screening in October 1985
24 must have made cryoprecipitate a more attractive choice
25 than it had been before October 1985?

1 A. I think so, yes, with the caveats that you mentioned
2 yesterday about false negative results on screening and
3 the window period. We really didn't know how much safer
4 cryoprecipitate was for that screening that started
5 in September 1985.

6 Q. Right. But I think we understand that cryoprecipitate,
7 even before October 1985, is still seen as having a part
8 to play. It's mentioned in the December 1984 guidance
9 document, and perhaps slightly more so. It's difficult
10 to quantitate that but slightly more so
11 after October 1985. That's the really hard choice,
12 isn't it, between heat-treated concentrate and
13 cryoprecipitate?

14 A. Yes.

15 Q. And the factual scenario in which it's going to crop up
16 is the patient with no previous exposure?

17 A. Or little.

18 Q. Or little. No or little previous exposure. Having
19 established, as we have, that plainly the circumstances
20 of any one individual are relevant, did you take steps
21 to go a little beyond the guidance for your particular
22 staff, so as to give them, as it were, a bit of a steer
23 as to the general policy that you might want to see
24 applied in Edinburgh Royal Infirmary for patients in
25 that category?

1 A. I think it would be quite clear that patients in that
2 category should be discussed at a senior level, because
3 it's not just a matter of cryoprecipitate versus
4 concentrates being, if you like, very equal; it might
5 depend on the clinical circumstances of the patient.

6 Q. Right.

7 A. At one extreme a baby comes in, a new child with a major
8 intracranial bleed, life-threatening. I think my
9 judgment would be that child should receive
10 a concentrate because you could make it up quickly, you
11 knew exactly how much you were giving, it was easy to
12 give, it hopefully would be effective treatment.

13 Q. Yes.

14 A. So there is an instance where I would have given
15 Factor VIII concentrate to, if you like, a previously
16 untransfused baby.

17 Q. Yes.

18 A. Because cryoprecipitate, as I think has been explained
19 here, takes time to make up, the dose is unknown, the
20 volume greater, harder to give to a small baby. So
21 there's an instance where I wouldn't have given
22 cryoprecipitate for that particular situation.

23 Q. Yes.

24 A. So these situations, as you see, arise uncommonly and
25 it's difficult to make up categorical guidance, if I can

1 put it that way.

2 Q. Yes.

3 A. And each has to be considered on its merits and that's
4 why we have senior doctors who are available to discuss
5 these issues, and sometimes I have difficulty deciding
6 what the best thing is for a patient and I telephone
7 someone else, who I think can offer me better guidance.

8 Q. I think we understand the point you are making,
9 professor, and other professions don't confront it in
10 such stark terms perhaps because what's at stake is
11 uniquely difficult in medicine, but other professions do
12 have a similar issue, which is for senior people, do
13 they try to be prescriptive as much as they can to
14 assist junior members of the team, or do they say, "If
15 this sort of situation arises, contact somebody more
16 senior?" And I think we can understand that both of
17 these are reasonable solutions to that sort of
18 situation.

19 How do you think staff would appreciate that in that
20 situation it was their responsibility or your
21 expectation that more senior support would be sought?

22 A. For a patient who has not been treated before?

23 Q. Yes.

24 A. That's a very unusual situation.

25 Q. Yes.

1 A. And I would almost certainly be contacted.

2 Q. Right. But I think I'm interested in how practically it
3 actually worked. I mean, when a new doctor arrived,
4 either a junior member of staff or somebody who had
5 worked elsewhere, did they have some sort of induction?
6 Did you say to them, "Here are my policies?" We have
7 established, I think, that it's difficult to recall, and
8 I understand why, it's a long time ago, how much use was
9 made of written material, but do you have any memory of
10 sitting down with more junior staff and explaining to
11 them some of the more important expectations you had of
12 them?

13 A. I think a lot of the day-to-day knowledge about the
14 patients, knowledge about our policies, was known to the
15 haemophilia sister, who was, if you like, the constant
16 feature, very much at the front end of our service.
17 Unlike now, when trainee doctors, trainee registrars,
18 are on very formal rotations and come to work for us for
19 just a few months and it is quite a short period, at
20 that time our staff were with us for often several
21 years, so there wasn't a large turnover of staff like
22 there is -- of junior staff like there is now. Coupled
23 with that, we had a lecturer post that was a more
24 permanent post. So there were people who were
25 conversant with treating haemophilia. There wasn't

1 a large turnover of staff and the need to have an
2 induction programme like there is now.

3 Q. Right. So I think what I'm picking up then is just
4 that, that new people would pick it up; they would pick
5 it up from staff who were already there and had
6 absorbed the way you worked?

7 A. It was very easy for them to enquire if they didn't
8 understand something, didn't know something as well.

9 Q. Well, what about a slightly different event then? What
10 about something like the introduction of screening of
11 donated blood in October 1985, which is going to have an
12 effect on the assessment of the relative merits of
13 different blood products? What happened then? Did you
14 gather the staff together and say, "This has now
15 happened. You will all appreciate that that makes a bit
16 of a difference"? Did you do something like that?

17 A. I don't think so, because it was a difficult time and
18 there was discomfort in using cryoprecipitate,
19 sufficient discomfort that some haemophilia centres
20 didn't use it at all.

21 Q. Right.

22 A. They didn't have it on the shelf for treating
23 haemophilia. They were treated with Factor VIII
24 concentrates or DDAVP.

25 Q. You are answering in relation to my specific example.

1 Let's pull back from that and just think in the general
2 that any event in haemophilia care which is happening,
3 has happened, a new product or a new piece of research
4 or something of that nature, did you have team meetings
5 or any sort of gatherings where you would discuss that
6 with the staff?

7 A. We had weekly educational meetings, at which we would
8 discuss our internal arrangements, our internal
9 policies, we would have outside speakers. I seem to
10 recall a speaker from the blood transfusion coming to
11 talk about developments in clotting factor concentrates.

12 Q. So these were a fixture?

13 A. These were a fixture, yes.

14 Q. And during the day?

15 A. Yes, they were at half past eight on Friday mornings.

16 Q. Right. Did you sometimes discuss issues of this nature,
17 treatment dilemmas?

18 A. Yes, they were meetings to keep us up-to-date and to
19 introduce us to new topics, new issues. There were
20 clinical presentations of a patient with a particularly
21 interesting story or medical condition. So that
22 happened every week.

23 Q. Right. So in terms of assisting more junior members of
24 staff -- and everybody is junior to you -- more junior
25 members of medical staff to respond to these patients

1 who present particular difficulties, I think we
2 understand that they might have been discussed at the
3 weekly meetings, but your general expectation was of
4 junior staff contacting more senior staff if such
5 a patient should present. Is that right?

6 A. Absolutely, yes.

7 Q. Yes. And in response to the question about how junior
8 staff would know that that was expected of them, you are
9 telling us that they would learn that from others
10 around?

11 A. 99 per cent of people who come up to the
12 haemophilia centre, it's all very straightforward.

13 Q. We are talking about the 1 per cent.

14 A. Yes, and the 1 per cent does stick out as being
15 different.

16 Q. Right. What about giving assistance to other staff in
17 defining that group, making sure that other staff
18 understood that this is indeed the 1 per cent, that this
19 is the group with whom these difficult decisions arise?
20 How did junior staff actually learn that?

21 A. Because these are likely to be patients that aren't in
22 our records.

23 Q. Right.

24 A. We have case notes for all our known and registered
25 patients. So that was all very clear from the case

1 notes and the general expectations. If we had the sort
2 of people who came as unknown to us, which were mostly
3 visitors coming to Edinburgh on holiday or on business
4 and they had a bleed and they needed treatment, and they
5 come to the haemophilia centre and they will have
6 a haemophilia card saying they have got haemophilia,
7 where they are registered, what kind of haemophilia it
8 is they have got, what the severity is of their
9 haemophilia, and it may or may not say what they are
10 treated with. So it's a sort of an introduction.
11 Whoever sees the patient would look at this, probably
12 ask the patient, apart from what was wrong and so on,
13 what they were normally treated with, and most patients
14 knew what they were treated with and we took it from
15 there.

16 Q. And did junior staff always just have to speak to the
17 person on the next rung above or can they come straight
18 to you?

19 A. They would come straight to me.

20 Q. And that would be true in the mid-1980s as well?

21 A. Yes, I made myself very available.

22 Q. Right. So I think we understand the position to have
23 been that there were no set guidelines that, as it were,
24 refined the UKHCDO document and that you preferred to
25 see the 1 per cent, if we can call them that, as people

1 in relation to whom specific issues would arise and
2 should be resolved with the involvements of senior
3 medical staff?

4 A. Yes. I can't recall whether there were written
5 documents or not.

6 Q. Right. I should say that when I'm asking you about
7 these sort of policy questions, I am meaning the whole
8 of our difficult period, notwithstanding that there was
9 quite a significant change in October 1985. We are
10 thinking about the years 1985, 1986 and the first part
11 of 1987, and I think the answers you are giving are your
12 best recollection of what happened around that time. Is
13 that right? Is that correct?

14 A. I think so, yes, sorry, I was just reflecting on --

15 Q. Sorry, I didn't mean to interrupt your thought.

16 THE CHAIRMAN: Take your time, Professor Ludlam, if you want
17 to answer it more fully.

18 MS DUNLOP: Excuse me a moment. (Pause)

19 A. I think in general, although as you were asking the
20 questions, I was thinking more in terms of 1985.

21 Q. Right. So do you think it changed in 1986 and 1987?

22 A. That's what I was thinking about.

23 Q. Right. (Pause)

24 A. I don't think so, no.

25 Q. No. I just wanted to pick you up on your answer about

1 junior staff having the right, as it were, to come
2 straight to you.

3 You said, "They would come straight to me". Now,
4 they could come straight to you, we understand. They
5 would come straight to you is perhaps slightly
6 different. Are you saying that in a particularly
7 difficult situation, that would have been your
8 expectation and if so, how would they know that?

9 A. If they have got a situation that they are not quite
10 sure how to deal with, they would ring me up and I would
11 walk down the corridor and see the patient.

12 Q. What about the over-confident?

13 A. If I perceived someone was being over confident, I would
14 offer them some tuition.

15 Q. All right. But all of this is, with respect, a little
16 bit reactive. If someone has gone beyond the reach of
17 their learning and competence and dealt with a patient
18 on their own initiative without seeking help when they
19 should have, the damage has been done, has it not?

20 A. Mostly. The queries came to me and there is a fine line
21 about giving people responsibility and them being able
22 to manage, to practise as a physician. They are in
23 training. I personally -- someone in my position can't
24 oversee everything they do, but when someone comes to
25 work with me, I very quickly get an impression of their

1 general level of competence and understanding and I say
2 to people when they first start with me, "Please, if you
3 have a query, get in touch with me. I keep my door shut
4 to keep the noise out, not to keep people out." I try
5 and make myself very available, because it is -- some of
6 these patients, even though they are known patients,
7 come up with a medical problem that may not be entirely
8 straightforward. So I'm not only consulted about the
9 1 per cent, there were lots of more percentages which --
10 there are shades of grey and different ways of
11 potentially responding, and my responsibility is to give
12 as much responsibility as I can to my staff in training,
13 as I feel comfortable and as they feel comfortable.

14 Q. Right.

15 A. But with an understanding of the sort of areas and
16 topics that I like to be informed about anyway, even
17 though they may know what the right thing is to do,
18 there are certain situations I would like to know about
19 anyway.

20 Q. Professor Ludlam, because this is an Inquiry, I think
21 I have to probe just a little bit further and put to you
22 that the sort of scenario we have been discussing --
23 that is the patient with mild haemophilia who needs
24 treatment, who has had no or minimal previous exposure
25 to concentrates, needing treatment, where there is

1 a continuing risk of hepatitis, which is in a very
2 significant adverse consequence and the treatment
3 decision is a very difficult dilemma -- that whole
4 package is something that called for specification, so
5 a written document or an advance instruction from you
6 communicated to all staff.

7 Looking back, even just in retrospect, what's your
8 response to that?

9 A. Well, it could give rise to the wrong therapy. Let me
10 caricature. A patient with mild haemophilia is involved
11 in a road traffic accident, comes into hospital
12 unconscious, may have an intracranial bleed. The
13 recipe, the guidance says give DDAVP for mild
14 haemophilia. That would be totally inappropriate for
15 many reasons I could go into, if you wanted to.

16 Q. I was wondering perhaps about a simpler response. What
17 if the guidance said in block capitals "phone me".
18 Would that not help?

19 A. That is, in a sense, what the guidance was. Here is an
20 unusual situation.

21 Q. But you didn't see the need for making that kind of
22 provision in advance, as it were, for putting down in
23 writing, so there wasn't debate, what you expected the
24 response to be?

25 A. I expected people to get in touch with me if it was not

1 clear how they should proceed with the medical care of
2 patients. That applied not just to mild haemophilia.
3 I looked after patients with leukaemia and lymphoma and
4 a whole range of conditions, and if one of my staff had
5 some doubt about how to proceed, then they asked me.

6 Q. Right.

7 Professor, this has all been about what I was
8 terming "vertical dissemination". I would like to turn
9 to horizontal dissemination because we mentioned that
10 a little bit yesterday. By that, I mean getting the
11 current thinking distributed around Scotland, in
12 particular to the more geographically distant areas.
13 Would I be right to deduce from what you said yesterday
14 that you didn't see yourself as having a role in
15 ensuring that that happened?

16 A. As I think I clarified yesterday, the haemophilia centre
17 in the Royal Infirmary in Edinburgh was one of, I think,
18 six in Scotland, and they were seen, particularly by the
19 Scottish Office, as very much sort of equal and all
20 services should be provided at all of them. That is how
21 the original health circular was set out and defended.

22 We had meetings with the Scottish Office blood
23 transfusion and haemophilia directors about twice a year
24 from the early -- I think they may have been at the end
25 of the 1970s as well but certainly in the early 1980s,

1 and reference has been made to those here in this
2 Inquiry.

3 It was -- and I had no managerial responsibility,
4 financial or otherwise, for haemophilia centres in the
5 other hospitals.

6 It wasn't really until, I think, 1988, when the
7 Factor VIII working party was established for a whole
8 range of reasons, that brought us together regularly.
9 The arrangements between Edinburgh Haemophilia Centre
10 and the other haemophilia centres in Scotland was much
11 the same as it was between other reference centres in
12 England and other non-reference centres or haemophilia
13 centres. But there weren't regular meetings. They were
14 given guidance, if you like, centrally from UKHCDO, and
15 if there were any queries that needed discussing, the
16 directors of those centres would either phone up the
17 chairman or the secretary of UKHCDO or they might have
18 phoned me. I'm just trying to recall.

19 When I arrived in 1980, the other three haemophilia
20 directors in the East of Scotland were very senior,
21 experienced clinicians. Dare I say it, much more
22 experience in looking after people with haemophilia than
23 I had.

