THOMPSONS
SOLICITORS & SOLICITOR ADVOCATES

Berkeley House
285 Bath Street
Glasgow
G2 4HQ

t 0141 221 8840
f 0141 226 5738
dx GW162 GLASGOW
e mail@thompsons-scotland.co.uk
w www.thompsons-scotland.co.uk

Please quote this reference

FTM/Hepatitis C

Vijay Meehan
Fenton Solicitors
99 Bloomsbury Square
London
WC1A 2NS

13 May 2008

Dear Vijay

ARCHER INQUIRY
HEPATITIS C

I refer to my telephone conversation with you on 8 May 2008 and enclose the undernoted documents as requested.

I confirm that I would be able to give evidence in the week commencing 9 June 2008. I can confirm that our office in Aberdeen is officially opening on 10 June 2008.

If there is any further information or clarification you require, I would be happy to provide this.

Yours sincerely,

GRO-C: M Connelly

pp Frank Maguire
THOMPSONS

Enc

- Minutes of Health Committee Meeting
- Written submission to Health Committee by Frank Maguire
- Correspondence with Minister

FTM/MC

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SCOTTISH EXECUTIVE

Minister for Health & Community Care
Andy Kerr MSP

St Andrew's House
Regent Road
Edinburgh EH1 3DG

Telephone: 0845 774 1741
scottish.ministers@scotland.gsi.gov.uk
http://www.scotland.gov.uk

Roseanna Cunningham MSP
Convener
Health Committee
Scottish Parliament
Edinburgh
EH99 1SP

20 February 2006

Dear Roseanna

This letter follows my letter of 31 January in relation to traceability for those infected with Hepatitis through blood transfusion. I now enclose a paper which sets out fully our response to the issues raised during the Committee discussion.

I hope this is helpful.

GRO-C

ANDY KERR

HEPATITIS C: NHS TREATMENT WITH BLOOD AND BLOOD PRODUCTS

HEALTH COMMITTEE: 31 JANUARY 2006: ISSUES RAISED

1. This note sets out my response to the issues raised in the Health Committee on 31 January.

Process for lookback and tracing of Hepatitis C cases

2. I undertook to respond fully to the Committee on the public health aspects of this, and the arrangements that are in place for traceability. I set out details in my letter of 31 January of the lookback exercise that was undertaken in 1995. It is not the case that no efforts have been made to trace and inform people in Scotland who have contracted Hepatitis C from blood transfusions.

3. SNBTS recognises that it has a duty of care to patients who contract or may have contracted infection through a transfusion of blood components or products. Since 1985 it has maintained an archive of all donations of blood which is linked to a computer record of the issue of blood from a blood bank to a named patient. This linkage does not provide complete coverage across Scotland for the period involved. The archive, however, enables SNBTS to test donations back to 1985 which might be implicated in transmission of Hepatitis C and provides the basis for lookback and tracing possible infections from blood donation.

4. Following the introduction of testing in 1991, considerable work was carried out to trace any links between blood donors infected with Hepatitis C and patients who had received infected blood. A pilot exercise was carried out in Edinburgh, and this developed the methodology for a lookback exercise which was undertaken by UK blood services from 1995, and completed in 1997.

5. The lookback exercise was based on tracing the past donations of blood donors found to be nfected with Hepatitis C. Where this was the case, a thorough search of records was carried out vith the aim of identifying recipients of the blood and offering them counselling and testing for the irus. A helpline was also established for members of the public who wanted further information)out Hepatitis C and blood transfusion. Any patients who were worried or unwell were advised to)eak to their GP, and tell him or her when they had a blood transfusion. The GP could then assess ıether anything needed to be done. Patients could also be referred if necessary to their local nsfusion centre for advice and counselling.

This lookback exercise was carried out as follows:

- Where a returning blood donor was identified as infected with Hepatitis C after 1991, records were identified for any donations made prior to September 1991 and for each blood component made from these donations;
- SNBTS identified which hospital blood bank (or alternative uses, such as quality assurance) components had been sent to;
- Where there was a computer record of the blood bank issue to a named recipient, the recipient was identified and the responsible clinician was notified. In the absence in some areas of an IT link, blood banks were requested to identify recipients through hospital records;

The clinician who had been responsible for care of the patient at the time of transfusion was then asked to inform the patient, and arrange for counselling and testing as necessary.

