Friday, 28 March 2012

(9.30 am)

(Proceedings delayed)

(10.05 am)

THE CHAIRMAN: Good morning.

Mr Di Rollo, you have to begin?

Submissions by MR DI ROLLO

MR DI ROLLO: Thank you, sir. I think the first thing that I have to do is to say something about our approach to written submissions.

As requested, by you, sir, we were required to make written submissions which were to be with the Inquiry on Monday of this week.

We have made substantive submissions in relation to most of the topics covered in the public hearings, starting with the four deaths.

In relation to these, the submissions used the model of a determination under the Fatal Accidents and Sudden Deaths Inquiry (Scotland) Act 1976. In relation to the other topics, we have followed the structure set out by you, sir, at the hearing on 30 October 2011.

The documents have been placed in court book and I should indicate the numbers, I think, so that they can be accessed from the transcript.

Our submission in respect of the four deaths: first

of all, [PEN0190773] is the Reverend David Black; [PEN0190777], Mr Laing; [PEN0190779], Mrs O'Hara and [PEN0190783], Mr Tamburrini.

The list of issues for the patient interests is [PEN0190806]. And our submissions in respect of those are, in respect of B1, [PEN0190466], B2, [PEN0190476], B4, [PEN0190552], B5 [PEN0190571], B6, [PEN0190593], C1, [PEN0190600], C2, [PEN0190605]. C3A, [PEN0190657], C4, [PEN0190712], C5, [PEN0190742] and C6, [PEN0190761].

Sir, we have attempted to answer the questions posed in our issues. We have, of course, done so from the perspective of patients, relatives and the Haemophilia Society. What is stated is intended to provide the Inquiry with a point of view in relation to the evidence on these topics.

We have tried to be as thorough as we possibly can taking into account all of the material made available. Throughout, we have tried to support what is stated with references to the testimonies, statements and documents. We very much hope that the Inquiry will find our submissions of assistance in the preparation of the final report.

There are three topics in relation to which we have not made a submission. These are statistics and the two viral inactivation topics, B3 and C3.

Statistics is a topic that we would wish an opportunity to make a submission on once the Inquiry has made available all the material which will form the basis of its analysis.

In relation to B3 and C3, what I would like to say is that it is of course in everyone's interests that term of reference 12, "to report as soon as practicable", is observed. We understand the need for a tight deadline for the production of submissions by the core participants, and as the deadline for submissions approached, we concentrated our efforts on certain areas of particular concern.

I took the decision that it was not necessary to put in a response in relation to C3 and B3, having regard to the absence of any real controversy in the evidence on these topics during the public hearings. We have posed certain questions in the issues lodged by us, and I hope these provide an indication of some of the points to be considered by the Inquiry in the final report.

Before finishing, in relation to our submissions, I think now would be an appropriate point, for my part, and I think on behalf of the other core participants, to thank the very exceptionally helpful treatment we have received from those in charge of the documents, Neil, Oliver and Keith, and also from the secretary and deputy

secretary of the Inquiry team, Maria and Sarah, and also Margaret who looked after the witnesses. I would also like to thank, on behalf of the core participants, our stenographers, Stuart and Catherine.

Thank you, sir.

THE CHAIRMAN: Yes, Mr Anderson?

Submissions by MR ANDERSON

MR ANDERSON: Yes, sir. In relation to the submissions, you will be aware that I represent the interests of both the SNBTS and also the Scottish health boards who, of course, employed the haemophilia clinicians at the relevant time.

You will also be aware that, although I have had the excellent support of the solicitors from the Central Legal Office, I don't have a junior counsel. So the submissions, as you will no doubt appreciate, have been divided up.

I have been responsible for drafting those submissions on behalf the health boards and a couple of those on behalf of the SNBTS. The others within the SNBTS have been the work of individuals within that organisation and have been vetted and revised by the legal representatives.

The approach taken to the submissions was not to answer every question posed by every core participant

but rather to seek to concentrate upon those areas where it was felt that there was the potential for some controversy, and in this regard we have taken the lead, largely but not exclusively, from the questions posed by Inquiry counsel and sought to answer those in a way that it is hoped will be of assistance to you in determining the final report.

I would simply seek to associate myself with the sentiments expressed by my learned friend Mr Di Rollo in thanking all those concerned.

THE CHAIRMAN: Mr Johnston?

MR JOHNSTON: Thank you, sir.

The Scottish Government submissions appear at [PEN0190274].

THE CHAIRMAN: Mr Johnston, excuse me just a moment. It has been drawn to my attention that Mr Anderson has not followed the practice of reading in the numbers, and that might be helpful, as Mr Di Rollo has done, in order that people can link through to them. I am sorry for interrupting you but we should get all of those.

MR ANDERSON: My apologies, sir. All the documents have the preface "PEN019".

The introduction is [PEN0190355], issue one is [PEN0190360], issue 2 is [PEN0190401], issue 3 and issue 4 are [PEN0190428]. Issue 5 is [PEN0190439]. Issue 6

is [PEN0190447] and the methodology of the collective response is [PEN0190454]. And finally the list of issues is [PEN0190805].

Submissions by MR JOHNSTON

THE CHAIRMAN: Mr Johnston, if I can start you afresh.