24 Q. Yes.

25 A. I was an even younger man in those days.

1 Q. So you exercised humility?

2 A. Well, you know, they had been around for a long time.

3 Q. Yes.

4 A. And were, I think, good clinicians.

5 Q. Right.

6 A. In their different ways.

7 Q. Obviously we are thinking about this difficult period
8 and if it were to be thought that it would have been
9 a good idea for somebody to try to make sure that all
10 hospitals in Scotland had some assistance with the
11 current thinking on how to deal with patients with
12 haemophilia presenting for the first time, say, or
13 patients with mild haemophilia who hadn't had previous
14 exposure to concentrates, the patients who present the
15 particular dilemmas. If it had been thought that it
16 would be a good idea for all the hospitals in Scotland
17 to know what the thinking was, whose job would it have
18 been to make sure that that sort of information is sent
19 round?

20 A. Well, I suppose it's a medical policy decision. It
21 perhaps should come from the chief medical officer.

22 Q. Excuse me a moment. (Pause)

23 Just one more thing, Professor Ludlam. What was the
24 arrangement for when you were on holiday? I'm sure you
25 did -- no doubt, occasionally -- go on holiday. What

1 was the senior support for staff then?

2 A. That was my colleague, Dr Alistair Parker.

3 Q. The other haematologist who was on the headed paper at

4 that time?

5 A. Yes. He had had a lot to do with looking after people

6 with haemophilia and I think understood therapeutic

7 policies and knew a lot of the patients, the regular

8 patients, and he would know -- it would be brought to

9 his attention if there were new patients, different

10 patients.

11 Neither of us were adverse to phoning up someone

12 else if we didn't know what to do in a particular

13 circumstance. It's slightly more tedious then that it

14 is now because you would have to go through the hospital

15 switchboard and it was a very lengthy process but, you

16 know, you could get advice from people in Glasgow or

17 Oxford or London.

18 Q. Just one last matter, professor. When this supply of 8Y

19 was obtained in the summer of 1986, was it for Edinburgh

20 patients or was it for everybody in Scotland?

21 A. Well, as I think is clear, I requested it and it was

22 held primarily at the protein fractionation centre and

23 therefore it was available for anyone who wished to

24 apply to use it.

25 Q. Yes. And Dr Perry didn't sent you all 50 vials?

1 A. He sent me 20, I think.

2 Q. But as matters turned out, I think you used the whole 50
3 vials. Did you ever mention to any of your colleagues
4 in Scotland that that stock existed?

5 A. I assume that would be a responsibility for Dr Perry.
6 He had a new product available for patients.

7 Q. Right. Is that a "no". Do you have any memory of ever
8 saying in a conversation, "Oh, there is a stock of 8Y at
9 PFC?"

10 A. I'm sorry, I can't remember.

11 Q. You can't remember. Right. Excuse me. (Pause)

12 It has been pointed out to me that the other
13 question, I suppose, that arises in relation to 8Y as
14 well, is that when that development occurred in the
15 summer of 1986, did you mention that to the staff?

16 A. I'm sorry, which staff?

17 Q. When the 8Y arrived in Edinburgh, some vials you have
18 and the balance is at PFC. I think it's the 20/30
19 split. Did you specifically speak to your staff about
20 that?

21 A. I'm sure I must have told them about that, yes.

22 Q. But you don't have an actual recollection?

23 A. I'm sorry, I don't, but it was an important new product
24 available and I'm sure I would have told my staff.

25 Q. Right. And would you have given them any instructions

1 as to the sort of patients for whom this precious
2 commodity might be used, or would you have asked them if
3 they were considering using it to talk to you?

4 A. I would have told them that it was for people who we
5 thought either hadn't been exposed to blood products or
6 had little exposure and might not have hepatitis.

7 Q. So would you have led them to understand that they
8 should speak to you or were they free to give it if they
9 saw fit?

10 A. Oh no, it was a very precious product.

11 Q. So they are expected not to do it on their own
12 initiative?

13 A. Correct.

14 Q. Thank you very much, professor.

15 THE CHAIRMAN: Mr Di Rollo?

16 MR DI ROLLO: I'm not sure exactly what we should do next
17 because --

18 THE CHAIRMAN: Can I tell you that I think that a lot of
19 questions have now been asked by Ms Dunlop that raise
20 issues that I would have thought that if you wished you
21 could pursue. For example, there has been no reference
22 to departments other than Professor Ludlam's own, but do
23 you want him to leave and raise an issue with me?

24 MR DI ROLLO: No, it's just that, in view of this morning's
25 discussion, I wasn't entirely sure whether it would be

1 better to ask some questions now and then deal with
2 matters later or to come back again and deal with this
3 witness all in one go. That's what I'm unsure about.

4 THE CHAIRMAN: It did occur to me that what has now happened
5 might change the focus quite a bit for the future. And
6 if there is anything you think you can ask at this
7 stage, then I would be content. I have to tell you,
8 I would quite like to know the answer myself at this
9 stage to the horizontal dissemination of instructions
10 within the East of Scotland and not just throughout
11 Scotland.

12 MR DI ROLLO: I'm quite happy to try and explore that.

13 I was going to ask him quite a number of questions in
14 any event, as --

15 THE CHAIRMAN: I know that.

16 Questions by MR DI ROLLO

17 MR DI ROLLO: Perhaps, professor, can I deal with one point
18 that emerged from your statement? Can we have your
19 statement up? If we go to paragraph 10, we see what we
20 are dealing with there:

21 "The number of patients not infected with non-A
22 non-B Hepatitis virus(es) and requiring treatment in the
23 period December 1984 to May 1987 was very small (in
24 Scotland during this period it might be as few as ten
25 individuals or less). It comprised of new patients

1 (mainly small children) with severe/moderate
2 Haemophilia A and an occasional adult with mild
3 haemophilia or von Willebrand's disease."

4 Is that right? What I was wondering is, if we look
5 at the preliminary report at paragraph .9.326, we have
6 there the statement that:

7 "The number of people treated for the first time in
8 Scotland with a blood product during the period from
9 1 September 1985 to 30 June 1987 was ... 18 in the East
10 of Scotland and 13 in the West of Scotland."

11 I'm just wondering how we marry up those two
12 statements, yours and it. Is there some reason to think
13 that what's contained in the preliminary report is
14 inaccurate?

15 A. No, I think that is a reasonable estimate from --
16 I think this was from the Scottish Office investigation
17 in the year 2000, these figures.

18 Q. I think you played a part in providing the figures for
19 that?

20 A. I did, yes. I think perhaps what my statement in
21 paragraph 10 is -- clearly it does not match that and
22 I think it is an underestimate. I think I was more
23 thinking in terms of patients per year who might turn
24 up. The number of people with severe haemophilia
25 turning up each year in Scotland is only about three or

1 four. I have to accept the figure in paragraph 9.326 as
2 being the best estimate. I'm sorry, mine is perhaps
3 a little misleading.

4 Q. Looking at systemic issues then, if we could just
5 anticipate what could happen, stepping back for
6 a moment, the patient, the potential patient, what those
7 on the ground, as it were, the casualty officers and all
8 the rest of it, might have to worry about might be the
9 person who has not come to the attention of the
10 haemophilia services before. This is the unusual
11 patient. Babies, you are going to be referred to, and
12 presumably it's possible or likely that you were going
13 to be around, but the one that the casualty officers are
14 going to be concerned about are the ones that are not in
15 the severe category potentially, the milder end of the
16 spectrum. They might not even be haemophiliacs, in the
17 strict sense of the word, at all. You are nodding. Is
18 that correct?

19 A. Casualty officers see a lot of bruised people and they
20 have to make an assessment as to whether the bruise is
21 in keeping with what seems to be the injury or whether
22 it's a bigger bruise, more extensive. And we do quite
23 a lot of clotting screens for patients who turn up in
24 casualty with some sort of haemorrhage. With a bit of
25 luck, the casualty officer will have enquired about the

1 past history of bleeding. So we do a lot of clotting
2 screens; bruising is a common presenting situation in
3 a big casualty department.

4 Q. So just from the point of view of the worrying about
5 what could happen and giving instruction as to what you
6 should do in certain types of situation, one of the
7 kinds of patient that one might have in mind is the
8 patient at the mild end of the spectrum who could,
9 potentially at least, have a clotting problem that would
10 require some sort of clinical intervention?

11 A. Yes.

12 Q. Now, just following that through then, I think we have
13 heard that from your evidence to my learned friend this
14 morning, your position on this is that you would expect
15 those that were dealing with the problem at the ground
16 level, if you like, if they were unsure what to do and
17 had a doubt about what to do, they would refer to you
18 for advice?

19 A. Yes, if a patient turned up in Accident & Emergency with
20 a large bruise, and we did -- we were asked to do some
21 clotting tests and the results showed that the patient
22 had mild haemophilia, then that would be a very unusual
23 event and one that -- we would go down and see the
24 patient in casualty ourselves because it's very unusual.

25 Q. You have mentioned twice there, in the course of my

1 asking you questions, doing clotting tests. Obviously,
2 before administering Factor VIII or IX or any other kind
3 of course of action, presumably the cryoprecipitate as
4 well, you would have to have a clotting test carried
5 out. You would have to do a screening, a clotting test
6 of some kind?

7 A. For a new patient who wasn't diagnosed with haemophilia.

8 Q. Yes.

9 A. Yes, you can't make a diagnosis without measuring the
10 clotting factor levels.

11 Q. You can't make a diagnosis but you wouldn't treat with
12 Factor VIII or a concentrate without that information,
13 that specific information?

14 A. I wouldn't treat a patient unless I knew what the
15 diagnosis was.

16 Q. All right. And you can't making a diagnosis, and the
17 diagnosis obviously depends on the results of the
18 clotting test?

19 A. Of a clotting test, yes.

20 Q. So it follows that the questioning of the person on the
21 ground, that person would have to be instructed or would
22 have to know not to give or administer Factor VIII
23 without a clotting test having been performed?

24 A. If they had never been investigated before. If they had
25 been investigated before, then one would ask them what

1 the results of the blood tests were.

2 Q. Can I just ask you about what being "investigated
3 before" actually means? We know that haemophiliacs
4 carry a card and that card has information on it, and
5 that immediately gives a treating doctor, whoever it
6 happens to be, specific information about that person
7 that tells them a lot about what to do next, and in that
8 situation the problem doesn't arise in the kind of
9 situation that we're dealing with here, which is the
10 previously untreated patient. So can you give us some
11 content to the information that they would get, apart
12 from this haemophilia card?

13 A. There are sometimes patients who have actually very good
14 histories suggestive of bleeding disorder, and either
15 you can't find a laboratory abnormality or they have got
16 a sort of borderline abnormality, and those individuals
17 I'm often hesitant to label as having a disorder because
18 I may not be quite sure what it is, because once you
19 have put a label, a diagnostic label on someone like
20 that, it's very difficult to erase it if tests in future
21 show it's actually not the case.

22 There are all sorts of other implications for
23 labelling patients having bleeding disorders, for
24 example life insurance and so on.

25 I have a small number of people who I say actually,

1 "I'm very sorry, I think you have got some sort of
2 bleeding disorder. I can't quite put my finger on it.
3 If you find yourself seeing other doctors, mention that
4 you may have a bleeding disorder. We have your records
5 in our haemophilia centre. The doctor can phone us up
6 and we could look at them."

7 Q. What I'm interested in, I think, is the instructions
8 given to staff in a situation like this. I'm not asking
9 what you would do yourself. What I'm interested to know
10 is to what extent they would be instructed, that you can
11 rely on what they tell you about their history, which
12 may or may not be informative, in the absence of a card,
13 or you must perform a screen before you do anything
14 next. Do you see the problem, potentially?

15 THE CHAIRMAN: Could we just pin down whether you are
16 talking about staff within Professor Ludlam's department
17 or staff in Accident & Emergency?

18 MR DI ROLLO: I appreciate that. I would be interested to
19 know how it would work with the Accident & Emergency,
20 and then if they then referred to your staff, who would
21 be on duty at the particular time. So it is both in
22 fact, that I'm interested in how they would be
23 instructed to deal with a situation like this.

24 A. This is a patient -- can we just clarify --

25 Q. What we are talking about is the potential problem that

1 arises in this period, to give it a timescale, of an
2 individual who presents, unannounced, with a problem,
3 that you do not have any specific information about the
4 level of clotting factor in their bloodstream?

5 THE CHAIRMAN: When you are considering this, professor,
6 bear in mind that I have an interest to know whether
7 there was anything parallel to the system you operated
8 with your own staff, of weekly educational meetings, or
9 whether there was any other mechanism by which the views
10 of the haemophilia clinicians were made available to
11 non-haemophilia doctors within the wider hospital
12 set-up.

13 I think it may be that how the A&E man on the spot
14 responded might be influenced or affected by general
15 guidance you had already given or not. If you could
16 bear in mind the wider context, please, when you are
17 dealing with specific questions that are being put to
18 you.

19 A. Thank you, I will.

20 MR DI ROLLO: Is it reasonably clear what I'm asking?

21 A. A patient turns up.

22 Q. Yes.

23 A. With a haematoma, a large bruise.

24 Q. Yes.

25 A. With or without a history --

1 Q. You get a history of some sort. I mean, I suppose
2 potentially, you might get a history that, "I bleed
3 easily," or something like that. What instructions do
4 you give to your staff to deal with a situation like
5 that?

6 A. Well, the doctor concerned would send some blood off for
7 clotting tests. They have a very low threshold for
8 doing that.

9 Q. That's really what I'm interested in. The doctor would
10 have to have information about what the clotting level
11 was in order to make a diagnosis. Is that the standard
12 practice?

13 A. Yes.

14 Q. Unless you had a clear history in the form of specific
15 information about the person's history, such as
16 a haemophilia card, or that they were registered as
17 a haemophiliac, something along those lines, and they
18 were able to give you reliable information about their
19 history, about what their clotting factor level was,
20 otherwise you are not in a position to make a diagnosis?

21 A. No, you are absolutely correct. Before offering
22 treatment, one has to be very clear as to what the
23 condition is, what the level is of the potentially
24 deficient clotting factor.

25 Q. How was it that staff were told what you have just told

1 me? How were they told, "You have got to be very clear
2 about these things"? How did you do that? Not just you
3 but we are talking about systems here. How was it done
4 during this period?

5 A. The system was that clotting tests came -- we get a lot
6 of requests for clotting tests from Accident & Emergency
7 and if one turned up with an unexpected abnormality, as
8 might occur in haemophilia, then that result was
9 reported back to the person who requested it, and our
10 duty registrar was informed and our duty registrar would
11 then use his judgment as to whether or not to follow it
12 up, and certainly if there was a question of a screening
13 test potentially identifying a patient with haemophilia,
14 then he would make sure the Factor VIII and Factor IX
15 levels to start with were measured, and he would go and
16 liaise with the doctor in the Accident & Emergency
17 department.

18 Q. What I'm interested to know is how did the Accident &
19 Emergency staff, referring perhaps for advice to your
20 department -- how were they instructed how to deal with
21 this situation? Who instructed them and how were they
22 instructed?

23 A. Well, in one sense you would need to ask the people in
24 charge of the Accident & Emergency department, but
25 I would say that it was also part of general medical

1 education. If someone turns up with what looks like
2 a bleeding state, a bit unexplained, that they might
3 have a bleeding disorder.

