HEALTH AND COMMUNITY CARE COMMITTEE

Wednesday 14 March 2001
(*Morning*)

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HEALTH AND COMMUNITY CARE COMMITTEE
8th Meeting 2001, Session 1

CONVENER

*Mrs Margaret Smith (Edinburgh West) (LD)

DEPUTY CONVENER

*Margaret Jamieson (Kilmarnock and Loudoun) (Lab)

COMMITTEE MEMBERS

*Dorothy-Grace Elder (Glasgow) (SNP)
*Janis Hughes (Glasgow Rutherglen) (Lab)
*Mr John McAllion (Dundee East) (Lab)
*Shona Robison (North-East Scotland) (SNP)
*Mary Scanlon (Highlands and Islands) (Con)
*Dr Richard Simpson (Ochil) (Lab)
*Nicola Sturgeon (Glasgow) (SNP)

*attended

THE FOLLOWING ALSO ATTENDED:

Brian Adam (North-East Scotland) (SNP)

WITNESSES

Philip Dolan (Haemophilia Society)
Dr Peter Foster (Scottish National Blood Transfusion Service)
Professor Ian Franklin (Scottish National Blood Transfusion Service)
Angus Macmillan Douglas (Scottish National Blood Transfusion Service)
Patricia McAughey (Haemophilia Society)
Dr Brian McClelland (Scottish National Blood Transfusion Service)
Karin Pappenheim (Haemophilia Society)
Ken Peacock (Haemophilia Society)
Bill Wright (Haemophilia Society)

CLERK TO THE COMMITTEE

Jennifer Smart

SENIOR ASSISTANT CLERK

Irene Fleming

ASSISTANT CLERK

Joanna Hardy

LOCATION

Committee Room 1

Scottish Parliament

Health and Community Care Committee

Wednesday 14 March 2001

(*Morning*)

[THE CONVENER *opened the meeting at 09:42*]

The Convener (Mrs Margaret Smith): Good morning and welcome to this meeting of the Health and Community Care Committee.

We begin with agenda item 1. Is the committee happy to take item 5, which is discussion of a draft report, in private?

Members *indicated agreement*.

Subordinate Legislation

The Convener: The committee must consider the Coffee Extracts and Chicory Extracts (Scotland) Regulations 2001 (SSI 2001/38), which is a negative instrument that was circulated to members on 27 February. We have received no comments from members on the instrument, the Subordinate Legislation Committee has no comments to make and no motion to annul has been lodged. The recommendation is that the committee does not wish to make any recommendation in relation to the instrument. Are members agreed?

Members *indicated agreement*.

Hepatitis C

09:45

The Convener: We move to agenda item 3, which is evidence on hepatitis C and the treatment of blood products for haemophiliacs in the mid-1980s. Everyone is aware of the fact that, due to circumstances in the 1980s, a certain number of people contracted hepatitis C. The committee has received two petitions on hepatitis C. The first petition, PE185, is from Thomas McKissock, who calls on the Scottish Parliament to establish a system of compensation to assist the people who contracted hepatitis C infection as a consequence of infected blood transfusion. The second petition, PE45, is from the Haemophilia Society, Mr Philip Dolan's organisation, and calls on the Scottish Parliament

"to hold an independent inquiry into hepatitis C and other infections of people with haemophilia".

Members of the committee will be aware that, following representations made to the Minister for Health and Community Care, the minister set up an internal inquiry into the matter last year. The committee decided to await the Executive's response before taking further action. After we received the Executive's report, we discussed the matter again in December and decided to take further evidence.

Today, we have with us representatives of the Scottish National Blood Transfusion Service and the Haemophilia Society. We will ask them to make a statement and then will ask questions about the petitions. The questions are likely to cover areas from representation to the screening of blood products and the chronology of what happened to blood products throughout the 1970s, 1980s and 1990s. We will also ask questions about whether the Executive's report is satisfactory or whether further work should be done and about the position of people with hepatitis C and the impact that the disease has had on their lives. This is a complex issue for members. At its roots lie the personal tragedies of the people who contracted this terrible disease as a result of the events that took place.

I welcome the witnesses from the Scottish National Blood Transfusion Service. Please begin by making any comments or statements that you would like to make. My colleagues and I will then ask questions. We received your written submission, which was helpful.

Angus Macmillan Douglas (Scottish National Blood Transfusion Service): Thank you. I will make an opening statement of about two and a half minutes, following which I am sure members of the committee will have questions.

The SNBTS is part of the national health service in Scotland, which it provides with blood components and plasma derivatives. I want to describe the difference between those products and how it is now possible to ensure that they are safe and do not transmit hepatitis C and other viruses such as HIV.

Blood components are mainly cellular products, such as red cells and platelets, which are supplied from a discrete donation from a single donor. Blood components undergo little processing and therefore their safety is dependent on the health of the individual blood donor. The selection of blood donors—in Scotland, they are all unpaid volunteers—and the testing of donations is critical in minimising the risk to patients. Selection is carried out by the Scottish National Blood Transfusion Service to the required UK standards, which are determined by a UK regulator that has the reputation of being one of the strictest regulatory regimes in the world.

Plasma derivatives comprise factor VIII and factor IX concentrates for haemophiliacs. I understand that we are here primarily to discuss those. In contrast to blood components, plasma derivatives are highly processed pharmaceutical products, each batch of which has been pooled from thousands of individual donors' donations.

The manufacturing process includes steps that are capable of eliminating the hepatitis C virus and other viruses, thereby making the products safe. Factor VIII concentrate, which is the subject of the Scottish Executive's investigation, is the most fragile of the plasma products that we manufacture. That makes it one of the most difficult to make safe, to ensure that it does not transmit hepatitis C. Yet, in 1987, the Scottish National Blood Transfusion Service made a factor VIII product that was safe from hepatitis C, before the hepatitis C virus was discovered and before a screening test for hepatitis C was available anywhere in the world.

Scotland was the first country in the world, bar none, to be able to provide a hepatitis C-safe factor VIII product to all Scottish people who suffered from haemophilia. In doing so, Scotland and the Scottish National Blood Transfusion Service was genuinely working at the cutting edge of science. The tragedy is that that huge scientific achievement came too late for some haemophiliacs, although the same is true of any medical advance.

The Convener: I would like to pick up on some of the information in your written submission, which the spirit of what you said backed up.

In the SNBTS submission, you wrote:

"Scotland has a record of achievement in this field which is second to none."

You have just said that Scotland's blood transfusion service was the first to have safe blood products for all Scottish people. We know, however, that we were some time behind the English transfusion service in finding suitable heat-treated blood products that were safe, at least for some people. Scotland then caught up, but the Scottish Executive report found that Scotland achieved the introduction of suitably heat-treated factor VIII blood products some 18 months after they were introduced in England. I refer back to your comment about Scotland being second to none; in fact Scotland was second to England, regardless of the Executive's finding of non-negligence. You told us that the SNBTS caught up quickly, but you were 18 months behind your southern neighbours and, during that time, Scottish haemophiliacs were at risk, while English haemophiliacs were not.

Angus Macmillan Douglas: I will ask Dr Peter Foster to answer that question in detail, but before he does, I would like to make one or two comments.

Certainly, our sister service in England developed a hepatitis C-safe factor VIII blood product in the autumn of 1985, some 18 months ahead of our introducing a product that was available to all people in Scotland. However, the service in Scotland was able to provide a blood product for every haemophiliac in the country earlier than was the case in any other country in the world. The United Kingdom as a whole was in advance of every other country in the world. In that respect, the English and Scottish services worked together closely, in advance of all the other countries in the world. The English developed the technology 18 months before the Scottish service did so, but we introduced the product in sufficient quantities to cater for all haemophiliacs in Scotland before our English colleagues managed to do the same thing in England.

Dr Peter Foster (Scottish National Blood Transfusion Service): During the period in question, intensive research was taking place throughout the world to try to solve the problem of hepatitis C infection in haemophiliacs and to make blood products safe. A number of experimental products were being tested—some ultimately were successful and some were not. Our colleagues in England were the first in the world to develop the 80 deg C-heated product. In 1985, we were exploring a number of potential options, but it was not known whether any of them would work. At the end of 1985, we selected the option that had been pioneered by our colleagues in England and put it into practice as quickly as we could.

The procedure involved developing a completely new factor VIII product—the technology could not be applied to the established products. The factor

VIII process is an extensive, complex, sophisticated and specialised operation, and applying the procedures was not straightforward. Eighteen months is a very short time in biopharmaceutical manufacturing to achieve such an outcome. We were the second in the world to achieve the technology, behind our colleagues in England, and we did it by working closely with them.

The Convener: I want to pick up on another point made by Mr Macmillan Douglas, which is also in your written submission and in your response to the Executive's inquiry. You say that you had produced this safe, dry-heated blood product—factor VIII—by 1987, before a screening test was available for hepatitis C. Was not a screening test available for what was, at the time, known as non-A, non-B hepatitis? Is not it a spurious argument to say that, just because hepatitis C did not have its own title, the screening test should not have been undertaken?

I ask you to bear with me, and I will expand on some of the information that we have been given. The non-A, non-B hepatitis test appears to have been available for some time, but was not introduced in the United Kingdom until September 1991, which was some time before various countries in the west introduced it. We have received minutes of various meetings of blood bank directors, doctors, Department of Health representatives and regional transfusion directors. I will not go into them in detail, but I wish to consider some of them.

I will start with the minutes of a regional transfusion directors' meeting in April 1986. I quote:

"Should the National Blood Transfusion Service carry out a study on non-A non-B hepatitis? (now known as hepatitis C) … After discussion it was agreed that this should **NOT** be pursued because of lack of time and resources."

There are various minutes—I will pick out just some of them. I quote minutes of a meeting of the Blood Transfusion Service western division consultants, held in October 1990:

"The hope was expressed that the Department of Health would sanction sufficient funding … for early initiation of Anti-HCV screening, as the UK is falling short of Standards set by most other Centres in Europe and the US."

I quote minutes of the meeting of the national management committee of the national directorate of the National Blood Transfusion Service, held in February 1991:

"Members were disappointed to learn that the Department of Health would **NOT** provide additional funds for anti-HCV testing."

I quote a letter from Dr Lloyd, director of the National Blood Transfusion Service, dated 2 May 1991:

"there was a date of 2nd July set for Hepatitis C antibody testing. Fairly recently this changed with the provisional date for September 1991 … My personal view is **that not to test now that we have the ability to test would be indefensible**".

The minutes of meetings of various transfusion directors' meetings show that a number of comments were made in discussions by the people at the sharp end of all this. I will paraphrase, by saying that a question of resources was attached to the decision on whether to screen in the way that was being done in other countries at the time. Throughout the papers, we see that there was an on-going discussion from April 1986 right up to 1991, when the UK started screening.

You have told us that donations are made by thousands of individual donors, but that screening was not undertaken until 1991. It is clear from the various minutes that a significant amount of discussion was going on within the service. That discussion came out in a letter to *The Lancet* from the Scottish National Blood Transfusion Service directors themselves, dated 15 June 1987. I quote:

"Starting now will give us an answer in 3 to 4 years and that is probably 3 to 4 years too late. The introduction of surrogate marker testing for Non-A Non-B is now virtually inescapable, for three reasons."

The letter goes on to discuss new European legislation and new blood products being perceived as simply any other product. It poses the question whether resources were being used effectively, given that, if people got hepatitis C, a cost would obviously be involved.