7. The results of the lookback for Scotland were:

- Hepatitis C positive donors who had given before 1991 — 360
- Donations by these donors — 1658
- Components prepared from these donations — 2026

of which traced 1,356
not traced 670

(this will consist mainly of components not transfused, and will also include those not traced through hospital records)

- Number of recipients identified by hospitals — 880
- Potentially eligible for counselling and testing — 266

of which
- counselled and tested positive — 133
- counselled and tested negative — 70
- other – declined; not appropriate for testing; results not reported back to SNBTS — 63
- Deceased — 536
- Not traceable — 78

Note: These figures relate to the final lookback report in June 1998. The lookback was a complex peration, requiring the coordination of reports from a number of centres over several years, and volving records of donations going back over a long period prior to 1991. There were some anges in the reported total number of donors who were identified during the course of the lookback ogramme. This was due to double counting of some donors that was later recognised and rrected, and to the inclusion of some donors who subsequently proved to have no previous iation – hence the difference in the figures in my letter of 31 January 2006 which relate to the iod up to October 1997, before the figures were finally validated.

The lookback exercise was concluded in 1997. It was considered that at that point most ors who were likely to return would have done so. However, there may still be some donors who nfected with Hepatitis C, but have not returned to donate since donor testing was introduced. , it is possible that clinicians have been unable in some cases to identify through hospital ds, living recipients of infected donations. Where SNBTS is informed of any patient who is vered to be infected with Hepatitis C - and transfusion may have been the route of infection - a vestigation is carried out, as detailed below.

9. Where returning blood donors from pre-1991 test positive for Hepatitis C, or where patients present with Hepatitis C infection which may be linked to blood transfusion, SNBTS investigates thoroughly the background and circumstances to these cases and initiates lookback procedures so that any patients potentially affected can be offered counselling and testing. The patient's hospital case notes from the time of the transfusion are examined to identify the donation numbers of the transfusion that they received. This allows SNBTS to trace archived specimens of blood from the original donations. These can then be tested to find out if they were, or were not, the cause of the Hepatitis C transmission. If this is confirmed, the patient's doctor is informed. Other donations from the implicated donor are then traced within the archive and tested. Any positive results lead to a search for the recipient of those positive donations so that the recipient themselves may be informed and offered advice and testing.

10. During the period 1998-2004 SNBTS investigated 32 potential transfusion-transmitted infections related to Hepatitis C. In half of these cases - 16 - the blood units transfused were negative and it was possible to rule out transfusion-related transmission. A number of cases could not be resolved because they relate to transfusion before the donor archive was established in 1985 or in some cases, because hospital records were not available. In six cases a blood transfusion - received before testing for hepatitis C commenced - was identified as the possible source of infection and appropriate follow-up action was taken to trace any other recipients from the donor involved.

11. The results of these investigations indicate that the number of cases of Hepatitis C now arising which result from blood transfusions before 1991 is very small. I am satisfied that SNBTS does have effective arrangements in place for tracing donors and recipients where there is a suspected link between Hepatitis C and blood transfusions, and that these will ensure that any new suspected cases emerging are fully investigated and followed up.

12. Since the introduction of donor screening for Hepatitis C in 1991, there has been an extremely small chance of acquiring Hepatitis C infection through blood transfusion. SNBTS is not aware of any reports of infection with Hepatitis C through blood transfusion over this period. Because there is a short "window period" after infection where tests will not identify the Hepatitis C virus if a donor has been very recently infected, there cannot be absolute certainty that no episodes of transmission will have occurred. However, the risks are extremely small – of the order of one in half million.

In relation to the widely quoted figure of 3,500 people in Scotland infected with Hepatitis C through blood transfusions, as we made clear in evidence, this is a statistical estimate which was prepared for the Expert Group chaired by Lord Ross on Financial and Other Support in 2003, based on work by Dr Kate Soldan, an epidemiologist at the Department of Health's Public Health Laboratory Service Communicable Disease Surveillance Centre. The figure depends on a number of assumptions to estimate the prevalence of Hepatitis C from blood transfusion or tissue transfer, and will be subject to a range of error. The work was based on testing blood donations for Hepatitis C in studies after the introduction of tests in 1991, and using this information to estimate the prevalence of Hepatitis C from blood transfusions (or tissue transfer) in the population as a whole. Because this is a statistical estimate, it cannot be used as a basis for tracing individuals infected with Hepatitis C. Because of the age and state of health of those receiving transfusions, it is likely that many of those receiving transfusions or tissue will have died, often from the underlying condition for which they received the transfusion.