4 Q. Right. Now, in the management then thereafter, the
5 question then is what to do as to how to treat them, if
6 it's discovered that they have a Factor VIII deficiency,
7 for example. I think you are telling me that at that
8 point a decision might be made by the registrar as to
9 whether or not to administer Factor VIII without
10 reference to any higher up the chain?

11 A. The haematology registrar?

12 Q. Yes.

13 A. It would be an unusual situation and they would almost
14 certainly make some rather detailed enquiries, and
15 I would have thought might well have reported to me.

16 Q. "Might well have" suggests that they may not?

17 A. I appreciate that. I can't say categorically they
18 would. It depends on their level of experience and
19 their training. But any new person with haemophilia
20 that appeared in Accident & Emergency I would probably
21 expect to hear about.

22 Q. Before any decision is made as to what treatment to
23 give, is the question.

24 A. It might depend on the severity of what the clinical
25 problem was, whether I was immediately available to

1 offer an opinion. So it depends a little bit on the
2 circumstances.

3 Q. Well, that seems to be the system in your hospital. Was
4 that the system in other hospitals that you know about
5 in your area? Is that how it would generally be done?
6 It wasn't just the Royal Infirmary that has an Accident
7 & Emergency in Lothian and South of Scotland. Is that
8 how it would be dealt with otherwise, do you know?

9 A. I think in other hospitals, if they thought they had
10 a patient with mild or any sort of haemophilia, they are
11 very ready to pick up the phone to us and ask what they
12 should do.

13 Q. And do you know, did they?

14 A. We occasionally get calls, yes.

15 Q. But it would be a matter for them to decide whether to
16 pick up the phone or not. It's up to them really?

17 A. Yes.

18 Q. If it was generally not known or not disseminated that
19 there were particular issues with the use of
20 a particular blood product during this period, how would
21 they be informed about that?

22 A. Any patient who crossed the threshold into the Accident
23 & Emergency department we would hear about. The
24 Accident & Emergency staff, as soon as they identify
25 either an existing patient or a new patient, they get in

1 touch with us directly.

2 Q. Presumably blood concentrates were available to be used
3 in these other areas, were they?

4 A. They were.

5 Q. And decisions made to use them could be made without
6 reference to you particularly?

7 A. Could be.

8 Q. Or even your department?

9 A. Could be.

10 Q. And so the problem then might be that they might use
11 them in situations where you, on reflection, might think
12 that perhaps wasn't such a good idea for that particular
13 patient?

14 A. They might do but many people have very low threshold
15 for phoning us for advice when a patient turns up
16 unexpectedly with a bleed situation.

17 Q. To what extent were they informed of the particular
18 need, perhaps, to avoid giving this product to someone
19 who had never been given it before, during this period?

20 A. They would be -- a haematologist would be alert to that,
21 and they are the people who would be in the position of
22 having the information from the blood test if it was a
23 new patient, but -- it possibly had haemophilia.

24 Q. There is a tension, is there not, between solving the
25 immediate problem of stopping the bleeding in the

1 quickest and simplest and easiest way possible, against
2 the long-term consequences that using a particular
3 method might involve?

4 A. Entirely. But --

5 Q. And the question is how this decision-making on the
6 ground is informed by a specialist, up-to-date, clear
7 information and how that's disseminated down the chain,
8 as it were. That's really what we are interested in.

9 A. Well, the way that the system works is, as I say: as
10 soon as a patient appears in a casualty department, we
11 are invited to offer advice as to how they should be
12 managed.

13 Q. I mean, I appreciate your point that this sort of thing
14 won't happen that often, of course. It is a relatively
15 unusual event but it is a predictable event, isn't it?
16 It's one that one can anticipate occurring. Is that
17 right?

18 A. It does occur, yes.

19 Q. And the question is, if Factor VIII is available or
20 Factor IX is available during this period to be used,
21 what is or who is ensuring that it's not being used in
22 situations where it isn't really necessary?

23 A. Yes, I thought I had been fairly explicit that there is
24 a very low threshold for us being consulted about such
25 patients when they turn up in other casualty

1 departments. Mostly they are known patients who turn up
2 in other casualty departments. So we know about them;
3 we can offer advice over the phone. If it's a new
4 patient who looks like they have got haemophilia and
5 it's not immediately life-threatening, we would probably
6 get them sent over to our hospital.

7 Q. The question about whether you are a haemophiliac or not
8 as defined -- and there are all sorts of definitions
9 about that -- the two things that really matter are the
10 nature of the bleed that needs to be stopped and the
11 ability of the body's system to stop that bleed by
12 itself without assistance, whatever this happens to be.
13 Those two things have to be assessed, presumably?

14 A. Yes.

15 Q. One thing that you have to do is work out what ability
16 of the body has to stop the bleed and that requires
17 detailed information.

18 A. Yes, it requires a Factor VIII or IX level, or whatever
19 the disorder might be or potentially be. Yes.

20 Q. All right. I want to ask you about another matter --

21 THE CHAIRMAN: I would like to follow up on some of these
22 areas myself.

23 Professor Ludlam, we have, I think, a fairly clear
24 picture of how your department operated, and I think
25 also a fairly clear picture that from time to time

1 patients would present at other departments of the
2 hospital with signs and symptoms that could give rise to
3 a suspicion that they might have clotting deficiencies.

4 The response to that might be prescribed by
5 a written protocol and handed down or it might depend on
6 practice or a combination, and it might depend on
7 experience and all sorts of other things.

8 Did you ever, as a haemophilia director, issue
9 anything in the way of written instructions or advice to
10 the Accident & Emergency department as to how they might
11 respond to possible clotting defects generally?

12 A. Yes, we have.

13 THE CHAIRMAN: At this time, had you done that, 1985 to
14 1987?

15 A. Not at this time, I think. Subsequent to this time, for
16 other reasons I'm happy to go into, if you want.

17 THE CHAIRMAN: At the moment I want to stick to this bit.
18 Other people later will ask why there were changes
19 perhaps, but just concentrating on this period, there
20 wasn't a written instruction, directive, advice or
21 anything of that kind?

22 A. There was advice that was given to the people in charge
23 that if a patient came in to Accident & Emergency, to
24 contact our service immediately.

25 THE CHAIRMAN: Could I explore that just a little?

1 A. Yes.

2 THE CHAIRMAN: The person in charge would be, what, A&E
3 senior consultant, or something of that kind? How would
4 that be done? Was there a meeting of heads of
5 department, or some other way for disseminating
6 information of that kind?

7 A. No, but that was what was known. If a patient came in
8 to casualty and was known to have haemophilia, the
9 automatic response was to phone up the haematology --

10 THE CHAIRMAN: The critical case is not the patient who is
11 known to have haemophilia; it's the patient who is
12 displaying signs and symptoms that might lead to an
13 inference of haemophilia.

14 A. Yes.

15 THE CHAIRMAN: Can we concentrate on that one, please?

16 A. Certainly.

17 THE CHAIRMAN: What was the established practice or protocol
18 or whatever, if any, in respect of them?

19 A. I think if a patient turned up with either a haematoma
20 or something bleeding, particularly if it was out of
21 context in terms of injury, then the casualty officer
22 would ask them about previous events that might have
23 given rise to bleeding, like dental extraction or
24 tonsillectomy, or any other operations, and even if the
25 answer to all those was negative and the bruise or

1 bleeding seemed a bit out of context, they would send us
2 a blood sample and we would assess it.

3 THE CHAIRMAN: This happens at 2 o'clock in the morning in
4 the hypothetical case and the A&E officer hasn't seen
5 the problem before but sees swelling, let us say, or
6 bruising that seems disproportionate to the history of
7 trauma that he has received. At that point, I suppose
8 one possibility is that he would think of clotting
9 disorder. Are there other circumstances that he ought
10 to have in mind among the range of possible causes of
11 a disproportionate bruising? Leukaemia, for example; is
12 that a possibility?

13 A. Some disorder of the blood clotting system, which has
14 many components, and there might be an underlying
15 malignancy, for example, or a fracture that hadn't been
16 diagnosed after an injury, a tumour on the bone,
17 something of that sort.

18 THE CHAIRMAN: And is it, at that stage, that the
19 haematologist comes into the picture or does the
20 haematologist get information about it after a lab test
21 or what? What triggers the next step?

22 A. Usually blood tests and then the blood -- and another
23 investigation. An X-ray might be very appropriate. The
24 blood tests would be the next investigation. The
25 results of these would be phoned back to the requesting

1 unit and we had a system where, if the results were
2 outside certain limitation or were unexpected, our
3 laboratory staff knew to phone the duty doctor.

4 THE CHAIRMAN: That's two contacts by the lab staff so far.
5 One is back to the requesting A&E doctor, who clearly is
6 entitled to know what's going on. One is at the
7 initiative of the lab technician to contact you. Might
8 the lab technician also contact the haematologist on
9 duty at that point or not?

10 A. Yes, the duty haematology doctor, yes.

11 THE CHAIRMAN: So these things are things that happen
12 always? Are they things that are prescribed or what?

13 A. This is how we run our service. One of our major
14 responsibilities is to keep a watching brief on the
15 results that go out from the laboratory, to try and pick
16 up those that are abnormal and unusual in that
17 particular clinical context, and that's the tricky thing
18 because if you have, for example, a renal unit, the
19 haematological indices in people with chronic renal
20 failure are different from normal people or from people
21 who are getting cardiac surgery. So you have to have
22 some system for filtering out what's expected and what
23 isn't expected, what's unexpected.

24 Some of this is done by computer screening these
25 days, because we get over 1,000 blood samples a day.

1 But clotting tests that are unexpectedly abnormal are
2 one of the things we take a particular interest in and
3 get in touch with the clinicians because often, when we
4 report the results back as being abnormal, they are not
5 picked up by the clinician who saw the patient, or they
6 don't understand the significance of it, and that's why
7 our laboratory staff get in touch with our registrar,
8 who then gets in touch with the clinical unit and asks
9 them about the patient.

10 THE CHAIRMAN: Mr Di Rollo, we are going to rise now since
11 it's 1 o'clock but you may wish to come back on some of
12 that before you go on to your other material.

13 MR DI ROLLO: Thank you very much.

14 (1.07 pm)

15 (The short adjournment)

16 (2.00 pm)

17 THE CHAIRMAN: Mr Di Rollo?

18 MR DI ROLLO: Thank you, sir.

19 Professor Ludlam, we were talking before lunchtime
20 about systems, and I think we have heard a little bit of
21 evidence about that. As I have understood it, this is a
22 pretty basic and standard situation, that you rely on
23 Accident & Emergency to refer to haematology anything
24 which they feel requires consideration and haematology,
25 within that department, if it's someone at a low level,

1 if there is something that requires to be considered as
2 unusual or out of the ordinary, you would expect that
3 person to go further up the chain, and the next level up
4 the chain would be to registrar and then to you. That's
5 the situation, as far as systems are concerned?

6 A. That is correct and I wonder if I could use this as
7 an opportunity just to correct some incorrect
8 information I gave to the chairman just before lunch.

9 I was asked about protocols in the Accident &
10 Emergency department for referring patients and I said
11 that there were protocols recently, and I indicated that
12 at this time I thought there probably weren't. I was
13 thinking about that over lunchtime and I clearly
14 remember that we, every two or three years, met with the
15 A&E consultant in charge and brought up-to-date
16 a protocol that we had that was in -- they had got
17 a book of protocols and guidance for their doctors and
18 we did have a guidance sheet in there as to how the
19 staff in A&E should respond to someone with haemophilia,
20 or potential haemophilia presenting.

21 Q. What I want to know, Professor Ludlam, is in the course
22 of this critical period that we are talking about,
23 between 1985 and 1987, did you, with a particular
24 concern about this type of previously untreated patient,
25 instruct your staff that if they were informed about

1 that patient, that they were to get in touch with you so
2 that you could then take the clinical decision as to
3 what sort of treatment they were to get?

4 A. I don't think it was a specific instruction for this two
5 or three-year period but I think there was a general
6 understanding that when a new patient presented, I or
7 someone senior in my department should be consulted
8 about treatment, because all the other patients -- the
9 patients who were known to us -- we had records of how
10 they should be treated. It was in their case notes, it
11 was in our computer system register, so if a patient
12 turned up and there was someone who was new, then that
13 would be a decision for someone with some experience and
14 reasonably senior in the department.

15 Q. Can I just understand what you mean by "reasonably
16 senior" then. Do you mean consultant?

17 A. Consultant, or in those days we had senior registrars,
18 who will have been in training in those days for five or
19 six years perhaps, coming up to consultant status. Some
20 of them may have a special interest in clotting. And
21 again, depending a bit on the circumstances, if they
22 felt comfortable making the decision, then they might
23 make a decision; but new patients with haemophilia turn
24 up very infrequently. They are quite an event, and so
25 if I was there, or even if I wasn't there, my colleague

1 Dr Parker was there, we would almost certainly get to
2 hear about them unless the person who was acknowledged,
3 as it were, was confident about what was appropriate to
4 do.

5 Q. Were you ever aware of that situation in the period that
6 we are talking about, where a new patient was given
7 Factor VIII without you being informed about that?

8 MR ANDERSON: Don't answer that, please, professor, unless
9 instructed or directed to do so by the chairman.

10 I do have a concern, sir, that we are going from the
11 general to the particular. I don't think I have to say
12 any more about that because it's clear to all of us in
13 this room after this morning's decision.

14 THE CHAIRMAN: I think that is so, Mr Di Rollo, and I would
15 prefer you to follow the other course that I suggested,
16 if you wish to pursue that type of question.

17 So again, I think that the proper answer, although
18 this is not the particularly appropriate place to be
19 doing it, is to say that I won't allow it in hoc statu.

20 MR DI ROLLO: Very well.

21 THE CHAIRMAN: I want to talk to you later about whether we
22 are going down that route and how far to go, but
23 I think, as a straight matter of form, that's what
24 I should do right now.

25 MR DI ROLLO: There is another one or two matters that

1 I want to explore. One matter I would like to have
2 guidance on is whether I may go -- in my list of
3 questions there is reference to the letter which was --
4 THE CHAIRMAN: A letter that has been in the evidence
5 before?
6 MR DI ROLLO: Yes.
7 THE CHAIRMAN: Well, if it's in the evidence, I don't
8 think --
9 MR DI ROLLO: But I do want to explore what might have been
10 meant and what was said and the history of that.
11 THE CHAIRMAN: I think what was meant, what was said and
12 then adding or "and the history" may be quite difficult.
13 I'm conscious that questions are being asked about what
14 was said and what was meant but I think the history had
15 better stay subject to the general reservation at the
16 present time.
17 MR DI ROLLO: Very well.
18 I think you were shown yesterday, Professor Ludlam,
19 a number of letters. This is in connection with the
20 request that was made for Factor 8Y, in the middle of
21 1986, and what I want to do is to put before you
22 a number of specific letters.
23 Could we have [SNB0075871](#) on the screen?
24 This is part of the correspondence that followed --
25 am I right to think -- you said this morning it was your

1 request for Factor 8Y?