I have two questions. First, why, despite the significant amount of discussion going on in the blood transfusion service throughout the UK, were blood products not screened for non-A, non-B hepatitis, which is just another name for hepatitis C? Secondly, were the blood products not screened because of a resource issue?

10:00

Dr Richard Simpson (Ochil) (Lab): Before Mr Macmillan Douglas answers, I would like to add to the question. It would be helpful if he could take us through the screening process separately from the process of making the blood products safe. The two strands are parallel, but they do cross and meet. Where were the products rendered safe? At what point was screening of the use of those products no longer necessary? When did screening come into the discussion or become an option? What were the tests, and how specific and effective were they?

The Convener: I understand that that is a tall order, but we can work our way through it all.

Angus Macmillan Douglas: I will hand over to Dr McClelland and Professor Franklin later, as

they might like to add to my answers.

We are not talking about one test. During the 1980s, there was a test referred to as ALT testing—or alanine amino transferase testing. Throughout that decade, and until 1990, there was no specific test for hepatitis C—or non-A, non-B hepatitis; we do not make a distinction, as they are, as the convener so correctly says, the same thing—anywhere in the world.

There was another test, also referred to as ALT testing, which was for inflammation of the liver, but it was not the same thing. It was a very inaccurate test and was intended to act as a surrogate for a test for hepatitis C. Because it was inaccurate, it led to people who did not have the disease showing up as having it, and people who did have the disease being shown as safe. Had that test been introduced, it would have put the blood supply at risk. Nevertheless, because the test existed, however inaccurate it was, there was a lot of genuine debate about the issue. There was no consensus anywhere. Germany happened to introduce ALT testing in the 1960s; France introduced it in 1989; the United States introduced it in part in the late 1980s; and Sweden, Norway, the Netherlands and the United Kingdom never introduced it. There was genuine debate and genuine disagreement.

By the time a specific test for hepatitis C was made available—it was discovered in 1989 by an American company—blood products such as factor VIII had been made safe in Scotland by the process that Peter Foster described. Brian McClelland will be able to go into more detail on that than I can.

Dr Brian McClelland (Scottish National Blood Transfusion Service): A summary might be helpful to provide some follow-up clarification. I will briefly reiterate the points that Angus Macmillan Douglas made.

Until the mid-1970s, everyone involved in transfusion was aware that there was a problem and that some patients developed hepatitis following a transfusion. It was called post-transfusion hepatitis. In the early 1970s, the hepatitis B virus was identified. Within months, transfusion services here and in the United States started testing for it. We hoped that that was the solution to the problem, but it was not, because some patients continued to develop hepatitis.

At about the same time, another hepatitis virus, called hepatitis A, was discovered. It was quickly realised that that virus was not transmitted by transfusion. That is where the term non-A, non-B hepatitis came from. It was a simple way of saying that something was continuing to be transmitted by blood and other means, which we believed to be a virus infection but for which we could not find the virus and for which we therefore could not test.

In the Scottish blood transfusion service and in England and elsewhere, a huge amount of work was undertaken from the mid to late 1970s until 1989 to try to find the key to testing for the virus or viruses—we did not know whether it was one or several. As Angus Macmillan Douglas said, the best that anyone could do was to use a non-specific test, which we call a liver function test, to check whether the liver had a bit of inflammation. The ALT test checks not for a virus in the blood, but for something being a bit wrong with the liver. As has been said, there is half a library's worth of professional debate about the pros and cons of introducing that non-specific test in the 1980s. There were arguments in favour of introducing it and some quite powerful arguments against doing so. It was difficult to perform the test safely, securely and consistently.

It is important to emphasise one point for the current discussion. The consensus among people who understood the issues of plasma fractionation and making plasma derivatives safe was that, because the test would miss a significant proportion of infections, products such as factor VIII, which are made from a large number of blood donations, would probably not be made any safer by the test. Probably the toughest of all the regulatory agencies—the Food and Drug Administration in the United States—concluded in 1986 or 1987 that there appeared to be little benefit in testing plasma for further manufacture with the ALT test, as the pool sizes—the number of donations put together—were large and the test lacked sensitivity. That was an issue for debate. The conclusion of the debate in the UK was that we would not test.

The Convener: So resources came into the decision, but it was fundamentally a clinical decision, based on the effectiveness or non-effectiveness of the test.

Dr McClelland: Resources were probably not the driving force for not using the ALT test.

The Convener: I want to open up the questioning to other members. We should bear in mind that comment, but remember that we have papers from which we can pick out all sorts of examples of discussions that took place. For example, the National Blood Transfusion Service's north London centre said:

"We feel that the **Department of Health** does not understand the full implications of screening for anti-HCV. It is not only that the blood derivatives will be more expensive but donors who are found to be positive will have to be counselled and, if necessary, referred to liver specialists who will treat them with expensive drugs such as Interferon. Who will pay for this? … At a cost of over £2 per test … it will cost this centre at least £600,000 to implement screening. I do not feel that it is justifiable to implement screening at the expense of waiting lists and bed closures.

Moreover, Non-A Non-B post transfusion hepatitis does not seem to be a significant problem in this country."

I could read out another three or four similar quotes, but I do not really want to. Resources were part of the considerations. However, if I read the witnesses correctly, they say that the clinical reasons for not testing were paramount.

Professor Ian Franklin (Scottish National Blood Transfusion Service): The important point, which Dr Simpson tried to make, concerns the safety of plasma products for the treatment of haemophilia. The safety of those products was not affected by ALT testing. It would not have been affected whether we undertook testing or not. Products that were imported to the UK and were made from ALT-tested plasma still transmitted hepatitis. What protected people with haemophilia from hepatitis C was effective heat treatment. A specific test would have had an impact, but it became available only in 1990. We protected haemophilia patients with heat treatment of their plasma products from 1987.

Many different views were heard and presented. ALT might have had an impact on the safety of red cells and platelets. That was where the main argument lay. It is fair to say that in the mid-1980s, when the debate was raging, there was doubt about how serious the problem was. That doubt has been removed, but it was in a series of publications from major groups in the UK—particularly a group from Manchester, which said in the *British Journal of Haematology* that it considered that non-A, non-B hepatitis in people with haemophilia was not a serious disorder. Those people were wrong, but that view was then current. It was not until the Sheffield group with Professor Preston and Dr Hay started doing liver biopsies that it became apparent that people with haemophilia were suffering liver damage from non-A, non-B hepatitis. There was a genuine debate, but I assure the committee that the safety of factor VIII products for haemophilia was not affected by whether we did ALT testing.

The Convener: So you are saying that the Scottish blood transfusion service started effective heat treatment in 1987, that the hepatitis C test was available from 1989 and that that test was put in place in the UK from 1991 onwards. Is that correct?

Professor Franklin: Yes. That would have had an impact, depending on the incidence of hepatitis C, on people who received single donation red cells and platelets, but not on haemophiliacs.

Nicola Sturgeon (Glasgow) (SNP): I have three points, which are partly points of clarification. I do not know whether you have had a chance to review the minutes that have been provided to the committee. Your argument that it was a clinical, not cost, decision not to introduce the ALT testing is not borne out by even a cursory reading of the minutes. Throughout, the discussion concentrates on cost-effectiveness.

The minutes of a meeting of the regional transfusion directors in 1986 talk about making an application to the Department of Health and Social Security for funding for a study to introduce ALT. That is just one example of many that do not bear out what you say.

The next point is more one of clarification of what you said about clinical effectiveness. A minute dated February 1989—early in that year—from a meeting of an advisory committee says that

"in Scotland the methodology for ALT testing had been examined and a standardisation had been agreed upon."

However, the committee still agreed that there would be no recommendation to institute ALT testing. I am not sure why that was decided.

The last point concerns the situation after 1989, when a specific test became available; however, there continue to be lengthy discussions about introducing such a test in the UK. It might be just bad minute-taking, but all the discussions seem to be about costs.

The minutes show that doctors applied to the health department for funding, the health department refused those applications and people were left disappointed by the response. Indeed, it became the issue that was holding up the introduction of the test. Although I hear what you are saying, your comments are not borne out by the papers in front of us.

10:15

Angus Macmillan Douglas: I will try to answer the first of your points and perhaps Dr McClelland or Professor Franklin can answer your question about the introduction of ALT methodology in Scotland and what happened after 1989.

I have not seen precisely what you are reading, but if I understand correctly, the minutes to which you refer are from meetings that took place in England.

Nicola Sturgeon: But the SNBTS was present at all of them.

Dorothy-Grace Elder (Glasgow) (SNP): Dr Whitrow was there.

Angus Macmillan Douglas: I have been in this service only four years; however, after considering all the facts that I have found, I have come to the conclusion that no resource issue altered the decision whether to apply ALT testing. It was a clinical decision. Indeed, as far as Scotland was concerned, there was adequate financing for research, and it allowed Peter Foster and his team

to become the most advanced service in the world to provide a hepatitis C-safe factor VIII. Furthermore, there was no funding restriction on anything else in that respect. We want to refute the idea that decisions on ALT testing in Scotland were not clinically driven—they were.

Convener, I would like to answer the other two points, because they are important.

The Convener: Before you do so, I should say that you have been given a copy of our papers; indeed, some members received them only this morning. As we will return to this issue next week after we have had a chance to read through the papers, we will take on board any written comments you might have, which will also give you a chance to read through the papers.

Earlier, I read out part of a letter dated 15 June 1987 from the SNBTS directors. It says:

"It is agreed that the size of the benefit to be gained from surrogate testing cannot be accurately established without a prospective study. However we argue that the time for the study has now passed. Starting now will give us an answer in 3 to 4 years and that is probably 3 to 4 years too late. The introduction of surrogate marker testing for Non-A Non-B is now virtually inescapable".

That means that it was an issue in Scotland as well as in England.

Angus Macmillan Douglas: I accept that. However, although we have not yet read these papers, which we will certainly do—and thank you for the offer to come back on them—I must repeat our very firm belief that the decision not to introduce ALT testing was clinically driven; it was not a resource issue.

A member mentioned that we considered ALT methodology, but did not introduce the test. I suppose that that was part of the debate at the time. Perhaps Dr McClelland will comment both on that point and on *The Lancet* article.

Dr McClelland: As I said before, the ALT test is difficult to do, because it is a variation of normal; it is not like looking for the presence or absence of a virus. As a result, it is very difficult to screen a healthy population with ALT testing in a way that will not produce vast numbers of false positives. As there was much debate about whether it would be a useful test or whether it had any safety gains, we felt that we had a duty to explore the test as fully as possible, including undertaking some pilot testing to establish the normal ranges in the healthy donor population to work out how we would implement it.

A letter contained in the minutes mentions a study. The SNBTS carried out a study—which we can make available to the committee—that examined the epidemiology of the ALT test in a healthy donor population. That made a material contribution to the debate, as it showed that there was some other perfectly straightforward explanation why most of the donors who obtained an abnormal test result did so—perhaps they had had a good drink the night before.

Our internal professional debate about this issue was made very transparent and public, because the correspondence columns of the same edition of *The Lancet* you have referred to contain two or three other letters raising different aspects of the debate. As a result, I feel that we were being very open about the fact that we were not sure what to do.

The Convener: Any published study or similar material would be helpful to the committee.

Nicola Sturgeon: I am aware that the point about the situation after 1989 still has to be addressed. However, a minute dated 24 February 1989 strongly suggests that there was some delay in introducing the test at a point when it could reasonably have been introduced. It says that

"in Scotland the methodology for ALT testing had been examined and a standardisation had been agreed upon."

That seems to suggest that something had been agreed. The minute goes on to say that it

"was available in RTCs if ALT testing was agreed."