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Transmission of Hepatitis C

14. Concern was raised about possible routes of secondary infection with Hepatitis C through sexual intercourse, or other close social contacts. Mother to baby transmission does occur but appears to be uncommon, with upper estimates of 6% across the UK. Sexual transmission of Hepatitis C is possible but uncommon. The evidence indicates that there is a 3% life-time risk of transmission (there is no risk of Hepatitis C transmission through everyday social contact). Because of these risks - and for a number of other reasons - it would be normal clinical practice to inform a patient where a diagnosis of Hepatitis C had been clearly made.

15. Before 1991, however, when the relevant test became available, it was not possible for a clear clinical diagnosis of Hepatitis C to be made, because tests before this date were non-specific for the virus, which was not isolated until 1989. Up until that date, there was in any case no clinical consensus that NonA-NonB Hepatitis constituted a serious medical condition.

16. In many cases infection with Hepatitis C does not give rise to related symptoms for many years after the event, another reason why the specific diagnosis might not be made, at least initially.

Anti-D

17. Antibodies for intramuscular administration - such as Anti-D - are prepared from blood plasma. Anti-D has been provided by SNBTS since 1968 for the prevention of rhesus sensitisation in women whose blood group is Rh-negative, and there has been no evidence of any Hepatitis C transmission.

Informing patients

18. Questions were raised about the position in relation to current practice where people diagnosed with Hepatitis C have not been told about it. This is a matter mainly of professional practice for clinicians in relation to their patients. We are fully committed to a patient-centred approach which involves the sharing of information and decisions about treatment with patients. This would also be in line with best professional practice.

). GMC guidance states that good communication between patients and doctors is essential to fective care and relationships of trust. Good communication includes giving patients the ormation they ask for or need about their condition, its treatment and prognosis. In relation to ious communicable diseases - which includes Hepatitis C - GMC advice (issued in October 1997) hat doctors must obtain consent from patients before testing for a serious communicable disease. information provided when seeking consent should be appropriate to the circumstances and to nature of the condition or conditions being tested for. If a doctor diagnoses a patient as having a ous communicable disease, they should explain to the patient the nature of the disease and its ical, social and occupational implications, as appropriate; ways of protecting others from tion; and the importance to effective care of giving to the professionals the information which need to know about the patient's disease or condition.

Where blood donors test positive for Hepatitis C, they are informed and counselled by S. They will then be referred to their GP, or to a liver clinic as appropriate. SNBTS then es the lookback and tracing procedures which are described in para 9 above.

Supply of blood products

21. In terms of the supply of blood products, there was a clear professional and scientific consensus - reflected in the policy of the government and the SNBTS at the time – that the best way to safeguard the blood supply from viral infection was to monitor and control carefully blood donations. For this reason it was a key aim of policy to achieve self-sufficiency in Scotland in the supply of blood products. Factor VIII concentrate that was later shown to be safe with respect to Hepatitis C as a result of heat treatment became available from SNBTS in 1987.

22. While Scotland became self-sufficient in blood products, and this was a key safeguard against viral infection, it remained possible for clinicians to prescribe alternative commercial products, including products imported from other countries. There were various possible reasons for this. Clinicians may have believed that specific products were more effective, or more suitable for their patients. Given that such products were licensed for use in the UK, they would have been regarded as equally safe and clinicians were entitled to prescribe them if they wished. In 1987, 2% of blood Factor VIII products purchased were from commercial/ non-SNBTS sources. This included products to treat some specific conditions (for example, von Willebrand's Disease) which were not available from SNBTS.

23. The issue was raised as to whether we are still receiving blood products from outside the country, or from relatively high-risk sources such as prisoners. It is worth mentioning at this point that some blood products - in particular, blood clotting factors for the treatment of haemophilia - are now produced using recombinant technology, rather than being made from human plasma. This further reduces the risk of viral contamination.

24. Products fractionated in Scotland are now produced from plasma which is imported from other countries to limit the risk of transmission of vCJD through blood. These supplies are obtained wherever possible from unpaid donors, in line with long standing SNBTS policies. However, pressures of international demand for plasma mean that it is sometimes necessary to use paid plasma sources in order to maintain the supply of essential products for NHS patients. This imported plasma has never been sourced from the prison population. Careful analysis of the risk profile of donors is undertaken, and all suppliers are inspected by SNBTS and approved by the Medicines and Healthcare products Regulatory Agency (MHRA).