MR JOHNSTON: Thank you, sir.

I'll just repeat what I said, which is that the Scottish Government submissions appear at [PEN0190274].

In the written submissions the Government does not attempt to address every issue raised by the Inquiry team but it does try to cover all of those that particular affect the government as a core participant.

So for that reason, the introduction deals with the administrative structures that were in place for obtaining advice and formulating policy and guidance, and for providing the necessary resources to the Scottish National Blood Transfusion Service.

In addition, the introduction deals with the standard of scrutiny that it is thought appropriate for reviewing decision decisions that were taken in the reference period for the Inquiry.

So far as the specific topics that have been investigated are concerned, the Government submissions follow the order of the topics which the Inquiry team identified. Here, they don't attempt to grapple with

the difficult issues of science and medicine, or to enter into questions that are thought to be properly matters between doctor and patient, but rather they focus on issues that particularly affect the Government, such as the provision of necessary support and resources for the blood transfusion service and the way in which policy was formulated and communicated.

So I hope, beyond that, the submissions can speak for themselves, and I would simply like also to associate ourselves with the thanks that Mr Di Rollo expressed earlier.

THE CHAIRMAN: And you have a single document that you have given the reference number for?

MR JOHNSTON: Yes, that's correct.

THE CHAIRMAN: Thank you very much.

Mr Di Rollo, we move to the second phase of today's business, when you have the opportunity to make a closing statement.

Submissions by MR DI ROLLO

MR DI ROLLO: Thank you, sir.

On behalf of the patient and relative core participants and on behalf the Haemophilia Society, I would like to make some remarks at the conclusion of the public hearing phase of this Inquiry.

The fist matter I would like to address is the need

for this process. The process that we have been engaged in is designed to provide answers to questions concerning a very complicated series of events that occurred over many years from at least 1974 right up until the present day.

Countless hours have been devoted to considering a truly awesome quantity of material. There should be no doubt that you, sir, and your brilliant team fully understand the importance of this process to the many thousands of people whose lives have been deeply affected, either by the loss of a loved one or in so many other ways by the twin tragedies of infection with Human Immunodeficiency Virus and the Hepatitis C virus as a result of treatment with blood or blood products by the NHS in Scotland.

Those lives include not just the patients and their families but also the many dedicated professionals responsible for all aspects of the blood transfusion service and for the treatment of patients throughout the period. This last aspect is perhaps more apparent after the public hearings than it was before.

It is axiomatic that twin disasters such as HIV and the Hepatitis C, as traumatic and far reaching as they are, should be the subject of some form of official public Inquiry. It is a pity that, because of the

surprising and disappointing failure by Government until now to appreciate the need for a detailed official public examination of the facts, evidence has been lost, witnesses have died and memories have faded.

On the other hand, it is still possible to reconstruct a great deal from the testimonies and documents that are available, and it is clear from the material that some of the key players appreciated the likelihood that a retrospective would one day be necessary and so recorded and made available much information with that in mind.

The Inquiry has investigated a number of topics in the course of this phase and the final report will hopefully contain many of the answers sought.

Some of the answers are relatively straightforward but nonetheless need to be set out with clarity. Some answers are more complicated, although not necessarily controversial, and it is to be hoped that it will be possible to explain these matters in a way that is accessible and comprehensible to the layman.

An attempt has to be made to answer more controversial issues. It is inevitable that at the end of the process, with the best will in the world, it may not be possible to provide a complete answer to all of the questions. But even the exercise of narrating that

state of affairs in relation to such questions has a value for those involved.

I have referred to the disasters of HIV and Hepatitis C as "twins", but they are not identical twins. One of the important tasks of the Inquiry is to understand, explain and highlight the differences as well as the similarities of the disasters, and the impact each had upon the other.

I would like to say something now about the nature of the process, and what I have to say applies to the whole of the Inquiry as opposed simply just to the public hearing phase with which we have been involved.

In some ways it's easier to characterise the nature of the Inquiry by saying what it is not. It is most certainly not a civil litigation. There is no place for legal concepts such as the standard of care, fault and causation, or even for concepts borrowed from administrative law.

The search for answers is not about pointing the finger or attributing blame, although it will no doubt be necessary to criticise certain decisions as mistaken, incorrect or wrong, just as other decisions were fortunate or sensible or wise.

Explaining what occurred in clear terms and acknowledging decisions good and bad is important. Our

understanding is that the Inquiry's intention is to examine decision-making at a strategic level rather than scrutinising decisions of particular individuals.

If that is so, one wonders: why all this defensiveness? Why is it so hard for institutions like the NHS and Government departments responsible for its administration to admit publicly mistakes and misjudgments? If the submissions on behalf of the NHS and Scottish Government are to be taken at face value, then no mistakes were made, no regret is expressed and communication with patients was as good as it possibly could have been.

Such defensiveness is not helpful but it is also not necessary, given the nature of the project in which we are all engaged. A fearless recognition, where appropriate, that mistakes were made would be so much more constructive and beneficial for everyone.

More than anything, this process will have a value if it can repair some of the mistrust that was created by unrealistic expectations, a lack of transparency, a failure to communicate effectively and an unwillingness to be upfront if relations to the threat posed by the risks that were present.

