Tuesday, 6 December 2011

(9.30 am)

(Proceedings delayed)

(9.51 am)

THE CHAIRMAN: Yes, Ms Dunlop?

Submissions by MS DUNLOP

MS DUNLOP: Yes, sir. We have received a number of applications since 12 October, applications for additional evidence, sometimes from witnesses or sometimes documentation. There are, I think, at the moment 12 in total and most of these have been dealt with already.

The Inquiry solicitor sent a message last week indicating that some of them could be granted unless some note of opposition was received by yesterday and no notices of opposition came in, so those ones, effectively are going through but there remain, by my calculations, three which require to be addressed in oral session, and we would hope to be able to deal with those today.

THE CHAIRMAN: How are we going to identify those?

MS DUNLOP: I thought perhaps it might assist if I identify some of the concerns that the team of counsel have about these particular applications and then counsel for the core participants, to whom the applications relate,

could address you on why the applications should be granted.

It might be better to do them one at a time rather than me speaking on all three.

THE CHAIRMAN: Yes, I think, as I understand it, they don't all involve everybody in the same respects anyway.

MS DUNLOP: Yes.

THE CHAIRMAN: I think that sounds a good idea to me, so just do that, please. So where do we start?

MS DUNLOP: Well, the first one for shorthand I think we have described as the application relating to Dr George Masterton, although there is slightly more to it than that and it's an application by the Scottish health boards to allow some additional material to come in really in relation to topic B5. Perhaps I should just go through it for the sake of the transcripts.

THE CHAIRMAN: Yes, I think so.

MS DUNLOP: The application is an application from Mr Anderson to allow firstly an email from Dr George Masterton, consultant psychiatrist, dated 27 June 2011, with an accompanying document entitled "Differentiating Audit, Service Evaluation and Research" by NRES ethics consultation E group.

Secondly, an article from the British Medical Journal entitled "Monitoring the Prevalence of HIV" by

Gillon et al, dated 25 November 1989. And thirdly, a letter dated 7 November 2011 from Professor Peter Simmonds to be received and entered into court book.

What is said in the application is that the Inquiry has the benefit of a statement from Dr Masterton, which is [PEN0120366], and it was anticipated that he was to give evidence in relation to topic B5 but the Inquiry team deemed this unnecessary.

Accordingly, it has not been possible to put the matters contained in the emails and attachments to Dr Masterton in evidence.

So that's what the application says. I have a number of points to make in response, I think in broad terms they number six. The first thing to say is just in relation to that statement at the end of the application about an anticipation that Dr Masterton would be giving evidence. That, in my submission, is a bit of a red herring. Dr Masterton's statement and possible involvement was on another matter completely, the Central Legal Office had drawn Dr Masterton to the attention of the Inquiry team as someone who had participated in the support of haemophilia patients and staff after the HIV diagnosis.

It was never suggested that he was a potential

witness on research ethics and his statement, which was referred to in a hearing session on 30 June, relates only to the matters I'm describing; that is his participation in support of haemophilia patients and staff.

The second point I would make is that there does actually appear to be a bit of confusion about what had been said by Dr Nathanson on 23 June and what might be said to be possible criticism of Professor Ludlam.

Dr Masterton's response appears to be focused on whether or not the testing of patients at Edinburgh Royal Infirmary in 1984 was research but that is, with respect to Dr Masterton, not really the point that was covered in evidence with Dr Nathanson. That part of the story -- that is the testing of samples from patients in the autumn of 1984 -- was examined against a backdrop of whether or not it should have been done without the consent of the patients.

So it's not that that particular part of the story was being examined to see if it was research and required some sort of validation or authorisation as research; the question in relation to that is: should it have been done without the consent of the patients?

Dr Nathanson did cover this in her testimony. One would look particularly at page 94 onwards on 23 June.

Dr Nathanson in fact was not critical of testing the stored samples and gave quite a lot of evidence about how there was a sea change in medical practice really as a result of the whole HIV period.

THE CHAIRMAN: Unfortunately her evidence tended to waver, if I can use that expression, with reference to the Declaration of Helsinki and matters of that kind.

MS DUNLOP: Well, but in terms of the events at Edinburgh Royal Infirmary on which she was asked to comment, that is how that particular part of the story was being discussed and that is the possible angle of any criticism or objection. The research aspect relates really to events before and after; that is to Professor Ludlam's AIDS study, which also was covered in evidence, and to such work as may have been done in connection with the patients diagnosed as HIV positive in the years following that diagnosis in 1984.

I thought, on looking again at Dr Nathanson's evidence, that her evidence, which can be found around page 162, on the work after diagnosis was actually very like what Dr Masterton is saying. I didn't see much difference between them. The other reference I should make is to her evidence at page 135, where she does talk about the AIDS study in 1983, but actually that's not what Dr Masterton is talking about.

So, as I read the email which he has sent, he does not appear to me to be talking about what Professor Ludlam himself called his AIDS study.

So if I could sum up my second point, it is that there is an element of confusion actually as to what point Dr Masterton is addressing and what he thinks the criticism of Professor Ludlam might or might not be.

The third point is a simple one, that Dr Masterton's involvement in serving NHS RECs didn't begin until 1987, so prima facie he was not involved at the crucial point -- that is 1983 and then 1984 and thereafter.

Fourthly, it is not clear that in putting together his comments, Dr Masterton had all the B5 evidence in front of him.

Fifthly, Inquiry counsel take the view that if further expert assessment of all of these events were to be considered necessary by yourself, sir, it would be more appropriate that a further report, further evidence, be commissioned from another expert.

Finally, I would say that Inquiry counsel were concerned about what I might call a precedent element. The contact at the end of June in response to the evidence of Dr Nathanson came out of the blue, and it is hard to see a distinction between this and any other expert evidence which a core participant subsequently

decides to challenge by submitting a report or comments from someone else.

This Inquiry has an extremely wide remit and if parties are to be allowed to come along after a witness has testified with expert comment on that testimony, then the process is in danger of becoming never ending.

That then is what I would say in response to Dr Masterton or in response to the comments of Dr Masterton. This application also includes the article from the British Medical Journal, and I would simply say that it wasn't clear to me the basis on which this article was being submitted and what the Inquiry team was supposed to take from it.

Finally, the letter from Professor Simmonds, which is dated 7 November 2011, again is something that the Inquiry team was not expecting. It need not in itself be fatal but it's certainly not something that the Inquiry team had asked for. He comments also in his first paragraph on whether the testing in the autumn of 1984 was research or diagnosis, and I don't really think that there is, as I have said already, any difficulty about this.

He goes on to comment on whether there was a requirement for anonymisation or not. If we read on to (d) and (e), he is talking about a general view at

that time that a clinician had a right to perform whatever diagnostic tests were thought necessary for patient management.

THE CHAIRMAN: This was at the time what he was a postgraduate student?

MS DUNLOP: Right.

THE CHAIRMAN: He was doing his PhD --

MS DUNLOP: That may be another difficulty, sir. But he is then referring historically to what the prevailing position might have been about the conduct of diagnostic testing, and he refers by way of example to an article published in The Lancet in 1985 referring to HTLV-III antibody in Edinburgh drug addicts. Again, I would make the point that this doesn't really seem to me to be very different in its terms from what was said by Dr Nathanson and so the need for it is not obvious.

But no doubt Mr Anderson will be able to explain more fully why it's thought that this letter, and indeed the article and the email from Dr Masterton, satisfy your test, sir, of such additional material in some way filling a gap, which the Inquiry has or could be said to have in the material available to it.

THE CHAIRMAN: Mr Anderson?

Submissions by MR ANDERSON

MR ANDERSON: I'm obliged, sir, thank you. I'm not sure

whether it's an objection or comments from counsel to the Inquiry.

THE CHAIRMAN: I think it's comments to assist me in making up my mind. But since it focuses matters of the objection, this you must deal with. You had better deal with it, Mr Anderson.

MR ANDERSON: However one characterises it, they appear to proceed upon the basis that Dr Nathanson was critical. That is not the basis upon which these documents are proffered and they are not proffered in any way as being a challenge to Dr Nathanson, far from it. The purpose of seeking to put these before you, sir, is simply for such assistance as they may provide, not having been previously made available.

THE CHAIRMAN: You know, at this stage, Mr Anderson, that really won't do. For you or for anyone else. There has been a huge amount of evidence in this Inquiry. Witnesses have been called to deal with matters and often they have dealt with them in very great detail. Throwing extra salt into the pot might increase its savour but it doesn't really help me terribly much to have it put in that way.

What is the point that is made by these documents that has to be made and isn't made by Dr Nathanson, for example, is a relevant question, I think.

MR ANDERSON: Well, I think I have to accept, sir, that if it's such a high standard of strict necessity, then I would say that these are not strictly necessary and that Dr Nathanson has covered this, and as I say, they were not proffered because they sought to address any omission or any criticism from her; they were proffered, as I say, for such assistance as it is thought you may gain from those.

If you think you do not gain any assistance from them, then maybe that's an end of the matter.

THE CHAIRMAN: What I'm saying, Mr Anderson, is I think it's up to you to tell me what assistance I would get from them at this stage in the Inquiry. I really can't allow infinite elasticity.

MR ANDERSON: I understand that. There are two main aspects I would rely upon. The first is within the email from Dr Masterton himself and it is his, if you like, experience at the coalface in relation to REC matters.

THE CHAIRMAN: At what date?

MR ANDERSON: You have read this.

THE CHAIRMAN: At what date?

MR ANDERSON: In --

THE CHAIRMAN: His experience at the coalface when?

MR ANDERSON: 1987, I think it begins.

THE CHAIRMAN: Which is not our period so far as this

issue --

MR ANDERSON: I accept it's not in 1984, but it's near and presumably he would be aware.

THE CHAIRMAN: No, there is no presumption. With the greatest respect, you can't just say, "Let's assume it's all right".

You know, Ms Dunlop has made what appears to me on the face of it to be quite a neat point, that Dr Masterton is giving an expert view, which you have described as "coming from the coalface", about a period when he was not involved.

He might, as a historian, sometimes give a view on the basis of reading or whatever but not from the coalface, Mr Anderson. You know, I do have to bring this Inquiry to an end. I really do. In everyone's interest, we have got to have answers. The answers will never be completely comprehensive. There is no way on earth that when this Inquiry is done, there will not be people who can identify other gaps and who can suggest it should be reopened, who can suggest that it's not complete. Absolute completion is an aim beyond attainment.

So we have had a huge amount of evidence and I really need to know precisely what's to be achieved by allowing additional evidence in now. It's a test I'm

going to apply to everyone, not just you. I really do need to know.

MR ANDERSON: If that is where the barrier is set, then I have to accept that this is not strictly necessary and does not meet that test and on that basis I will say no more.