Advances in regulatory standards and viral inactivation procedures mean that, in general, blood products from both private and public suppliers are now considered a low risk category by regulatory agencies.

Donations from prisons in Scotland

It is the case that for many years SNBTS did collect blood from prisons in Scotland. At no time was blood imported by SNBTS from US prisons. SNBTS practice reflected the general policy of government and other UK blood services at the time, and donors from prisons were subject to the same screening and medical checks as other donors. This practice took place at a time when there was no evidence to suggest that there were particular safety or viral infection risks involved. In addition it was regarded as enabling prisoners to make a positive contribution to society, and encouraging their rehabilitation, and also made a significant contribution to the blood supply in Scotland.

27. In the early 1980s, when concerns about the potential for viral infections to be transmitted through blood began to grow, Medicines Inspectors recommended that the practice of collecting blood from prisons should be reviewed. The collection of blood from prisons was then phased out and stopped by March 1984. Blood collected from prisons made an important contribution to overall blood supplies, and had to be replaced from other sources and there was no unreasonable delay in bringing collection from prisons to an end. There is no specific evidence that blood supplies from prisons in Scotland represented a higher risk than supplies from other sources, nor is there any evidence of a direct link between prison donations and individual instances of viral infection.

Donations from US military personnel

28. As far as donations from US military personnel are concerned, SNBTS did in the 1980s - and continues to - collect blood from volunteer non-UK nationals resident in the UK. Normal practice in terms of monitoring and - where necessary - exclusion of donors was followed. Epidemiological data now available indicates that blood donors from US military bases in Scotland did not carry any higher risk of transmitting viral infections than the indigenous population[1].

Clinical trials

29. Concerns were expressed as to comments from clinicians about failure to agree a compensation scheme for patients participating in clinical trials.

30. The papers released on Hepatitis C include correspondence in relation to eligibility for compensation for patients taking part in clinical trials. This took place around the introduction of the SNBTS heat-treated Factor VIII product in 1987. Although there were concerns expressed by clinicians about compensation arrangements, these issues were resolved and did not delay the introduction of a heat-treated Factor VIII product which was safe in terms of the transmission of Hepatitis C.

dependent testing of documents

The Committee has raised the issue of whether the information that has been released has n tested independently. The documents we have released are a primary evidence source, and ord events as they occurred and were seen by the people and organisations taking part at the time. ould be possible to test the background and context of these documents through the testimony of esses. However, witnesses would be speaking of their recollection of events that took place 20 ore years ago. There is a risk that these recollections would not be completely clear, or would ve a degree of hindsight, and that it would be difficult to establish a more complete or accurate re of what occurred. We would not accept that there is a need to test these documents further.

cil of Europe resolution

The Council of Europe is a political intergovernmental organisation. Its recommendations to ments set out policy guidelines on issues such as legal matters, health, education, culture and Its recommendation R (83) 8 makes a number of recommendations in relation to AIDS[2]. nake no specific reference to Hepatitis, although some are generally relevant to combating ision of viral infection through blood.

he recommendations dealt with the use of coagulation factor products prepared from large ools; informing physicians and recipients of the risks of blood products; and providing ors with information. Policy in Scotland in relation to blood products fully reflected these and recommendations.

34. The risks of large plasma pools were recognised and appropriate warnings were provided on products. SNBTS also pursued a policy of maintaining self-sufficiency and, as noted above, Factor VIII concentrate that was later shown to be safe with respect to Hepatitis C as a result of heat treatment became available from SNBTS in 1987. Treatment with factor concentrates was generally the preferred option of clinicians in treating haemophiliacs at this time because of the improved clinical outcomes (including life expectancy) and quality of life they offered. As far as Hepatitis C is concerned, it was well known in 1983 that there were risks of hepatitis from blood products and this information was included in product labels and leaflets. In addition to having two warnings about hepatitis in product information leaflets, SNBTS products carried a warning of hepatitis on the bottle label and two warnings on the box containing the bottles.

35. In terms of informing patients, decisions on how best to treat and inform individual patients are, as noted above, generally the responsibility of the clinician involved. There is no question, however, that it would be best clinical practice for patients to be fully informed of their condition, and of any tests carried out and the results. Clinicians would be expected also to explain any risks of treatment to their patients. However, as previously mentioned, this has to be seen in the context that Non-A, Non-B Hepatitis (later identified as being predominantly caused by Hepatitis C) was not at this time seen as necessarily being a serious medical condition.