One of the those important themes to emerge is the difficulty of effective communication, not just between

doctors and nurses on the one hand and patients on the other, but also between organs of central government and the transfusion service, and within the transfusion service itself.

I will return to the theme of communication in a few moments.

I would like now to make some remarks about the need for the process to recognise the harm.

One of the most important functions of the Inquiry is to record the harm suffered by individuals and their families as a result of the twin disasters. That is not simply a case of recording the numbers of lives lost or the numbers infected, difficult though these two things are; it is also necessary to narrate the far-reaching consequences of infection and treatment on individuals and their families.

Chapter 4 of the preliminary report records the experiences of patients and their families. It seems to be entirely accurate.

In addition, during the evidential hearings we heard exceptionally powerful testimonies, from Amy, Christine, David, Elaine, Frances and Mark in relation in particular to HIV, and Alex, Anne, Bridie, Colin, Gordon, Laura and Stephen in relation in particular to Hepatitis C.

The Inquiry also has important evidence from experts on the effects of HIV and Hepatitis C, the effects of treatment and the consequences and effects of co-infection. It also has a considerable number of witness statements from patients and relatives who, although not called to give evidence, have taken the opportunity to tell their stories.

The Inquiry also has material from Jean Tamburrini, Roseleen Kennedy, as well as the statements from Mrs Black and Mrs Laing in relation to the individual deaths.

Further work is ongoing in relation to giving reliable figures for the numbers infected and the numbers of deaths as a result of treatment by the NHS in Scotland.

The Inquiry also has significant material in relation to the financial consequences of infection and co-infection. There is, therefore, every reason to be confident that the final report will carefully document all of the effects, so that a permanent, accurate record of the adverse consequences of the disasters suffered and continuing to be suffered by patients and their families will be available.

I would now like to make some remarks about certain themes that emerge from our submissions.

Our detailed written submissions expand upon some of the more contentious areas covered by the Inquiry. Some of the themes that emerge from those submissions should be highlighted. There are five of these in relation to HIV.

One, we say that the "business as usual" decision by senior haemophilia clinicians, and seen in the letter from Professor Bloom of May 1983, was wrong in the light of the available information at that time. Patients should have been offered different treatment from that point on.

Two, we say that there was complacency, at least for a time, that HIV was an American problem for which recipients of blood and blood products would be protected due to the voluntary donor system.

Three, we say that the Government, the Department of Health and Social Security, the Scottish Home and Health Department and the Scottish National Blood Transfusion Service and clinicians all publicly understated the risk posed to the blood supply from AIDS long after it must have been known that there was a significant danger.

It was represented in the press that the public had nothing to worry about, even after haemophiliacs in Edinburgh had tested positive for the presence of the virus.

Four, there was a failure to share information across disciplines. In 1983 the transfusionists were very concerned about the prospect that HIV had entered the donor population but they do not appear to have shared those concerns with the haematologists. The attitude of the latter might be summed up by the statement of one of them during the evidence, which was:

"We were not in the infectious diseases business."

One lesson that this Inquiry should be able to drive home to anyone interested is that treating patients with blood or blood products is very much being in the infectious disease business.

Five, time and time again blood samples were analysed without express knowledge or consent of patients providing those samples. This was a widespread practice that occurred in the West of Scotland as well as Edinburgh.

It was wrong, it was compounded by a failure to obtain express permission from patients to publish the results of continuing studies in relation to those samples, even yet permission in respect of work conducted in relation to samples obtained many years ago has not been sought. This practice has made a significant contribution to the anger and mistrust on the part of patients in relation to those responsible

for their long-term treatment.

In relation to Hepatitis C, I have seven points.

First, the most important point is the lack of appreciation on the ground of the threat from non-A non-B Hepatitis and the lack of action in response to the threat. No doubt the insidiousness of the disease meant that the danger was not fully appreciated but it was known from the mid-1970s that there were unidentified hepatitis viruses in the donor pool, and it was known from the early to mid-1980s that the virus known as "non-A non-B Hepatitis" would be likely to result in serious adverse consequences for patients.

It was also known from the early 1980s that blood products made from large donor pools would almost certainly transmit the virus.

Secondly, an unnecessary risk was taken by continuing to collect blood from prisons until early 1984. The decision to leave it to regional transfusion directors to decide whether and when to stop collecting blood was wrong. In the lighted of the available evidence, a direction to stop collecting blood from prisons should have been taken nationally by the end of the 1970s at the latest. Such a decision would not have adversely affected the blood supply.

Three. Surrogate testing for non-A non-B Hepatitis,

as Hepatitis C was known, should have been introduced when the Scottish National Blood Transfusion Service made its recommendation to the Scottish Home and Health Department in March 1987.

The Scottish Home and Health Department underestimated the significant public health risk posed by non-A non-B Hepatitis and did not react urgently and adequately to the threat posed.

Four. It took far too long to introduce screening tests for Hepatitis C between the isolation of the virus in 1988 and their introduction in September 1991.