THE CHAIRMAN: I will take it that that's your position now. Ms Dunlop, shall we move on?

MS DUNLOP: Yes, thank you, sir.

Submissions by MS DUNLOP

MS DUNLOP: The second application which Inquiry counsel felt needed to be addressed orally is the one in relation to Dr Cuthbert. And just to make clear again for the transcript that this is an application on behalf of the Scottish health boards to allow the report dated 19 September 2011 from Dr Cuthbert to be received and entered into court book. The information contained therein being a useful addition to that given by Professor Ludlam in relation to topic B5.

Dr Cuthbert is a consultant haematologist at Belfast City Hospital and he worked as a clinical lecturer/registrar at the haemophilia centre, Edinburgh Royal Infirmary, during the period 1 August 1986 to 31 May 1989. He worked with Professor Ludlam. He undertook routine clinical work and a research project

investigating immunological function in haemophiliacs. He describes what was involved in that research project and talks about practice in relation to obtaining consent from patients.

The concern which the team of Inquiry counsel had about this is rather similar to some of those we have just discussed. That again this appears to be an after the event statement coming in from someone else who is considered to be supportive of a witness who has testified before the Inquiry. If Dr Cuthbert's name had been suggested before this topic was dealt with, the team of counsel would have considered taking a statement from him but it's rather late to be thinking about receiving one now.

If one were having regard to the actual value of his comments, it does have to be noted that they relate to a period which is later than that in which the Inquiry is primarily interested. So it was those reservations that led the Inquiry team to suggest that this too was one that had to be dealt with orally.

THE CHAIRMAN: Yes, Mr Anderson, what's your position on that?

Submissions by MR ANDERSON

MR ANDERSON: Sir, I suspect I find myself in the same position.

MS DUNLOP: Sorry, Mr Mackenzie was making to me an additional point, which is of course that Dr Cuthbert was under the direction of Professor Ludlam and we have heard from Professor Ludlam.

THE CHAIRMAN: Well, I'm not absolutely sure about that. I occasionally hear from junior counsel who are under the direction of senior counsel, without taking an objection on that ground so far. Mr Anderson.

MR ANDERSON: I must have misheard, I thought I had been invited to address you.

Sir, I suspect I'm in the same position as in the last case. This again was proffered for such assistance as it may give. You will be aware, sir, that those instructing me have no power whatsoever in relation to what evidence is led. Unlike a litigation, they cannot choose the witnesses.

THE CHAIRMAN: That is so.

MR ANDERSON: This area was one which, I think it's fair to say, was very fully ventilated and I think those instructing me were somewhat taken aback at just how much time had been spent with Professor Ludlam on this matter. Dr Cuthbert was mentioned on a couple of occasions, and it is, I think, fair to say that although my learned friend Mr Di Rollo examined Dr Ludlam at very great length, he did not, I think very reasonably, at

this stage seek to question the reliability or probity of Professor Ludlam's evidence. So one can perhaps suggest that again this may fail the very high test of necessity. But given that there was such a thorough examination of only one witness in relation to this, it was felt that it may be helpful for you, sir, to have evidence from another source but again, if the test is the very high one of strict necessity, then again I accept that strictly speaking it is not necessary.

Perhaps I've too traditionally a mindset of litigation, where if I were conducting a litigation for one side, I would have led Dr Ludlam as a witness but of course I'm not in that position. If counsel to the Inquiry don't feel the need for it, there is nothing much that I can add.

THE CHAIRMAN: I would have to discourage any thought that one needed corroboration or supplementary evidence in an Inquiry of this kind. That would be quite inappropriate. I realise that if this were a litigation and I were sitting in another place, we probably wouldn't have got past Dr Ludlam yet this year. So I don't think that's a terribly persuasive point to make, Mr Anderson, but thank you for your position on that.

Ms Dunlop?

MS DUNLOP: Yes, sir, the final application which falls to be considered this morning is in relation to the patient interests, the families and the Haemophilia Society, and it is an application to put to Professor Ludlam further questions in relation to our topic C3A. It appears to me that the questions fall into two main categories, namely general questions relating to systems and so on, and questions relating to the treatment of particular individuals.

In relation to the former, it has appeared to Inquiry counsel that core participants had a sufficient opportunity to explore these matters at the last hearing; that is when the topic was dealt with in the week of 10 October. It is not obvious why these general matters should be gone into again. I attempted in my questioning to deal with the systemic issues comprehensively and I covered the ground at some length.

For clarification, it is my view that there are three systemic issues here: the non-achievement of an adequately heat-treated product in Scotland, which has been covered in our topic C3; the obtaining and distribution of a supply of 8Y from England, which has been covered in topic C3A and which core participants will be able to cover further with Dr Perry tomorrow;

and the thinking of haemophilia clinicians on the treatment of patients during this period, which is a matter already covered with Professor Lowe and Professor Ludlam and which core participants can explore further with Dr Colvin, who is also returning tomorrow.

Turning to the category of questions which relate to the treatment of particular individuals, it is the case that this was really stopped at the last hearing and you, sir, indicated that you wished formal notice to be given and application to be made if this line was to be pursued, and that is what brings us to this point today.

It is, of course, a matter for you, sir, whether you wish to allow this second category of questions but I would suggest that it is important to try to decide whether these questions are likely materially to assist you in fulfilling the terms of reference.

More specifically, to what extent is it likely that wider inferences or conclusions can be drawn from this line of questioning and to what extent is this evidence likely to be confined to the particular patient concerned? It has struck Inquiry counsel that the questions really belong to that latter category; that is, they are confined to the particular individuals concerned.

That is because an attempt is being made to

investigate the circumstances of, I think, really two individuals. I should say at once that it is entirely understandable that those individuals would wish such investigation to be made and the circumstances in which they themselves became infected are plainly and appropriately of prime concern to them.

The Inquiry, of course, has to bear in mind that such a particularised Inquiry would be desired by many in the group of those who have contacted us, who have provided statements either about themselves or about a loved one who died of Hepatitis C.

At a more practical level, were these questions to be allowed, the Inquiry would presumably require to take statements from the other clinicians involved in the patient's treatment, recover and examine medical records and possibly also seek a report from an independent expert.

That sort of examination of a particular case seems at odds with the more generalist approach of a public Inquiry.

THE CHAIRMAN: Yes, but it is also the problem here that I would have to resolve whether it was competent for me to make findings of fact of such specificity as to deal with the particular, rather than the general. I am quite concerned, and the circumstances in which I have

had terms of reference do identify particular individuals whose cases have to be considered. The contrast does tend to suggest that what one ought to do is look for generalities rather than particulars in other respects. So this does worry me.

MS DUNLOP: Certainly, a contrast can be drawn between the term of reference which names individuals into whose circumstances you are required to enquire because, of course, term of reference 6 does name the individuals who have died of Hepatitis C and into whose cases we have looked in particular detail. And a contrast can be drawn with term of reference 5, which does require examination of the circumstances generally in which patients became infected with Hepatitis C.

I'm aware that mention has been made in correspondence also of term of reference 8. That relates to the steps taken by those involved in the NHS in Scotland to prevent the provision of infected blood and blood products, but I had understood that to be going rather further back in the supply chain, as it were, and looking at screening and manufacturing steps.

THE CHAIRMAN: Yes, and to the scientific research into the products.

MS DUNLOP: Yes. It is not apparent to the team of counsel that there would be any wider benefit to the task of the

Inquiry as a whole from mounting the sort of detailed Inquiry that's being proposed into the circumstances of two individuals. There is the old point about every case turning on its own particular circumstances, and it is my view that the sort of examination I have made of the general issues should be adequate, I would hope, to enable you, sir, to answer the systemic points which arise.

THE CHAIRMAN: Mr Di Rollo?

Submissions by MR DI ROLLO

MR DI ROLLO: Sir, counsel to the Inquiry has, I think, helpfully divided up the issue into the general question and the specific question, I suppose; in other words, she has looked at the examination that the Inquiry has in relation to general questions and the examination of the Inquiry in relation to the circumstances of particular individuals. In addressing you this morning, she has addressed you in respect of both of these matters.

As you are aware, a detailed application has been submitted on behalf of patient A and patient B, and the justification for seeking to ask the questions set out in that application is also set out in the application.

In relation to the issue as far as general questions are concerned, we have, it is correct to say, gone some

way down the road to examining systems in relation to C3A, but my submission is we have not completed the job and in particular we have not completed the job as far as Professor Ludlam is concerned.

THE CHAIRMAN: I don't quite understand what that means. You are going to have to help me. C3A is not complete, as Ms Dunlop has made clear. Further witnesses are coming.

MR DI ROLLO: Dr Perry, as I understand it, and Dr Colvin are still to be asked certain questions, and also she hasn't, I don't think, addressed the Inquiry at the end of the topic in the way that she would normally do.

But what she did say in the course of her remarks to you was that Professor Ludlam has already been examined on this topic. Well, he has already been examined on the topic but he has not been completely examined on the topic, because it hasn't been put to him -- because I was prevented from doing so -- specific questions about the failure of the system in relation to, in particular, patient A and -- just bear with me and I'll try and explain to you what I'm saying.

THE CHAIRMAN: Yes.

MR DI ROLLO: What the application has done is to set out what, as far as the core participants for the patients and the Haemophilia Society are concerned, are the

questions which fall within the Inquiry's terms of reference, and those questions are whether a previously untreated patient should have been given SNBTS Factor VIII concentrate at all during the period between 1985 and 1987 and --

THE CHAIRMAN: Sorry, just let's pause there. That's the first specification you provided in relation to one because I have to say that when I read it, it seemed to me to be very wide, so there's a specific period involved in question 1.

MR DI ROLLO: Of course there is. The reference to "this period" is the period between 1985 and 1987.

THE CHAIRMAN: 1 September 1985 and 30 June 1987? Or what?

MR DI ROLLO: The period of the topic, sir, is the use of blood concentrates in Scotland in the period between the introduction of NHS heat-treated products in 1984 and the supply of NHS products sufficiently treated to inactivate Hepatitis C.

THE CHAIRMAN: So what period is it that I have to take?

MR DI ROLLO: It would be December 1984 until April 1987.

THE CHAIRMAN: Yes.

MR DI ROLLO: So that's the first question. The second question --

THE CHAIRMAN: Sorry, and it's any patient at all? So long as it's previously untreated, nothing else matters: the

circumstances that caused treatment to be considered, whether the patient is severe, whether the patient is mild; it's just any patient. It's an attempt to persuade me to enter into the whole treatment regimes open in relation to any patient presenting and being considered for Factor VIII treatment over that period?