However, it

"was agreed that there should be no recommendations to institute ALT testing although there was a degree of inevitability about the introduction of the test."

That suggests a situation where although the studies had been carried out and the standardisation agreed on, and although everyone at that meeting seemed to think that the introduction of the test was inevitable, there was a period during which they refused to introduce it. That passage seems quite important in these papers.

Dr McClelland: I completely understand your puzzlement. There are two points that must be made. First, in his introduction, Angus Macmillan Douglas said that we were working at the cutting edge; we were working all the time in an environment in which things were changing and new possible ways of addressing the problem were emerging. That was about 1989. Around that period, we had already begun to know on the scientific grapevine that a group in the US had done something completely new with new genetic technology and had managed to construct the hepatitis C virus from a fragment of a gene and had begun to develop what proved to be an extremely good specific test. By the time that the whole professional transfusion community was revisiting the question of ALT testing, it was already becoming evident that a much better and much more definitive test was available.

The second point has not yet been mentioned in the discussion, and it is important that we do so. There was a UK advisory committee on blood safety, whose specific topic was transfusion hepatitis. It channelled its advice through the Department of Health in England and shared it with health departments in Scotland, Wales and Northern Ireland. A number of specialists were on the committee, including people from the blood service, clinical specialists and others. They were not representing any particular service but were selected by the department's advisers as being the best people to give good professional advice.

Towards the end of 1988—although I would have to check the date—the committee said that, although a lot of work had been done on ALT testing, it was not going to advise the health departments to introduce it. I was not a member of that committee, but I believe that that recommendation was made in the knowledge that a much more powerful test was coming along. Given the finite resources—not so much of money but of people—it was decided that those resources should probably be directed towards the new and better test.

Nicola Sturgeon: And yet it was almost three years before that test was introduced.

Dr McClelland: That takes us on to a separate issue. At the moment, we are considering the development and timing of the practical introduction of ALT testing.

The Convener: All right. John McAllion, Dorothy-Grace Elder and Shona Robison wish to ask questions.

Nicola Sturgeon: Can we have some answers on the post-1989 period?

The Convener: I am trying to deal with things chronologically. Screening questions will come before heat treatment questions. In the earlier committee discussion on the questions that we would ask, a number of issues on heat treatment arose. I want to give members a chance to ask questions on screening before we move on to discuss heat treatment.

Mr John McAllion (Dundee East) (Lab): For the record, can the witnesses confirm that the decision not to test plasma products for the ALT enzyme was completely irrelevant to the safety of patients with non-A and non-B hepatitis? If it was irrelevant, were there other groups of patients who were using the service for whom it would have been relevant? If so, who were those groups? If that was a clinical decision, was it based on the overwhelming weight of clinical opinion internationally? If so, why were other countries testing for the enzyme when we were not?

Professor Franklin: I do not believe that ALT testing had an impact on the safety of plasma products for haemophiliacs.

Mr McAllion: You do not believe or you do not know? Was it belief or knowledge?

Professor Franklin: I know that it would not have had an impact because if we consider the statistics for the incidence of hepatitis C in the population, the number of people with hepatitis C who have a normal ALT and would therefore slip through the net and the size of our pools, we can provide calculations to show that all our pools would have been infected by donations—even with ALT testing.

You asked about other groups of patients, which is another issue. If one is not using any form of test, the number of positive donations for a red cell transfusion to a patient having hip surgery or whatever will depend on the incidence in the population. At that time, we had various donor exclusion criteria—excluding people with a history of hepatitis or with various other lifestyle markers. Those criteria were introduced mainly because of HIV but they covered many hepatitis C risks as well. Excluding the people covered by those criteria would have reduced the risk to below the level that it would have been for the general population. Some people would still have slipped through—even with ALT testing. However, ALT testing may have had some impact and may have excluded a few people who had hepatitis C. It is difficult to know how many. Once testing came in, there was a look-back study that was quite well publicised

My colleague, Mr Macmillan Douglas, has clarified the point that various countries such as the Netherlands, Norway and Sweden did not introduce ALT testing and that other countries did, either completely or partially.

10:30

Mr McAllion: Were the decisions marginal in those countries? Were they 60:40 decisions, 50:50 decisions, or what? Did some people not know whether we should introduce the tests? Were we taking risks that other countries were not taking?

Professor Franklin: Some countries weighed the evidence and decided to go for testing and others decided not to.

One point that we have not yet got across is that there were problems with the blood supply. The number of people who carry hepatitis C in Scotland is well below 1 per cent—I think that it is something like 0.03 per cent. If a non-specific test is brought in that takes out people who do not have the virus, it may take out 5 per cent of donors. We always run close to the limit—and we certainly did at that time. We keep blood stocks

that, ideally, last for about five days; usually, we are running with about three days' supply. That is quite a bit better than England usually manages. It often runs with about 12 hours' supply.

In the late 1980s, there was a perception that the level of blood supply was as important as measures such as ALT testing. Sitting here now in 2001 we might say that safety is paramount, but at that time there was a debate that balanced concerns about blood supply—considering whether we would run out of blood for lifesaving surgery—against concerns about unnecessarily worrying donors who did not have hepatitis but who had an abnormal test, and against concerns about safety.

Mr McAllion: Are you saying that concerns about costs played no part in decisions?

Professor Franklin: I was not a member of the service at that time and I was not present at those meetings. I therefore do not feel that I can categorically refute that suggestion. However, colleagues who were around at the time have made me confident that cost was not a significant issue.

Mr McAllion: The expert opinions that we have heard this morning have all been very learned and professional, but no one can confirm that consideration of resources did not play a major part in the decision not to go for surrogate testing, because no one was around when those decisions were taken.

Angus Macmillan Douglas: What we can do—and I have certainly relied on this—is go back and read in considerable depth the papers of the time.

Mr McAllion: But you have not read the collection of papers that we have here.

Angus Macmillan Douglas: To be honest, I do not know whether I have read them because I do not know what they are—although I have read the one on the top. I know from discussions within our service now, based on going back and reading the earnest and very professional debates that took place at the time, that resources were not an issue. They were not an issue in research into safe factor VIII and factor IX products—as is perhaps borne out by the fact that Peter Foster's team managed to produce a factor VIII product for all people with haemophilia in Scotland. That is not an absolute proof, but it does give an indication. Scotland was the first country in the world in which such a thing happened.

The debate on whether to introduce ALT testing seemed to me, from reading the papers, to be based on two things. I am talking particularly about the debate in Scotland but also internationally. First, ALT testing would have no effect on factor VIII and factor IX treatment for people with haemophilia—for the reasons that Professor Franklin has given—and secondly—

The Convener: Right. Two colleagues want to ask questions on this issue. We will hear both questions, after which the witnesses can answer them together. We will then move on to other questions.

Dorothy-Grace Elder: The minutes of the regional transfusion directors' meetings regularly mention the presence of Dr W Whitrow of the Scottish National Blood Transfusion Service. Is he still attached to the service in any way?

Angus Macmillan Douglas: No—he retired some years ago.

Dorothy-Grace Elder: Is he in Scotland?

Angus Macmillan Douglas: I do not know. I would have to check.

Dorothy-Grace Elder: It occurs to me—and it may have occurred to you—that Dr Whitrow might have been a valuable witness, as he represented the SNBTS at those meetings. Like my colleagues, I can find references only to money and time in those minutes. Indeed, it seems that Dr Whitrow, as usual, represented SNBTS at a meeting on 8 October 1986 at which—in connection with new legislation being introduced, possibly in 1988, to bring the UK into line with an EEC directive on product liability—the following statement was made:

> "The change could mean, for example, that recipients of blood who develop Non-A Non-B Hepatitis could sue successfully even if there were no negligence. To have done our best, or to plead insufficient funding would be an inadequate defence."

The warning was being given very clearly. Susan Deacon was incorrect—I think that you will agree—when she stated that hepatitis C was not identified until the late 1980s and early 1990s. We know from your earlier statements that hepatitis C was the successor name to non-A, non-B hepatitis.

I would like you to pick up on another point. Our memories must clash, because I was a journalist in the early and mid-1980s and I remember the Scottish National Blood Transfusion Service appealing many times to the then Thatcher Government for sums of money and being rejected. I recall that the SNBTS required only hundreds of thousands of pounds in those days for heat treatment and other experiments that it wished to carry out. Do you have no memory of the SNBTS appealing to the Government and being rejected? The service eventually got some money when the panic over AIDS was quite widespread. Please comment on those points.

The Convener: We shall take the question from Shona Robison first. The witnesses can then

answer both of them.

Shona Robison (North-East Scotland) (SNP): Were any of you in the blood transfusion service during the mid-1980s?

Angus Macmillan Douglas: Dr McClelland and Dr Foster were.

Shona Robison: One of the things that I am finding difficult is that we are having to look back at the debate that took place about 16 years ago.

You have said that there was a clinical difference of opinion on whether the test should be introduced. Why was the decision made not to introduce the test, when "the debate was raging"? Those words, which you used, suggest that there was a great difference of opinion.

The minutes from that period, which we have in front of us, should give fairly strong evidence about what the key debate of the time was. We have not seen any clear evidence from you to show what the debate was. The minutes talk about nothing other than cost. They contain no clinical debate. That is surprising, given the fact that you have on a number of occasions repeated that cost was not a factor and that the debate was about clinical judgment. If that was the case, why do the minutes that we are reading not represent that? Why is the main debate of that time written only as being about cost, not clinical judgment?

The Convener: It may be easier to answer that question once you have had a chance to read what we have in front of us. You may give us a written response or you may give us a response at the present time.

Angus Macmillan Douglas: I ask Professor Franklin to answer Dorothy-Grace Elder's questions.

Professor Franklin: I will have a go at answering them anyway.

I was the director of the haemophilia centre in Birmingham from 1983 until 1992, when I moved to Scotland. I dealt with adult patients; a colleague at the children's hospital looked after children.

I am not competent to judge the funding in Scotland and whether funding was denied or accepted, but I know that my colleagues used to look northward with some envy. When David Owen was a health minister in the 1970s, he made a commitment to self-sufficiency for England: that it would collect enough plasma to produce enough factor VIII for haemophilia patients. That was never achieved.

In the early 1980s, a new plant was established at Elstree. It was commissioned around the time of the identification of HIV in 1983-84. When it was realised that heat treatment would make the products HIV-safe, the plant had to close down for about nine months, as it could not carry out such a procedure. However, during that period, Scotland was able to supply the same products and was self-sufficient.

It is impossible for me to say that money was not requested and that some was not given, but it is clear that Scotland was doing an awful lot better than England. I suspect that your comment about appeals to the Thatcher Government relates more to the requirements of the haemophiliacs in England than to those of haemophiliacs in Scotland.

Dorothy-Grace Elder: No. There may have been double appeals from England and Scotland, but I clearly remember the Scottish appeal.

Professor Franklin: I understood that Scotland was self-sufficient very early.

The Convener: On the basis of the comments that have been made by committee members, and having read through the document that we have in front of us, which I accept is selective, I think that there are other issues than the resource issue. However the issue of resources comes across loud and clear. If, after reading the document, you could respond to us in writing with any further evidence that you want to weigh against it, that would be useful. Shona Robison's question to you was based on the document, which we accept is selective. To give a full answer to that question, you will have to read the document. You have tried to give us as much information as you can, and I now want to move on to heat treatment.

Nicola Sturgeon: We have not yet had the chance to discuss screening. The document contains minutes from the period after 1989, when all the witnesses will accept that there was a test, but there was still a delay in introducing screening.