Scotland lagged considerably behind other countries in this regard. Japan, Australia, France, Finland, the United States, Germany, Canada, Belgium, Switzerland Italy, Norway, Sweden, Netherlands, Denmark, Malta and Cyprus, among others, all beat us to it. In the dithering that went on between 1989 and 1991, the SHHD and SNBTS lost sight of the interests of patients. As was put by Dr McClelland in his evidence:

"Nobody appeared to consider the question: what about the patients?"

Five. There was a failure to reduce to a minimum the risk to virgin and minimally-treated haemophiliac patients in the period between January 1986 and April 1987, when Scottish Factor VIII was not

sufficiently heat-treated to inactivate the virus causing non-A non-B Hepatitis.

This was at a time when it was known that treatment with SNBTS Factor VIII would certainly infect a patient with that virus and that it was likely that such infection could result in cirrhosis of the liver, hepatic cancer and death.

Six. Look-back -- that is the tracing of the recipients of infected blood -- should have started when screening for Hepatitis C was introduced in Scotland in 1991. As Dr Gillon of the SNBTS maintained at the time and maintained in his evidence:

"It was the ethical thing to do."

He was right then and he was right when he gave his evidence.

Seven. One of the most damaging aspects for patients has been the extent to which sufferers of Hepatitis C have been stigmatised as abusers of alcohol because of a failure by health professionals to appreciate the damage to the liver caused by the virus. This is an experience repeated time and time again in the case studies. The problem stems from a lack of appreciation of the long-term liver damage caused by the virus.

I do want to say something in relation to

communication which relates to both HIV and Hepatitis C.

The evidence of patients is clear that, one, they were not given sufficient information about the risks associated with treatment by blood and blood products; two, patients were not told that they were being tested. This occurred in relation to Hepatitis C, even after it must have been obvious that testing for HIV without consent was unacceptable from the point of view of patients.

Three. There were significant and unacceptable delays between a positive test for infection and that information being relayed to patients.

Four. Patients were given incomplete, inadequate and misleading information about the consequences of being infected with the virus.

Failure in communication occurred not just between doctor and patient, but also within medical disciplines; between the top and the bottom and across medical disciplines, between transfusionists and haematologists and haematologists and virologists.

I want to make some concluding remarks.

It would be wrong for anyone to think that the National Health Service can always offer relief from the heartache and the thousand natural shocks that flesh is heir to. Indeed, it is right that tribute should be

paid to all of the hard-working medical staff, all the hard-working fractionating staff, who provided treatment and products to patients during the time we have been examining.

Although a critical eye is cast in relation to certain decisions, it is right to record genuine and heartfelt gratitude for the excellent treatment received by patients much of the time.

But three key words are worth emphasising, and I do so in reverse order: service, health and national.

It is a service for the benefit of patients and their families. Their welfare should always be at the centre of all decision-making. The patient should be in control, not the health service professional. The essence of this is the autonomy of the patient. Decisions in relation to treatment and care are for the patient and, where appropriate, their carer.

Health. Decisions should always be taken in the best interests of promoting the health of patients. Some of the delays that occurred in Scotland were because other considerations overrode the interests of patient health, and we make specific reference to these instances in our submissions.

National. There are two points here. The first is the obvious regional variation in practices and

standards during the reference period. There was a lack of national direction and decision-making throughout. Standards of service varied throughout the country.

Dr Cachia's testimony that he was a bit horrified by what he found when he arrived in Dundee in 1992, to find that Hepatitis C testing was being carried out on patients' stored samples without consent being obtained, is one example of many regional variations in standards.

The second point is the failure of the Scottish Health Service, legally and administratively autonomous as it was, to make decisions for itself. There were many situations, such as the delays in the introduction of donor screening and surrogate testing and look-back of HCV to name but three, where the decision not to implement these things was taken so as to avoid stepping out of line with the rest of the United Kingdom.

This is not a political point but where the NHS in Scotland has the autonomy, and we most certainly do not accept that it did not have the autonomy at the relevant time. If it's right to do something or follow a particular course of action in the interests of patient safety, then it should get on and do it and not wait for a lead from anywhere else.

Sir, you have heard many harrowing stories from

patients who suffered the terrible consequences of HIV or Hepatitis C, and in the case of haemophiliacs frequently both. You heard of mothers, who, as carriers of haemophilia, had to come to terms not only with passing on the condition to their son, but then administering what they thought was life-transforming medication only to realise that their child had been infected with HIV, and then they had to stand by and watch as the child fell ill and died.

The twin disasters have really happened to real people. They needed and need support. Many of them have suffered significant deteriorations in their conditions since the start of this process. They needed and need understanding, they needed and need explanations, and they needed and need mistakes to be acknowledged and improvement to be made.

I am confident that the Inquiry will do what it can in fulfilling its terms of reference to meet those needs.

Thank you.

THE CHAIRMAN: Mr Anderson?

Submissions by MR ANDERSON

MR ANDERSON: Thank you, sir.

Today's final hearing has been long awaited. It is almost three years to the day since the preliminary

hearing in this Inquiry was held at Edinburgh International Conference Centre on 31 March 2009.

Since then, the first phase of the Inquiry has resulted in the publication of the preliminary report, a notable achievement in itself and the result of an in-depth analysis by you, sir, as chairman of this Inquiry and the Inquiry team of the great mass of documentation recovered under the Inquiry's terms of reference from numerous sources, including both the SNBTS and the Scottish health boards.