36. Steps were also taken by SNBTS to ensure that potential donors in high risk groups were excluded from donation. Clear warnings were provided to blood donors by SNBTS in 1983, specifically in relation to risks of transmission of AIDS. Based on information about at risk groups from the USA, the following groups were asked to refrain from donating blood: homosexual men; women who continually have multiple sexual partners; partners of bisexual men; anyone who abuses drugs; and anyone who has been in contact with a case of AIDS.

Inspection of PFC manufacturing processes and facilities

'. Questions were raised in relation to manufacturing standards at the Protein Fractionation ntre, and possible safety implications. The operations of the Centre were essential in achieving f-sufficiency in the supply of blood products in Scotland. This was widely recognised as a key reduction and safety measure.

The operations of the Centre were inspected on a regular basis by the Medicines Inspectorate ng the 1980s although under Crown Immunity PFC was not at the time required to hold a ufacturing licence. This involved applying pharmaceutical industry standards to the operation of TS, and inevitably identified areas for improvement in practice. The deficiencies and ovements required were addressed and dealt with by SNBTS. There is no evidence that these serious implications for product safety, and or that they were in any way linked to the nission of infection through blood products.

Reference was made to the statement that PFC has "unequivocally endangered the lives of s". This is contained in a letter of 1988 released under the terms of FoI from the-then Medical r of SNBTS. The letter continues, "The two recorded occasions since it was commissioned in he second just months ago) were of course investigated and it is my view that breaches of Good Manufacturing Practice) could not be ruled out".

40. The first occasion is believed to relate to a batch of Factor VIII which was found to be contaminated with bacteria. This batch, however, failed the routine quality control test for sterility, and was not released for use. In this case, therefore, the GMP system in place was effective in protecting patients. Following this incident an independent expert investigation was carried out to determine the cause. This was identified as probably due to the failure of a membrane-filter used to remove bacteria from the solution immediately before aseptic dispensing.

41. The second occasion concerned the infection of a small number of patients with Non-A, Non-B Hepatitis from a batch of SNBTS intravenous immunoglobulin. This was one of a number of similar incidents across the world at the time which affected both publicly-owned and commercial manufacturers of plasma products. These infections occurred before the Hepatitis C virus was identified, but at a time when Non-A, Non-B hepatitis was a known risk, and were discovered as a result of careful monitoring of patients. Subsequently, when a test for the Hepatitis C virus became available, no evidence of infection was found in this batch. SNBTS nevertheless accepted that it was the most likely source of infection to the patients involved. The transmission of Non-A, Non-B Hepatitis by this batch was described by SNBTS medical staff, and published in medical journals, soon after the event and has thus been in the public domain for some time.

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ng the 1980s the prevalence of Hepatitis C virus infection among deployed US military personnel was estimated to %. During this period the prevalence of Hepatitis C among the population of Scotland is estimated to have been timately the same (Hawkins R, et al. Risk of viral hepatitis among military personnel assigned to US Navy ships. *J Dis.* 1992; 165: 716-719. Brodine S,, et al. The risk of human T-cell leukaemia virus and viral hepatitis infection US marines stationed in Okinawa, Japan. *J. Infect Dis.* 1995; 171: 693-696)

nmendation No R (83) 8 of the Committee of Ministers of the Council of Europe recommends the governments of t states:

all necessary steps with respect to the Acquired Immune Deficiency Syndrome and in particular:

d wherever possible the use of coagulation factor products prepared from large plasma pools; this is especially it for those countries where self-sufficiency in the production of such products has not yet been achieved;

m attending physicians and selected recipients, such as haemophiliacs, of the potential health hazards of rapy and the possibilities of minimising these risks;

de all blood donors with information on the Acquired Immune Deficiency Syndrome so that those in risk groups n from donating.

20

FTM/HEP C

Mr A Mackenzie
Legal & Parliamentary Services
Office of the Solicitor
To the Scottish Executive
Victoria Quay
Edinburgh EH6 6QQ

If telephoning please ask for Mr Maguire

13 April 2006

Dear Sir

MARY MCARTHUR –V- THE LORD ADVOCATE AND THE SCOTTISH MINISTERS
ROSELEEN KENNEDY –V- THE LORD ADVOCATE AND THE SCOTTISH MINISTERS
JEAN BLACK –V- THE LORD ADVOCATE AND THE SCOTTISH MINISTERS
PETITIONS FOR JUDICIAL REVIEW

We refer to your letter of 30 March 2006 and you will have our letter of 5 April 2006.