MR DI ROLLO: It's whether a previously untreated patient, ie a patient who had not previously been given the factor concentrate, should have been given an SNBTS Factor VIII concentrate at all during that period.

THE CHAIRMAN: And if the answer is that it's a matter of clinical judgment depending inter alia on the circumstances in which the patient presents, other risks to which the patient is exposed and other factors concerning the availability of treatments at that stage, what good does it do me?

MR DI ROLLO: Well, that is what the point of the second question is.

THE CHAIRMAN: No, with respect, the point of the second question is to attempt to get a catalogue of all circumstances in which one might deviate from the first. I'm being deliberately picky about these two because in fact I can see no limit to the research that would be necessary to follow this up.

MR DI ROLLO: No, I don't think that's correct at all, if

I may say so. It's a perfectly straightforward situation in which the Inquiry has been asked to give an indication, make a finding as to what the circumstances would be in which a previously untreated patient would be given SNBTS factor concentrate, and we have addressed that in evidence so far.

THE CHAIRMAN: Sorry we ...?

MR DI ROLLO: It has been addressed in evidence from Professor Ludlam, in evidence from Professor Colvin and it may be from other witnesses, but certainty it has been addressed I think by Professor Lowe as well.

THE CHAIRMAN: And what additional questions are to be asked?

MR DI ROLLO: I haven't got to that yet. If you just bear with me, I'll explain. What we have on page 2 is an indication of the questions which fall within, in my respectful submission, the Inquiry's terms of reference. If we go to question 3, if you are with me so far:

"Whether there were systems in place for ensuring that previously untreated patients were not put at unnecessary risk by being given Factor VIII concentrate unless the circumstances in question 2 were satisfied."

In other words, what steps were taken to prevent a patient being given Factor VIII concentrate where such a patient should not have been given Factor VIII

concentrate, given the known risks during this period.

The next question is, if there were such systems in place, why they broke down and what steps were taken to avoid a recurrence.

That is the critical question in relation to Professor Ludlam, which we have not been given an opportunity to ask.

THE CHAIRMAN: Is this a general question?

MR DI ROLLO: It is a general question.

THE CHAIRMAN: How many occasions do you suggest there were on which this question might arise?

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

THE CHAIRMAN: I'm not going down a dark lane with no guidance, Mr Di Rollo.

MR DI ROLLO: There certainly may be one such --

THE CHAIRMAN: You see, that is the point. One must come clean on this. You do not know of any circumstances.

MR DI ROLLO: When you say I don't know, the point about it is that there is material available to me which suggests that the system may have broken down in patient A's case, assuming there was a system, but if you ask me the question as to how many occasions the system broke down, the answer to that question, coming cleanly, as I always do, is I don't know the answer to that question.

THE CHAIRMAN: So the position is it is likely to be that

there was a system, if there was one, that it obtained throughout, that as a system it did not break down -- the system did not break down -- but on one occasion something happened that was not consistent with the system. That's not a breakdown of a system.

MR DI ROLLO: I'm sorry, with respect, you have no basis for forming that conclusion whatsoever. You do not know either how often the system broke down. If you don't ask the man how it broke down, or if it broke down, and if we don't explore that with him, we will never find anything out. And his position in evidence is that everything seemed to be fine, as far as he was concerned. There was a system and it didn't break down.

My suggestion is that that is in fact not correct. His reaction to the breakdown and how he goes about dealing with it may tell the Inquiry something about his attitude and the general attitude of clinicians at the time.

That's what number 4 is about. And it's that matter which I submit this Inquiry should allow me to ask questions about.

THE CHAIRMAN: Well, it may be that there are two questions there: one, whether Professor Ludlam should be asked questions; and the other whether you should be allowed to ask them, because cross-examination is not a normal

function of an Inquiry of this kind and I have already allowed a great deal of latitude in that respect, and I think that at this stage I might not be prepared to allow that. I might, if I allow this in at all, consider it's a matter for me to ask Professor Ludlam, with a view not least to keeping the matter under my control, rather than perhaps yours, Mr Di Rollo.

MR DI ROLLO: Certainly, sir. If I may say, of course, another alternative would be to invite Inquiry counsel to conduct this question, of course.

THE CHAIRMAN: That is another possibility.

MR DI ROLLO: Indeed. I accept, of course, that primarily in this forum it is for Inquiry counsel to ask the questions and we have throughout these proceedings tried our best to provide detailed indication of the questions that we would like to ask.

THE CHAIRMAN: I know you have and I'm very grateful, and I think that my defence of informality would be that on this occasion there has been such cooperation that matters have really worked to everyone's best advantage.

MR DI ROLLO: I also would accept that the informality has been of assistance to all parties and we are grateful for it. So that's item 4.

The next general questions do address matters which as I understand it, are still to be developed with

Dr Perry and perhaps also with Professor Colvin, who are coming back, as I understand it, tomorrow, and we have intimated detailed questions for Professor Colvin. We have also indicated a justification in a document of the questions that we have for Dr Perry relative to this topic.

So questions 5, whether during the period it would have been preferable for previously untreated Scottish patients to have been given treatment with products other than SNBTS Factor VIII concentrate, and whether it was possible to obtain English 8Y product to treat previously untreated Scottish patients so as to reduce the risk of NANB Hepatitis, and if it was possible to obtain English 8Y, whether clinicians were given sufficient information as to its availability and appropriate use for previously untreated Scottish patients.

Again, these matters are to be developed, as I say, with Dr Perry and Professor Colvin. There may be, depending on what Dr Perry has to say, some requirement to seek further information from someone else at Scottish National Blood Transfusion Service about what steps were taken to inform physicians generally, but that is, in my submission, clearly covered by the general.

THE CHAIRMAN: I'm not sure where Professor Ludlam actually comes into this. We know that when a request was made, it was Dr Perry who made it and I also have sufficient information to enable me to make findings in fact about the availability of 8Y. It's documented at the time -- it is not a matter of any secret at all -- that it was available in England and Wales only; that it was available pro rata to RTCs, contributions of plasma to BPL; and that there was only one exception to that and that that was the provision of 8Y for clinical trials.

We also know that Dr Smith made 8Y available to Scotland on the clinical trial protocol. The fact that that was ignored in Scotland doesn't help one but I think there is a lot of information here already that would suggest that whoever is the right person to answer questions about this, it's not Professor Ludlam.

MR DI ROLLO: I understand that. Of course, the point about setting out the questions in page 2 of the application is to basically provide a sort of route map as to where this is going as a topic. The individual Professor Ludlam answers really address the issue of question 4, not the others in particular. So I accept that in relation to the general issue as to the supply of 8Y and information given throughout Scotland, that Professor Ludlam is not necessarily the right person to

ask.

THE CHAIRMAN: I think you can take it at the moment I'm not inclined to subject Professor Ludlam to wider questioning at this stage of the Inquiry than is necessary. I think that whatever one thinks of his evidence, he has been exposed to this Inquiry frequently enough and over long enough periods to make it necessary for me to be just a little protective of his position and as I say, I think 5, 6 and 7 are not questions for Professor Ludlam of such centrality that they can't be dealt with adequately by someone else.

MR DI ROLLO: I think that's all I would like to say about the general matters. To sum up what I have to say in relation to that: there are matters of generality that require further questions of Professor Ludlam and they relate to, in particular, patient A, but I would wish to ask certain questions about how someone in the position of patient B should have been dealt with, having regard to that patient being an example of an infant with severe haemophilia at a relatively late stage receiving a batch of Scottish Factor VIII for the first time in January 1987, ie late in the period under examination.

Turning then to the issue of particular individuals, I do not accept the proposition that it is not

appropriate to investigate individual cases; in other words, any individual case whatsoever beyond the five deaths. The terms of reference are broad enough to allow the Inquiry to investigate individual cases. If those individual cases do shed light on the general position -- and the two terms of reference to which attention has been drawn are term of reference 5 and term of reference 8. Both of these terms of reference are referred to in our application and have been referred to by my learned friend.

I accept, of course, that in terms of term of reference 5, it does refer to the circumstances generally in which patients treated by the NHS became infected and, of course, term of reference 8 does not restrict that investigation, in investigating the steps taken by those involved and those responsible for the NHS in Scotland, including the NHS boards and SNBTS, their officers and employees and associated agencies, to prevent the provision of infected blood and blood products.

I don't accept the restriction that that does not cover the situation where SNBTS products are being administered in the hospital and the decisions taken by those responsible for the decision to administer those products. In my submission, in relation to this

critical period that we are dealing with -- and it is a restricted period and it involves a restricted number of patients -- 31 only would be candidates. What we are considering here is the steps taken to prevent someone from becoming infected as a result of administration of a particular product, known to have a risk of infection during that time.

THE CHAIRMAN: So this is a submission that would lead to a conclusion in each and every one of those 31 patients' cases? Is that right?

MR DI ROLLO: No, and I say that because I know nothing of the circumstances of 29 of these patients.

THE CHAIRMAN: But you know that concerns me greatly because what in effect this amounts to is an argument that self-selection of individual cases should determine how I exercise my discretion.

MR DI ROLLO: Sir --

THE CHAIRMAN: And self-selection is always dangerous in cases like this.

MR DI ROLLO: When you refer to "self-selection", who is the self involved. It certainly is not me --

THE CHAIRMAN: No, it's the two patients.

MR DI ROLLO: No, because what happened here, sir, is that you chose the two patients as core participants --

THE CHAIRMAN: As core participants, yes.

MR DI ROLLO: -- at the beginning of the process.
THE CHAIRMAN: And I made it clear that this did not mean that they were likely to be witnesses.
MR DI ROLLO: I understand that. I'm not asking for them to be witnesses. What I am asking is that their circumstances be investigated, the circumstances surrounding their infection be investigated and conclusions drawn about how it happened.

I say that because those two individuals were selected by the Inquiry. The selection by the Inquiry of those two individuals, as I understood it at the time, as representatives of others, created in my mind at least the impression that there would be an opportunity to explore their circumstances or the circumstances of their infection.
THE CHAIRMAN: Mr Di Rollo, did I not make it clear? It was to ensure that you and the solicitors instructing you had full and adequate instructions as to the factors that should be raised?
MR DI ROLLO: I'm sorry?
THE CHAIRMAN: That you and Thompsons should have full and comprehensive instructions from people with knowledge as to the issues that ought to be raised in the Inquiry. That was the purpose.
MR DI ROLLO: Yes.