The Convener: Yes, screening was not introduced until 1991.

Nicola Sturgeon: The paper suggests that that delay was for financial reasons. Rather than take up time today in discussing that, perhaps the issue could be—

Dr Simpson: With due respect, as the fractionated blood products were rendered safe in 1987, is the debate about any general screening of blood in 1990-91 relevant to the debate on haemophilia? It is into the haemophilia issue that the committee is conducting an inquiry. If we chose to pursue a further inquiry into screening for hepatitis C after the test was available, and if Nicola Sturgeon proposed it, I would be happy to discuss the matter. However, that issue is not relevant to the inquiry that we are pursuing at the moment.

Nicola Sturgeon: I am not suggesting that we take up any more time on the issue today.

However, the Scottish National Blood Transfusion Service may want to comment on it in its written response to us.

Dr Simpson: We should not confuse the issues, though.

Nicola Sturgeon: No, but the matter is relevant.

The Convener: I take the points that colleagues are making. I agree with Richard Simpson's comment, but if you could cover that issue in any written response that you give to these papers, that would be useful. Let us move on to our original second question.

Dorothy-Grace Elder: I dare say that you have read the written statements of the Haemophilia Society. Can you comment on the fact that approximately 400 haemophiliacs in Scotland depend on the safe factor VIII? Could it not have been considered the duty of the Scottish National Blood Transfusion Service to adopt the tested heat-treatment methodology that was used in England?

Angus Macmillan Douglas: I shall ask Peter Foster to answer that in detail in a moment. Let me first clarify your question, which I did not hear properly as the door opened and closed in the middle of it. Are you asking why Scotland was not able to introduce the hepatitis C-safe factor VIII product in autumn 1985, although it had been introduced for a minority of patients in England?

Dorothy-Grace Elder: Yes.

10:45

Angus Macmillan Douglas: Peter Foster will be able to answer that in detail, as he was instrumental in discovering the safe product in Scotland. Everyone in developed countries was struggling to produce a hepatitis C-safe factor VIII or factor IX product at that time. Our colleagues in England, with whom we were working, got there first but were unable to scale it up to supply the product to more than a minority of people with haemophilia in England. Peter Foster and his colleagues in the Scottish National Blood Transfusion Service were able to scale up that cutting-edge technology so that there was sufficient product safe from hepatitis C for everyone with haemophilia in Scotland.

Dorothy-Grace Elder: Is the issue not linked to the question that I asked earlier? Was there not a controversy raging—which anyone who was in your organisation at the time will remember—over your appealing urgently to the Government of the day, over several years, for money for a new factor VIII heat treatment centre?

Angus Macmillan Douglas: I invite Peter Foster to answer that, as he was there at the time.

Dr Foster: The fractionation centre at which we carry out manufacturing was constructed in the mid-1970s. Funding was given in 1980 for an extension to it for research laboratories and expensive equipment. That was instrumental in allowing us to develop heat treatment subsequently. The building of those laboratories began in 1980 and they were available by 1982, before HIV emerged. They helped to support our work on dealing with hepatitis C. I am not aware of any funding restrictions on developing heat-treated factor VIII.

Dorothy-Grace Elder: You say that that was before the discovery of HIV, but regular applications for more money were made to the Conservative Government after 1982, which is the last date to which you refer. Do you not recall any of those appeals for several hundred thousand pounds to apply the proven heat treatment?

Angus Macmillan Douglas: People who work in public services bid for money every year.

Dorothy-Grace Elder: I know, but those bids were linked to AIDS research and all the problems that we were having.

Dr Foster: Funding was not an issue in the development of heat treatment and the manufacture of heat-treated products; the funding and facilities were available for that work.

Dorothy-Grace Elder: So why is funding such an issue in the minutes?

Dr Foster: Please allow me to continue. We made further improvements and expansions throughout the 1980s and into the 1990s, and there may well have been additional bids for money, but lack of funding did not prevent us from developing or introducing heat-treated factor VIII.

The Convener: Let us establish a layperson's view of what you were trying to do in the early 1980s. You appear to have pursued a different type of system—a pasteurisation system, as I understand it—and HIV was what you were mainly trying to protect people from. Is that a fair reflection of what you were doing?

Angus Macmillan Douglas: I invite Professor Franklin to answer that.

Professor Franklin: There are two important facts to realise. First, the intention to use increasingly rigorous heat treatment was based on the assumption that it would provide a general enhancement of safety. We did not know until later that 80 deg C was the magic figure that dealt with hepatitis C. The feeling was that we were trying to increase the rigour of the heat treatment to improve safety generally.

The other important point is that if we get it wrong we can damage the factor VIII. That can

lead to reactions—called inhibitors—in the patients, which make it impossible for them to receive the usual treatment thereafter. There is therefore a down side to simply turning up the oven. There are actually two down sides. The other is that a lot of material is wasted and not enough is produced to treat the patients.

It is important to realise that we were generally trying to improve the rigour of the heat treatment not knowing at what point it would become hepatitis safe. At the same time, we were ensuring that we could maintain self-sufficiency and that the product was safe.

The Convener: Are you saying that, while you were going down your track, your colleagues in England were going down a slightly different track?

Professor Franklin: The track was pretty similar. I think that there were a few technical differences, which I am sure Dr Foster could describe for you.

The Convener: Your colleagues in England were going down a slightly different route. Can you talk us through what changes were made in your system to make you self-sufficient and able to make a safe product available to all haemophiliacs in Scotland, from the point at which it became clear that they had made the breakthrough? Can you talk us through the convergence of the different routes?

Dr Foster: Yes. During the 1970s, everyone in SNBTS and other blood transfusion services was working to address hepatitis. By the early 1980s, the concept of applying heat treatment was emerging and scientific breakthroughs around the world were beginning to influence the research and how we might be able to advance it.

The Germans were working on a pasteurisation process. There was some evidence that that might be effective against non-A, non-B hepatitis. That is why we began to work on that process. There were a number of serious difficulties with the process at that time and it was not viable. Our colleagues in England were also examining it and we were discussing it with them.

Another approach, which was being developed in the United States of America, was to heat the product in its freeze-dried form. We were looking at that too and so were our colleagues in England.

We were exploring the options not knowing which might work. That was all to address hepatitis. Then HIV came along, and we proceeded on a parallel track. We continued our research on pasteurisation because there was some evidence that that procedure might be effective. The evidence was not good, but there was some. There were problems with the process and we were trying to improve it.

Our colleagues in England were also looking at the dry heat treatment. By the mid-1980s, they made a breakthrough, in which they were able to increase the temperature to 80 deg C. To do that, they had to prepare factor VIII in a completely different way.

Dry heat treatment at 80 deg C could not be applied to the established product, which could be heated up to about 68 deg C, but above which it was destroyed and of no value. It turned out, fortuitously, that heating to 68 deg C is sufficient to deactivate HIV and we did that immediately. Our colleagues in England did not do that; they chose to continue to work on the 80 deg C dry heat treatment and subsequently managed to bring that into their manufacturing practice.

That was in September 1985. During 1985, we were still working on all the options. There were two difficulties with the 80 deg C dry heat treatment. First, there was no evidence that it would be effective against non-A, non-B hepatitis. Secondly, what our colleagues in England had done in their process to allow the product to tolerate being heated was not known. They had stumbled upon the process and did not understand it fully. Our research in late 1985 revealed what it was about the process that allowed it to work. We discussed that with them and assisted them to control their process better and have a better understanding of it.

It was at that point that we decided to go forward with the technology ourselves. As I explained, it is a complicated bio-pharmaceutical manufacturing process. In order to put it into place, we had to design a new process, specify all the operational steps, establish all the operating conditions, purchase and specify equipment and train staff. We had to document the process, trial the process at pilot scale and scale it up to manufacturing scale.

To give the committee a sense of what was involved, it is important to appreciate that manufacturing one batch of factor VIII—to carry out the process and do all the testing—takes three months. It cannot be done in a few hours or in a day. We had to put in place a whole new manufacturing process to manufacture a large number of batches of factor VIII to treat haemophiliacs and we did that very rapidly.

By the autumn of 1986, we were already beginning to trial full-scale manufacturing batches in our facility. That material was available from December 1986 for clinical trial. The preparation of those clinical trial batches had begun before there was any evidence that the 80 deg C dry heat treatment would be effective against non-A, non-B hepatitis.

The Convener: Your clinical trials were therefore within about a year of the English stumbling, to use your word, on the treatment.

Dr Foster: Our ability to prepare a product in an appropriate manner that was suitable for clinical use allowed us to carry out clinical trials in the early part of 1987 to demonstrate that the product was effective and that it could be tolerated by patients.

Nicola Sturgeon: I suspect that no member of the committee is properly qualified to judge whether enough was done between 1985 and 1987 to introduce the heat treatment quickly enough. Notwithstanding that, it was known between 1985 and 1987 that there was a non-A, non-B hepatitis virus that could be transmitted through factor VIII. Do you think that during that period enough information and advice was given to people who were receiving factor VIII treatment, to warn them of the risks?

Professor Franklin: Responsibility for advising people with haemophilia lies with the doctors who look after them. The detail of the question therefore needs to be directed at the haemophilia directors.

When we met the Haemophilia Society late in 1999, I hope we were able to satisfy it that the product literature that we had to provide with all factor VIII made clear that we could not guarantee that it would be free of the risk of hepatitis or, indeed, other viruses. At that time, we also had meetings—we still do—with the haemophilia directors in which we discussed product specifications and the amount they would need to treat patients, which has gone up as treatment has changed and improved. I therefore think that there was an awareness that those products could transmit viruses.

Nicola Sturgeon: I appreciate that advice to patients would be provided by doctors, but did the transfusion service say to people expressly, "There is a virus around. We do not quite know what it is yet but we know that it is around, it can be transmitted through factor VIII and that is a definite risk posed by the product"? I say that as a lay person.

Professor Franklin: There is not really a forum for the SNBTS to meet directly with patients to put that across.

Nicola Sturgeon: Was that risk made known to doctors, who were, as you say, given product information?

Professor Franklin: I think that the answer to that is yes, because we met regularly. People with haemophilia are treated by a very small number of doctors directly. They are haemophilia centre directors and are basically grouped in Scotland's major cities. The subject is highly specialised. A lot of nursing support, physiotherapy and expert orthopaedic back-up, for example, is required. Treatment takes place in only about five or six hospitals—not in every district general hospital—— perhaps seven if you add in the paediatric centres.

All the doctors who are responsible for the direct care of people with haemophilia in Scotland and Northern Ireland attend what is now called the coagulation factor working party—I am not sure whether it had that exact title in the early and mid-1980s. Members of that working party discussed with the doctors the safety of the products and their specification, or how pure they were, which was not directly related to virus risk. Open discussions took place about the quality of the products, and the general purity of the products improved throughout that period.

11:00

Dorothy-Grace Elder: Could I just ask—

The Convener: No. I want to move on to Richard Simpson.

Dr Simpson: Do you think that the information that is now given to patients is appropriate and adequate? My other question is much longer, as it relates to the time frame and follows on from and completes Nicola Sturgeon's question, which I was down to ask.

Professor Franklin: I am not really the right person to answer that question. Although it is a little while since I was a haemophilia centre director, the awareness among the haemophilia patient population and the doctors who treat them is such that I would be amazed if full and open discussion were not taking place. I should mention the obvious concerns about variant CJD and so on, about which I understand a lot of debate and one-to-one discussion is taking place.