The second phase, the oral hearing, started approximately one year ago on 8 March 2011 and concluded on 20 January this year.

It has been apparent throughout this period to all those involved that the Inquiry team has been extremely diligent in its research into what are matters of considerable scientific and medical complexity. In the first place, therefore, I should wish to express my appreciation on behalf of NHS Scotland of the Inquiry team's dedication and also the very competent manner in which it has carried out this challenging task.

It is also appropriate to record appreciation to both those bereaved relatives who gave evidence in relation to the specific deaths and to the anonymised witnesses who gave evidence regarding the effects of

living with either HIV or Hepatitis C, or both viruses.

It requires little imagination to appreciate how difficult it must have been for those individuals to give evidence before this Inquiry about such painful events and with such admirable restraint and dignity.

Next, it is appropriate, I think, to record appreciation of other witnesses who gave oral evidence to the Inquiry, and particularly those who attended despite their advanced age.

Some witnesses gave evidence on more than half a dozen occasions. Two witnesses, I think, each making as many as ten appearances. Many were in their 70s, some in their 80s, and much of the time were having to recollect events that took place 30 or so years ago.

I'm sure that everyone involved in the Inquiry will agree that all of the many witnesses from whom the Inquiry took evidence displayed a real commitment to assist the Inquiry in its investigations. Of course, many were giving evidence about what was effectively their life's work.

Notwithstanding the difficulties presented by the passage of time, the fact that some key participants have died and the wide-ranging nature of this Inquiry, there seems little doubt that the thoroughness with which this Inquiry has been undertaken should provide

all those with an interest in the subject with a definitive statement in the form of the final report.

None of the previous Inquiries held in this and other countries have gone into such depth of detail about both treatment and scientific issues as has the present Inquiry.

For this reason it is hoped that this Inquiry will provide the foundation for a new, more balanced and evidence-based understanding of events in the past.

In this regard it has, in recent weeks, been disappointing to see that even after the conclusion of hearing almost a year of oral evidence, there are still those who persist in describing the subject matter of this Inquiry, in a media context, as "a scandal".

No doubt some will say, and indeed has just been said, that certain things might have been done differently or that different decisions might have been taken. That may or may not be correct. But of this there should be no doubt: there is no justification for the description of events as "a scandal". There is and was no scandal. That word always carrying with it the connotation of wrongdoing of one sort or another.

It may be appropriate now to comment briefly on the synopsis presented just now by my learned friend Mr Di Rollo of the criticisms contained within their

very full written submissions. I would propose to deal with only those that might be regarded as the more controversial.

Starting in relation to HIV, there is repeated criticism made in relation to testing without consent. This is a criticism that is now made but significantly was never apparently made at the time. This is, in my submission, perhaps the most obvious case of looking at events of the early 1980s through 2012 spectacles.

Careful analysis of the evidence from independent expert witnesses will, I suggest, confirm that there should be no criticism of clinicians who tested stored samples in what was considered to be their patients' best interests, and it is, in my submission, not justified to characterise that practice as "wrong". It may be wrong by present day standards but it was not wrong by the standards of the early 1980s.

In relation to Hepatitis C, dealing with surrogate testing, it's important to appreciate that there was never at any time any consensus on the usefulness of surrogate testing. To suggest now that just because it was not introduced, it should have been introduced is simply not accepted. But, sir, you have the full submissions in relation to that, both of course on behalf of the NHS and the submissions on behalf of the

Scottish Government.

In relation to donor screening, again, the criticism is not accepted. Despite what my learned friend has just suggested, the world was different then. This was, of course, a pre-devolution era. Health is now a devolved matter. Then Scotland had no autonomy. The introduction of donor screening was a large national exercise in which the Department of Health naturally took the lead. Again, it's perhaps sufficient to refer to the written submissions of the NHS, and indeed again of the Scottish Government, on this point.

We can perhaps now look back from 2012 and see, as counsel to the Inquiry very aptly put it, that a number of small delays may have added up to a bigger one. But the suggestion that SNBTS had the power to cause a departure from the well recognised status quo, in my submission ignores the realities of the situation and the suggestion within the written submissions that this was an abrogation of responsibility by SNBTS is to misunderstand the role of the SNBTS.

Finally, in relation to the criticism, caution, I think, requires to be exercised in relation to the difficult topic of communications between doctors and patients.

The difficulty, I would suggest, is that the

criticisms that my learned friend Mr Di Rollo makes are predicated upon simply accepting everything that the patients say is right, and I would simply suggest to you, sir, that facts are not as simple as that.

It has also been noted that the written submissions made to the Inquiry on behalf of the patient interest core participants make repeated criticisms based on suggested alternative strategies or treatment which were never explored with any witnesses in evidence. These submissions and what it is said should have been done represent an exercise in hindsight which frequently ignores the totality of the evidence.

The fact is that there are risks associated with all medical procedures and the transfusion of blood and use of blood products are no different. Despite the considerable number of blood transfusions carried out in Scotland every year, the possibility of transmission of an unidentified infective agent, which is naturally present in the human population, is rare; nevertheless, this rare risk is inherent in treatment with blood and blood products.