THE CHAIRMAN: That's right.
MR DI ROLLO: Those instructions include, I suspect, the desire to understand how it came to be that those individuals were infected.
THE CHAIRMAN: That becomes very particular, you know.
MR DI ROLLO: Well, the situation is that there is nobody else instructing me to enquire into their circumstances and --
THE CHAIRMAN: I can't restrict it. You see, if I once were to allow them in, I can't stop a queue of people forming outside the door who say, "I'm not instructing Mr Di Rollo but I'm in the same place as patient A or patient B, and I want my case to be heard too."
MR DI ROLLO: Well, the more difficult feature of this is that there can be no getting away from the desire -- and I'm grateful to my learned friend for expressing it at the end of her remarks -- that it is perfectly understandable that the individuals themselves should require to know what happened to them and they looked to this Inquiry for that purpose.
THE CHAIRMAN: Yes, but that's not enough. I can understand anybody in this position wanting to have their personal circumstances ventilated. Ms Dunlop is absolutely right: on a human level, it's perfectly understandable. I can't approach it in that way, Mr Di Rollo.

MR DI ROLLO: I think you may have to, in my submission. There is, in my submission, a clear requirement for the state to investigate the individual circumstances of someone whose life has been put at risk in circumstances that we see here and --

THE CHAIRMAN: But that doesn't mean I have to do it.

MR DI ROLLO: I would say that if you are given the terms of reference, given your knowledge, given the Inquiry that's here now, it would be a pity if these two individuals were required to go and ask for an Inquiry from someone else, conducted by someone else, to investigate their individual circumstances.

THE CHAIRMAN: It wouldn't be a pity for me.

MR DI ROLLO: It would be a pity for them.

THE CHAIRMAN: I'm not sure that it would.

MR DI ROLLO: It would be a pity for the public expense.

THE CHAIRMAN: You know, if they want an individual remedy, then maybe that is what they have to seek and I'm using "remedy" in a very general sense, not in the sense of seeking damages or anything else, but an answer to their questions. If they want an individual answer to the question, and the mechanism exists for it, perhaps that's what they ought to do.

MR DI ROLLO: Talking about individual remedies -- this is an independent Inquiry -- not a case of writing a letter

and asking for some questions to be answered, but seeking a proper Inquiry independent of those that, it's being suggested, may have created the situation in which they became infected. Could I just refer you, sir, to a case. I'm slightly diffident about doing this but I feel as though it is necessary in the circumstances. It's called Oyal v Turkey, and it's reported at [2010] 51 European Human Rights Reports at page 30, and I have a copy of it.

THE CHAIRMAN: Bear in mind that it's so long since I have been compelled to read anything of this kind, that I will require guidance.

MR DI ROLLO: I think we are possibly in the same boat, sir, given the length of this Inquiry.

THE CHAIRMAN: At least I hope you have something else to do, Mr Di Rollo, that involves looking up the law.

MR DI ROLLO: What I would say is that of course this Inquiry is a public authority and of course this Inquiry is bound by the Human Rights Act and requires to act compatibly with it.

The proposition that I take from this case -- and it's always dangerous to take propositions from European cases -- is that there is a procedural requirement under Article 2 of the Convention, which says that:

"Everyone's right to life shall be protected

by law."

That's the only part of this that matters for the purposes of this submission:

"Everyone's right to life shall be protected by law."

That's the opening sentence of Article 2, and as far as this particular case is concerned, the state has a procedural requirement to investigate even though the person who is seeking the investigation is still alive.

In other words, the procedural requirement under Article 2 applies where a life-threatening condition has been sustained, and as far as Hepatitis C is concerned, in the context of these two individuals, patient A and patient B, it would be my submission that the criteria for that has been satisfied in respect that they are in a situation where their lives are at risk.

The evidence in relation to patient A, for example, whom the Inquiry has a statement from, is that he is on the cusp of cirrhosis; in fact the medical condition has advanced beyond that. So it's beyond peradventure that his life is at risk as a result of the condition which he has sustained.

The other point to take from the case is that a medical mishap of the type that may have occurred in this case is the sort of event which is worthy of an

investigation by the state. This case concerned a Turkish infant who became infected with HIV as a result of blood being received at a very young age and, despite criminal and administrative proceedings, it was held that those proceedings in Turkey were not adequate to fulfil the procedural requirement of Article 2, and of course the boy was still alive and the case concerned the adequacy of financial redress and the fact that proceedings were not concluded within a reasonable time.

The particular passage that I would wish to draw to your attention, sir, is at page 726 and it's under the discussion relative to admissibility.

What is stated there at page 726 at paragraph 51 is:

"The government submitted that Article 2 of the Convention did not apply in the circumstances of the present case. It maintained that the applicants were no longer victims of a violation of the aforementioned provision, following the redress provided by the authorities, within the meaning of Article 34 of the Convention. It further noted that in the case of D v the United Kingdom, which concerned the attempted expulsion of an AIDS sufferer to St Kitts, where he would have been deprived of the medical treatment he was receiving in the United Kingdom, the court had examined

the complaints of the applicant under Article 3 of the Convention rather than Article 2.

"The applicants claimed that Article 2 of the Convention covered not only incidents which resulted in the death of the victim, but also cases where the victim suffered life-threatening serious injury. Bearing in mind that the first applicant's disease was not curable, the State was responsible for violation of the right to life of the first applicant. They thus claimed that Article 2 of the Convention applied in the present case.

"The court reiterates that Article 2 does not solely concern deaths resulting from the use of unjustified force by agents of the state, but also in the first sentence of its first paragraph lays down the positive obligation on states to take appropriate steps to safeguard the lives of those within their jurisdiction. Those principles apply in the public health sphere too.

"The aforementioned positive obligations therefore require states to make regulations compelling hospitals, whether public or private, to adopt appropriate measures for the protection of their patients' lives. They also require an effective independent judicial system to be set up so that the cause of death of patients in the care of the medical profession, whether in the public or private sector, can be determined and those responsible

made accountable.

"Furthermore, on a number of occasions the court has examined the complaints raised under Article 2 of the Convention, where the victims had suffered serious injuries as a result of illegal acts perpetrated against them and has accepted that the aforementioned provision could apply in exceptional circumstances, even if the victims have not died. Likewise, in the above cited LCD case, where the applicant had suffered from leukaemia, diminishing her chances of survival, and the case of Karchen v France, where the first applicant had been infected with the HIV virus, which put his life in danger, the court held that Article 2 of the Convention was applicable.

"In view of the foregoing, the court sees no reason to depart from its established case law and considers that Article 2 of the Convention applies in the circumstances of the present case."

What I say is that it would be in my submission appropriate to say on behalf of patient A and patient B, particularly in relation to the circumstances of patient A, given the medical situation, that he is entitled to a judicial investigation in relation to the circumstances of his infection.

THE CHAIRMAN: This is not a judicial investigation.

MR DI ROLLO: No. But it's an independent Inquiry, which in my submission has been set up with a view to complying with -- one of the most important features of this Inquiry, as I understand it, and one of the reasons why we are investigating five particular deaths is that the Inquiry is seen as complying with the State's obligations in this regard to the investigation of individual circumstances.

So my submission to you, sir, is that this Inquiry -- I accept it's not a judicial investigation but it would satisfy the requirements if it conducted its inquiry as I invite it to do -- would satisfy the requirements of Article 2 in respect of patient A and patient B, and it would be a pity, as I say, if they had to resort to other means to seek that remedy when we have an Inquiry with, as I say, an expert in the chair, a medical assessor, a counsel to the Inquiry well briefed in all manner of aspects of the subject matter here to investigate those particular matters.

Those are my comments in relation to the particular and that's why I'm not trying to suggest that we are seeking to -- put it another way: what I am seeking to do is to have these two individuals' circumstances properly investigated. It is perfectly understandable at a human level that that should be the case. It is

also, in my submission, a requirement of law that it happen and I invite this Inquiry to carry it out.

THE CHAIRMAN: Can I be absolutely clear as to the scope of this investigation? You say that these individuals are entitled to have their circumstances investigated. Does this relate to two particular points in time and the events of those points in time? Does it refer to the whole of the individuals' lives? Does it relate to the interaction between them and specific people? Does it relate to all interactions that bear upon their state of health? What is it you are actually asking me to do?

MR DI ROLLO: Specifically I'm asking you to investigate the circumstances in which those individuals became infected with Hepatitis C. By that I mean the decision to administer to them Scottish Factor VIII concentrate; in the case of patient A in May 1986 and in the case of patient B in January 1987.

THE CHAIRMAN: Yes. Mr Anderson, you have a clear interest in this matter. Mr Johnston, you may have also. Do you wish to make submissions either of you or both of you?

MR ANDERSON: I would welcome the opportunity to say something but I will try and make it brief.

THE CHAIRMAN: This is too important to restrict it by rules about brevity.

It's 11 o'clock and I don't know about the rest of

you but I could do with a short break. I don't want to refer to my age again but please remember that I have a need to survive this Inquiry. But please think about the procedural aspects of this during the break so that you can come back and let me know what you have to say.

(11.04 am)

(Short break)

(11.42 am)

THE CHAIRMAN: Have the logistics been worked out?

Submissions by MR ANDERSON

MR ANDERSON: I think I go and then Mr Johnston and then I think Ms Dunlop briefly, as I understand it.

THE CHAIRMAN: Okay.

MR ANDERSON: Sir, can I start by making comment on the case of Oyal, which, in my submission, provides no assistance for my learned friend, Mr Di Rollo.

The obligation upon the State is to provide an effective independent judicial analysis, and that is precisely what the Court of Session does, and precisely what is available to both patient A and patient B in relation to the actions that have been raised by them in the Court of Session.

THE CHAIRMAN: Does that necessarily solve the problem?

MR ANDERSON: It does in my submission because what my learned friend seeks to take from that case is that

patient A is entitled to an investigation of the circumstances of his infection and the state provides that investigation by way of the availability of an action in the Court of Session. Which, as it happens in his case and the case of patient B, have been raised.

Of course, they also require to be timeous investigations, but the reason that we have not reached fulfillment is simply that both actions have been sisted at the pursuer's instance. But both of those actions will provide a far fuller investigation than would be possible in the circumstances of this Inquiry, because parties will choose to lead such evidence as they wish.

It also provides, of course, for a remedy which is not available in this Inquiry. So the obligation of the state, in my submission, is entirely fulfilled by the availability of that action, which, as I say, provides a full, effective, independent judicial analysis of the circumstances of infection and furthermore, will provide, if successful, a remedy.

That, in my submission, is the short answer to such assistance as my learned friend seeks to draw from the Oyal case.

The reference to litigation is apt in my submission. You will see, sir, that at page 8, I think it is, of the application --

THE CHAIRMAN: This is the argument that it's not a relevant consideration?

MR ANDERSON: Absolutely. What is said:

"It is irrelevant that litigation may be contemplated or in existence. The matter, as succinctly set out in section 2 of the Inquiries Act ..."