2 A. Yes.

3 Q. So it was you that requested it?

4 A. After discussion with my colleagues in blood
5 transfusion, yes.

6 Q. Yes. And who did you actually make the request of
7 initially?

8 A. My recollection of the correspondence is that I asked
9 Dr McClelland or Dr Boulton and they wrote, as you see,
10 to Dr Perry, I think it was, to try and --

11 Q. I think it was you initially put the request -- or at
12 one stage you put the request in the form of a letter.
13 It is referred to in some correspondence. Do you
14 remember doing that, that you did write a letter about
15 this?

16 A. I don't remember writing a letter but the correspondence
17 states there was a letter so I presumably did write
18 a letter.

19 Q. I just want to try and understand, leaving aside the
20 history that's given. The passage that I'm interested
21 in is the passage that says:

22 "Christopher is a bit ruthless with his own staff
23 about this because he feels that this patient should
24 have been received 8Y or an equivalent product."

25 Do you remember discussing this matter with

1 Mr Boulton?

2 MR ANDERSON: Again, I'm hesitant keep jumping up to object
3 but with the greatest of respect, this seems to be an
4 investigation into a particular set of circumstances
5 involving a particular clinical decision by particular
6 clinicians who are not involved in this Inquiry.
7 I appreciate, it may be difficult in certain
8 circumstances to distinguish the general from the
9 particular but in my submission. This is verging over
10 that line into the particular and is not in the general.

11 THE CHAIRMAN: Again, I think that's correct.

12 Professor Ludlam, when did you get to know that
13 there was a product that was known, or came to be known
14 as "8Y"?

15 A. I knew that the Blood Products Laboratory at Elstree was
16 developing a new product called "8Y", that they were
17 hoping to heat at 80 degrees for 72 hours, some time in
18 1985. I think that was generally known. I would have
19 known that.

20 THE CHAIRMAN: You would hear about it at meetings of the
21 UKHCDO reference doctors, apart from anywhere else?

22 A. Yes.

23 THE CHAIRMAN: What was your understanding of the procedure
24 that would be followed in relation to the development
25 and introduction into use of such a product if it were

1 to be introduced?

2 A. In England?

3 THE CHAIRMAN: No, at all.

4 A. At all? It would require to be given as test infusions
5 into a number of people, probably with severe
6 haemophilia, who hadn't been treated for several days,
7 to assess the post-infusion Factor VIII level and the
8 half-life, the time that it remained in the plasma, the
9 rate at which it disappeared from the plasma, to make
10 sure that you got the expected therapeutic rise. That
11 will be done in a number of patients. Nowadays,
12 I think, the regulations are that you have to do it in
13 about ten or 15 patients. You would then have to study
14 those patients later to ascertain whether or not they
15 had developed an antibody, an inhibitor to the
16 Factor VIII, to see whether it had altered its antigenic
17 structure.

18 It would then be necessary to give it -- if that was
19 all satisfactory, to give it to patients who were
20 bleeding with conventional bleeds, to make sure that it
21 stopped the bleeding. How that is assessed has changed
22 over the years.

23 THE CHAIRMAN: Can we just pause at that stage then.

24 At what stage would the basic clinical trials on
25 a CTX come to an end? Would it be before or after the

1 final comment you have just made, that it would go to
2 patients who were bleeding with conventional bleeds? Is
3 this a separate step?

4 A. That's a separate step but it would be part of a CTX.

5 THE CHAIRMAN: It would be part of the CTX?

6 A. Yes.

7 THE CHAIRMAN: I want to ask you a little about CTXs.

8 I know that one would apply to get one and specify
9 the product and indicate what was going on and make
10 proposals for the scope. Was there a regulatory
11 constraint on the scope of CTX work?

12 A. My understanding of the CTX arrangement was that an
13 application was made to do a study. The conventional --
14 the full, if I can put it this way. The full way to do
15 it would be to apply for a clinical trial certificate,
16 and in that I think there was then a very formal
17 assessment of the protocol. That took up quite a lot of
18 time. It was very lengthy. So, as a sort of, as
19 I understand it, short cut, someone who wished to --
20 usually a manufacturer who wished to conduct a trial
21 under the CTX regulations, put in their proposal and if
22 there wasn't an objection within six weeks, they could
23 then get on and conduct the study.

24 THE CHAIRMAN: If we can come from the general to the
25 particular, when you heard about the development of F8,

1 of the English product, what did you understand was
2 going on?

3 A. My understanding is that they applied for a CTX.

4 THE CHAIRMAN: And did you have any understanding at all
5 about the geographical or other scope of the clinical
6 trials that were anticipated in that application?

7 A. No, I have merely seen the front sheet with the
8 signatures on it.

9 THE CHAIRMAN: Were you asked, asked, by anyone to take part
10 in those clinical trials?

11 A. No.

12 THE CHAIRMAN: A stage came when you made an intervention,
13 as it were -- and I'm trying to choose some sort of
14 totally general word that carries no implication with
15 it -- into the process and asked for some of the
16 material. What was the state of play at that point, as
17 you understood it? Had the clinical trial process ended
18 or was it still current?

19 A. It was still current.

20 THE CHAIRMAN: Did you understand that you were making this
21 request at a time when the trials were still current and
22 before they had been completed and before any question
23 of general release would have arisen? Have I run too
24 many things together?

25 A. No, I think I appreciated -- I certainly appreciated it

1 didn't have a licence and I think I knew it had a CTX --
2 was there another part to your question?

3 THE CHAIRMAN: Yes. It was merely to define the time period
4 and if it was still unlicensed then, that answers my
5 final point.

6 A. Yes, it was certainly unlicensed at this time, is my
7 recollection.

8 THE CHAIRMAN: Can you remember now what it was that
9 prompted you to make the request for some 8Y?

10 A. I think it was the appreciation that it was perhaps less
11 likely to transmit non-A non-B Hepatitis than the NY
12 product, Factor VIII product, that was available in
13 Scotland, the 68 degree, 24-hour material.

14 THE CHAIRMAN: I think we know a whole background to the
15 question of the effectiveness of the Scottish product,
16 but Mr Di Rollo, that takes me to a certain point. If
17 you think that you can ask any further questions now on
18 this topic, please do and we will see what Mr Anderson
19 says. Otherwise, I think I would prefer you to adopt
20 the alternative route and consider whether you want to
21 pose them in another way.

22 MR DI ROLLO: Very well. Can I just ask you this, and it is
23 relevant. It's about your relationship with
24 Brian McClelland. In terms of geography, he was next
25 door to you in the Royal Infirmary.

1 A. He was down a different corridor but they almost
2 abutted, a short distance away.

3 Q. He was somebody you would see on a regular basis?

4 A. Yes.

5 Q. And have conversations with all of the time, and
6 exchange information with all of the time and throughout
7 your professional working life?

8 A. At that time, yes.

9 Q. And if he was aware of something of interest to you, it
10 would be very likely that he would pass that on to you,
11 in relation to developments in this area of treatment of
12 patients, haemophilia patients?

13 A. Yes, I think that's right. If he thought --
14 particularly if he thought I wasn't aware of it.

15 Q. Indeed. If we go to [PEN0161152](#), these are minutes of
16 a meeting, the Central Committee for Research and
17 Development in Blood Transfusion, the Central Blood
18 Laboratories Authority, and present at the meeting we
19 can see a number of people. That includes
20 Dr McClelland. Obviously, I appreciate you were not
21 present at this particular meeting. Were you aware of
22 this particular organisation, its existence?

23 A. I'm not sure that I was. It was part of the blood
24 transfusion arrangements -- they had various committees
25 and meetings. I didn't know exactly what they were, who

1 went to them.

2 Q. Those that were present, not those in attendance, not
3 the civil servants, but the actual doctors that we see
4 there, did you know all of those individuals or had met
5 all of those individuals?

6 A. I know who they all were apart from Dr Gibson.

7 Q. If we look at paragraph 14.3, which is on page 1153:

8 "Dr Rizza reported upon further trials carried out
9 with heat-treated Factor VIII, which he had now been
10 using for approximately nine months. He confirmed that
11 none of his patients, including children, had become
12 clinically ill and therefore the immediate signs were
13 encouraging."

14 There is other information that you were shown
15 yesterday about developments relative to the English
16 product and I'm not going to go back over them. I'm
17 just interested in this particular item at the moment.
18 What's interesting about this is that, first of all,
19 Dr McClelland was at the meeting and secondly, it is
20 being reported that the trials have been going on for
21 approximately nine months.

22 From my limited understanding of these matters, the
23 fact that a patient had been exposed to Factor VIII --
24 if hepatitis emerges, it may well emerge at a relatively
25 early stage. So the fact that there are no clinical

1 signs after that period seems to be encouraging in
2 respect of the clinical trials so far. So it's a case
3 of so far so good, but these signs are encouraging. Is
4 that right? That's what it says.

5 A. That's what it says.

6 Q. Did Dr McClelland share with you that information?

7 A. I don't think so, no.

8 THE CHAIRMAN: Do you know whether Dr McClelland would have
9 been free to share with you information about a research
10 and development committee?

11 We have been over this area before, Mr Di Rollo.

12 I think that one has to be clear whether this is an open
13 meeting or a private and confidential meeting.

14 MR DI ROLLO: I don't know, is the answer to that.

15 A. If I could say that the minutes that I was shown
16 yesterday by Ms Dunlop and the meeting in March 1986, it
17 said "Confidential" at the top, and that was some
18 information about this trial.

19 THE CHAIRMAN: I don't think it does say "Confidential" on
20 these.

21 A. No.

22 MR DI ROLLO: I don't think that was an issue that was
23 explored with you yesterday, in fact. I thought the
24 point about the minutes of March was that you weren't at
25 that meeting but you were meant to be at the meeting.

1 Is that not right?

2 A. In that case there were two sets of minutes. There was
3 a meeting of the Scottish Home and Health haemophilia
4 directors and blood transfusion, that I was sorry not to
5 be there and sent my apologies. There were some other
6 minutes from a central blood transfusion research
7 meeting or something -- I forget what it was -- that had
8 handwritten at the top "Confidential", just off the top
9 of the screen.

10 Q. Yes, "In confidence"?

11 A. In confidence.

12 Q. Yes, that's a different one. I think that's at an
13 earlier stage. I think the question that I asked was
14 whether Brian McClelland did indicate or you were aware
15 of information about how things were going down south,
16 and the supposition that he didn't share that
17 information with you, whether it was confidential or
18 not.

19 A. I don't recall him sharing it with me and even -- there
20 are a number of issues that are raised by this. Even if
21 initial results, treatment of the first few patients
22 looks encouraging, that is not a reason to presuppose
23 a successful outcome to the study. Medicine is full of
24 examples of drugs that look promising to begin with and
25 patients -- it applies particularly in the cancer

1 field -- are desperate to get hold of the drugs and then
2 when all the results are pulled together at the end of
3 the study, the drug is found not to be useful.

4 I think the issue here, one of the very pertinent
5 issues is how many patients have to be studied before
6 you can be reasonably certain that 8Y is
7 a hepatitis-safe product.

8 MR DI ROLLO: Can I just take issue with that in this way:
9 Obviously, if you are going to present it as
10 a hepatitis-safe product, then I can understand that
11 matter. The question we are dealing with, the context
12 of this, is adding that extra element of safety, which
13 is not there currently with the product that you have,
14 which is why, as I understood it, an order was made
15 in May/June 1986 -- so it's not a case of it being
16 hepatitis-safe or guaranteed as hepatitis-safe or
17 scientifically proven as hepatitis-safe, it's a case of
18 having sufficient information to take the view, "Well,
19 we have got these people that may have to be given it
20 for the first time. They are very rare but what about
21 catering for them?" As I understand it, that's
22 essentially your approach in June of that year, and what
23 I'm trying to get at is what has changed between the
24 turn of the year and June?

25 A. More patients will have been recruited and studied. So

1 there will be more information on more patients that
2 looks encouraging.

3 Q. You didn't have any specific information to that effect
4 in terms of a document or -- as I understood it
5 yesterday, what has prompted a change of decision to
6 make a request is information that you have been given
7 by a colleague, isn't it?

8 A. Yes.

9 Q. So somebody has told you something about this English
10 material, which you have then said, "We should get some
11 of that".

12 A. Yes.

13 Q. Does that bear any relationship to treating a previously
14 untreated patient in May of that year?

15 A. It became clear in May 1986 that the NY 68-degree,
16 24-hour concentrate that we were using could and did
17 cause non-A non-B Hepatitis.

18 Q. You knew that anyway. You knew that it could, maybe
19 that it did, in that particular case.

20 A. All right, it did.

21 Q. But you knew that?

22 A. It did, yes.

23 Q. So the question is what has changed between the
24 information that was available to you or your
25 colleagues -- I mean, you had the good idea of trying to

1 get some material in June. The question is that there
2 were those responsible for the provision of material to
3 hospitals in Scotland who had as much information as you
4 had at an earlier stage.

5 THE CHAIRMAN: Sorry, I think that you may be running more
6 than one thing together there again. Do you want to
7 look at the question as it is put, Mr Di Rollo. I'm not
8 sure it's easily answered.

9 MR DI ROLLO: I'll take it out.

10 THE CHAIRMAN: No, no. I don't want you to take it out.

11 The question is that:

12 "There were those responsible for the provision of
13 material to hospitals in Scotland who had as much
14 information as you had at an earlier stage."

15 That's what's confusing me and I'm just inviting you
16 to think whether you want to rephrase it, not take it
17 out.

18 MR DI ROLLO: Perhaps I can rephrase it. Let's break it
19 down.

20 In June, you have been given certain information by
21 a colleague about the effectiveness in preventing non-A
22 non-B of the English 8Y. There were others that had
23 that information before June in Scotland. That's right,
24 isn't it?

25 A. It seems to be.

1 Q. And the information that you had in June, if it was
2 available to them at an earlier stage, the question that
3 I would like to know the answer to is: why did it not
4 happen that a request was made for 8Y to be made
5 available for previously untreated patients at an
6 earlier stage?

7 A. I understand your question and I think you need to put
8 it to someone from the Blood Transfusion Service,
9 because they were responsible for providing
10 National Health Service Factor VIII for use in Scotland.

11 Q. Did you ever speak to Dr Rizza at UKHCDO meetings?

12 A. Yes.

13 Q. Did he ever mention how things were going with
14 Factor 8Y?

15 A. I can't remember, beyond what's in the minutes of the
16 meeting, I'm sorry.

17 I don't know if it would help but the first, as far
18 as I know, bringing together of the 8Y data for
19 consideration was in September 1986. Before that it was
20 just being gathered patient by patient. There is the
21 possibility that it was also presented at the WFH
22 meeting in Milan in June. We thought about that
23 yesterday. I certainly wasn't at that meeting.

24 Q. You seem to have known a few weeks earlier. These
25 letters, dated 27 June, talk about you having

1 a conversation with Brian -- that's what's referred to,
2 using Christian names, obviously -- with Dr McClelland,
3 concerning obtaining this material for a specific -- it
4 does look, does it not, Dr Ludlam, that it was for
5 a specific reason, that something had happened that had
6 made you think that it would be good idea to get some of
7 this stuff?