Also, in the context of media coverage, it should be stressed that the use of the term "contaminated blood" is a misnomer insofar as that term implies that something has been added to blood.

Both HIV and Hepatitis C are naturally occurring blood-borne viruses and the vast majority of patients to whom these viruses were transmitted were infected before the viruses had been discovered by medical science, before medical science had devised tests to detect these viruses and before it was possible to screen blood donors.

Across the world, making blood and blood products safe from these viruses represented significant milestones in the advance of transfusion science and transfusion medicine.

In this global sense, Scotland not only played its part in these advances but was at the forefront including being, firstly, one of the first countries in the world to provide Factor VIII concentrate from its own donor population in sufficient quantities to treat its own patient population; an achievement described by the Inquiry's expert, Professor van Aken from the Netherlands, as "remarkable" and "a real big success".

Secondly, Scotland was the first country to supply sufficient heat-treated Factor VIII concentrate safe from HIV.

Thirdly, it was the first country to supply sufficient heat-treated Factor VIII concentrate safe from Hepatitis C long before the major commercial

companies did.

Fourthly, it made Factor VIII and Factor IX concentrates safe from Hepatitis C, even before the virus had been isolated; and finally, it was one of the first countries to conduct a Hepatitis C look-back exercise.

Although the achievement of making blood and blood products safe from the transmission of HIV and Hepatitis C represented significant medical advances, nevertheless it is a highly regrettable but unavoidable fact that whenever such advances exist in medicine, there will always be patients who are unable to benefit from the development having been treated at an earlier time.

Following on from these advances of the 1980s and early 1990s, there have many further significant developments in the safety of blood and blood products provided to Scottish patients. To give but one example: following the licensing in the UK of commercial recombinant non-human factor concentrates in 1995, Scotland achieved their routine use several years before the rest of the UK.

Developments such as these have not been able to be explored in evidence having been considered by the Inquiry team to fall outwith the historical scope of

this Inquiry as set out in its terms of reference.

It should not be forgotten that the development of concentrates prolonged the lives of many patients with haemophilia and greatly enhanced their quality of life; nor should it be forgotten how difficult a position haemophilia clinicians found themselves in when faced with the dilemma of continuing to treat their patients against the background of the emergence of HIV, a totally new and unprecedented fatal virus, and one about which medical science was initially divided as to its origin and its mode of transmission.

Equally, haemophilia clinicians faced further challenges due to the emerging knowledge throughout the 1980s of the consequences of non-A non-B Hepatitis, later identified and described as "Hepatitis C".

In his evidence, another of the Inquiry's experts, Professor Lever, expressed the opinion that:

"During the emergence of HIV there would not have been an expert there at the time who could justifiably have said what was going to happen with HIV, far less go on to specify what clinicians must do."

As Inquiry witness Professor Forbes, formerly of Glasgow Royal Infirmary, put it, it was certainly not possible to stop the use of concentrate as bleeding would have resulted in death.

As events unfolded around HIV, it was the dedicated efforts of the haemophilia clinicians, and in particular the close monitoring of their patients, which resulted in early confirmation that HIV had entered the Scottish donor population, which resulted in a swift and effective response from the SNBTS in terms of virus inactivation.

Whilst in no way minimising the devastating outcome for the patients who acquired HCV, Hepatitis C and/or HIV, the low rate of infection in Scotland by international standards stands as testimony to both the efforts of the SNBTS to make blood for transfusion and blood products as available and safe as possible and possible for clinicians to use blood and blood products wisely and only where necessary.

The SNBTS has always been driven by the commitment to save and improve lives and counter illness while fully supporting its donors. It has worked tirelessly throughout its history to provide sufficient, safe and effective treatment for all patients who require life-saving blood and blood products. The development of such life-enhancing treatment has always posed challenges to which the SNBTS has consistently faced up as and when they arise.

Equally, Scottish clinicians have at all times been

driven by what they considered to be in their patients' best interests. The evidence before this Inquiry has, in my submission, demonstrated that they acted in good faith to administer what they in their clinical judgment considered to be the best available care.

These events had a profound and lasting effect on those working within the SNBTS and on the medical and nursing staff within the health boards, who dedicated their professional lives to the development of safe products and to the care of their patients.

It is a matter of the greatest regret to NHS Scotland that patients were infected with the HIV and Hepatitis C viruses as a result of medical treatment, and every sympathy is extended to those infected and perhaps, above all, to the bereaved relatives.

Finally, as previously noted, this Inquiry has dealt with events which occurred some 30 or so years ago. This should not detract attention from the fact that blood testing and processing systems used in Scotland today provide extremely high levels of safety and that NHS Scotland continues now, as before, to rely heavily upon blood donations given voluntarily by the people of Scotland.

In Scotland around 50,000 patients every year receive life-saving blood transfusions. Accordingly, it

remains as vital now as it always has been for donors to continue to support the Scottish National Health Service in caring for the people of Scotland.

Thank you very much, sir.

THE CHAIRMAN: Thank you, Mr Anderson. Mr Johnston?

Submissions by MR JOHNSTON

MR JOHNSTON: It was on 23 April 2008 that the Cabinet Secretary for Health and Wellbeing announced to the Scottish Parliament the establishment of this Inquiry.