And helpfully section 2 is set out in a footnote on page 8. It then goes on to suggest that:

"The only relevant consideration for the Inquiry is whether the questions are necessary for the proper and fair determination of its terms of reference."

In response to that, sir, I can say that I accept that clearly a relevant consideration for the Inquiry is whether the questions are necessary for the proper and fair determination; it does not follow from that, in my submission, that the existence of litigation is irrelevant.

THE CHAIRMAN: Yes.

MR ANDERSON: If one looks to the question set out on page 5, for example, these are very specific questions, which are entirely apt for litigation and precisely the sort of matters that one would expect to be covered in the context of a litigation.

THE CHAIRMAN: Of course, the focus can be very different. In litigation the questions would arise with reference

to a particular set of criteria, whereas in this sort of Inquiry, the questions may arise simply as matters of fact without reference to wider criteria, and indeed often as matters of impression that could have no bearing on litigation.

MR ANDERSON: It is, of course, true that in the context of a litigation, it will be necessary for the pursuer to have an independent expert report to support the allegations in the summons, and that the factual investigation is, of course, always seen against the background of the test for medical negligence.

So one can accept perhaps that the thrust may be different but nevertheless the investigation into the facts should be no different. And indeed, I would suggest, sir, that the investigation into the facts in any litigation would be likely to be far more comprehensive than would be appropriate in the context of a public Inquiry.

THE CHAIRMAN: Yes. Where the individual case is not made the focus of a specific term of reference, particular cases can only be contributions towards some much more general investigation, and I suppose that must be so.

MR ANDERSON: The other point, which I hope is worth making, is that it is in my submission inappropriate to use this Inquiry to assist litigation and in effect to seek to

precognosce on oath a material witness.

This, of course, is not to mention the other aspect, that counsel for the Inquiry alluded to, which is the very full investigation that would have to be undertaken but that, of course, brings us to the specifics and perhaps it might be more appropriate if I deal with the general questions first.

In relation to those, I think I'm generally content to adopt the observations made by counsel to the Inquiry. But if one has regard to the general questions that my learned friend Mr Di Rollo has concentrated upon, and those are numbers 5 to 7 over pages 2 to 3 of the application, I have to say, when I read the evidence on this topic last night, it appeared to me that these matters had essentially already been dealt with and I struggle to see what the remaining witnesses on this topic -- that is to say Dr Perry, who, of course, has a very discrete role in this matter, and the independent expert, Dr Colvin -- are likely to add to this.

So there does seem to be two points to be made in relation to the general questions: firstly, that as far as I can see, these matters have been dealt with and if they haven't been dealt with to my learned friend Mr Di Rollo's satisfaction, then it is not clear to me why such questions have not been asked, because as

I say, my impression is that these matters have been covered.

THE CHAIRMAN: Since clearly your document doesn't have the same pagination as mine, pages 2 and 3 you mention, questions 5 to 7, are they the questions:

"Whether during the period it would have been preferable for --

MR ANDERSON: That's number 5.

THE CHAIRMAN: That's 5. So it is that 5 to 7?

MR ANDERSON: Yes.

THE CHAIRMAN: I thought Mr Di Rollo had some points to make about the earlier questions too, especially question 4.

MR ANDERSON: This is where the specific and the general shade into each other in a way that is problematic. The difficulty is that there is a suggestion that in two cases in the whole of Scotland, the therapy that was given was, to use as neutral a term as I can, inappropriate and the conclusion that my learned friend seeks to draw from that is that that system has somehow broken down.

In my submission, that is a logical non sequitur and no doubt, sir, you may have seen the discussion that has already taken place in relation to this the last time, which prompted this application. I think at that stage I suggested that simply because the preferred treatment

in a particular case may be A, the fact that a treatment happens to be B does not lead necessarily to any inference that it's either the wrong treatment or that a system has broken down, let alone that any adverse inference can be drawn.

That is the problem in my submission with question 4. It supposes that, because of a particular circumstance, there is a logical conclusion from that that a system has broken down. In my submission that just does not follow; it's a logical non sequitur.

If I can deal with the specific questions, as it were, my learned friend's proposition, as I understand it, is that the terms of reference are broad enough -- was the way he put it -- to enable you, sir, to investigate into two specific instances, and if I may say so, to his credit he has been very candid in saying that what he is seeking is an investigation into the circumstances of two individual patients.

That immediately raises the question in my submission of the competency of that, because in my submission it is of dubious competency at very best and secondly it is simply not necessary.

My learned friend acknowledges that terms of reference use the word "generally", and one sees there:

"To examine the circumstances generally."

And if that were not explicit enough, the last two lines of the terms of reference would further demonstrate the character of the investigation contemplated, where we see that it is taking account of the development of scientific and clinical understanding and evidence internationally. When one reads the whole of terms of reference 5 together, it's very difficult to see how that encompasses an investigation into two specific situations.

Nor, in my submission, can it be properly suggested that it is necessary -- that it is necessary, sir, for you to investigate two specific circumstances to enable you to deal with the generality of the question.

THE CHAIRMAN: On the other hand, if one were able to confine the questioning to a rather narrow compass and ask what happened to patient A on such and such a date in -- goodness, I can't read my own writing: March, is it, 1986?

MR DI ROLLO: May.

THE CHAIRMAN: May 1986, what happened to him in May 1986. Was there in the Accident & Emergency book of instructions at that time a relevant set of instructions in how to deal with patients and did what happened fall within the scope of that or not? It might help one to work out the answer whether the prescription in the book

actually reflected the reality of what happened on the ground over that --

MR ANDERSON: If there is suggestion that that was a widespread problem -- and there is no suggestion, as I understand it, that it is a widespread problem -- then I might be prepared to accept that. But until it is suggested that there is a widespread problem and that the systems were not put in place or that there were no systems, then I have great difficulty, I have to say, sir, with the proposition that an investigation into one circumstance assists you in fulfilling term of reference 5, to examine the circumstances generally in which patients were treated by the NHS in Scotland.

So unless it's a very much broader problem than two individuals in the whole of Scotland, then I fail to see how it is of any assistance to you, sir.

THE CHAIRMAN: You and Mr Di Rollo may be making the same mistake as to the scope of outcomes of such investigation. One possibility is that there was a perfectly good system in operation, that it showed the application of clear thinking to finding solutions to problems such as those that arose but in the middle of the night, someone presents with a need for treatment, the choices practically were not open, a course was adopted and as a result someone became infected.

However, one can draw no general inference whatsoever adverse to the system. The system stands up.

So, Mr Anderson, the investigation of this could actually strengthen the position of the hospital service quite considerably for all I know.

MR ANDERSON: Well, that--

THE CHAIRMAN: I'm saying I do not know, I have no idea about the circumstances.

MR ANDERSON: That may be so but this application appears to be predicated upon the assertion that this happened on two occasions, full stop. It is not suggested that there was no system or --

THE CHAIRMAN: I know, but the terrible problem is that I have got to express an opinion on this one way or another, which is likely to have much wider implications than the two cases in point.

MR ANDERSON: And evidence has been led upon the systems without, as I understand it, any challenge to it. Whether that's the appropriate language to use in the context of an Inquiry may be doubtful but there has been evidence about the systems, and that's the problem for the applicant in my submission, because if it could be said, "We question the evidence that has been given thus far about the systems. The systems simply weren't working throughout Scotland", or, "Weren't working in

a particular hospital," or whatever, and there is ample evidence to suggest this, then that may well be something that would be apt for an examination of the circumstances generally. But that's very different in my submission to the situation that does obtain, where, as I say, my learned friend very frankly says, "I just want an investigation into how these two people became infected". That's all that he is saying and in my submission, that is not a matter for you that assists you or is likely to assist you to fulfil the terms of reference.

The terms of reference 8, which is also prayed in aid in my submission, although it does not use the word "generally", it does not do so because it is not necessary to do so. If one looks at the very width of those involved, those involved are the NHS in Scotland, including NHS boards and SNBTS, their officers and employees and associated agencies. And it deals with preventing the provision of infected blood and blood products.

The very width of the definition of those involved in my submission clearly demonstrates the character of the investigation that is contemplated.

So the answer in relation to the two specific circumstances that you are being urged to investigate,

in my submission lies within the terms of reference themselves. In my submission, it is of dubious competency at best and secondly it is simply not necessary to enable you, sir, to fulfil your obligations in terms of the terms of reference.

Other than that, I think I'm content to adopt counsel for the Inquiry's observations at the outset.

THE CHAIRMAN: Mr Johnston?

Submissions by MR JOHNSTON

MR JOHNSTON: Thank you, sir. I just have one observation to make in relation to the question regarding the particular patients and how those two individuals came to be infected. I shall say that the Scottish Government -- I don't have instructions either to oppose or to support this application.

What I would draw to the Inquiry's attention, however, is that given the marked contrast between terms of reference 6, which relates to specified individual deaths, and terms of reference that otherwise appear to be in general terms, there clearly is a serious question whether these matters fall within the existing terms of reference and if not, what can be done about that.

As you are well aware, of course, sir, the terms of reference were fixed by the cabinet secretary. One would expect, therefore, if they need to be amended or

extended, that should also be done by the cabinet secretary, who would need to report that to Parliament.

Given the desire not just of yourself, sir, but also of the cabinet secretary to have the report as soon as practicable, as we see in the 12th term of reference, I think one can anticipate that the cabinet secretary would want some detailed explanation from the Inquiry team or indeed from you, sir --

THE CHAIRMAN: It would have to be from me, I suspect, Mr Johnston.

MR JOHNSTON: -- as to why it would be necessary for this expansion of the terms to take place.

Those are the only points that I would wish to make unless I can clarify anything helpfully further.

THE CHAIRMAN: I understand your position very well. I have to say that the cabinet secretary assured me that I would not be subject to interference in the way I interpreted and applied these terms of reference, and I have had an open and unqualified remit to carry them out. So it's perfectly consistent with that that you shouldn't try to persuade me one way or the other, and I do thank the cabinet secretary for leaving me to it. I think it has been a great benefit to this Inquiry to have that.

I don't have in mind at the moment to apply for any

variation of the terms of reference.

MR JOHNSTON: Thank you, sir.

THE CHAIRMAN: Ms Dunlop, have you anything further to add?

Submissions by MS DUNLOP

MS DUNLOP: I would like to make one or two comments in response, sir, if I may.

THE CHAIRMAN: Yes.

MS DUNLOP: The first three points relate to the submissions that Mr Di Rollo made about the process of the Inquiry, if I can call it that. The first is to say that the approach which the Inquiry team has taken has not been in any sense a fishing approach. We have noticed decisions or events in the 17-year reference period, which one could perhaps query or probe, but in the absence of a suggestion that these affected an identifiable group of people, we haven't followed them all up. So we have adhered to a self-imposed stricture that prima facie there should be some evidence that a particular decision or a particular event affected some people, some patients, some individuals, before we have investigated it.