Dr Simpson: It is obvious that the current debate about new variant CJD is similar to the debate in the mid-1980s about hep C. It would be interesting to see whether we have learned any lessons about recording information and about ensuring that the debate is as transparent as possible, as we do not want to have another inquiry in 16 years' time.

Dr McClelland: We can document the fact that, over the relevant period, members of staff from the Scottish National Blood Transfusion Service were constantly involved in publishing, teaching and giving lectures as well as exhorting clinical colleagues to think about the fact that, in the broadest sense, blood had risks and, like most effective treatments, was not completely safe. If it becomes a matter of evidence, we can show that we were very busily involved in trying to maintain a

flow of technical and educational information to the professional medical community. As Angus Macmillan Douglas implied, the appropriate role for us as a manufacturing organisation was to try to reach patients through their clinicians.

Dr Simpson: Yes—it is all about benefit and risk. That is the problem.

I will move on to my other question. We have been talking a lot about time frames—much of the inquiry and the Executive's report concentrated on the time frames. Can you talk us through it? The English started to provide some product to some patients before we did; we then caught up and, I think, provided treatment to all our patients. At that point, were there still patients in the rest of the UK who were receiving what we now know to have been unsafe blood—blood that was not treated in the new way?

Angus Macmillan Douglas: Yes, there were.

Dr Simpson: For how long did that go on? Can you tell us a little about that?

Dr Foster: If we are talking about products that have been treated and made safe in relation to hepatitis C transmission, we know that our colleagues in Bio Products Laboratory began to issue products heated to 80 deg C near the end of 1985. A relatively small proportion of patients in England was treated with that product at that time. In 1986 and 1987, 30 per cent of the factor VIII in England was of that type; the remainder of the factor VIII in England was imported almost entirely from US paid donors and was not made safe, as far as I can judge and as we would recognise it today, with regard to hepatitis C. In 1988, more than half the factor VIII used in England was still being imported and was not made safe. I do not know exactly when all the factor VIII used in England was made safe with regard to hepatitis C.

Angus Macmillan Douglas: But from July 1987 there was sufficient hepatitis C-safe factor VIII in Scotland to treat all people with haemophilia in Scotland. We cannot say with absolute certainty whether every person with haemophilia was treated with our product, because it is open to doctors to decide which product to use.

Dorothy-Grace Elder: Convener, may I ask—

The Convener: No.

Dorothy-Grace Elder: —about American blood imports—

The Convener: No.

Dorothy-Grace Elder: —of skid row blood—

The Convener: I said no, Dorothy-Grace.

Mary Scanlon (Highlands and Islands) (Con): Most of the questions that I wrote down have been answered somewhere along the line. I will raise two fairly brief points about negligence, which is at the heart of this issue.

Most of my colleagues have concentrated on resources. I appreciate that that is a serious issue. I put it to you that procrastination is also an issue: the matter was not taken seriously enough and there was an unwillingness to address the situation. When members came to your committee meetings, either they were unprepared or, quite often, they were thwarted—I am reading between the lines. Were you negligent in addressing the situation?

The heat treatment and the fractionation process inactivated hep C, but the same process in Scotland was ineffective for hep C. With hindsight, is there anything that you could have done to protect patients in Scotland that you did not do? The petitions call for a public inquiry and for compensation. Can you put your hands up and say that you were negligent in relation to either of those issues?

Angus Macmillan Douglas: I will ask Peter Foster to answer your question about whether there was anything else we could have done between the autumn of 1985 and the spring of 1987.

First, for the sake of absolute clarity, we are saying clearly that we do not believe that there was a resource issue. I know that you did not ask that specific question, but that is what we are saying.

From reading through the material from the time—I do not think that the Scottish National Blood Transfusion Service could be blamed for, or rather accused justifiably of, procrastinating. The introduction of a factor VIII product that was hepatitis C-safe has been dealt with fully. We were the first nation in the world to be able to provide hep C-safe factor VIII product for all our people with haemophilia. If we could do that while procrastinating, what was everyone else doing? We believe that that was a considerable achievement for the people involved at the time—I take no credit for that achievement.

On ALT testing of donors, a rigorous international debate was going on. On the one hand, those involved in the debate said, "You have to introduce this test because, although it is imperfect, it might screen out some people with hepatitis C." However, that test would not have screened out enough people to have had an impact on products for haemophiliacs, although it might have had some impact on people who were getting red cells. The risk was that there would not have been enough blood to treat people who needed it. We had to weigh one risk against another risk. I do not think that there was

procrastination—rather there was earnest, international debate.

That brings us on to what went on during those 18 months in the mid-1980s. Peter Foster will deal with that.

Dr Foster: First, I would like to remind the committee that there were two aspects to the heat treatment: HIV and hepatitis C. In relation to HIV, we introduced a heat-treated product in December 1984. Because we had healthy stocks of factor VIII, we were, in effect, able to heat treat those stocks and, in a sense, back-date the treatment to 1983 as the key date is when the donor donates, not when the heat treatment is performed. We were well in advance of anyone else in the world in providing HIV-safe factor VIII for our population. Our colleagues in England did not do that. They did not have the stocks of factor VIII that we had and they did not introduce heat treatment until later.

In relation to hepatitis C, our colleagues in England were the first in the world to heat treat factor VIII at 80 deg C and we were the second. As the process was difficult—we know of two other manufacturers who were trying to do what we were doing and failed—I do not think that we can be judged to have been negligent because we were second.

Mary Scanlon: With the benefit of hindsight, is there anything that you could have done to change the situation that we are faced with?

Dr Foster: Even with the benefit of hindsight and all the current knowledge of the hepatitis C virus, I do not think that we could have done anything sooner than we did.

Shona Robison: Professor Franklin made an interesting comment about safety being paramount at all costs these days. Does that mean that, today, there is a different standard in the making of judgments about bringing in tests and so on and that we would err on the side of caution more now than we would have done 15 or so years ago?

Professor Franklin: There was a bigger concern in the past that blood supply was important. In most developed western countries, blood usage is beginning to plateau or reduce slightly, as it has in France and the USA. The concerns about having enough blood are therefore less important. The perfectly legitimate concerns that have been expressed by the Haemophilia Society and others at today's meeting show that time moves on. The European Commission aims to have zero risk from blood. I do not think that anyone believes that that can be achieved, but I have heard that statement made.

Shona Robison: I know that this is a difficult question to answer, but does not what you have just said about standards changing add weight to the claim of people who are seeking compensation that the standards were different 16 years ago?

Professor Franklin: I do not think that you can expect me to answer that question about the compensation claim. That has to be addressed to the minister. I will try to answer it in a different way. If we had a test for variant CJD that was as unsatisfactory and non specific as ALT, I think we would have to implement it.

Shona Robison: Your submission says that you are concerned about the supply of blood because of the debate that has been going on. Do you have any evidence to suggest that there might be a problem with the supply of blood?

Professor Franklin: I do not have that evidence with me so I cannot give you the figures, but we could include some evidence in a further written response.

Angus Macmillan Douglas: I think that it was probably me who mentioned the concern about the supply of blood. I did not raise that concern because of the on-going debate but because ALT was an inaccurate test. It delivered a lot of false positives. In other words, it indicated that many people had or might have hepatitis C when they did not. They would have been excluded from the blood supply and there would have been no blood for those who went in for emergency operations.

Shona Robison: My point was about media representations. You have said that you fear that there is a causal connection between those representations and the fall in blood donations. Do you have evidence to support that?

Professor Franklin: No. There have been concerns that people who usually donate blood would not come forward because of scares. That happened with HIV, but the general population is much more knowledgeable now. When we switched from Scottish plasma to American and German plasma because of variant CJD worries, we were concerned that there would be anxiety among donors, but the number of donors did not drop.

11:15

Dr McClelland: For many people who have volunteered and psyched themselves up to give a blood donation, it is quite distressing if we tell them that they cannot give blood. People always ask me about that. When they find out what I do, that is the first thing that they tell me—"I went to try to give blood but you wouldn't accept me." Between 5 per cent and 10 per cent of people who volunteer would be turned away if we had to do ALT testing. We know from our own and others'

research that most of those people will never return. The effect on the long-term ability to motivate people to give blood can be profound. The risk is quite substantial.

Janis Hughes (Glasgow Rutherglen) (Lab): Have any cases been brought against the SNBTS as a result of infection with hepatitis C?

Angus Macmillan Douglas: I think that there are about 50 cases, which relate mainly to transfusion of red cells. Those cases await decisions. In England, there are about 10 times that number of cases.

Janis Hughes: So those cases are continuing and following the legal process.

Angus Macmillan Douglas: In Scotland, they are not continuing. I am not a lawyer, but I know that, although they are lodged with the court, they are not being progressed.

Mr McAllion: You described the report of the Scottish Executive's inquiry as an accurate, if simplified, account. Others have said that the Executive's reporting on the SNBTS, which is part of the Scottish national health service, amounts to little more than an internal inquiry and that, because of the controversial nature of the issue, that is not good enough. Is that fair criticism?

Angus Macmillan Douglas: All that I can answer on is how we were brought into the process and what we did. I understand that, as the result of a meeting between the minister and the Haemophilia Society, it was decided to have an investigation. We answered as best we could all the questions that were asked of us. We submitted a full report. We were pleased to be found to have acted properly with regard to the report. It is not really for me to comment on whether the remit of the report was right or on any other aspect of it.

Mr McAllion: Will you confirm whether Government officials are members of the board of the SNBTS?

Angus Macmillan Douglas: They are not. The management board of the service contains no external directors. It is true that the deputy chief medical officer is an observer member of our medical and scientific committee. The deputy chief medical officer and a nominee from the chief scientist's office are members of our research advisory committee.

Mr McAllion: However, you are accountable through the Scottish national health service to the Scottish health department and the Scottish ministers, so in that sense the inquiry was completely internal.

Angus Macmillan Douglas: You describe our reporting relationship correctly.

Mr McAllion: None of the evidence that doctors, medical professionals and even infected haemophiliacs submitted to the inquiry was published with the report. Is that good? Earlier, you talked about the importance of transparency and openness.

Angus Macmillan Douglas: I do not honestly think that I can comment on that. I know what our service tries to do, which is to be as transparent as possible. What has changed in the recent past is that there is now consensus that even—or particularly—when risks are involved, they should be made transparent. The handling of the variant CJD issue, to which Professor Franklin referred, bears that out.

Mr McAllion: Are you classified as civil servants?

Angus Macmillan Douglas: I am very sorry, but I am unsure.

Mr McAllion: You do not know what you are?

The Convener: We are all civil servants in the broadest sense.

I have a compromise. I am trying to be as fair as possible. I am well aware that we have kept the witnesses for a considerable time and that representatives of the Haemophilia Society are waiting. I ask Dorothy-Grace Elder to put her question to the representatives of the SNBTS on the record. They can answer as part of their written submission, which will take care of the time issue.

Dorothy-Grace Elder: Your submission says that you believe that, following the Executive's inquiry, information that is given to patients should be accurate. What information is now being given to patients?

The Convener: Sorry, Dorothy-Grace, I meant the question that you tried to ask about American blood products. Please put that on the record, so that we can obtain a response later. You were excited about getting that on the record, so I am giving you the option.

Dorothy-Grace Elder: I thought that we were following the list of questions. Thank you, convener—I appreciate the opportunity to ask my question.

Dr Foster, you mentioned blood products that were imported from the United States. Do you recall that happening?

Dr Foster: I do.