Before we address your comments about the hearing being fixed for 29/30 June 2006 we should be pleased if you could address a matter pertaining more to the substance of these petitions.

We are concerned that even now no decision has been made one way or the other by the Lord Advocate to hold an Inquiry. We had first intimated this case to the Lord Advocate on 30 April 2004. This was against the background of the death having occurred on 31 October 2003 and some initial investigations by the Procurator Fiscal including a post-mortem. We raised the lack of progress regarding the decision in a letter to the Deputy Crown Agent of 26 January 2005. In the letter of 4 February 2005 the Deputy Crown Agent advised us that a definitive response in relation to further inquiries being carried out would be given as soon as possible. We again raised the matter in our letter of 30 June 2005 which received a reply of 5 July 2005 when it was currently estimated that it would be possible for Crown Counsel to reach a concluded view by the end of September 2005. The court itself was advised in July and August 2005 that a decision should be made by September 2005 regarding the holding of an Inquiry. It is now 13 April 2006 and still no decision has been made regarding an Inquiry.

The Convener: We will consider public health for our work programme, so we may return to you on several issues. Thank you for coming along.

14:58

Meeting suspended.

15:01

On resuming—

Hepatitis C

The Convener: Item 2 is our consideration of the case for a public inquiry into infection with hepatitis C as a result of NHS treatment. Members will recall that on 31 January we heard evidence from the Scottish Haemophilia Forum and the Minister for Health and Community Care on the case for a public inquiry into infection with hepatitis C as a result of NHS treatment. During the evidence-taking session, the minister agreed to provide supplementary written evidence on the traceability of blood transfusions or blood products that people received prior to 1981. He also undertook to write to us on governance arrangements as they relate to potential private suppliers of blood or blood products and on the compensation scheme for those who were infected with hepatitis C as a result of involvement in clinical trials. The committee also agreed to write to the Lord Advocate for a clarification of practice concerning deaths that result from hepatitis C and of post-mortem practice. We also agreed that we would reconsider the case for an inquiry once we had received all the additional information.

We have now received a response from the minister, which has been circulated to committee members. We have also received submissions from the Scottish Haemophilia Forum and Thompsons Solicitors and a response from the Crown Office, all of which have been circulated to members. Today, we need to consider all the evidence and decide whether we want to call for an inquiry into infection with hepatitis C as a result of contaminated blood and blood products.

We have in attendance today Euan Robson and Carolyn Leckie. The resignation of Mike Rumbles from the committee prior to the Easter recess means that we are one member down. As a result of the timing of that resignation, we have as yet been unable to replace Mike Rumbles with another Liberal Democrat member. Our standing orders do not allow a substitute to attend in the case of a position being vacant. I take this opportunity to give the committee's best wishes to Mike Rumbles. He was on the committee for a very long time and was always a very dynamic committee member. He contributed hugely to our debates and will be missed. I anticipate that at some point in the future Euan Robson will come on to the committee, but perhaps we should not prejudge that decision.

Carolyn Leckie made a specific request to speak this afternoon. As members of the Parliament,

both Carolyn Leckie and Euan Robson are entitled to do so. Carolyn Leckie also asked me to circulate to committee members a set of papers that she made available late this morning. We received the papers too late for all members to receive them in advance of the meeting, so I am not inclined to allow the papers to be submitted formally at this stage.

However, all committee members have received a copy of Carolyn Leckie's covering letter, which was sent to me and to those members who managed to get a copy of the set of papers. I would expect her comments to be in keeping with the issues that she raised in that covering letter. I would have preferred it if the papers that were circulated so late in the day had been made available earlier, because it is impossible for us to ensure that all committee members have all the paperwork under these circumstances. It is a courtesy to members to allow them the maximum amount of time possible to read submissions.

Carolyn Leckie (Central Scotland) (SSP): If I may explain, although the papers that I circulated this morning were in my possession as the result of a freedom of information request, they had not been examined and their relevance was not noted until yesterday afternoon. Given the importance of today's discussion, it was a courtesy to the committee to circulate them. I thought that it was right to circulate the papers rather than keep them in my possession. I intended to take up the relevant issues anyway.