Very much in a related sense, I would say, secondly, that it was not apparent to me how the circumstances of these two patients differ from others who are known to the Inquiry team who say, for example, "I should not

have received a blood transfusion. I would like to know why I was given a blood transfusion. I didn't need one."

Or patients who would like an investigation of why they or their relative received a blood product. There was nothing in anything said by Mr Di Rollo that communicated to me why the circumstances of these patients are different. Therefore, the submissions he makes have very wide ramifications.

Thirdly, I am not aware of it ever having been said that selection as a core participant implied that the circumstances of that person's own infection would be investigated by the Inquiry. Indeed, I would submit that there is a lot to suggest the contrary, that it was not to imply that there would be any such individualised investigation.

Moving to the case that has been mentioned, Oyal v Turkey, I think the first point that concerns me is one of competence, that one wouldn't want to use the existing terms of reference as some sort of device to offer the conduct of an Article 2-compliant Inquiry to an individual; it would be greatly to be preferred, for the sake of all concerned, that the terms of reference say clearly that an Article 2-compliant Inquiry into the circumstances of an individual is required. And I have

some reservations, as indeed I think do you too, sir, about the competency of some sort of de facto amendment of the terms of reference to offer an Article 2-compliant Inquiry to particular individuals.

Secondly, I am uneasy at the limited exploration we have made of the jurisprudence in this area. Many people die in NHS care and there is a lot of law about what sort of enquiry should be made available to such individuals and what is required by way of a trigger before the procedural aspect of Article 2 is engaged.

I can perhaps mention -- and I apologise, this is rather on the hoof, but the Inner House decision in the case of Emms is a recent example of an examination of --

THE CHAIRMAN: It's not so recent, I think I actually have heard of it, notwithstanding my effective retirement.

MS DUNLOP: There is discussion in Emms of the sort of situation in which the Article 2 procedural requirement is engaged. The date of it is 28 January 2011.

THE CHAIRMAN: Then it's not the Emms I'm thinking of. Was there a previous stage --

MS DUNLOP: Yes, it was the Outer House decision but there is an Inner House decision as well.

I mention that simply to reinforce my unease at trying to decide what are really very difficult legal questions about the reach of the procedural aspect of

Article 2, with what I think we would all recognise are incomplete legal submissions.

That brings me to my next point.

My learned friend Mr Di Rollo referred to the medical mishap. I can see two candidates for that description and they are very different. I'm speaking now about patient A. One could characterise as the medical mishap the non-availability of 8Y, and if that's the medical mishap which we are to bear in mind, then that is being investigated. We are looking into that in some detail.

But if the medical mishap of which he is speaking is the use of a blood product when a blood product was not required, that's a very different category of event and it is one which does appear to be suited to civil litigation and indeed, as has already been observed, both patient A and patient B have ongoing actions in the Court of Session.

I also note that the section of the court's decision in Oyal which was discussed, which deals with the availability of an Article 2-compliant Inquiry for someone who is alive, refers at paragraph 55 to the application of Article 2 in exceptional circumstances, even if the victims had not died.

THE CHAIRMAN: Yes, I noticed that but I always worry about

exceptional circumstances in an opinion of the court which seems to have a flexibility that is unpredictable, let's say, in its outcome.

MS DUNLOP: Yes. I'm not sure what it means, is all I'm saying.

THE CHAIRMAN: It's certainly saying it is not to be assumed it is generally available.

MS DUNLOP: At first blush Article 2 and the procedural aspect of it would not apply in the circumstances of patients A and B. So perhaps one could simply say that there would be an onus on those who argue that it should to demonstrate why in these particular cases the Article 2 procedural requirement applies.

THE CHAIRMAN: I am quite concerned about the implications if Article 2 does apply. It seems to me that there is no logical point at which one could prevent individual investigations in an Inquiry such as this.

MS DUNLOP: Yes. I don't understand Mr Di Rollo to be saying that you have a duty, sir, to conduct Article 2-compliant enquiries into the circumstances of patients A and B.

THE CHAIRMAN: I think he stopped short of that.

MS DUNLOP: That would be one thing, but I don't think he is saying that. I think he is saying that you would have a discretion to do so. I suppose, either to solicit

some kind of amendment of the terms of reference to permit you to do so openly, or perhaps -- although as I said, I don't favour this -- to interpret the existing terms of reference generally and say that they permit an Article 2-compliant Inquiry into the circumstances of these individuals, but I have great difficulty in seeing a logical stopping point with these two patients.

I'm repeating myself now but there are many others. We have 160 statements or thereabouts. They don't all refer to individual cases. Some of them refer to the same patient, so we are not talking about 160 patients but on any view, a large number of individual sufferers from the two viruses with which the Inquiry is dealing. And if the Article 2 procedural requirement applies here, I really can't see why it wouldn't also apply to the many other people who have been sufficiently concerned to contact the Inquiry at all.

THE CHAIRMAN: Very well. Thank you all very much. I don't think this is an easy issue and I'm going to go and see whether I can reach conclusions on it immediately or whether I have to consider it further.

MR ANDERSON: I wonder, sir, if I might, with some hesitation, raise one other matter and explain why I raise it at this point.

You will remember, sir, that Dr Colvin went through

his evidence-in-chief, if I can put it this way, at something of a canter and afterwards the question arose as to whether he should be asked to return or whether he would be able to deal with questions in writing. Those instructing me have recently intimated questions that they would wish to put to Dr Colvin, which I have to accept are very largely -- there are about a dozen of them or so. I suspect you may not have seen them. And I have to accept that most of them do not relate to the topic C3A which he was discussing when he was last here in October.

The purpose of those questions is quite simply this, that whereas the performance of the fractionation centre and the SNBTS has been the comment of various independent experts from furth of Scotland, there has been no similar evidence led in relation to the performance of the various clinicians.

When this was raised with the Inquiry team, it was suggested by those instructing me that Professor Mannucci might be an appropriate witness but that did not gain any favour with the Inquiry team, as I understand it.

In an email from the solicitor to the Inquiry on 20 September, it was intimated that Professor Mannucci was not to be entertained but that as Professor --

I can't remember if it was professor or doctor -- Professor Colvin was returning in October, that would be an opportunity to deal with matters with him.

We didn't appreciate until very recently that Professor Colvin was going to appear tomorrow. I think we only learned that some time late last week. So these questions do come rather soon, I appreciate, beforehand.

The reason that I raise it now is simply that we have a late start tomorrow. We have two witnesses and rather than take up time tomorrow, it seemed appropriate that I should raise this with you and I think you have previously suggested that such matters should be dealt with in open session rather than in chambers, as it were.

So the second reason I raise this is that I understand that those instructing me have received an email today simply commenting upon the questions and observing that the majority do not deal with topic C3A, and that in those circumstances it might be appropriate to raise the matter with yourself, sir.

So that is what I'm doing and I apologise if you think it's inappropriate but, as I say, it seemed to be better to deal with this now rather than wait until tomorrow and deal with it then, when there may be a shortage of time, and we don't want the same thing

happening to Professor Colvin as happened the last time.

MR DI ROLLO: Sir, can I just say that we haven't seen these questions, therefore I'm not in a position to give any indication --

THE CHAIRMAN: Have you seen them, Ms Dunlop?

MS DUNLOP: I have seen many, many questions, sir. There is a huge list of questions from Mr Di Rollo and his team for Professor Colvin. I have also seen the list of questions from Mr Anderson, which is not nearly as numerous but far more wide-ranging in its subject matter.

Perhaps, sir, can I suggest that we reconvene after whatever time is most appropriate for you, and in that interval I will try and clarify whether Mr Anderson and his team have been given an understanding that tomorrow, with Professor Colvin, was to be a more general questioning, rather than simply topic C3A.

It's certainly our understanding that Professor Colvin's return tomorrow is to deal with C3A and C3A only. That's also Professor Colvin's understanding.

THE CHAIRMAN: Well, I'll give you the opportunity to have a discussion. I have to say that a black cloud is falling fast over my head.

(12.18 pm)

(The short adjournment)

(2.30 pm)

RULING

THE CHAIRMAN: Sorry to have kept you all waiting but it was pressed on me that there were practical advantages if I could dispose of the matter.

So, further questioning of Professor Ludlam in connection with the circumstances surrounding the infection with HCV of patients A and B has been proposed. So far as material for present purposes, terms of reference 5 requires the examination of the circumstances generally in which NHS patients treated in Scotland became infected with HCV through the use of blood products.

A limited period, from December 1984 to April 1987, has been identified as raising specific issues that are material to this term of reference. They relate generally to the continued use in Scotland of Factor VIII concentrate that can be assumed for the purposes of argument to have been effectively heat-treated against transmission of HIV but which continued to transmit HCV infection in the source plasma from which they were prepared, notwithstanding the degree and period of heat treatment to which they were subjected in the course of processing.

There is in my view ample evidence from which it could be concluded that some PFC Factor VIII concentrate did transmit HCV infection up until the NY product, in its several developments, was superseded by the product Z8.

That was because the degree of heating and the duration of the heat treatment process were not adequate to kill HCV, and any virus in the product would have survived manufacture and indeed survive to the point of infusion.

The research and development work carried out in Scotland over the material period has been extensively examined, in particular in the evidence of Dr Foster, Dr Cuthbertson, Dr Perry and others in Scotland, and of Dr Smith from BPL/PFL in England. There is ample evidence from which a comprehensive account of that work can be constructed and from which one can identify critical stages in it, pinpointing the points, the stages at which PFC move towards production of a Hepatitis C virus-free product.

Over the same period, research and development work in England led to the development of 8Y, a Factor VIII preparation that was effectively heat-treated against transmission of HCV. Again, the evidence already led is sufficient to instruct an account of that process and to

identify the critical stages in bringing the product into regular clinical use.

The availability of 8Y in Scotland has already been considered in part. It is to be explored further in the evidence of Dr Perry and Dr Colvin. There is documentary evidence of the official policy of the BTS in England and Wales, and of BPL as manufacturer, relating to the distribution of the product for regular clinical use and of its distribution for clinical trial purposes. This evidence is not necessarily complete at this stage but, subject to developments and leaving aside the issue of clinical trial, there is material that suggests that the product was available for distribution in England, Wales and Northern Ireland on a pro rata basis according to the volume of plasma supplied to BPL.

That was not a policy devised for the purposes of dealing with 8Y; it was established from 1 April 1981 by agreement between the regional transfusion centres in BPL and it was applied to 8Y in July 1985, when the distribution of that product became a practical reality.