Dorothy-Grace Elder: That was in the 1980s. As you said, that blood was untreated and was regarded as suspect, because some of it came from bought donations. I recall that the phrase that was used was that Britain was buying skid-row blood. Patients who were infected through that

were largely in England. I do not think that Scotland bought direct from America—I may be wrong. Perhaps you could clarify that. However, do you know of Scots or English folk who came up to settle in Scotland and who received treatment via that infected blood, which was bought from the United States to save money?

The Convener: I will clarify that point. Did the SNBTS make use of imported US blood products? What was the efficacy and safety of those products? Please could you respond in writing to that, as we are up against time constraints.

Dorothy-Grace Elder: I also asked about patients who may have been infected through the importation of that blood into England.

The Convener: I thank the witnesses for their submission and their oral evidence, and for answering extensive questioning. Without wanting to prejudice anything, I will say on a related point that, as Shona Robison said, committee members are well aware of the spread of the work that the SNBTS does. Most people in this room will probably have cause to make use of it. I am sure that we will have you back to talk about other aspects of your work, which I hope will be more pleasant to you and those that use the service. I thank the witnesses for their time. We will now have a three-minute comfort break.

11:23

Meeting adjourned.

11:29

On resuming—

The Convener: We will now hear evidence from the Haemophilia Society. I welcome the witnesses. Thank you for your patience in listening to the evidence that we have taken today from the SNBTS. We have your written statement and various other pieces of evidence that you have given us over time. Most of us, at one point or another, have also had the opportunity to meet some of you to discuss this matter. If you begin with a short statement, that will lead into questions from committee members.

Philip Dolan (Haemophilia Society): On behalf of the Haemophilia Society, I welcome the opportunity to share with the committee our concerns about the report on hepatitis C and the heat treatment of blood products for haemophiliacs, which was published in October.

I am the chairman of the Scottish groups forum and the vice-chairman of the Haemophilia Society in the UK. I have haemophilia and, like many people with haemophilia, I have been infected with hepatitis C through blood products, so I state my particular interest. Our representatives today are Karin Pappenheim, the chief executive of the Haemophilia Society, Pat McAughey, a trustee of the Haemophilia Society and the wife of a person with haemophilia, and Bill Wright and Ken Peacock, who are also members of the Haemophilia Society and have haemophilia.

We have lodged a letter from Lord Morris of Manchester, who is the president of the Haemophilia Society. He has been very supportive of the haemophilia and hepatitis campaign for many years, and I am sure that you will be interested in his comments.

It is our contention that the Executive's report failed to address the main concerns of the members of the haemophilia community who are affected by hepatitis C. In our submission, we highlighted some of the issues; we will be pleased to answer any questions that arise from it.

The committee will be aware that the petition on haemophilia and hepatitis that was lodged with the Parliament on 9 December 1999 is an on-going issue. Indeed, it was referred to earlier today. It was on the committee's agenda for years and months, awaiting the outcome of a ministerial report.

We are delighted by the cross-party support given to Brian Adam's motion—84 MSPs supported it—calling for a hepatitis C inquiry. It said:

"That the Parliament calls for an independent inquiry into hepatitis C and other infections of people with haemophilia contracted from contaminated blood products in Scotland."

We contend that the report, which was published in October, failed to address the issues that were raised with the minister. In our submission to the Scottish Executive in December 1999, the society said that the inquiry into contaminated blood products in Scotland had to be undertaken by an independent body and not by officials of the Scottish Executive. As there were questions, which still remain, about negligence and liability, we pointed out the possible conflict of interest that could arise if a Government body investigated the use of contaminated blood products in the NHS. That advice was ignored. The Minister for Health and Community Care and her department have never addressed the conflict of interest. An internal inquiry has been carried out behind closed doors, so it has not been open or transparent, despite assurances that were given when we first met the minister and officials in September 1999.

Today, we are asking the Health and Community Care Committee to review our request for an independent inquiry. We need an explanation of why so many people with haemophilia have been exposed to hepatitis C. We are not looking for sympathy; we are looking

for justice and an understanding of why this has happened.

The Convener: Thank you very much, Mr Dolan.

Mary Scanlon: Given your statement and the opinion of the Executive inquiry that you expressed in it, do you believe that anything would be gained by an independent inquiry now that the Executive inquiry has been completed? You have said that the process was not open and transparent, that you were not consulted and that scientists and medical experts were excluded from the process. What else could be gained from an independent inquiry?

Philip Dolan: First and foremost, we believe that an independent inquiry would examine all the issues that have arisen in the contamination of blood products.

I say to Mary Scanlon and the convener, if I can crave your indulgence, that my colleagues each want to make a short submission, which would address some of those issues.

The Convener: May I crave your indulgence? You know what your colleagues know to a greater extent than we do. As we fire questions at you, I ask you to do what the witnesses from the Scottish National Blood Transfusion Service did earlier, which is to parcel the answers out among yourselves. We will be taking further written evidence from the blood transfusion service, as you heard earlier. If, at the end of your evidence today, any of you feel that would like to make further points, I am perfectly relaxed about letting you pick up on points that in retrospect you feel you have not covered.

We do not have the time to allow every witness to respond to every question. It is in your hands, Mr Dolan, to parcel out the questions to the most appropriate people in your team.

Philip Dolan: I thank you for your advice.

I ask Karin Pappenheim to follow up on the point that Mrs Scanlon raised.

Karin Pappenheim (Haemophilia Society): We are pleased to have the opportunity to speak with the committee about these issues.

On why we have called for a public inquiry, I draw the committee's attention to one of the documents that we have distributed to you this morning, which is from Dr Peter Jones, a haemophilia centre director and haemophilia expert who has worked in haemophilia care throughout the period that we are discussing. He is now a member of the World Federation of Haemophilia.

Dr Peter Jones has made a powerful statement, as somebody who has worked in the sector and seen many of his patients become ill and die as a result of contaminated blood. I will read some of the most noteworthy passages from his statement. We are speaking about somebody who worked as an expert clinician throughout this period. He states that:

> "there has, to my knowledge, never been full disclosure of the facts relating to the management and funding of the UK blood and blood product supply. The public need to have confidence in their blood supply. Yet there remains serious public concern at how people became infected and the consequences of those infections … It is a basic human right that patients have their questions about treatment answered and that actions occurring in the course of that treatment are fully explained. There is a need for closure within the haemophilia community and that will not come about until everybody has had the opportunity to ask their questions and have them answered in a dignified and compassionate way by the authorities."

For all those who are with me today, who have haemophilia, this is perhaps the first opportunity that they have had to say something about their experiences. Having been exposed to contaminated blood products and contracted hepatitis C, this is their first opportunity to speak about it. Each one has a personal story to tell. Many of the questions that we raised with the Minister for Health and Community Care in September 1999, when we first had a meeting with her, remain unanswered. We feel, from what we have heard so far, that many questions, some of which my colleagues will mention, are left unanswered.

Mary Scanlon: This is a very important point, and I am not unsympathetic to your inquiry. There are two separate issues: do you simply require more explanation and need to have questions answered, with more open dialogue with the Minister for Health and Community Care, or do you have further evidence that needs to be taken into account, which is perhaps more important for our purposes?

Philip Dolan: The Scottish Executive's report wrote off the Haemophilia Society and the people who gave submissions in one paragraph. It dismissed us. The Executive did not invite us to give information. A lot of evidence is now available—it is coming out regularly. Since May last year, there has been a tribunal of inquiry in southern Ireland. That is still going on, and a lot of information is coming from it.

Mary Scanlon: That is the crucial point, Mr Dolan. This is a cross-party issue, and I am sympathetic if you feel that there is further evidence that has not been taken into account, or further evidence that you have, which would make this an open, honest, transparent process. If you are saying that you have further evidence, that is what I want to know, and is the crucial point for me.

Philip Dolan: Further evidence is available.

Mary Scanlon: Is it the case that that further evidence has not been taken into account?

Philip Dolan: That is correct.

Mary Scanlon: Can I confirm that the Executive's report wrote off the Haemophilia Society's submission in the space of one paragraph out of 22 pages?

Philip Dolan: That is correct.

Mary Scanlon: However, you feel that the evidence in your submission would make a difference to the outcome—in other words, that it is crucial evidence.

Philip Dolan: That is our belief.

Mr McAllion: I want to be clear about this. You will have heard the earlier evidence from the Scottish National Blood Transfusion Service. It was aware of the risks, and directors of haemophilia centres were aware of the risks in the 1980s. The real question is whether the patients were informed of those risks in every case. Is one of your points that the Executive inquiry did not give patients and you the opportunity to present contrary evidence, that patients were not being informed of the risks at the time?

Philip Dolan: Yes. I will make a brief comment about that, and Ken Peacock will speak after that. I, as a person with haemophilia, have been treated for a long time. I am the person at this table with the grey hair.

The Convener: We all end up with grey hair here, Mr Dolan.

Mr McAllion: Some of us quicker than others.

Philip Dolan: I had never previously been warned about a virus in the blood. Being one of the older people with haemophilia, I am not on self-treatment, so I do not take packets of factor VIII home with me. When I go to hospital, the factor VIII arrives in a syringe. There is no label on the syringe, saying, "This has a virus."

I was having treatment only last week. There is no warning or sign up in the Royal infirmary in Glasgow to indicate that there are viruses around. I can assure members that the only reason that I knew that I had hepatitis C was because I was active as a member of the Haemophilia Society, and had asked my consultant about it. Only at that point was I told, "You don't want to know about these things." Then I was given the information. In that sense, we were not told.

Ken Peacock (Haemophilia Society): Like Phil Dolan, I was eventually told that I had hepatitis C in 1992. I was not told that I was going to be tested for it; I was told that I had it. I have severe haemophilia, but I can tell you something: when someone tells you that you have something like hepatitis C, your whole life changes.

Even to this day, there are no warnings in treatment rooms. There are warnings on the packets, but I ask anyone on this committee: if you get a packet of pills from the doctor, how often do you read the wee bit of paper inside the packet, which tells you about the product? People do not do that: the doctor prescribes the medication for people, and they take it. When the box is finished, they throw it in the bin. It might not be perfect, but that is what people do. In my experience, we have never been told about the risk from blood products, which still exists.

Mr McAllion: And your evidence did not form part of the Executive inquiry into this issue.

Ken Peacock: Nobody seemed to put much credence in it.

Philip Dolan: We were never asked.

11:45

Nicola Sturgeon: If the committee decided that your calls for a public inquiry were justified, the grounds for such an inquiry would have to be very clear. From the evidence I have heard this morning and from what I have read, it seems that an inquiry could be justified on three grounds: the conflict of interest; the fact that the report did not consider screening or some of the evidence that was available on that debate; and the question whether sufficient information was available to patients. Could a public inquiry cover those three areas in a way that the initial Executive inquiry did not do?

My second question leads on from that. The central conclusion of Susan Deacon's inquiry was that, between 1985 and 1987, the blood transfusion service had not been negligent in the length of time it took to manufacture heat-treated products. Are you happy to accept that conclusion or do you challenge it?

Karin Pappenheim: The committee has picked up on the issue of whether information was adequately provided to patients. We are extremely concerned that the Executive department report has been conducted without patients having been consulted. At the Haemophilia Society, we have continually heard that people were not warned. Parents were not warned about the possible risks of viral transmission in treatment for their children, and adults were similarly not informed. People have often said that they first became aware of hepatitis when they received some information late in the day from the Haemophilia Society.

That very significant area has not been covered, and we hope that a public inquiry would examine

it, but not purely for the purpose of looking backwards. This issue is critical for public health and the communication of risks around public health in future. For example, it has already been mentioned that variant CJD is a theoretical risk in blood products. As a result, examining this issue in an inquiry not only will give us an understanding of the past, but will help us to deal with the issues better in future.