8 A. There had been a transmission of non-A non-B by the
9 Scottish Factor VIII NY product and therefore it seemed
10 appropriate to think about what other products might be
11 available that wouldn't have this.

12 Q. The point I'm making is the prompt for that seems to be
13 that particular event. Is that not correct? The event
14 of the transmission of non-A non-B Hepatitis.

15 A. I can't be absolutely certain at this time but it must
16 have been part of the discussion.

17 Q. Which is why, when we look at Dr Perry's letter, he
18 talks about just concluding these discussions. It's
19 a specific reference to that event as well. The whole
20 context of the request is the context of this event,
21 isn't it, not the information that you were given about
22 the relative safety of Factor VIII, do you see what
23 I mean, of 8Y?

24 A. There was clearly a general discussion. I'm sorry,
25 I can only speculate as to what precipitated it.

1 Q. We've talked about September, now go to the BPL annual
2 report. It's dated March but it's actually published
3 in September, I think, and that's [DHF0021590](#).

4 It would be misleading to say that the date of this
5 is March 1986 because I believe the publication for this
6 to be at a later time. Look at the next page.
7 It's September, I think. But it's covering the period.
8 The specific page I want to go to is page 5 of [DHF0021590](#).

9 This says at paragraph 2:

10 "The 'AIDS-related' problems at BPL had been
11 addressed at BPL and PFL the previous year so that
12 by April 1985 all Factor VIII intermediate concentrate
13 leaving the laboratory was heat-treated at 70 degrees
14 centigrade for 72 hours and a new high purity
15 concentrate, designated 8Y, entered clinical trial.
16 Factor 8Y replaced the older concentrate
17 after August 1985 and, dry-heated to 80 degrees
18 centigrade for 72 hours, set the international standard
19 for products of this type. After 12 months' use, there
20 were no reported cases of ... HIV and, more important,
21 no evidence of transmission of non-A non-B Hepatitis
22 virus to recipients at risk of infection."

23 That would be a public document, or at least it
24 would not be confidential.

25 THE CHAIRMAN: I think it is, with respect, if you look at

1 the first page you looked at. It's a confidential
2 document. First page of text.

3 I'm sure I saw somewhere that it was confidential.
4 I can't read that. Yes:

5 "The report is from the director of BPL and PFL to
6 the CBLA and is confidential."

7 MR DI ROLLO: Does that mean that that information would not
8 be available to those people in Scotland? You are
9 shaking your head, professor.

10 A. I have never seen this document before. We don't get
11 the annual report of BPL.

12 Q. This information is available somewhere and I suppose
13 the question one has to ask is: it's obviously
14 significant information relative to the issue that does
15 arise; why is it that, following your intervention
16 in June, a request is made? Why is it that Factor 8Y is
17 not available to deal with previously untreated patients
18 in Scotland even in September of 1986?

19 What is the reason why this material is not
20 provided, not just in Edinburgh but throughout Scotland?

21 A. I think the answer to that partly -- you would perhaps
22 need to address this to representatives of the Blood
23 Transfusion Service but the anticipated plan was that
24 Z8, heated at 80 degrees for 72 hours, was going to be
25 available in either August or September 1986, and in

1 fact the first two batches, I think, had been made
2 in July and then they ran into a bit of a problem, is my
3 recollection, and production got put back two or three
4 months.

5 Q. Right, so the question then is what about getting some
6 English material in the intervening period?

7 A. I think you should put that question to the Blood
8 Transfusion Service and they would say that there was
9 some available at PFC probably.

10 Q. Can I ask you what steps were taken to alert physicians
11 throughout the country what they could do, that this
12 material was available and would be useful for
13 previously untreated patients?

14 A. I think you would need to ask Dr Perry, who was holding
15 the stock of this at PFC, which is the national centre
16 for NHS blood products.

17 Q. Although this document is described as "confidential",
18 does that mean that PFC would not be privy to this
19 annual report or would it be circulated to them at all?

20 A. I can't answer that question, I'm sorry.

21 If I can just say, I think -- I think this
22 discussion is a bit viewed with hindsight of 8Y, which
23 we now know to be a very safe product and this was very
24 early days in it being assessed. We considered this
25 yesterday and there were some examples where in a sense,

1 the thresholds were breached for it potentially being
2 labelled as transmitting non-A non-B Hepatitis. These
3 were very early days in the assessment of a new product.

4 Q. Yes, but, Professor Ludlam, it is not hindsight for you.
5 You were there, you ordered it.

6 A. Yes, but for -- but I think there has been -- the view
7 in some of the consideration of it recently, in the last
8 day or so, is that it was safer than I thought it might
9 be; in other words, I thought it was perhaps a little
10 bit safer but not completely safe.

11 Q. The trouble is obviously, clearly you thought it was
12 a better option because there is less risk. Let's put
13 it like that. Is that fair? It is a lower level of
14 risk for non-A non-B as far as you can tell?

15 A. Yes, and it's a question of how much better.

16 Q. Well, anything that's materially better, which is
17 obviously you thought it was sufficiently, materially
18 better because that's why you put in the request that
19 you did, clearly.

20 You say this discussion is affected by hindsight but
21 I don't know if that's really correct, given that we are
22 in a situation where increasingly, throughout 1986, it
23 became clear that all -- the signs were encouraging even
24 in 1985. They were even more encouraging in 1986 and
25 there was nothing that was discouraging, and we had

1 already passed the point by the middle of 1986 where
2 someone had thought it sensible to have this material
3 available. Is that not a reasonable summary?

4 A. I think that's a reasonable summary, yes.

5 Q. I'm not getting at you personally in relation to this,
6 it just happens that you are the person that I'm asking
7 questions, but the question is: why is it that nothing
8 was done to make this material more generally available
9 for patients throughout the country?

10 That's a legitimate and reasonable question, isn't
11 it?

12 A. I think the response to that would be the trial was
13 ongoing and in a sense I had perhaps jumped the gun
14 a bit by asking for it when I did. Perhaps it looked
15 like the right thing, if you like, to have done in
16 retrospect but supposing in fact 50 or 75 per cent --
17 there was 50 or 75 per cent chance of it transmitting
18 hepatitis, then my idea wouldn't have been quite so
19 clever.

20 Q. It would still have been clever because it was still
21 less of a risk than the existing Scottish material.

22 A. Well, we didn't actually know what the risk of the
23 Scottish material was. We knew it had transmitted non-A
24 non-B Hepatitis on an occasion.

25 Q. Presumably, the increased heat and increased length of

1 time is designed to give a greater level of protection
2 from that point of view?

3 A. Yes.

4 Q. I don't see how you can have it both ways,
5 Professor Ludlam. It was either a good idea or it was
6 not a good idea to order the material or request the
7 material in the middle of June, and if it was, then
8 presumably, as time went on, it would become an
9 increasingly good idea to order the material as time
10 went on, or make it available for more than just
11 patients at Edinburgh or patients that might come into
12 Edinburgh Royal Infirmary?

13 A. Perhaps the distinction could be drawn between what
14 I thought was a good idea and what should be national
15 policy in Scotland. If we had had a discussion about
16 what should the national policy be in Scotland, that
17 might or might not have come up with the same answer.

18 Q. The problem about national policy is that there doesn't
19 seem to have been anyone in charge of assisting or
20 instructing those in the regions, if you like, apart
21 from outwith the central belt, as to how to deal with
22 this particular problem during this particular period of
23 time. As I understand it, no one seems to have had the
24 responsibility to change the guidance that was given
25 between 1984 and 1986, given that there had been

1 a change in the relative merits of the different options
2 available.

3 A. I think that's fair comment. It's always difficult to
4 know when to rewrite guidelines, how much has to go and
5 change before guidelines are rewritten.

6 It was quite a fast-moving area, this, as you can
7 see. Particular months when decisions were thought
8 about or made differed from month to month. Things were
9 moving quite rapidly. It was a very, very confusing
10 period to be working in and there were many meetings
11 as -- I have learned about more meetings in the last two
12 or three days than I knew took place. It was a very
13 confusing time to be working in this area, for the Blood
14 Transfusion Service, for the fractionators, both in
15 Scotland and in London, and in an international context,
16 particularly in relation to the safety of dry-heated
17 products.

18 We were bereft of guidance from -- perhaps from the
19 Committee On the Safety of Medicines. They are
20 responsible for licensing the products and offering
21 guidance on therapy. It was a very difficult area and
22 it might have been helpful to have had some high level
23 guidance but it wasn't forthcoming.

24 Q. It does seem to have been a practical possibility for
25 Factor 8Y to have been made available in Scotland to

1 deal with a specific problem, which is the previously
2 untreated patient. That does seem to have been
3 practically possible. Is that right?

4 A. Clearly it was practically possible but if I can say, my
5 English colleagues were desperate for NHS, heat-treated
6 Factor VIII. They had been through an awful period in
7 1985 when there was a paucity, and if I can go back
8 a few years before that, haemophilia physicians in
9 England had campaigned vigorously and repeatedly through
10 the 1970s to get an adequate supply of NHS Factor VIII,
11 and the unfortunate things that rolled out in the 1980s,
12 and particularly acutely in a sense in 1986, was because
13 of inadequate funding for the preferred product; in
14 other words, a National Health Service product, and my
15 physician colleagues in England were desperate to have
16 8Y and it still only fulfilled a third of their need,
17 and the sort of word on the street was that I would be
18 jolly lucky to get some.

19 Q. There was word on the street then? People say, "You can
20 try it if you like but you might not get any"?

21 A. Yes.

22 Q. That's a good reason for perhaps not even asking, but it
23 is a reason for not asking. "We didn't want to ask for
24 the English Factor VIII because we didn't want to
25 deprive the English of a heat-treated product which they

1 didn't otherwise have." Is that why you didn't ask
2 before June?

3 A. No, I don't think that's why I didn't ask before June
4 but if I wrote to BPL, I was very unlikely to get any
5 and that's why I went through these rather formal
6 channels, because I thought that he had more influence
7 and leverage than a mere physician in Edinburgh.

8 Q. It does appear that somebody who is aware of the facts
9 and has all the information, such as yourself, sees
10 a gap and appreciates the need to fill that gap. Is
11 that right? And what I'm wondering is that that gap, as
12 it was at Edinburgh in June or May or whatever, remained
13 throughout the country right up until the point at which
14 the Z8 became available and produced in Scotland.

15 A. No, because there was some 8Y at PFC available, and as
16 it emerged yesterday, I managed to wheedle some out of
17 Newcastle.

18 Q. Provided the person was smart enough to know to ask for
19 it, they would get it. The trouble is there might have
20 been one or two doctors throughout the country who
21 didn't have their finger quite so much on the pulse as
22 you did?

23 THE CHAIRMAN: It's all right. I think actually that might
24 have been a compliment, professor. You don't need to
25 hesitate quite so long --

1 MR DI ROLLO: It was meant to be a compliment with a slight
2 sting in the tail.

3 THE CHAIRMAN: I thought so. It's the "et dona ferentes"
4 bit. So you have got to look out.

5 MR DI ROLLO: Which is why he was hesitating perhaps.
6 I think that's probably as many questions as I can
7 ask at this stage.

8 THE CHAIRMAN: Mr Anderson?

9 MR ANDERSON: I'm in a slight quandary when my learned
10 friend finishes by saying "at this stage".

11 THE CHAIRMAN: He knows that there is the direction I gave
12 earlier that if he wishes to raise any other particular
13 matters, he should adopt a particular approach to it;
14 adapting slightly what was concerned with a different
15 matter yesterday, of course, but following broadly the
16 same procedure and give notice. I think that's what "at
17 this stage" means in this context.

18 If I'm wrong, Mr Di Rollo, you had better tell me.

19 MR ANDERSON: Well, I have one or two questions. It seems
20 to me appropriate that I should ask Professor Ludlam
21 those questions. If it be the case that my learned
22 friend wishes and is able to ask further questions of
23 this witness, no doubt I will be allowed to ask question
24 that may arise from that.

25 THE CHAIRMAN: I do anticipate that further matters would

1 follow a rather tighter procedural course and you will
2 have a chance to make representations about the scope of
3 questioning before we got to questioning at all.

4 MR ANDERSON: I'm much obliged. In that case, I will
5 proceed, if I may.

6 You will be relieved to hear, Professor Ludlam, I
7 have only one or two questions, I hope.

8 Questions by MR ANDERSON

9 MR ANDERSON: Could we have up to the screen two pages from
10 your report. Page 2 and page 5 of [PEN0171790](#)?

11 What I'm interested in, professor, is in the main
12 body of the report at paragraph 3, and although it's
13 entirely plausible I'm being slow about this, there is
14 a possible dislocation between that and paragraph 8 in
15 your appendix. If we can take them one by one. In
16 paragraph 3 you say in the second sentence:

17 "It was not until mid 1986 that evidence started to
18 be reported to suggest that it might be
19 a hepatitis-reduced concentrate. This concentrate was
20 only available to me to approximately one third of the
21 total use of Factor VIII in England. The majority of
22 patients were treated with commercial concentrates which
23 were likely to transmit hepatitis."

24 Do you see that?

25 A. Yes.

1 Q. So we appear to be talking about a period in mid-1986
2 and a third, which I take it would have available to
3 them the new 8Y product. Is that correct?

4 A. Yes.

5 Q. If we look at paragraph 8 in the appendix, it says this:

6 "In early 1985 at BPL the initial batches of 8Y,
7 heat-treated at 70 degrees/72 hours, were available for
8 use in patients, however, it was not until October 1985
9 that 8Y at 80 degrees for 72 hours was in full
10 production. At that time it only represented about
11 one third of Factor VIII concentrate used in England,
12 the other two thirds were of commercial origin (of
13 unproven viral safety and likely to transmit non-A non-B
14 virus(es))."

15 I just wonder about this period between mid-1986
16 and October 1985. Do you see the possible dislocation?
17 When was it that a third was available to the English
18 population? Do you know that?

19 A. I think that was actually addressed in the report from
20 BPL that we had up on the screen a few minutes ago,
21 which I think suggested that the predecessor to 8Y was
22 heat-treated until about April 1985. 8Y was
23 introduced -- now, 8Y may have been treated at the
24 slightly lower temperature initially, and I'm not sure
25 when the 80 degrees came in, whether it was in the

1 spring or in October 1985, but overall, during this
2 two-year period, approximately a third of the
3 Factor VIII that was used in England was of NHS origin
4 and two thirds was commercial.

5 Q. Right.

6 A. The proportions didn't change very much over this
7 two-year period. So the majority of patients, or the
8 majority of infusions being given in England all
9 transmitted the commercial -- would all have transmitted
10 non-A non-B Hepatitis.

11 Q. All right, thank you.

12 THE CHAIRMAN: I think in due course, Mr Anderson,
13 Professor Ludlam, I will be looking at a whole series of
14 answers here, including paragraphs 9 and 10 and so on.
15 I rather suspect it's quite difficult to work out
16 precisely the sequence of events in England. But it
17 clearly took place over a long period of time right into
18 1993 before there was a full evaluation of 8Y.