The exception to that scheme that was recognised, and the only published exception, related to its use for clinical trial purposes. And it is not in dispute that a small quantity of the product was sent to Scotland by

Dr Smith for that purpose.

The series of documents that Dr Smith sent with the product make it abundantly clear that the purpose was that, namely for clinical trial, which implies not just the selection of patients but the whole procedural requirements surrounding the protocol that dictated its use.

It is not in dispute that Dr Ludlam misused that product in the sense that he applied it in an irregular manner outwith the scope of the trial protocol, which he effectively ignored. Equally, it is not in dispute that at a later point Dr Ludlam obtained a small quantity from Dr Jones in Newcastle on a personal basis, and issues may arise with Dr Colvin or with Dr Perry about those particular transactions. What is abundantly clear is that neither of them can point to any general availability of the product for use in Scotland and each of them, only to a limited extent the first, can be brought within the specific terms of the circular I have referred to.

In my view Dr Ludlam's involvement with 8Y has been adequately explored. It will be for Dr Perry to give evidence on the circumstances in which Dr Ludlam's original request for a large volume of 8Y was not pursued and to answer other questions relating to the

availability of that product in Scotland. Dr Colvin can be expected to give evidence on the supply position in England and Wales and so I shall not allow further questioning of Dr Ludlam on topic 6 and 7 in the application, or on any of the particular questions relating to those topics set out in the body of the application.

Still moving backwards, topic 5 is whether during the material period, it would have been preferable for previously untreated Scottish patients to be given treatment with products other than SNBTS Factor VIII concentrate. Again, I consider there is ample evidence on which findings and fact can be made to evaluate (a) the comparative benefits of SNBTS Factor VIII and imported commercial products, (b) the considerations affecting the use of DDAVP, cryoprecipitate, SNBTS Factor VIII and, for that matter, the comparative advantages of using SNBTS Factor VIII and 8Y, if 8Y was available generally.

I suspect that while the topic is drawn without restriction, the last point of comparison is what is thought is material. I do not consider it necessary to ask Dr Ludlam again whether he thought 8Y to be a superior product. He clearly thought so and sought supplies for treatment of his patients on that basis.

Questions 1 to 4 are again drawn in terms of such generality that it is difficult to be confident that they can be dealt with in a summary fashion. However, I have come to the view that the preferred courses of treatment of previously untreated patients have been explored adequately at an appropriate level of generality. The recommendations of the UKHCDO, promulgated from time to time, have been examined and there is ample evidence that they were adopted as the basis for practice in Scotland. Those recommendations left the ultimate clinical decision to the practitioner in charge of treatment at the time. Those circumstances are almost infinity variable and clinical judgment is required to take account of them.

The second topic, which seeks a comprehensive account of the circumstances in which SNBTS Factor VIII "should" have been given to a previously untreated patient, is so wide as to be impossible of rational answer. The scope of the evidence would be impossible properly to control.

The third topic, if one can ignore its rather tendentious terminology, is dependent on the answer to the second, as is the fourth. As generalities, none of these topics in my view need be explored further.

It is contended, however, that the circumstances of

two patients should be explored particularly as having a bearing on the general issues. Despite Mr Di Rollo's careful argument, I'm unable to distinguish these two patients from the much larger group of which they appear to be part. That number has been suggested as 31, if one counts only previously untreated patients, first treated in Scotland in the material period. But in fact the number is open-ended.

The actual number may be less, since one does not at this stage know how many of the 31 were infected in that period, and on the other hand it may not include all potential candidates from cohorts who are treated or may have been treated with English product, foreign products, cryoprecipitate, DDAVP et cetera, in the past.

Whatever the precise number, there is necessarily a large cohort of individuals, each of whom has an interest similar if not identical to patients A and B, and all of whom would have a claim to have their cases heard individually at this Inquiry on the basis of the argument I have heard.

The issue is one of general application, notwithstanding Mr Di Rollo's argument and notwithstanding the fact that he represents two only among the many who might advance this point.

The terms of reference distinguish those cases in

which individual enquiry is instructed. Terms of reference 5 is particularly and deliberately drawn in terms of generality. It should not be forgotten that the chairman of an Inquiry such as this does have input into the terms of reference and avoiding a proliferation of mini inquiries into individual circumstances was an important consideration in this case.

Terms of reference 8 is similarly carefully drawn. It is concerned with steps taken to prevent provision of infected products, for example to prevent the provision of imported products into a country committed to self-sufficiency. It is not concerned with clinical management of patients. Neither term of reference on which reliance has been placed covers the investigation of particular patients' cases in my view.

Other means do exist for the exploration of these patients' cases. One can understand their wish to use every means open to them to get answers to their own particular questions. This is not however, a ditch I came to cross, non haec in foedera veni. I shall not allow Dr Ludlam to be recalled to deal with these topics.

I was referred to Oyal. I should say that I have come to the conclusion that this is not the right forum to dispose of the human rights issues said to arise from

that case. That is a matter, if it is to be raised, that should be raised elsewhere.

Where do we go?

MS DUNLOP: Well, sir, the remaining matter is the two sets of questions for Professor Colvin and your decision does, I think, have implications for the questions which the patient family and Haemophilia Society team can put to Professor Colvin.

I don't know whether it might be better just to leave that until tomorrow. I'm in your hands, sir. I'm happy to discuss with Mr Di Rollo how far the questions can go and to point out which ones I see as problematic. Alternatively a revised list can be prepared and then there is the quite separate matter of Mr Anderson's list of questions, which are very wide ranging.

THE CHAIRMAN: I'm a little bit anxious that today should not be unused, if I can put it that way, if some benefit can be obtained from discussing matters further.

I don't want to press it too far but I think tomorrow looks like being quite busy anyway.

MS DUNLOP: Yes.

THE CHAIRMAN: And I would have thought it preferable if discussions could take place, to see whether there is any narrowing of the range or whether there is any modification of the scope of questioning.

MS DUNLOP: Could we perhaps reconvene at 3 o'clock?
THE CHAIRMAN: Let's do that. I think that's a very good idea.
(2.44 pm)
(Short adjournment)
(3.09 pm)
THE CHAIRMAN: Yes, Ms Dunlop?
MS DUNLOP: I have had the opportunity to discuss matters with Mr Di Rollo and I have pointed out the questions that I think might be awkward and he is going to reconsider those questions, and I don't envisage any particular difficulties in that regard and with Mr Anderson's questions, it is the case that --
THE CHAIRMAN: I love them. Do you think Mr Anderson has been taking lessons in leading questions?
MR DI ROLLO: Excuse, I haven't seen these questions.
THE CHAIRMAN: You should certainly see them. I'm sure, Mr Di Rollo, you will enjoy propositions that run for several lines and end up with "Do you agree?"
MR DI ROLLO: Well, I thought I had been listening to questions like that since March, but there we are.
THE CHAIRMAN: You now know what the response could be. How are we going to solve it, Ms Dunlop?
MS DUNLOP: Well, I'm going to try to avoid any digs at any of my colleagues, sir. I can say that as a ground rule,

and in relation to the actual issue which is before you, questions 1 and 6 --

THE CHAIRMAN: Sorry, the prior question is Mr Di Rollo's.

MS DUNLOP: It has not been our practice to circulate questions submitted by core participants to other core participants. On several occasions we have been specifically asked to treat the questions as not for circulation and we have honoured that request. Circulating the questions as a practice, I think, would cause all sorts of new difficulties.

THE CHAIRMAN: Yes.

MS DUNLOP: Having said that, if Mr Di Rollo feels hugely disadvantaged by not having a set of the questions, please allow me to pass a set over right now. (Handed)

MR DI ROLLO: I can't really participate in the discussion without having seen the questions. I think that would be reasonable.

MS DUNLOP: I hadn't appreciated this was to be a three-way discussion.

THE CHAIRMAN: I think if you leave it to me to make points against individuals and not score points off each other, it might be better.

MS DUNLOP: Yes.

THE CHAIRMAN: You know you can't restrain me from doing it but ...

MS DUNLOP: Thank you, sir. I'm sorry, I was a little thrown by reference to the Inquiry having been conducted as a series of leading questions having been put to witnesses since March. That's not how I see things.

THE CHAIRMAN: I thought Mr Di Rollo was talking about himself.

MS DUNLOP: Anyway.

Question 1 appears to relate to the period covered by C3A and question 7 likewise. That appears to fall within the period we are discussing, and question 8 similarly. But the remaining questions do not appear to me to fall within our topic C3A. It was for that reason that we indicated that we didn't think that we could simply agree to their being posed and that the matter should be raised before you, sir.

THE CHAIRMAN: Right. Mr Anderson, I think that it puts the ball in your court.

MR ANDERSON: Yes.

Submissions by MR ANDERSON

MR ANDERSON: I don't know, of course, if you have seen these questions or not.

THE CHAIRMAN: Pardon?

MR ANDERSON: I suspect you have from the comment that you have just made.

THE CHAIRMAN: Yes.

MR ANDERSON: There are indeed 11 and I'm in agreement that three of them fall squarely within the topic of C3A and that the others do not. Perhaps I should simply explain to you, sir, why in my submission, notwithstanding that they fall outwith that topic, they would be helpful to the Inquiry.

This matter does have something of a long history. Almost two years ago in early 2010, there were discussions between the Inquiry team, or its solicitor, and those instructing me about the possibility of Professor Mannucci being instructed as an expert witness. And there have been discussions on and off since then. It was not until September of this year that those instructing me were told unequivocally that Professor Mannucci was not to be instructed, and what was said was:

"Likewise with Professor Mannucci, it is not considered that he can add materially to the expert evidence already available to the Inquiry. Haemophilia experts from outwith Scotland have included Professor Colvin, who returns in October."

Sir, rightly or wrongly, those instructing me took some comfort from that and thought that it might be appropriate to put to Professor Colvin as an independent expert furth of Scotland, the sort of questions that

they would have wished to have put to Dr Colvin [sic - Professor Mannucci]. Dr Colvin is someone who is well placed to answer these questions because he does have an intimate knowledge of the situation in Scotland and it would, of course, involve no further expense as far as the Inquiry is concerned.

THE CHAIRMAN: I don't know about that. It depends how long he would be here and how often he would have to come back.

You know, I don't know that I could make a decision on the basis of an assurance that it wouldn't cost any more. I don't know whether he charges by the question or whatever, Mr Anderson, but one would assume that time comes into it.

MR ANDERSON: Of course time comes into it, sir. I don't pray it in aid as the most material or compelling of reasons but simply it's a matter because, as Mr Di Rollo mentioned today, it's one of the factors to be taken into account by you, sir, in considering what evidence you wish to hear.

THE CHAIRMAN: That is so.