The Convener: The difficulty is that, because of the late notice of the papers, three committee members have not yet had them even now, as they were not available to them in the places where they were.

Carolyn Leckie: Their offices have now received them. I made sure of that.

The Convener: That may be, but—

Carolyn Leckie: I am just making this explanation for the record.

The Convener: At this very late stage, it is difficult to ensure that committee members have the paperwork. In future, I urge all MSPs who have things that they wish to bring to the attention of members of any committee to do so at the earliest possible opportunity. That makes it considerably easier to deal with the issues involved.

I want to open up the discussion on this subject. We should consider the evidence that we have heard. We need to decide whether we are going to call for an inquiry into infection with hepatitis C as a result of contaminated blood products. I invite members' views. Jean Turner, Shona Robison and Helen Eadie are indicating that they wish to comment on the subject.

Dr Turner: Reading through the evidence from Thompsons Solicitors, I am struck by the first three cases that are outlined, which describe how people did not know for some time that they had been infected by blood or blood products. In one case, the person did not know for 20 years; in another, the person did not know for around 12 years; and in another the person did not know for 14 to 15 years. That is a long time, whichever way we look at it.

To move on to the future, we must learn from the past. If I had received any such product, the most important thing for me would be to be notified of the potential hazard of being infected. Once it is known that people have been administered an infected product, it is important to track them down—to do one's utmost to find the people affected, whatever the cost. There is a duty of care towards the person who has been infected and towards their family. In one case, a spouse did not realise that they had been infected—I assume that it was because of the products that the wife had been given. Discovering such an infection affects the family. It can also give rise to problems among NHS staff and even among undertakers. When people died in the cases concerned, there was no further investigation. I think that investigations should be made even when the outcome is death.

Someone who has been infected but does not know it could be travelling about the country before developing appendicitis and turning up in a hospital to be operated on without anybody knowing that they have hepatitis C and the problems associated with it. To take another example, an undertaker might be working on embalming a body. Unless they were given specific information, they would be putting themselves in danger. That also applies to variant CJD. It is up to the professionals to let the patients know that they have an infection. I am aware of cases where the professionals know, but the patient does not know. It is imperative that people who could have an infection with such serious implications as hepatitis C has are told about it. There have been serious gaps in the attempts to find those people, which is a major flaw.

We all want to know why Scotland was so far behind in providing safe blood products. An astonishing letter that is part of the evidence refers to a head of department in the national service in Scotland tearing to bits somebody in the north of England because they were doing something that seemed to be best for patients. We need to figure out why that kind of thing can happen and how our processes for communicating with people can be made better than they have been until now.

It seems to me, after reading through all the evidence, that more questions remain than we have had answered. I am in favour of going ahead with an inquiry.

Shona Robison: I will focus my comments on the look-back exercise, which I think is the most significant piece of new evidence that we have seen. The minister refers to it extensively in his evidence to the committee. By his own admission in paragraph 6 of his evidence, the exercise concentrated only on the donor population and was carried out between 1995 and 1997. Why did it take eight years to begin to trace people, when it was known that hep C infections were happening up to 1987? Given that blood transfusions continued to infect people up to 1991, when screening was introduced, why did it take a further four years, to 1995, for any attempt to trace people to be made?

The term "look back" implies that all cases were looked at, but they were not. The exercise concentrated only on those donors who happened to come back to give blood. It did not address hep C infection from donors who did not come back. Unless anyone around the table can prove otherwise, it seems to me that the look-back exercise related to only a two-year window within which a donor may or may not have come back. That is a totally inadequate exercise in attempting to trace people who could have been infected.

Why did the look back cover only the period from 1995 to 1997? What if a donor returned between 1991 and 1995? What about those who returned after 1998? The minister states that he has computer records going back only to 1985. Why has he excluded a manual look back at hospital records prior to 1985 to identify those who had transfusions, which could have been done? A large number of recipients identified from the return donors were deceased. Why was no attempt made to counsel their relatives, particularly their partners? Why was there no recipient-centred strategy such as a system of recall, as we have had for smear tests when there were problems with those, which could have assisted in contacting those who had a transfusion during the danger years when people were being infected? There are hundreds of unanswered questions.

There is also the evidence in the letter from Professor Ian Franklin, dated 28 April 1998, which is on page 15 of the submission from Thompsons, which suggests that those not traced through the restrictive look-back exercise were ignored because of a lack of resources from the Scottish Office. That has to be investigated further to see whether it was the case.