19 A. That's correct but I think the original production was
20 certainly in existence by October 1985. The period I'm
21 a little uncertain about is the first two thirds of
22 1985. What the temperature was and which product was
23 being issued, and I know that they had at one stage
24 intended to heat-treat NHS Factor VIII in early 1985 and
25 I think they ran into difficulties. You would need to

1 ask the blood transfusion experts about that.

2 THE CHAIRMAN: We have Dr Smith coming and I'm sure that he
3 is the person who will tell us exactly what the sequence
4 of events was.

5 MR ANDERSON: I think that's right, sir. I'm quite happy to
6 move on from that and we will wait until we hear from
7 Dr Smith.

8 Professor, could you look with me, please, at the
9 letter, which is [SNB0075914](#)? This is a letter we have
10 looked at on a number of occasions before, from
11 Dr Boulton to Dr Perry at PFC. This is the letter that
12 makes reference to the letter you wrote, which we
13 haven't been able to find. It says:

14 "Last week Dr Ludlam wrote to Brian asking if it
15 would be possible to obtain some of the BPL products for
16 use if a previously untreated haemophiliac presented for
17 replacement therapy."

18 It then goes on to say:

19 "He said it would be difficult to estimate its
20 potential use accurately but I understand that he has no
21 haemophiliacs on his books at the moment who have not
22 been treated."

23 This is, of course, second-hand and there is
24 a quoting of what you have said to him, but when it says
25 "he has no haemophiliacs on his books," is that

1 a reference simply to Edinburgh Royal Infirmary or is
2 that to the East of Scotland?

3 A. Edinburgh Royal Infirmary.

4 Q. All right. Then it says:

5 "He has no haemophiliacs on his books at the moment
6 who have not been treated."

7 What does that tell us about how pressing you saw
8 the need to obtain this material?

9 A. You never know when a new baby is going to be born with
10 haemophilia or a new patient is going to appear.

11 Sometimes, yes, one does know. One makes a diagnosis
12 for some reason or other before treatment is necessary
13 and then you have someone you know hasn't been treated.
14 But usually patients present because they bleed and the
15 diagnosis is made after they have bled. And therefore
16 you need to have something -- you need to have treatment
17 available for them.

18 Q. You see it says here that:

19 "There are no haemophiliacs on his books at the
20 moment who have not been treated."

21 I think you told us yesterday that in fact the 20
22 vials that you got did not, in fact, go to a previously
23 untreated patient. Is that correct?

24 A. That's correct, yes -- at least I think that's correct,
25 yes.

1 Q. But rather they went to someone who had suffered
2 an allergic reaction?

3 A. That's correct, yes.

4 Q. Having used up those 20 vials, did you make any request
5 for any further supply of 8Y?

6 A. I can't honestly remember. I don't know whether I used
7 up the other 30 vials that were at PFC, assuming those
8 hadn't been used by someone else, or whether I went
9 directly to a colleague in Newcastle to scrounge some.

10 Q. You see, this is more than a year before the Scottish
11 product became available, but I don't think we have seen
12 any record of you making a subsequent request of BPL.
13 Is that right?

14 A. I certainly used some more 8Y, which I obtained from
15 Newcastle, and I can't remember whether that's because
16 I couldn't get any more -- BPL wouldn't give me any
17 more. I can't say whether we went back or whether the
18 blood transfusion went back to BPL and asked for more
19 and was told they couldn't have any. It wouldn't have
20 surprised me because the supply that I had been given
21 actually was on the understanding I would use it for
22 PUPs, previously untransfused patients, and actually
23 I had breached that; I had used it for someone else who
24 needed it for a different reason. So it's just possible
25 they may have had said, "Well, he didn't use the

1 original product under the conditions in which we gave
2 it." I'm sorry, I can't remember.

3 Q. All right. But you said yesterday that you used the
4 auspices of PFC to get the product because you thought
5 that as a lone physician from Scotland writing to BPL
6 direct, the request would have been unlikely to have
7 succeeded. Is that correct?

8 A. That's correct because there was quite a lot of
9 difficulty in England in allocating stocks of 8Y.
10 Without going into the details, which I'm not familiar
11 with, each English region had an allocation of 8Y,
12 depending on how much plasma it supplied to BPL. As
13 Scotland didn't supply any plasma to BPL, it had, in
14 a sense, no right of access to 8Y. So it was
15 a concession that had to come out of somebody else's
16 supply, one of the English health authority's
17 allocation.

18 Q. Yes. I take it that you thought it was unlikely that
19 you, as an individual practitioner writing to BPL, would
20 have been successful on your request and that problem
21 would have been the same for any other physician in
22 Scotland writing?

23 A. I imagine so, yes.

24 Q. Just before we leave this, the 20 vials you used, as you
25 say, not in a previously untransfused person but the one

1 who had an allergic reaction; can you remember when that
2 was? When did you use up your 20 vials?

3 A. I think it was the autumn of 1986.

4 Q. Can you remember when it was that you tried to obtain
5 further supplies from Newcastle?

6 A. Well, I think it was at that time. So it came out, in a
7 sense, of the Newcastle allocation.

8 Q. Yes. On this question of the efficacy of 8Y and what
9 was known about it at the time, I say that deliberately
10 to distinguish it from what we now know about its
11 efficacy; we now know it was very safe. But
12 in June/July 1986, your appreciation as I understand it,
13 is simply that there was less risk attached to it than
14 there was to the existence of Scottish product. Is that
15 correct?

16 A. Yes.

17 Q. At the time, had you any idea how much less risk it
18 might have represented?

19 A. No, and that's a point I was on the point of making.
20 Mr Di Rollo and I were having a discussion about this.
21 Because trying to allocate risk in this situation is
22 very difficult. There is an intriguing paper published
23 in 1983 entitled, "If nothing goes wrong, is everything
24 all right?" subheaded "Interpreting zero numerators".
25 And this offers guidance as to when it is reasonable to

1 say that something is safe if nothing goes wrong when
2 you are testing it, and in the context of -- we are
3 talking here about 8Y, which -- you must remember we
4 were looking at a surrogate marker for hepatitis. We
5 couldn't measure the virus at this stage. It became
6 much easier when we could measure Hepatitis C virus. We
7 were using a surrogate marker; in other words, a touch
8 of liver damage as assessed by the plasma level of the
9 ALT, the enzyme that comes out of liver when it's
10 damaged. And A very precise protocol for assessing it.

11 And we saw on the screen yesterday, some of the
12 results of patients in which there were raised levels of
13 ALT -- in a small child who didn't appear to have other
14 reasons for having a raised liver function test.

15 So you needed to have studied about 30 patients
16 before you get down to the 5 per cent risk level, which
17 is the conventional risk level, and by June it seems
18 that a handful of patients had been studied and the
19 handful that were shown on the screen, about half of
20 them were in fact previously transfused patients, some
21 of whom had -- at least one had a raised level.

22 So the number of patients who had been assessed
23 by June or even September 1986 was small, in a study
24 that, when it was completed, was defined as inadequate
25 and hence a further study was undertaken. So

1 in June 1986, if we had applied the rule of three that
2 comes out of this paper on zero numbers, zero
3 numerators, it might only have been a reduction from 90
4 or 100 per cent to perhaps 60 per cent.

5 Q. Would it be right to say that your individual request
6 for 8Y was more in hope than in expectation, or is it
7 partly in hope and partly in expectation?

8 A. I'm always hopeful. Dr Perry is a very influential man,
9 a very persuasive individual, and he was obviously
10 successful on this occasion.

11 Q. I'm much obliged to you. Thank you, professor.

12 THE CHAIRMAN: Ms Dunlop?

13 MS DUNLOP: Mr Johnston.

14 THE CHAIRMAN: I do apologise.

15 MR JOHNSTON: For once I do have one point I would like to
16 raise.

17 THE CHAIRMAN: I have no excuse. I should not have passed
18 you by.

19 Questions by MR JOHNSTON

20 MR JOHNSTON: Please don't apologise.

21 Professor Ludlam, it's just one point that arises
22 out of something you discussed at the end of answering
23 questions from Ms Dunlop. She put to you, if I may just
24 remind you, that if it were thought a good idea for
25 somebody to make sure that all hospitals in Scotland had

1 some assistance with the current thinking on how to deal
2 with patients with haemophilia presenting for the first
3 time, or patients not previously exposed to
4 concentrates, whose job would that be, and you said you
5 supposed it would be a matter of medical policy, and
6 perhaps it would be for the chief medical officer.

7 What I was wondering really is, if we are talking
8 about how to deal with a particularly tricky patient, as
9 it were, is it right to think of that as a matter of
10 medical policy or isn't it really something that the
11 clinician is going to have to assess for himself?

12 A. I think it's a matter of public policy. Every now and
13 then there are circulars issued by the health
14 departments, for example in relation to infectious
15 diseases, people returning from other parts of the world
16 where there are infectious diseases that doctors might
17 not think of when they are seeing a patient in this
18 country.

19 If I remember rightly, the health departments have
20 put out circulars to alert particularly general
21 practitioners to this situation, and particularly to ask
22 patients if they have been to particular parts of the
23 world where there have been little outbreaks of these
24 rather unpleasant conditions.

25 Q. So if you are thinking of guidance from the chief

1 medical officer, for example, I take it you are not
2 thinking that the chief medical officer will say, "In
3 this instance, use cryoprecipitate; in this instance,
4 use Factor VIII concentrate," or are you anticipating
5 that that sort of level of detail would be prescribed
6 from government?

7 A. It would be very helpful if the chief medical officers
8 would give that advice.

9 Q. But if they were to give that advice, do you not think
10 that they would in turn be taking it from those who
11 would have the appropriate expertise, namely the
12 clinicians?

13 A. It would give an opportunity for a very considered
14 opinion to be developed, a more general -- you would
15 have the benefit of more than just, for example, me as
16 an individual, providing an opinion.

17 Q. Isn't it right that, in any event, there was more than
18 that available; you looked at a document from
19 mid December 1984, the document from the
20 haemophilia centre directors, where they have spelled
21 out a number of things and then they set out the options
22 for treatment in a particular order of preference, and
23 then they made recommendations. I take it that would be
24 a document that would be helpful because it came from
25 those with the appropriate expertise. Do you agree with

1 that?

2 A. Yes, we were doing the best we could. Can I remind you
3 that there was a lot of -- there could have been more
4 guidance perhaps earlier by the Committee On the Safety
5 of Medicines about what therapeutic policy might be. It
6 was an extremely difficult time for us as clinicians and
7 it might have been useful to have people -- more than
8 just us to look in the broader context. It was a bit
9 left at our door, is how we felt. A very difficult
10 time.

11 Q. Yes, of course, everyone appreciates that but
12 ultimately, I suppose what I'm thinking of is that in
13 much of your evidence today and yesterday, you have been
14 talking about what happened where particularly difficult
15 issues arose with new patients presenting, for example.
16 Now, in that sort of situation, as I had understood your
17 evidence so far, you have squarely said that that is
18 a matter where, if it's me, I have to apply my own
19 judgment as to what the appropriate treatment is. If it
20 was somebody else, they would be in the same boat,
21 wouldn't they? You have to assess the particular
22 patient with the material you have?

23 A. You do, but to have some guidance, I think, and
24 potentially to address some of the issues that we have
25 been thinking about between England and Scotland by the

1 health ministers, the chief medical officers, I'm sorry,
2 might have been helpful.

3 Q. The document I just referred to with the various options
4 for treatment, you were asked about that this morning,
5 whether you disseminated that further and then you said,
6 "Well, actually this is what we were doing in my
7 department anyway". I just wonder, that being the case,
8 how much difference would it have made if somebody else
9 had given you what they thought was best practice, given
10 that you are yourself an expert in the area?

11 A. Well, as we have seen, things change fairly rapidly and
12 it would have been, I think, helpful to have had some
13 more input from the Department of Health.

14 Q. All right, thank you.

15 I have no more questions, sir.

16 THE CHAIRMAN: I think that we really must give the
17 stenographer a short break.

18 MS DUNLOP: Absolutely.

19 THE CHAIRMAN: And I would also like your help with the rest
20 of the day.

21 MS DUNLOP: Yes, I don't know to waste any time discussing
22 it. I want to press on. Dr Colvin has sat all day
23 waiting to give evidence. So if we can have perhaps
24 five minutes and start at half past three.

25 THE CHAIRMAN: Have you any further questions for the

1 professor.

2 MS DUNLOP: No, no. I think it's time Professor Ludlam had
3 a rest.

4 THE CHAIRMAN: I'm not sure about that. These questions
5 about the role of the CMO have really come out of the
6 blue and you clearly have views about the balance that
7 there might have been between general guidance and the
8 role of the clinician. If you think about it and want
9 to submit any later comment on that, I would be quite
10 happy to hear it.

11 (3.27 pm)

12 (Short break)

13 (3.33 pm)

14 DR BRIAN COLVIN

15 Questions by MS DUNLOP

16 THE CHAIRMAN: Ms Dunlop?

17 MS DUNLOP: Thank you, sir.

18 Good afternoon, Professor Colvin.

19 A. Good afternoon.

20 Q. You haven't been here since March, so to remind
21 everybody that your CV, which we do have, tells us that
22 you were at The London Hospital for 40 years. I think,
23 you were a consultant haematologist and the director of
24 the haemophilia centre there between 1977 and 2007.
25 Initially it was just The London Hospital but, as you

1 put it last time, there was a regimental merger and it
2 became Bart's and the London, and that was from the
3 early 1990s.

4 A. Yes.

5 Q. Good. Can we have your statement on the screen, please,
6 your report, indeed. [PEN0171674](#). Thank you.

7 Professor, because we are slightly short of time,
8 I think we can take the first couple of pages as read.
9 They are introductory. They outline the questions posed
10 to you and your own introduction about knowledge of
11 risks in general. So if we have a look at page 1 and
12 then page 2 perhaps.

13 I don't think anything you say on page 2 is
14 unfamiliar to us. There is perhaps only one point to
15 pick up and it is in 2.1, where you say:

16 "It is well-known that there was insufficient
17 Factor VIII concentrate derived from donors within the
18 UK to meet national demand."

19 I have to point out that the situation in Scotland
20 was better than the situation in England, and we have
21 had a lot of information that illustrates that certainly
22 in 1983, Scotland was close to self-sufficiency or at
23 self-sufficiency, whatever quite that means.

24 A. I'm certainly well aware of that. We were well aware of
25 it at the time and we were slightly envious of our

1 Scottish colleagues at the time, I think.

2 Q. Right. Can we look at the next page then, please.

3 You refer to a UKHCDO haemophilia working party
4 report for 1986 to 1987. That document is [SNB0017706](#).
5 I don't, I think, want to go to it but you extract the
6 relevant points from it. You say that the report acts
7 as a snapshot of the position in September 1987. It
8 makes clear that the incidence of symptomatic hepatitis
9 related to blood products is falling. It mentions eight
10 cases of non-A non-B Hepatitis related to Armour
11 heat-treated Factor VIII. It concludes that
12 pasteurisation of Factor VIII and IX, using current
13 techniques, is unlikely to be completely effective in
14 preventing transmission of infection, and it also
15 mentions the cases of HIV infection, and I know that you
16 want to correct the reference to "4.1" so that it in
17 fact reads "3.1"?