MR ANDERSON: The reason that it is put forward quite simply is because the clinicians themselves feel very strongly about this, that there has been examination in relation to the performance of SNBTS from outwith Scotland and

yet there has been no examination whatever of the performance of the clinicians.

So it is submitted that it would be of assistance to you but indeed it goes beyond that because if the test, as we have heard enunciated this morning, is one of necessity, then in my submission it is necessary. This is not evidence that would be in amplification or in corroboration or whatever; this would fill a gap, in my submission, because there has been no evidence and no witness has been led to deal with the sort of questions that one would wish to put to Dr Colvin.

THE CHAIRMAN: Give me an example.

MR ANDERSON: I'm sorry?

THE CHAIRMAN: Give me an example of what you have in mind. Let's take one of your questions and tell me what it implies.

MR ANDERSON: Do you have one in mind, particularly?

THE CHAIRMAN: I'm asking you because it's you who have to help me in this matter, Mr Anderson. Remember, I'm no more here to comfort individual clinicians than I am to deal with individual patients. Generality is what I'm after.

MR ANDERSON: I well appreciate that and I thought that I had adequately explained that what these questions are designed to elicit is some appraisal of the performance

of the clinicians during the periods which are set out in the individual questions.

THE CHAIRMAN: Put that way, it can only be individual clinician's activities that are in question. Why on earth should I entertain that when I have just made it clear that I do not consider this Inquiry is dealing with particulars of that kind in relation to patients?

MR ANDERSON: Because, with respect, sir, what it is designed for is not, in essence, particulars of any particular decision by any particular clinician; it is aimed to look at the general practice of the clinicians. It is aimed to look at their performance in general terms.

THE CHAIRMAN: But am I looking at the right document? Is this questions for Professor Brian Colvin?

MR ANDERSON: Yes.

THE CHAIRMAN: Starting with:

"The Inquiry has heard evidence ..."

Could you take one of them, please, and do as I have asked and illustrate for me just what it is you see happening in fact. Some of them are pretty obvious:

"In your statement can you confirm that your answer to question 2 is clearly hypothetical?"

And so on. I can actually follow that question. But give me one.

MR ANDERSON: Take question 5, for example. This is an attempt to put the performance of clinicians in an international context because one of the concerns has all along been that there is no attempt in this Inquiry to put anything in an international context as far as the clinicians are concerned, as opposed, for example, to the performance of the SNBTS, where we have heard from witnesses abroad as to, firstly what happened in other countries and, secondly a comparison and an evaluation of the performance of the SNBTS.

There is no such attempt been made to deal with such matters as regards the clinicians. So if one looks at question 5, for example --

THE CHAIRMAN: Let's look at question 4, which determines what question 5 means. We have got an advice sheet referred to. It says that:

"Everybody should wear condoms."

And things of that kind. Then the question:

"Was that advice and the advice seen in these documents an appropriate, adequate, timely response?"

Now, where does that lead?

MR ANDERSON: Well, it may assist you, given that no other witness has spoken to these matters and there has been no evaluation of those actions, to form a view, to put that view in context.

As I say, one of the matters that has troubled those instructing me from an early stage is the failure to put matters in any form of international context. That was a matter that was raised when the draft topics were intimated, and one of the responses to those draft topics was in precisely those terms and this is an attempt to address what is perceived as a problem in that regard.

THE CHAIRMAN: With the greatest respect, it simply seeks to compare what you say happened in Scotland with what happened in England and Wales, but the background to it is a reference to Mannucci. I am afraid you lose me somewhere along the line, Mr Anderson.

MR ANDERSON: Well, these were drafted after it was known that Professor Mannucci would not be available and therefore the question as to how such information was disseminated in England and Wales seemed a sensible one to ask Professor Colvin, who practised in London but who also, as I say, had intimate knowledge of the Scottish situation.

He, for example, it was, who carried out the audit on the performance of Glasgow Royal Infirmary. So he would be someone who would be, we hope, well able to answer such questions. We do not know, we haven't been in touch with him clearly because he is not our witness,

he is an independent witness, so no contact has been made with him. So strictly we don't know the answer to these questions but we know that he is in a position to be able to answer them.

As I say, I return to the proposition that what is set out here is an attempt to be of assistance to you and because it is perceived as being necessary. And if that is the test, in my submission and in the absence of any other witness to speak to such matters, that is the reason for them. But I accept, sir, that it's always a matter for you and I don't think I have anything further to add.

THE CHAIRMAN: Question 6 says:

"It appears that the decision when to tell certain parents of their HTLV-III positive status was individualised, made on a patient to patient basis, depending on that patient's particular circumstances. Was that reasonable?"

That's what happened in December, was it?

MR ANDERSON: I think it's over a longer period than that, as I recall, sir.

THE CHAIRMAN: Yes. But we know that there was a meeting in December which doesn't actually fit the proposition there, does it?

MR ANDERSON: In my respectful submission, it does. No one

was told at that meeting of their status at all. My recollection is quite clearly that they were told to make enquiries and thereafter letters were sent out from Glasgow and from Edinburgh. I think the Edinburgh letter, which is thought to be dated 31 December, cannot be found. We know we have the one from Glasgow, which was dated 8 January but there was no intimation to anyone at that meeting, as I recall, as to their status, whether they were infected or not.

THE CHAIRMAN: Question 9. Do we have the audit?

MR ANDERSON: The audits can be made available, yes.

THE CHAIRMAN: But we don't have them?

MR ANDERSON: The difficulty in these circumstances very often is that there is a reluctance to put them in the court book but they can be made available. It's up to Inquiry counsel whether they think it's necessary for them to be put in the court book or not.

THE CHAIRMAN: Ms Dunlop, what do you have to say about this?

Submissions by MS DUNLOP

MS DUNLOP: I'm very surprised, sir, at the suggestion that there has been no attempt to put matters in an international context. Throughout this Inquiry we have looked at articles from all over the world. Only last week we were looking at articles about screening of

donated blood for Hepatitis C from Spain, from Germany and from the Netherlands. We have considered the proceedings of international conferences, held in a number of different countries. We have looked at the workings of the Council of Europe. In short, whenever there has been an international contribution to haemophilia treatment in Scotland, we have looked at it.

The topic-based approach which we have followed in our examination of the evidence, has been known since the outset. In relation to topic B2, we heard from Dr Winter, who was the haemophilia clinician practising in England. In B3 we heard from Dr Smith and Professor van Aken. B4 and C4 were covered by Professor Leikola. B5 has been covered by Dr Nathanson from the British Medical Association, who is, therefore, giving evidence about the position beyond Scotland, and she has provided a report to similar effect for topic C5.

The C topics, we have had Professor Leikola talking on C2. C3A, we have Dr Colvin. C3, we have Dr Smith and Professor van Aken. We have made, I would submit, considerable use of evidence of what happened beyond Scotland. I don't completely understand what sort of exercise is said to be missing from our work and it seems to me that the exercise of bringing someone from

another country, whether Italy or England, and asking a number of extremely generalised questions about whether he or she agrees with what happened in Britain, is so broadly based as to be meaningless and therefore of very little assistance to you.

In this I think I'm essentially just repeating to you what you said yourself, sir, about the appraisal of individual clinicians, which would be required before this would become a meaningful exercise, that one would have to go through particular steps that were taken and ask for this external commentator's view of them.

It has not been suggested actually until yesterday that Dr Colvin should be asked a series of questions which all generally seemed to relate to haemophilia treatment. It was not suggested before Dr Colvin's last appearance, when one might have expected that some sort of notification of this proposed role for him might have been given.

I think I can only say in conclusion that some sort of structured approach to the evidence at the hearings in this Inquiry has been absolutely essential, and for it to break down now and ask to have some witness and just ask a series of questions relating to anything at all, provided it's covered by the terms of reference, would run completely contrary to the methodology that we

have used.

I don't see the gap and I don't see that we should be going down this route with Professor Colvin.

THE CHAIRMAN: What about Professor Mannucci? What is it you understand Mr Anderson seeks to get from him?

MS DUNLOP: I don't really understand that either, sir. It had been our anticipation that a special application was going to be made in relation to Professor Mannucci, and that not having been done, we rather thought Professor Mannucci had disappeared from the proceedings of the Inquiry. It now seems as though Professor Colvin is, in some sense, a substitute for Professor Mannucci.

I think what I'm saying would really apply to any attempt to bring Professor Mannucci as well. I don't really see how it would work. One would have, I suppose, to give him a very great deal of information about aspects of haemophilia care in Scotland and ask for his opinion about that.

I suppose, just plucked at random, an area which is particularly controversial is the giving of information to the patients at Edinburgh Royal Infirmary. So I suppose one can imagine one would brief Professor Mannucci on the whole story of the testing of the patients in the autumn of 1984, the arranging of the meeting at Edinburgh Royal Infirmary and so on, and then

ask him what he thinks. But I am unconvinced of the value of that sort of step.

I think I also would say that in my submission the sort of work that I'm describing -- of looking at articles from all over the world, the proceedings of international conferences, the workings of the Council of Europe, the views of the BMA and so on -- is far more valuable than bringing along one person from another country and asking a series of questions and checking that he agrees with various propositions. I don't really see that as adding to the material which is before you, sir.

THE CHAIRMAN: Yes.

MS DUNLOP: Thank you.

THE CHAIRMAN: Have you got any interest in this, Mr Johnston?

MR JOHNSTON: No, sir, I don't have any views to express.

THE CHAIRMAN: Have you, Mr Di Rollo?

MR DI ROLLO: All I would say is that I agree with the remarks of counsel to the Inquiry and adopt them.

RULING

THE CHAIRMAN: I think I should say, Mr Anderson, that my request of you to give me some particulars as to how this was worked out was not idle. I find it very difficult in some of these topics to understand just

where I would be taken. I'm very apprehensive that I should not allow myself in any circumstances to be led into the dark by any party at this stage in the proceedings.

The defence of individual clinicians, which seems to be implicit in what you have said, is not a matter for this Inquiry any more than the infection of particular patients is. I have got a lot of evidence of a general nature on which I think it will be possible to make sensible findings in fact, that cover the topics that I have to deal with.

Question 7:

"You published a paper entitled 'Heat-treated NHS Concentrate in the UK: A Preliminary Study'. Did you understand the position to be any different in Scotland?"

The answer is no, it was published here the same as it was in England.

I'm not just being nasty about it. The fact is the propositions that are here, to many of which general consent is sought, do not help me to know what it is that I'm asked to authorise. And so my decision has to be that so far as tomorrow is concerned, questions of Professor Colvin will be restricted to topic C3A.

Does that exhaust today's business?

MS DUNLOP: I think so, sir.

(3.34 pm)

(The Inquiry adjourned until 11.30 am the following day)

I N D E X