The Convener: The minister made a point that was made again this morning; indeed, I hear colleagues muttering it around the table. You have mentioned communication of information about risk. But should we not set this in the context of haemophilia patients receiving treatment which saves them from—what? Is the issue not about balance of risk? No treatment will ever be 100 per cent safe. Although there is a need for access to information, even if people with haemophilia had had the best information in the world, what choice would they have had?

Patricia McAughey (Haemophilia Society): My husband has severe haemophilia A and hepatitis C. His treatment was changed in 1980 from cryoprecipitate to factor VIII. We were given absolutely no warning that that product could transmit any viruses. Had he been given a warning, he would not have taken the treatment. It is false to say that all bleeds in haemophiliacs are life-threatening—they are not. They are uncomfortable, painful and troublesome, but not all are life-threatening. Haemophiliacs can usually distinguish between what will be a troublesome bleed and what will be a serious bleeding episode. I can speak only for my husband and me, but had we been warned of the risks, we would not have taken the factor VIII.

Bill Wright (Haemophilia Society): I am in the unique circumstance that I have only ever had one factor VIII dose. The situation is not black and white. Males have a factor VIII percentage of anything between 50 and 100. If you have a factor VIII percentage of less than 50 per cent, you carry a little card like the one I have here. You are then registered as a haemophiliac. My percentage is 41.

I contracted hepatitis C from a single, one-off factor VIII injection in 1986. I am not in a position to comment about warnings, because I was in severe shock at the time. However, the next day, after I had wandered into casualty, I was informed that I had at least a 50 per cent chance of contracting hepatitis C. Clearly, the medical world was aware that there was a serious issue in such circumstances. I was never in a position to judge; likewise, others who have been in those circumstances could not have made judgments. It is clearly those who are experienced in haemophilia who can make judgments.

The Convener: Now that you have heard this morning's evidence, read the Executive's report and the Scottish National Blood Transfusion Service submissions, and given your knowledge of the scientific and clinical debate in the 1980s, do you accept that the blood transfusion service acted in good faith, and did what it could as quickly as possible? It told us today that it acted quickly—far more timeously than in England—to make the service safe for all haemophiliacs.

Bill Wright: I remain concerned about the screening issue, which the minister's report does not cover in any depth. Many points have been made about that subject this morning. This hour with the committee is the first opportunity that we have had for any sort of public examination. We are grateful for that.

The second issue that was raised earlier was the brief for any public inquiry—it would have to be much more wide-ranging than the minister's. I suggest that the issue of impacts, and what the costs have been, be included in that brief. To date, all the investigations that have been carried out in any depth have been on technical issues. There is little comparison in the minister's report with other countries, for example, Germany, Italy, Canada or the Republic of Ireland.

A public inquiry could also look at the impact of hepatitis C. We all have different stories to tell about the effects on families, the financial implications for those who have contracted the virus and the worries about transmission to loved ones. The advice nowadays, since the mid-1980s, is to practise safe sex to avoid the possibility of sexual transmission.

Philip Dolan: I was a bit surprised that the witnesses from the Scottish National Blood Transfusion Service were not aware of the minutes that committee members have been discussing. We met representatives from the SNBTS in November 1999 and drew their attention to the fact that those minutes existed, as we did with the minister.

It was indicated that Scotland was self-sufficient, but the question arises whether it was self-sufficient at the expense of safety and whether the SNBTS just went ahead and carried on producing blood products. England had found in 1985 that heating a blood product to 80 deg killed off hepatitis C, so we are surprised that England and Scotland were not talking to each other about the techniques that were being used. However, we are not technical people.

The Convener: I am not a technical person either, but I asked the SNBTS witnesses to explain to us all, who are not experts, why there was a twin-track approach. The Scottish service took one approach and the English took another and there

was a point at which they converged. The phrase that one of the professionals, if I can call them that, used was that the English stumbled upon the 80 deg heat treatment and then had to do a little bit of work to find out what they had done. Maybe we have all watched too many Hollywood movies in which people stand in labs and suddenly shout "Eureka!" and understand everything instantly. I am not trying to be flippant. This is a complex issue and it is difficult for us, as lay people, to understand how England had that information and Scotland did not have it. As we have discovered this morning, how people share scientific information is rather a grey area; it is not as clear-cut as the lay person might think.

Dr Simpson: I have gone through the submission and I cannot see any grounds for suggesting that the SNBTS was negligent, which it was the remit of the committee that considered the case to investigate. The evidence makes it totally clear that there was no question of negligence.

There seem to be two issues. First, there is screening, which is a separate issue which we have tried to tease out this morning. From this morning's evidence, it appears that screening would not have protected haemophiliacs, because the test would not have eliminated the possibility of hepatitis C. There are too many false negatives with the ALT testing system to guarantee a non-risk of hepatitis C in the pool of blood needed for fractionation. I do not see that there is any case for negligence.

Secondly, the other issues that you have raised are important. I understand that the minister agreed to meet you and has not met you. I understand that the minister said that the basis of that meeting would be the production of new evidence or new material on new issues. What surprises me is that you have not laid out a case, saying what those issues are. I am trying to understand why the minister is saying no, and the only reason that I can come up with is that you are pursuing the negligence issue, which is, in my view, dead and finished. If that is the case, you can understand why the minister will not reopen the case. If there are other issues about patient care resulting from hepatitis C infection or concerns about whether patient information should have been more widely available, they should be considered separately.

The Convener: Although the report was meant to pick up on your second point, it was also meant to cover the information that was made available to patients. The fact that it did not was probably a failing of the Executive report.

12:00

Karin Pappenheim: One of the two focuses of the report was the information that was given to patients.

As the SNBTS written submission and oral evidence have shown, the SNBTS was not the only player in the complex picture of how and to whom the treatments were given. There is a significant, missing player, and that is the role of the haemophilia clinicians—the doctors who were working in the field at the time. They gave evidence at one stage of the Executive's inquiry, but we were not party to that. We welcome the opportunity for dialogue today and the fact that we are able to sit with the SNBTS and hear what it has to say. We have not had a similar opportunity with the doctors. There are issues, which have not been fully addressed, about which alternative strategies could have been employed.

I draw the committee's attention to the references in our written submission. As long ago as 1972, the *Journal of the American Medical Association*—or JAMA—an internationally respected publication, published an article on hepatitis and clotting factor concentrates. The article recommended bringing to world attention the risk of hepatitis in treating people with clotting factor concentrates. There has been a build-up of knowledge on the risk of hepatitis since the 1970s.

What strategies could have been employed? Pat McAughey described her husband making the significant change from treatment with cryoprecipitate, the old treatment product, to clotting factor products. We need to know more about the decision-making process and the strategies that might have been put in place. Was it not appropriate, at some point between 1972 and 1985-86, to put other strategies in place to protect people and so reduce the exposure to risk? The patients who are here today and others who have sent written evidence to the inquiry have not had an opportunity to discuss those issues. They have not been party to the process of deciding how much risk they want to take. I am flagging that issue up, as it has not been adequately covered in the report and, as yet, has not been answered today. If there is significant additional evidence to give, it has to focus around that issue.

The Convener: You have written to the committee in the past telling us that you have asked to have further meetings with the Minister for Health and Community Care and that those have been refused. Is that a fair representation of the situation?

Karin Pappenheim: Yes.

Philip Dolan: When the minister appeared before the committee in October, we understood that she had agreed to meet us. That information was given in reply to a committee member's

question. However, it was only in December that we received a letter telling us that she was not going to meet us. There has been no further dialogue. On several occasions, we have written to her, seeking a meeting. As Dr Simpson said, it is difficult to draw conclusions from a report when not all the parties had an opportunity to meet the people who compiled it. As I said, we understand that they were members of the minister's Executive department staff.

Ken Peacock: If we cast our minds back to the HIV/AIDS crisis of the mid-1980s, the screening criteria that were used did not eliminate all the false negatives either. However, the fact that screening took place vastly reduced the number of people who were affected. I was lucky; I did not get HIV through my blood treatment, but I sure as hell got hepatitis C. I acknowledge that the ALT test is a bit of a blunderbuss, but with a bit of skill and imagination, the false positives could have been addressed by using a simple questionnaire. It would not have been beyond the abilities of such intelligent people to come up with a suitable screening programme in the early 1980s, which would have hugely reduced the number of people who were infected with the virus.

Dr Simpson: Screening has arisen as a separate issue. The case was put to us quite clearly this morning that the discussions in different countries resulted in different conclusions. In this country, where unpaid volunteers are used for blood donation, it was decided not to proceed with screening on the basis that more people who required blood would be affected by the potential reduction in the number of donors. I understand the effect that infection has had on people with haemophilia; however, if people had died as a result of reduced blood donation, that would have been equally unacceptable. Do you understand and accept that argument, or would you contest it strongly?

Ken Peacock: I would understand it if evidence had been provided to back up the assertion that there would have been a huge drop in the amount of blood available. However, what Dr McClelland presented us with was a verbal summation of the Scottish National Blood Transfusion Service's study, in which he referred to the occurrence of false positives. If the service were able to find such occurrences, it would not lose the blood. If it can be shown that a false positive is a false positive, the blood is fine to use and the blood supply is not lost.

Mary Scanlon: I remind members that we are also here to examine the petition of Thomas McKissock, who contracted hepatitis C through routine surgery. He is very ill and cannot be here today.

We have heard the evidence from the Scottish National Blood Transfusion Service. I want to address the question of negligence. I have a briefing paper that says that laboratories in England

"used a time/temperature fractionation which fortuitously in-activated Hepatitis C".

It continues:

"The Protein Fractionation Centre (Scotland), on the other hand, used a different time/temperature combination, which turned out to be effective against HIV (the remit at the time) but ineffective for Hepatitis C."

The representatives of the Scottish National Blood Transfusion Service said that there had been no negligence and that everything possible had been done. They said that Scotland's position was envied and that every responsible process was followed. Do you disagree with them on that central issue? Should they have recognised the problem? Should more have been done? Do you agree with the information that the witnesses gave this morning, or do you agree with what the briefing paper says, that the English "fortuitously in-activated Hepatitis C" and that the time/temperature process that was used in Scotland was ineffective? Are you saying that people were acting in ignorance? Was the Scottish National Blood Transfusion Service negligent?

Bill Wright: We simply do not know, as we have not pursued a public inquiry into the issue of screening. I accept Dr Simpson's point, that the ALT test would not have been 100 per cent reliable. However, when I contracted the virus, the physicians were able to confirm, by using an ALT test, that I had what was then labelled non-A, non-B hepatitis. If I had then left the hospital, gone a few hundred yards along the road and walked through the door of the Scottish National Blood Transfusion Service, my blood would not have been eliminated. Although an ALT test would not necessarily have identified the virus in 100 per cent of cases—there would still have been a lot of false positives—at least it would have reduced the risk of so many infected donations entering the system. That fact is fundamental to the whole process.

Mary Scanlon: Given the knowledge that was available at the time, do you think that the Scottish National Blood Transfusion Service was negligent?

Bill Wright: I do not think that I am qualified to judge that. That is for a public inquiry to determine.

Mary Scanlon: This morning, you have heard all the information that is available. In the light of that information, do you feel that a public inquiry will reach conclusions that we cannot reach today? The reason you are here today is that you challenge the position of the SNBTS. That is the heart of the matter. Would a public inquiry get any

information in addition to what has been said?