18 A. Thank you.

19 Q. Yes. Because it's in paragraph 3.1 that you have
20 mentioned the transmission of HIV by Armour heat-treated
21 product.

22 The working party report also suggested that
23 surveillance of hepatitis-related blood products should
24 be enlarged to include all infections, including HIV, so
25 that information regarding the relative risk of

1 infection related to different products can be
2 collected. Your personal experience; you were obviously
3 well aware of the risks from fairly early on, and you
4 tell us that in 1986 you published "Heat-treated
5 Factor VIII Concentrate in the United Kingdom:
6 a Preliminary Study". That was a series of case reports
7 undertaken with colleagues at the Middlesex Hospital and
8 at BPL. If we have a look at that, that should be
9 [PEN0171782](#).

10 There it is. What's the full title of the journal,
11 please?

12 A. Clinical and Laboratory Haematology.

13 Q. Right, thank you. That's a fairly staple magazine for
14 haematologists, is it?

15 A. A general haematology magazine, perhaps not in the first
16 flight of magazines compared with the New England
17 Journal of Medicine or the Lancet, but quite widely used
18 by haematologists at the time.

19 Q. We can see your name obviously, also the name of
20 Dr Smith and Mrs Winkelman, who I think we recognise
21 from PFL and BPL. And we can see that it relates to
22 three patients given intermediate purity NHS
23 heat-treated Factor VIII:

24 "None had previously received more than six donor
25 units of blood products."

1 On the first page there is reference to papers at
2 which we have already looked, namely the papers by
3 Fletcher et al and Kernoff et al. And you go on to
4 observe, by way of background, that hepatitis is
5 asymptomatic in many cases but if patients are followed
6 carefully, there is often evidence of chronic hepatic
7 inflammation which can lead to permanent liver damage,
8 and one of the references for that is the article that
9 for shorthand we can call the "understated problem
10 article" or the "Sheffield article" perhaps.

11 There is then a reference to AIDS. If we look on to
12 the second page, we can see that in fact the product
13 that was being used there is a product heated at
14 60 degrees for 72 hours. Is that right?

15 A. Yes, indeed.

16 Q. And you call that, I think, a prototype product, and in
17 the rest of the paper you outline the characteristics of
18 the patients.

19 Can we just perhaps move through it on to the next
20 page, page 3. We can see who they were. Page 4,
21 details of the batches and then details of the results,
22 and then on page 5 we find the discussion. You are
23 pointing to the fact that three patients had not
24 previously been exposed to large-pool concentrates, and
25 then on to the next page, they had previously been

1 transfused with less than six donor units.

2 They would normally have been expected to develop
3 non-A non-B Hepatitis as a result of their treatment
4 after first exposure to large-pool concentrates, and you
5 refer to the Fletcher paper, in particular, and the
6 Kernoff paper, and you say:

7 "The continuing normality of our patients'
8 transaminase levels therefore implies that heat
9 treatment of the concentrate may have been successful in
10 neutralising non-A non-B Hepatitis virus, although this
11 approach has been previously disappointing."

12 Then on to the next paragraph. We can see some
13 references to heat treatment against HIV, and then on to
14 the final page of text, you are obviously saying that
15 this is work in progress, that there was ongoing
16 research. So I think you referred to this just as an
17 early piece of work on the likely success of
18 heat-treated product.

19 A. I think even perhaps just to demonstrate that we were
20 all looking at different concentrates to try to
21 demonstrate whether or not it was possible to neutralise
22 the non-A non-B Hepatitis virus. It was more to show
23 that we were looking into the problem.

24 Q. Yes. To go back to the report, please, in the next
25 paragraph, 1987; you published a study which related to

1 cryoprecipitate. The reference for that is
2 [LIT0010640](#). This time it is dealing with six
3 patients, we will see. Again, patients who had never
4 received large-pool concentrates. You say:

5 "No evidence of hepatitis or HIV infection was
6 detected in a follow-up period of one year."

7 You say:

8 "Following the introduction of screening of blood
9 donors for anti-HIV in the UK in October 1985, the use
10 of cryoprecipitate in selected cases should be
11 reconsidered."

12 And the narrative of background is perhaps
13 unsurprisingly that the association of HIV with the use
14 of NHS Factor VIII concentrate had provoked reluctance
15 to use cryoprecipitate as well, and you are reporting
16 a study which you had carried out between October 1982
17 and July 1984, looking at the risk of transfusion
18 hepatitis in the group, and you had already looked to
19 see evidence of HIV infection.

20 Then "Patients", "Methods" and "Results", the second
21 page, please. You tell us under the heading
22 "Discussion" that in your small study, admittedly small,
23 but in your study you had found no evidence of infection
24 with hepatitis or HIV viruses after careful follow-up of
25 each patient for one year, and you refer back to the

1 Kernoff paper. We have looked at that already this week
2 and I think we can perhaps recollect the table in that,
3 which occupies almost the whole page, and there is
4 a chunk of patients, perhaps two thirds of the way down,
5 who had been given cryoprecipitate and none of them had
6 developed hepatitis.

7 So these findings in the Kernoff paper were
8 consistent with your experience, as reported here? Yes.

9 Then can we just go on to page 3, please?
10 Essentially you are saying not to write off
11 cryoprecipitate, to reconsider its possible usefulness,
12 as you say, in selected cases.

13 So the point you are making is that even with the
14 screening that has been introduced in October 1985, some
15 of the perceived danger of cryoprecipitate has been
16 alleviated and it's available as a product and should be
17 considered for some patients?

18 A. I think that's true but I think, as time moved on, since
19 the study was for patients looked at in 1982/1984 and
20 since it was published in 1987, by that time really the
21 world had moved on, and I think by that time we had
22 really given up using cryoprecipitate. So in those days
23 particularly, it took a long while to get things
24 published, and I think by the time we published it,
25 probably the world had moved on.

1 Q. So it might have been more useful if it had been
2 published in 1985?

3 A. It's a question whether it was useful ever in a way, but
4 I think that it seemed a good idea at the time, but then
5 many things do. And I think it was worth publishing the
6 data. But the difficulty with cryoprecipitate was that
7 since it wasn't going to be heat-treated or otherwise
8 virally inactivated, then, if you did get a single donor
9 unit which was infected with Hepatitis C, or even
10 conceivably HIV in the infective window before
11 seroconversion, then, of course, you would be very
12 reliably infected with Hepatitis C or HIV.

13 So I think, once it became really apparent that
14 viral activation was going to be effective, then
15 cryoprecipitate became much less attractive. Again, the
16 reason that I presented this paper to you was to show
17 you the uncertainty of this period and the fact that we
18 were looking at various options in a scientific, or
19 quasi scientific way.

20 Q. Certainly, Dr Colvin, don't be too modest about it
21 because the factual position in Scotland in the
22 1985/1987 gap was that the heat treatment protocol that
23 was being applied to Factor VIII was not as severe as
24 what was being applied to the NHS product in England.

25 So cryoprecipitate certainly has been mentioned to

1 us as something that was on people's menu of products at
2 that time.

3 A. I think it's worth pointing out that the 8CRV product,
4 which you referred to in the previous paper, which was
5 less severely heated, may not have transmitted non-A
6 non-B Hepatitis because of the donor pool and the heat
7 treatment, and so I appreciate that it looks as though
8 that level of heat treatment wasn't fully effective in
9 neutralising the virus.

10 I think one would have expected a product like 8CRV
11 to transmit Hepatitis C in retrospect, and that's what
12 we thought, unless it had been heat-treated. When it
13 was heat-treated, it seemed that that did reduce the
14 infectivity, but one has to remember that the donor
15 pool, which contributes to the concentrate, probably
16 makes a difference in terms of the weight of virus that
17 has to be neutralised.

18 So I make no specific claims about the 8CRV
19 material. It may well have been that had you studied
20 enough patients with a particular donor pool that would
21 be treated in that particular way, then infectivity
22 might have been demonstrable.

23 Q. It's actually quite difficult, Dr Colvin, to arrive at
24 what appears to be an accurate sense of what might have
25 been the prevalence of HCV in the donor pool in the

1 mid-1980s. Extremely difficult, in fact. We have
2 various different figures. I think the last time you
3 were here, there was some discussion about whether the
4 prevalence might have been about 0.1 per cent. You said
5 you used to use 0.3 per cent when you were reckoning
6 such matters in England. According to
7 Professor Howard Thomas' map as at 1999, the prevalence
8 in the United Kingdom is shown as under 1 per cent.
9 Phil Minor in a paper in the Lancet in 1990 has
10 0.4 per cent.

11 So quite a lot of different numbers, and we do know
12 that in -- I think it's the six-month period immediately
13 after screening was introduced in Scotland in 1991, the
14 prevalence in the Scottish donor population was
15 0.088 per cent. So plainly it depends on the particular
16 population group you are looking at.

17 A. And of course, donors are likely to be less infected
18 than people who don't present themselves as donors.

19 Q. But certainly, when one tries to arrive at a rough
20 estimate of the infectivity risk of cryoprecipitate,
21 that question presents itself, well, what was the rate,
22 the background rate of infection in the population, and
23 it's rather difficult to answer.

24 A. Yes, indeed.

25 THE CHAIRMAN: Of course, there is another problem, isn't

1 there, that the rate in the general population cannot be
2 attributed to any particular subgroup of the general
3 population? It is an overall percentage, which may have
4 a very wide range of variation within the totality.

5 A. And of course, globally the variation is huge, so that
6 the prevalence in Egypt, for instance, is very high
7 indeed. 20 or 30 per cent, so we are told.

8 THE CHAIRMAN: I'm just thinking for a moment of the
9 background to your own papers, that the fact that there
10 may be a 1 per cent or a 3 per cent risk overall doesn't
11 mean that in respect of any particular batch, the donors
12 contributing reflect that overall percentage.

13 A. No.

14 MS DUNLOP: Next, Dr Colvin, in your report, which we should
15 look at again, please, if we could go back to 1676, 5.4,
16 you are telling us that you contributed the largest
17 number of patients to the UKHCDO study, which concerned
18 possible virus transmission in previously untreated
19 patients and related to 8Y and 9A.

20 Can we have a look first, at the interim report on
21 that study, which is [SNF0011123](#). We need to go into
22 the next page, please.

23 We looked at this yesterday and Professor Ludlam
24 pointed out that there are some flaws in it, I suppose.
25 I think we know it was difficult to find patients,

1 suitable patients, on whom to try new products and that
2 must have been one difficulty and perhaps a temptation
3 to relax the criteria here and there to get enough
4 people. But this talks about circulation of a protocol
5 in relation to the 8Y and 9A research in spring 1985.

6 Patient selection. The analysis which is collated
7 in this paper is restricted to patients who had had no
8 large-pool concentrate before 8Y and 9A but possibly had
9 had variable amounts of cryoprecipitate.

10 Then frequency of testing, and I suppose one can set
11 a desire for how frequently measurements might be made,
12 but you are obviously dependent on compliance by
13 patients turning up to have certain biochemical
14 measurements taken?

15 A. Indeed.

16 Q. Yes. Then the products tested. We can see a desire,
17 reflected here, to expose patients to many batches.
18 I suppose so that an over-optimistic verdict on the
19 safety of the products is not arrived at. Both
20 concentrates were heated in the freeze-dried state at
21 80 degrees for 72 hours.

22 Then the results. Doing the best the researchers
23 could to measure whether any NANBH had occurred, we see
24 that none of the patients in the group had any ALT or
25 AST above two and a half times the upper limit of

1 normal.

2 Then on to the next page in relation to HIV.

3 A larger number of patients is discussed, and here
4 it's rather easier perhaps to be definitive about
5 whether or not transmission of HIV had occurred. They
6 say:

7 "No case of HIV seroconversion has been reported in
8 over 100 patients."

9 Then "what next?":

10 "It's acknowledged that the present data are
11 inconclusive ... that are currently been more rigorously
12 assessed by a statistician."

13 Then there is the reference to the rule of three, to
14 which Professor Ludlam alluded.

15 So I suppose in very simple terms, this is
16 cautioning against extrapolating from small
17 measurements, I suppose, in trying to allow for the
18 picture that might be presented if a larger number of
19 subjects had been studied, and that's why the
20 infectivity rate is shown as possibly being zero to
21 14 per cent.

22 I suppose this is taking account of the fact that if
23 you look at 25 patients, you might get one result, but
24 if you looked at 75, the infected patients might all be
25 between 26 and 75, as it were; is it something like

1 that?

2 A. Yes, I think that the difficulty really is that the
3 numbers are very small, the patients are not truly
4 untreated; they have had previous treatments, albeit in
5 small-pool concentrates, and the distance between the
6 sampling is not entirely satisfactory.

7 Just to give an example, had one of these patients
8 been infected with Hepatitis C, cleared the infection
9 and therefore developed evidence of normal liver
10 function tests, then they wouldn't have shown up as
11 being infected because they had already been infected,
12 and there could be susceptibility to infection which was
13 being masked by the fact that the patient had already
14 been infected and recovered from the infection.

15 So the smaller the number of people you are looking
16 at, the greater the level of uncertainty, and the rule
17 of three is quite carefully discussed in the paper that
18 I referred to later in the account by Mannucci and
19 Colombo, which you may want to discuss. But the point
20 is that it's very unwise to make claims for a product
21 when there is still a level of uncertainty.

22 Q. Yes. And this is addressed, really, in the last
23 paragraph. I think this is actually pulled together by
24 Dr Smith. It looks as though he has prepared this
25 summary. He says that:

1 "The proposal is to follow this pilot study with
2 a more formal prospective clinical trial with a stricter
3 protocol."

4 So that's really addressing the very points you are
5 making, Dr Colvin.

6 A. Clearly there was, at this time, a great urgency to know
7 what the best concentrate to use was. So it seemed to
8 those of us who were investigating at the time that the
9 use of patients who were not truly untreated was a risk
10 worth taking to get the data that one needed to be
11 reasonably confident that a particular product was safe.

12 Q. Yes. And we have seen a number of references to
13 "relative safety" as well, or "relative infectivity",
14 and I suppose that concept must have been crucial, that
15 one might not have achieved perfection but, so long as
16 a new product was better than the current product, it
17 might well be worth changing to the new product?

18 A. It was indeed important to try to get this data because
19 there had been a number of disappointments at various
20 points. There was the disappointment over the
21 product -- the Hyland product, which was referred to in
22 the Colombo paper, which I'm sure you have seen. There
23 was the disappointment over Alpha Profilate, which was
24 a heat and heptane product, where, despite the lack of
25 HIV conversions, there were some non-A non-B Hepatitis

1 cases.

2 So there was a number of cases where the use of heat
3 treatment to inactivate Hepatitis C or non-A non-B, as
4 it was then, had been disappointing. So there was
5 a great deal of interest in trying to be as confident as
6 one could and not making unjustified claims for any
7 particular product.

8 Q. Yes. You go on to point out in your report, if we can
9 just go back to that then, please -- and we are at
10 paragraph 5.4 -- that the fuller study was published in
11 the Lancet on October 8th 1988, and you give us the
12 title of that paper.