The Government was conscious that the transmission of Hepatitis C and HIV through blood and blood products was a tragedy that had blighted the lives of many people in Scotland. Nothing could ever make amends to those people or their families for that but it was recognised that they were entitled to an explanation of how Hepatitis C and HIV came to be transmitted through NHS treatment in Scotland.

The setting up of this Inquiry reflects the policy that informs the whole NHS in Scotland nowadays to offer healthcare which is safe, effective and focused on patients.

In the spirit of that policy, it is important to provide explanations when things have gone wrong and assurance that lessons will be learned for the future.

Even at the outset, it was clear that the Inquiry

had an enormous task before it. It would have to carry out a detailed investigation into the circumstances in which Hepatitis C and HIV were transmitted through the blood and blood products used in NHS treatment.

It would have to consider whether, in light of the epidemiological and scientific knowledge available at the relevant times, all that could be done to protect the public had been done.

It would have to explore the consequences of transmission of these viruses for the patients affected. This would involve reconstructing events going back as far as 1974 with such help as witnesses could still provide and by reference to voluminous quantities of documentation which the government and other bodies would supply to the Inquiry.

By the time of the announcement in April 2008, many key documents were already in the public domain. There had also been a number of previous inquiries and investigations into the issues. But those inquiries, valuable though they were, were carried out by Government and lacked independence.

The Government recognised that it was essential to have an investigation which had the credibility and authority of a full and transparent Scottish public Inquiry.

Since the Inquiry was established, it has had the total support of the Scottish Government. While the Government has taken part as a core participant in the Inquiry, it has nonetheless respected the need for the Inquiry to be absolutely independent.

At this stage, after publication of the preliminary report in 2010 and after the completion of 88 days of oral hearings in 2011 and 2012, it is to the chairman of the Inquiry and the whole Inquiry team that particular thanks are due.

These thanks are not limited to those who are visible in the hearings, but extend to all those who have provided essential support behind the scenes. The Government is extremely grateful to the chairman and the Inquiry team as a whole for the extraordinary amount of work and commitment that they have devoted to identifying, investigating and analysing the issues.

The magnitude of the work facing the Inquiry has already been mentioned. In that context, the Government would also wish to express its appreciation of the fact that the Inquiry has succeeded in investigating so many complex issues so thoroughly.

It also pays tribute to the considerable efforts that the Inquiry has made to ensure the openness and transparency of its proceedings, not least by making it

possible to follow them from day to day on the Inquiry website.

Equally, it recognises the great efforts that the Inquiry has made to respect the privacy of the courageous individuals who came forward to give first hand accounts of their experiences of HIV and HCV.

As the Cabinet Secretary has previously acknowledged, nobody can undo the pain and suffering of the people who were affected by HIV or Hepatitis C as a result of treatment with blood and blood products; but they can be offered an explanation and they can be provided with assurances that lessons can be learned.

The Government expresses the hope that the Inquiry, when it reaches its final conclusion, will provide that explanation and those assurances. It therefore looks forward to receiving the final report and recommendations in due course.

Thank you.

THE CHAIRMAN: Ms Dunlop?

Submissions by MS DUNLOP

MS DUNLOP: Thank you, sir.

There are two principal areas I wish to address in my remarks.

Firstly, I should explain that the team of Inquiry counsel has itself produced a list of issues relating to

each numbered topic. This is at [PEN0190843]. These were the matters that seemed to us as Inquiry counsel to be the main points arising under each topic. We drafted these lists in the hope that they would be of assistance in the preparation of the final report.

We have not, however, proposed how those questions should be answered because they relate in many instances to issues which are controversial, and it appeared to us to conflict with our position of neutrality to advance submissions as to how controversial issues should be resolved.

At this point, I should refer to the matter of statistics. There is work ongoing, in particular in relation to the attempt to establish the number of people who acquired Hepatitis C as a result of blood transfusion. We will continue to keep all core participants informed of the progress of that work, which I hope will be concluded in reasonably early course.

In relation to statistics, I should also take this opportunity to correct an impression given by the transcript at the end of the day on 18 January 2012. In fact at that point Professor Goldberg of Health Protection Scotland had provided the Inquiry with further information on statistics, as he undertook to do

in his evidence last March, and had carried out extensive work in doing so.

The second area I want to address is in relation to the phase of the Inquiry which began when we took occupation of these premises, I think at the end of 2010. That phase, the hearings phase, followed a period of preparation during which the Inquiry team published the preliminary report. It would not be controversial to describe this hearings phase as "phase 2".

A great deal of effort on the part of many people in the Inquiry team has contributed to phase 2, and on behalf of Inquiry counsel I would like to thank those individuals.

Firstly, I must acknowledge, sir, on behalf of us all, your own industry in devoting so much time and effort to staying abreast of the evidence throughout.

In addition, your flexible approach to matters of timing and of procedure has greatly assisted in the running of the hearings. Professor James, the medical assessor, is not here today, but, of course, his willingness to help us all with the many incidental medical questions as they arose has been much appreciated.