Karin Pappenheim: In many ways, it is not fair to focus solely on the SNBTS. The complexity of the situation and the scale of decision-making processes have been spoken about many times. Some of those processes involved political and resourcing issues, which have been picked up.

The role of clinicians and decision-making processes in particular clinical circumstances in particular hospitals at particular times should be taken into account. To focus solely on the SNBTS does not provide a complete picture. The SNBTS said this morning, as it has previously said to us, that at the end of the day, it produces the product, but it does not administer its use in treatment. If the question is to be answered fully, the other players in the picture need to be taken into account. We are not in a position to answer the question today. There is, as I have said, a significant missing voice. We need to look at the role of clinicians, the stance that they took and the policies that they developed at the time.

Mary Scanlon: Do you feel that their role has been examined adequately in the minister's inquiry?

Karin Pappenheim: Not at all. It is a very partial report. We have said that.

The Convener: Your submission says that the patient's point of view does not come through in the Executive report in any way and that key issues have not been addressed. The submission says that there was a failure to take follow-up action. Ken Peacock spoke about people not being given information and about people being tested for hepatitis C without being told that they had been tested. All those issues cannot be laid at the door of the Scottish National Blood Transfusion Service, but they require to be explained and examined.

Dorothy-Grace Elder: That is one of the points that I wanted to close in on. The submission says that the original remit of Susan Deacon's internal inquiry was far too narrow, because it focused almost exclusively on the SNBTS. The word negligence has been used. Do you want the inquiry to be widened into a public inquiry, involving bodies such as the Scottish Office—as it was at the time—the Department of Health in London, clinicians and political decision makers of the time? Nodding your heads is good, but will you answer "yes" for the *Official Report*?

Philip Dolan: The answer is yes. We asked for that when we met the minister on 14 September 1999.

Dorothy-Grace Elder: What input did you have to the remit? Who decided the narrowness of the remit? Did you request of the minister that bodies such as those that I mentioned should be involved?

Philip Dolan: Initially we asked for a public inquiry. We had no further discussion with the minister after we asked for that. The minister said that the new Scottish Executive and Parliament would be transparent and that everything would be out in the open. However, the inquiry was not transparent. We did not get the opportunity for a public inquiry. To this day, I still do not know who the author of the report was. We can only speculate on that.

The Convener: Another point has not been dealt with. The report was significantly delayed. It did not come back when we expected it to.

Dorothy-Grace Elder: I want to ask a quick question. As has been mentioned, Mr McKissock is too ill to be here. He intended to deal with the matter of compensation.

The Convener: I am sorry, Dorothy-Grace. One of your colleagues will deal with compensation; Shona Robison will come to it in a second. John McAllion will ask the next question.

Mr McAllion: I am not certain that the question of negligence has been dealt with. Is not it the case that we could assume that there has been negligence? First, the Executive inquiry did not address whether screening for ALT would reduce the risk of people getting hepatitis C. Secondly, the kind of risk-benefit analysis to which Richard Simpson referred was made over the heads of patients, who were not allowed to make informed choices about the treatments that were available to them. Is that the basis of your case for saying that the Executive inquiry is not good enough and that we need an independent inquiry?

12:15

Philip Dolan: That is our position.

Shona Robison: What did you make of Professor Franklin's comment that, these days, safety is paramount at all costs? Did you sense that he meant that, if a test of the same level as the ALT test was developed for CJD, he felt that the blood transfusion service would err on the side of caution and might well introduce such a test, given the standards of today compared to those of 15 or 16 years ago? That was my interpretation of what he said. I would like your comments on that remark of his, particularly in the context of the compensation argument.

Will you clarify whether you are advocating a particular form of compensation and whether it is along the model of the Macfarlane Trust or any other? Would that compensation extend to the families of sufferers?

Philip Dolan: Karin Pappenheim will deal with compensation and Ken Peacock will cover testing.

Karin Pappenheim: One of the points that we made in our written submission was that the Executive's report has not examined any of the issues that surround financial assistance. A number of models could be considered. As we have said previously, a number of countries—Ireland, Italy and Canada—provide a financial assistance or compensation scheme for people who have haemophilia and who have contracted HIV, hepatitis or both through contaminated blood. In the United Kingdom, we also have the Macfarlane Trust, which was set up in 1988 to provide financial assistance for people with haemophilia who had contracted HIV.

There are a number of possible models, all of which are workable and have mechanisms that could be studied. We feel that they have to be examined. Obviously, when we met with Susan Deacon initially in September 1999, one of the first issues that we put to her was the case for some financial assistance to help people to cope with the losses that they have suffered as a result of the tragedy.

We are willing and able to provide evidence from other countries and the example of the Macfarlane Trust from the UK. The evidence is all there to be examined and learnt from and—we hope—acted upon. Sad to say, the report that was commissioned did not consider any of those options. We have therefore questioned the basis on which the report is used to rule out financial assistance.

Ken Peacock: As somebody who has hepatitis C, I was pleased to hear Professor Franklin's comments. It is just a shame that they were 18 years too late.

The Convener: You said that the Executive report does not, in your view, adequately cover compensation. I presume that you think that it fails to make a compelling argument for why the Government's HIV compensation for haemophiliacs and its CJD compensation do not set precedents for haemophiliacs who have contracted hepatitis C. Do you agree that the report also does not take the opportunity to consider the wider financial implications in terms of the impact on patients? Do you agree that it does not consider the impact of the tragedy on the national health service in Scotland in terms of the amount that the NHS has had to pay for treatment that could have been avoided? It has not considered the balance of financial risk.

Philip Dolan: In our submission, we say that the social implication of having hepatitis C is that one cannot get insurance or a mortgage. One can feel like a leper when trying to obtain those things. There is an immediate effect on individuals and their families. If one is trying to make financial arrangements for one's family's future, one is in extreme difficulty. Some people will succeed, but there will be so much of a loading that things will become extremely difficult financially.

Karin Pappenheim: It is true that the report does not consider the impact of hepatitis C on the whole haemophilia community. It does not consider the social impact to which Philip Dolan referred and it does not consider the fact that loss of health because of hepatitis C has caused people to give up work, or reduce the amount of work that they do and, therefore, lose money.

I would like to draw members' attention to a report by Dr Jennifer Roberts from the London School of Hygiene and Tropical Medicine that the Haemophilia Society has published. Dr Roberts was commissioned to do a study to try and identify the specific difference that having hepatitis C has made to the lives of people with haemophilia. Her study gives very useful information on the ways in which people who have haemophilia have suffered loss that can be traced to their hepatitis C, rather than their haemophilia. We recommend that that sort of method be used here in Scotland to assess how people who have haemophilia have suffered as a result of hepatitis C. That should be done as part of the wider investigation to understand the full impact that this tragedy has had.

Patricia McAughey: I would like to add one thing. The evidence that my husband submitted to the fact-finding exercise has gone missing. He was one of the original delegates who met Susan Deacon on 14 September 1999. He took his evidence and that of another young man from Perth, and handed it to Ms Deacon. That evidence was never in the final submissions that we obtained a copy of.

The Convener: I presume that John McAughey is your husband.

Patricia McAughey: Yes.

The Convener: I did not mention his name when I referred to the matter earlier because I could not recall whether we had his say-so. However, we did refer to that evidence in some of our earlier questions. That evidence was made available through your husband as chairman of the Haemophilia Society in Perth. We appreciate that the evidence in the report is selective and that, if it was not selective, we would have substantially more evidence from the minutes of various transfusion service groups. Nevertheless, that evidence has been very helpful this morning.

However, we can certainly take up the issue of why the information to which you refer was not included in the Executive report. We can ask whether it was considered at all. Committee

colleagues from all sides have found that the evidence opened up some interesting lines of questioning, and not only on resources. I have read the evidence and many issues other than resources are considered. Selective they may be, but these minutes contain much about the efficacy of ALT testing. They have been helpful to the committee and I would have thought that they would have been helpful to the minister as well.

Patricia McAughey: I was not talking about the minutes. My husband wrote to the minister about the minutes, but he also gave evidence on how he had been tested without his knowledge and on how hepatitis C affected him and the family. He handed that evidence to the minister, but it was not included in the final submissions. I have heard from other people who have haemophilia that their letters are also missing from the final submissions.

The Convener: Members have commented on the lack of a patients' voice coming through in the Executive report.

Mary Scanlon: You have had only one hour to give evidence and the blood transfusion guys had two hours, and we will now have to discuss the huge amount of evidence that the committee has heard. Did the previous witnesses make any points that you would like to contest? Did they say anything that you disagree with? Are there any points that you felt were contentious and that you would like to bring to our attention?

Philip Dolan: I would like to make a final point. We spoke about the MacFarlane Trust for people with HIV. We contend that it is an accident of history that people with hepatitis C were not included in the trust when it was established. I will tell members about a case that has been cited in discussions of the issue at Westminster. Of three English brothers, all of whom had haemophilia, two developed HIV and died, by which time the Government had set up the MacFarlane Trust and the financial arrangements. The third brother did not get HIV, but developed hepatitis C and died, but there was no provision for his family. He is but one of many people who have died as a result of hepatitis C. We are also aware that a large number of people who have HIV and who are dying are, in fact, dying as a result of hepatitis C. It might be purely an accident of history, but my case paper from 1979 tells me that I had non-A, non-B hepatitis then. It was not until the 1990s that somebody got round to telling me that I had been tested for that and that it was known that I had been infected.

Mary Scanlon: It would be helpful to the committee if evidence had been given that you disagreed with.

The Convener: Let me give you the option that I mentioned earlier: that if there are any other points that you want to make, which might include comments on the evidence from the SNBTS, you can write to the committee clerks. We shall attempt to come back to the matter, perhaps at next week's meeting, although we might need to give ourselves a little bit more time than that. If you want to avail yourself of that option, please feel free to give us further written evidence. You have waited a very long time already and I do not want you to have to wait longer than is absolutely necessary. In the end, a result is what you seek, and we must treat that with respect.

Dorothy-Grace Elder: Could we ask Mr Dolan for a copy of his case notes from 1979?

The Convener: No, Dorothy-Grace. I do not want to get into the realms of individuals' case notes. With respect, we are a parliamentary committee that is examining a strategic national issue—we can do that without considering Mr Dolan's case notes, interesting though they might be to committee members.

Philip Dolan: You would not want to see them.

The Convener: I thank all the witnesses for taking the time to come here this morning to share with the committee their experiences, their comments and their written and oral evidence. No doubt we will be in touch with one another again. I extend genuine thanks from the committee for witnesses' assistance in this matter.

Philip Dolan: As I said at the beginning, we are delighted that we were given the opportunity to come here today. I know that there must be a lot of people who would like to have been sitting at this table and, if they want to give evidence the next time, I am sure that they will be welcome to do so.

The Convener: Yes. People always think that they would like to come and give us evidence until they are actually sitting at the table.

We will return to the issue at next week's meeting and we will hold a discussion among ourselves. I hope that members agree to take that agenda item in private next week, along with the item on the measles, mumps and rubella vaccine. Is that agreed?

Members *indicated agreement.*

Regulation of Care (Scotland) Bill

The Convener: The next item on the agenda is the Regulation of Care (Scotland) Bill.

I move,

That the Health and Community Care Committee consider the Regulation of Care (Scotland) Bill at Stage 2 in the order of the Bill, save that each schedule is considered immediately after the section that introduces it.

That means that we shall follow the normal convention by which parliamentary committees have considered bills at stage 2.

The question is, that motion S1M-1735 be agreed to.

Motion agreed to.

12:31

Meeting continued in private until 12:55.

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