13 Perhaps I'll just give the court book reference for
14 it rather than going to it. It's [LIT0010330](#).

15 You have, I think, neatly abstracted for us,
16 Dr Colvin, the key features, and we can see that on the
17 screen now. 32 patients treated with a total of 30
18 batches of Factor VIII, ten batches of Factor IX, and
19 insofar as the Factor VIII product was concerned, it was
20 8Y and the paper found no evidence of hepatitis
21 transmission and suggested that the viral inactivation
22 process had reduced the risk from about 90 per cent to
23 a statistically determined rate of 0 to 9 per cent, and
24 I think from memory there is some further discussion of
25 the statistical angle in that paper.

1 Rule of three or similar.

2 You go on to tell us that you are quoting these
3 publications to illustrate that in the period 1985 to
4 1988, active investigation into safety was going on.
5 There were still cases of non-A non-B Hepatitis and HIV
6 even due to heat-treated Factor VIII concentrates, and
7 no claims had been made that any concentrate was free of
8 the risk of virus infection. So that's the landscape.

9 A. Yes, indeed.

10 Q. And you share with us your memory of telephoning from
11 Milan back to your own unit in 1986 because you were
12 very concerned when you heard about the transmissions of
13 HIV by the Armour heat-treated product.

14 A. Really, I think just to illustrate what a sort of
15 fevered time it was, where rumours would spread, if you
16 like, at conferences and one had the responsibility of
17 deciding what to do about such rumours. And being
18 a long way from home without mobile phones in those
19 days, I remember it was a particularly shocking thing to
20 learn and difficult to know what to do other than to
21 phone home and say, "Don't use this product".

22 Q. Yes. Section 6 is dealing with that very paper that you
23 mentioned. I think it's the Mannucci and Colombo paper?

24 A. Yes.

25 Q. In 1988, and even then some reticence demonstrated by

1 the authors, who say that the most they are willing to
2 conclude is that the products described are only
3 presumed innocent.

4 A. It's interesting to note that in the table 3 from that
5 paper, Mannucci --

6 Q. Let's get it up, so that we can see what you are talking
7 about. I think we should. [LIT0010456](#).

8 A. So this paper was published one week before the 8Y
9 study, and in this table you can see that
10 Professor Mannucci refers to patients studied, 16 under
11 the NHS. So that's the less than 20 patients. So 16
12 patients were studied by dry heat, whereas in the
13 publication which appeared the following week, there
14 were 32 patients studied, although some of those had
15 Hepatitis B.

16 So again, there was the problem of information
17 dripping out, if you like, and it was -- the numbers
18 were constantly increasing. So the perceived risk was
19 gradually falling. So whereas in the interim study
20 report I think they quoted 0 to 14 per cent, by the time
21 we had got to the final study report, we were down to 0
22 to 9 per cent, whereas in the publication from Mannucci
23 a week before, in the Lancet, the risk was regarded for
24 that particular product as 0 to 19 per cent. So it was
25 really very difficult to know what the true risk was,

1 even as late as 1988.

2 Q. Yes. Of course, our primary focus is on the period
3 between the end of 1984 and 1987, when Scotland achieved
4 its own product heated at 80 degrees for 72 hours. The
5 achievement having been before, but in terms of the
6 issue to clinicians, that was achieved in the spring of
7 1987. And that interval obviously creates some
8 treatment dilemmas for clinicians dealing with patients
9 with haemophilia in that interval.

10 Can we go back to the report, please, and look at
11 the final page. So [PEN0171674](#) at 1678.

12 We asked you to put yourself in the position of
13 a haemophilia clinician in Scotland in that interval.
14 You mentioned DDAVP and I think we all understand the
15 logic of that. Becoming more difficult, however, are
16 the questions you answer in the ensuing paragraphs. You
17 say:

18 "Where necessary, I would have used the concentrate
19 that I believed, on the evidence available to me, was
20 least likely to transmit NANBH or HIV."

21 "Where necessary"; does that mean that you would
22 have been trying to avoid the use of concentrate if you
23 could?

24 A. I think that where there is elective procedures that
25 could wait for a year or two, you might want to avoid

1 a procedure altogether. I think that where you had
2 a patient who could have responded to desmopressin, then
3 one would have used desmopressin, and then I think the
4 reality was that in many cases you couldn't really
5 postpone a procedure or it was necessary to get on with
6 it fairly quickly, and desmopressin simply wouldn't be
7 suitable. So that's what I mean by "where necessary",
8 it's where necessary.

9 Q. Yes. Fine.

10 In the next paragraph you say you would have
11 considered the possibility of using cryoprecipitate. We
12 have looked several times, and we are not going to look
13 again, at the UKHCDO reference centre directors' report
14 from December 1974, and it does talk about using
15 heat-treated NHS product or cryoprecipitate; easy to
16 say, difficult to apply, one imagines, in the field --

17 A. Yes.

18 Q. -- but you are saying you would have considered
19 cryoprecipitate for patients whose exposure to blood
20 products was likely to be very limited. I wondered if
21 you meant past exposure or were you including future
22 exposure?

23 A. Very much future exposure. To take up the point that
24 Lord Penrose just identified, that if we are talking
25 about the risk of donor infection, then the more units

1 of cryoprecipitate you give, the greater the likelihood
2 of one of those donors having Hepatitis C, and this is
3 like, sort of playing Russian roulette, which I think we
4 discussed the last time I attended the Inquiry, that
5 once you have, I don't know, 100 exposures, you are
6 getting pretty close to the point where one of them is
7 probably going to have Hepatitis C in it.

8 So if you were just going to take a tooth out, where
9 you knew you wouldn't need to use very much material or
10 do some very minor procedure, then maybe cryoprecipitate
11 might be an option, at least in the period 1984, rather
12 than 1987. But one knew that if one was going to use
13 a large amount of cryoprecipitate, then you were running
14 a greater risk of transmitting hepatitis because if
15 there was a unit of cryoprecipitate that you used that
16 was infected, then you would transmit it.

17 Q. So just to take that on a little bit, if you had
18 a patient who -- and I think for these purposes we have
19 to assume a small child, who has plainly had no previous
20 exposure because of their youth but whose Factor VIII
21 deficiency is severe, then are you saying that one might
22 reason that this child is going to have, in future,
23 extensive exposure so there isn't really anything to be
24 gained by trying to stick to cryoprecipitate?

25 A. Well, this is very tricky. My policy at The London,

1 until 1984, was for children to use cryoprecipitate if
2 I could. I think I may have said this at my last
3 appearance. That wasn't necessarily a very widely-held
4 view, but I am afraid to say that many of my severely
5 affected children with haemophilia simply weren't
6 manageable with cryoprecipitate, which is quite
7 difficult to use in many ways, did receive factor
8 concentrates and died of HIV infection.

9 So I make no claims at all to have protected my
10 children against Hepatitis C or HIV, but there were one
11 or two patients who were actually quite heavy users of
12 concentrate, who we did manage to get through with
13 cryoprecipitate and who didn't develop Hepatitis C
14 infection. So I think it was a really difficult
15 decision, and the reason I used cryoprecipitate in those
16 children, as and when I could, was that I appreciated
17 that certainly up to the period probably in 1984-ish,
18 those bags of cryoprecipitate that we used were very,
19 very unlikely to transmit AIDS.

20 Q. Yes.

21 A. So it was extremely difficult to know what to do. But
22 I think that for very small usage in adults, where you
23 were going to really have quite a small number of units
24 and then not use any more, for instance for very mild
25 haemophilia, where you couldn't use DDAVP, it was an

1 option. I think that for very small children, where
2 tiny volumes of cryoprecipitate would achieve
3 haemostasis, it was also an option but it was an option
4 with diminishing benefits as the number of units went
5 up.

6 Q. Yes. And I suppose the other consideration that struck
7 me is that in this period, even with a child who has
8 severe haemophilia, you could reason that a better
9 product might be going to come along, so you are not
10 talking about trying to assess how much cryoprecipitate
11 this child will require for the next ten or 20 years.
12 It might be for quite a short period?

13 A. That is exactly when my reasoning was in carrying on
14 with cryoprecipitate until 8Y became available for the
15 children.

16 Q. Finally, if we just move down the page, we did ask you
17 whether you would have been concerned if you had been in
18 Scotland and you had heard that there appeared to be
19 a hepatitis-safe product available in another part of
20 the UK that wasn't available for your patients. In your
21 answer you have said that there was no evidence that any
22 Factor VIII concentrate was hepatitis-safe and you have
23 talked about evidence emerging in 1986.

24 I think I'm wanting to press you perhaps on the
25 concept of a concentrate that was hepatitis safer; so

1 rather than absolutely safe, a concentrate that was
2 safer than what had gone before, and I know today you
3 have had a very lengthy opportunity to look at some
4 documents that I gave you this morning that are the
5 straws in the wind. Without going to them, because we
6 have only got a couple of minutes, the documents that
7 were emerging in England -- there is a CBLA set of
8 minutes, there is the product sheet 8Y, we then have
9 the --

10 We don't have a couple of minutes, we have slightly
11 more than that.

12 THE CHAIRMAN: "A couple" is such an indefinite expression
13 that I am not prepared to sign up to it.

14 MS DUNLOP: I want to go to this because we have an
15 unredacted version of it, which I should have used
16 yesterday, and that's something to celebrate. It's
17 [PEN0161142](#). This is the unredacted version of
18 [DHF0017386](#). As luck would have it, nobody from
19 Scotland was actually at this meeting. This is
20 9 July 1985.

21 A. Good Scottish names, and Charles Rizza is very much
22 a Scot but he wasn't working in Scotland.

23 Q. He doesn't count then. And Dr Fraser, we know, was in
24 Bristol. Dr Forrester had sent his apologies as had
25 Dr McClelland. But this one has information on the

1 third page, so 1144, about progress with 8Y. We have
2 looked at this before but I think you maybe recognise
3 this whole page, which is devoted to a new virus safer
4 Factor VIII concentrate and is, albeit in relation to
5 very small numbers of people, quite optimistic.

6 It's much the same information as is given in the
7 product sheet, which we won't go to but is also from
8 later in July 1985; [DHF0030476](#), just for reference.

9 Then the other two documents that we have looked at
10 in this regard are [SNB0015469](#), which we will look at,
11 if we could, please.

12 This is Dr Perry writing his report in January 1986
13 for a joint meeting in Scotland of blood transfusion
14 directors and haemophilia directors. If we could go
15 through it, I think it's page 3. No, it must be the
16 next page:

17 "Directors will be aware ..."

18 The penultimate paragraph:

19 "... that the Blood Products Laboratory are
20 currently issuing a Factor VIII product which has been
21 heated at 80 degrees for 72 hours, and preliminary
22 clinical data indicates that this material is
23 non-infective with respect to HTLV-III, NANB and
24 Hepatitis B."

25 This discussion is in the context of what are we

1 planning for Scotland. We have that and then finally,
2 and we won't go to this, but [SNB0075664](#) is a set of
3 minutes of a joint meeting between the English
4 fractionators and the Scottish fractionators
5 in July 1986, at which similar sorts of statements are
6 made. I just wondered, putting yourself in the position
7 of a haemophilia clinician in Scotland at that time,
8 what would your response have been to these indicators?

9 A. As you know, question 2 I found rather reminiscent of
10 the question, "When did you stop beating your wife?" It
11 kind of assumes an answer. That's why I found it very
12 difficult to answer because I didn't feel that it was
13 fair --

14 Q. I'm very happy for you to define and answer your own
15 question?

16 A. I did indeed answer my own question, rather than the
17 question that had been put to me.

18 Q. It often happens.

19 A. I think I really would like to refer to
20 Professor Mannucci's paper, dated October 1st 1988. If
21 I can quote it, he says:

22 "To date, published clinical studies indicate that
23 viral inactivation by pasteurisation and, to a lesser
24 extent, by vapour heating definitely improve the safety
25 from hepatitis of Factor VIII concentrates over that of

1 unheated concentrates and concentrates heated in the
2 lyophilised state at temperatures lower than 80 degrees
3 Celsius. Other methods, such as (inaudible)
4 superheating at 80 degrees Celsius and monoclonal
5 antibody techniques might prove to be of equivalent
6 safety but the small number studied and the lack of
7 details allow us at the moment only to say 'presumed
8 innocent'."

9 So the answer to your question is that we were in
10 the position where we could only do what seemed a good
11 idea at the time. This sort of decision-making was
12 based partly on science and partly on intuition and
13 I think the answer is that at an objective level you
14 couldn't say that one product was better than another,
15 despite this encouraging information. Then I think you
16 really are down to making your own judgment about what
17 is most likely to be true.

18 This is a slightly different issue to be faced with:
19 When we were faced with the problem of do you give
20 unheated NHS concentrate or heated commercial
21 concentrate in trying to prevent HIV infection, then the
22 science left you nowhere and the intuition also left you
23 nowhere because if you chose the unheated NHS
24 concentrate, you were going to transmit HIV, and if you
25 used the heated commercial concentrate, you were

1 probably going to transmit HIV.

2 Extrapolating that to the Hepatitis C issue, I still
3 feel that any decision made to use 8Y or the Scottish
4 equivalent at that point was based on a kind of informed
5 intuition. I certainly would have liked to have said at
6 the time that I was convinced that one product was
7 better than another. I think we were all extremely
8 relieved when it became apparent that 8Y and the
9 Factor VIII equivalent in due course actually were safe.
10 It was a piece of -- I was going to say good luck; it
11 wasn't good luck exactly but I think we were all
12 extremely relieved that in retrospect this was the case.
13 But I think there is huge danger of using the
14 retrospectoscope to say that one should have taken the
15 particular view because it later turned out that that
16 was the answer.

17 Q. Yes.

18 A. So what would I have done? I don't know. It's worth
19 remembering that it wasn't Scotland that was relying on
20 commercial concentrate, as you pointed out at the
21 beginning of this discussion. Scotland was largely
22 self-sufficient and, although commercial concentrate was
23 being used, it wasn't being used in great quantity. In
24 England we could only get hold of enough 8Y to look
25 after a pretty small proportion of the patients, so that

1 in a sense, even with the circumstances that we found
2 ourselves in, you could argue that the Scots were still
3 in a slightly better position than the English were,
4 particularly, I agree, after they introduced the
5 Scottish equivalent of 8Y, but even before that the
6 overall picture was relatively favourable.

7 Q. Right. Let's do it the other way round. When you were
8 in the Royal London, if you had heard at that time that
9 there was a more severely heated product available in
10 Scotland, in relation to which early, if limited,
11 results were optimistic, would you have taken any action
12 in response to that news or would you just have waited
13 to see what was going to happen in England and what
14 further information might emerge?

15 A. Frankly, I think the latter.

16 Q. Right. Thank you very much Professor Colvin.

17 THE CHAIRMAN: Yes. Mr Di Rollo, do you have any questions?

18 MR DI ROLLO: I would like to ask some questions.

19 THE CHAIRMAN: I can't possibly wait, I have another
20 commitment and I think that I have stretched my capacity
21 for waiting to the limit.

22 MS DUNLOP: My feeling at the moment is that we should stick
23 to our timetable because next week we are not sitting
24 and the week after witnesses are all programmed to come.
25 I think we will need to go away as a team and work out