To all the lawyers who have represented all the core participants, we express our sincere gratitude. We did

not always agree but the unfailing courtesy and good humour shown by everyone in the front rows has made the experience very much better than it could have been.

Our own solicitors, Douglas Tullis and Louyse McConnell-Trevillion, have kept us on the straight and narrow, we hope, and dealt with the reams of correspondence and probably a million emails. We thank you from the bottom of our inboxes for reliving us of that burden.

Our Inquiry secretary, Maria McCann, has helped at every turn, as have Sarah and Meg, and, normally back at Drumsheugh Gardens, Kate Miguda and Charles Rogers. The can-do attitudes displayed by all of you have been remarkable.

Margaret Fraser, as well as looking after witnesses throughout, has supplied us with multi-coloured witness availability spreadsheets, which were indispensable. I should of course acknowledge that the other half of that, the witnesses making themselves available to us, has also been something that we could not have done without.

We have been well catered for literally, too; Scott and Raymond, our security guards, have trudged out in all weathers, every day, for our lunches, as well as discharging their duties at the front desk and looking

after my bike every time I forgot my lock.

Our documents team have remained cool, calm and efficient at all times, despite, in their own words, having to "paddle madly below the surface" from time to time.

External contractors have also provided high quality assistance throughout, insofar as the task of assembling and displaying our many documents is concerned.

Neil, Ollie and Keith, court book stands as a monument to you all, to say nothing of the behemoth that is Signature, lying beneath. Our stenographers, who have provided the transcripts, Stuart and Catherine, have served us without fail and have produced the best transcripts I have ever seen. I do hope that even a small amount of the arcane vocabulary will be useful to you some day, somewhere.

Focusing more closely on the presentation of evidence brings me to the topics teams, Gregor Mair, Lindsey Robertson, Janet Marsh, Angus Evans, Gemma Lovell and Yasmin Shepherd, the lawyers who have assisted us. We simply could not have managed without you. Your knowledge of your own tranches of time within the Inquiry period from the documents exercise enabled you to move seamlessly to the in-gathering of statements and other material for the hearings. The preparation of

inventories and the assembly of folders for us all and your thoroughly dependable input on a range of tasks has massively assisted throughout phase 2.

Finally, I have for the first time in my career, had three junior counsel. I have never had it so good. Jane Patrick, Euan Mackenzie and Nick Gardiner have worked tirelessly and offered ceaseless support. All four of us have learned much during this exercise and it has been a privilege for us all to serve as Inquiry counsel.

Closing Statement from THE CHAIRMAN

THE CHAIRMAN: Ladies and gentlemen, you have heard quite diffusive thanks offered to many people, often with names that will mean absolutely nothing to you. I will have my opportunity to express my thanks to all those who have contributed to the work of the Inquiry in due course and I won't repeat that now.

It will be clear from what you have heard this morning that there is a great deal now to do to bring the Inquiry to a conclusion. There has been a staggering amount of evidence. All of it will have to be looked at, all of it will have to be analysed so far as it bears on the critical issues that still have to be resolved.

There are some issues of basic fact, there are some

issues of inference from fact and some impressions and it will not be possible to accept all the evidence as credible and reliable, although we have to say in this case reliability is likely to be the issue rather than credibility, which often causes trouble in litigation, which is not, of course, this case.

These investigations of the evidence, discussions and analysis, they will take time. I can't promise to produce a final report in a period of time that is shorter than necessary to ensure that the end product reflects the value of the input material, but it will be done as soon as reasonably practicable.

While I don't want to take time thanking all of those who have contributed to the exercise, I do want to express my deep gratitude to all of those who have attended and given evidence at this Inquiry. Those who have never given evidence hardly ever understand the demands that appearing before any sort of tribunal make on the individuals involved. Whether they are professionals, whether they are individuals directly and personally affected by the events, giving evidence is not easy for them.

It is particularly difficult, of course, for those who come to give personal accounts of experiences that have affected their lives very deeply, and that applies

principally to patients. It also applies, as has become clear, to some of the clinicians who have been directly involved in patient care.

I am very, very grateful that people have been willing to come forward.

I don't want anyone to underestimate the extent to which this Inquiry has been assisted, particularly by patients and by families of patients, in coming to give statements on which we can develop a picture of the impact of these diseases on people's lives. So I thank all of you really very deeply for the work that you have done, the preparations that you have made and for the willingness that you have shown, where you have been invited to do so, to come and give oral evidence to the Inquiry.

We are now at the end of the gathering of evidence, with one exception. Ms Dunlop has referred to it, the need to tighten up and reach a final conclusion on the statistical material available to the Inquiry, to assess the extent to which there are still people in the community in Scotland with Hepatitis C that is related to their treatment, so that the government can be informed of the extent of the continuing problem, a very important aspect of this Inquiry's work and one in respect of which I am personally less than happy to

reach a final conclusion without being satisfied that we have at least tried to identify the stones and turned them over, even if we don't manage to find all that lurks underneath.

With that exception, statement taking is at an end and evidence-gathering is completed. It now is for Professor James, for myself and for the Inquiry team to settle down and reach a concluded view on the very many issues that have been left for us to determine in the light of all that has been said and done.

Thank you all very much for your contributions.

(11.11 am)

(The hearing adjourned)

I N D E X