If no one around the table can answer the questions that I have asked—which are only a sample of the questions that I think are raised in the new evidence—surely the committee has a duty to recommend that an independent inquiry be established to get answers not just to those questions but to the hundreds of others that I think have arisen in the evidence that we have taken since we started to consider the matter.

15:15

Helen Eadie: At the weekend, I looked at the Inquiries Act 2005, which was passed just before the dissolution of the Westminster Parliament last April. If I am right—I look to the committee clerks to advise me—the legislation on inquiries has been changed significantly. I wonder whether Frank Maguire of Thompsons and all the patients whom he represents want the kind of inquiry that they would get under the 2005 act.

Having read Frank Maguire's papers and the minister's response, I am in no doubt that action needs to follow because both raise concerns that the public and I want to be reassured about. However, I am not certain that a public inquiry is the right forum for that. A group—a task force or whatever—must be convened to address public concerns and allay fears. After reading Frank Maguire's papers, I have questions such as why it is that when we give blood, it is not necessarily screened for hepatitis C. I see that Duncan McNeil is shaking his head, but I made notes—

Mr McNeil: That claim was countered this week.

Helen Eadie: Okay, I look forward to hearing what Duncan McNeil has to say about that. However, I assumed that when Joe Bloggs gives blood, a check for hepatitis C is carried out before the blood is passed on to other patients. That is the sort of concern that must be categorically refuted, which can be done only through the expertise of an action task force.

Frank Maguire raises points about computer records and the minister states in his response that hospitals were asked to undertake manual tracing. We need to find out who monitored the results from that manual tracing to be certain that hepatitis C sufferers were identified. Other people have asked what has been done to ensure that the relatives of those who died from hep C were tested. I want immediate action in response to those questions; I do not want to wait for any inquiry for that.

The Inquiries Act 2005 changed previous legislation so that an inquiry would be accountable not to Parliament but to the minister, who would choose the chairperson. I want whatever action we take to be accountable to the Parliament and not only to the minister.

On Shona Robison's point, although the look-back exercise lasted only from 1995 to 1997, I noted in the minister's response that it was

"a complex operation, requiring the coordination of reports from a number of centres over several years, and involving

records of donations going back over a long period prior to 1991."

It is not the case that the exercise looked only at that two-year period; it went back over many years prior to 1991. I wonder whether there has been a misunderstanding about that.

The Convener: I can see what the concern might be. Does Duncan McNeil want to come in at this point, as he was referred to?

Mr McNeil: It is difficult to keep pace with press conference after press conference and with all the radio shows. Many of the issues that I heard about during the recess last week were not before the committee. We did not have that courtesy. We did not get the papers until later, but we heard all those views being aired on our radios and televisions. Some members who are at the committee today participated in that process, but others who are not here gave a contrary view and stated that the head of the service had denied some of the things that were said. Carolyn Leckie has made some additional information available this morning and, apparently, that has been the subject of a press release as well. I do not know what position I am in today. If there is significant new evidence—not just new information, but significant new evidence—I want to hear both sides of the story.

The Convener: We will formalise the decision shortly, because there might be a couple of different positions that need to be considered.

Mrs Milne: I confess that I had no knowledge of the Inquiries Act 2005, to which Helen Eadie referred, but there are obviously still important questions to be answered. I am extremely concerned at the lack of patient information. There are still patients coming forward who are suffering from hep C and who did not know until recently that they had the illness even though they have obviously had it for a considerable time. I agree with Shona Robison that the look back has been severely inadequate. Therefore, it is terribly important to find out what exactly has gone on. Public confidence in the blood transfusion service and in the NHS itself is at stake.

As members will realise, I did not support the call for a public inquiry in the debate in December because, although I accepted that many questions needed to be answered, I took the view that they could be dealt with by taking a test case to court. However, at the committee meeting on 31 January, when I asked Mr Maguire about the feasibility of that and why an inquiry would be better than a test case, it was made plain that a test case was not a possible way forward.

I would like more information about the act that Helen Eadie mentioned, but we must by whatever means get to the bottom of what has been going on. I do not envisage that an inquiry would necessarily open the floodgates for compensation claims because negligence would still have to be established in any case, but it is terribly important that we find out what went on. I will be guided as to what the best way forward is on that.

Carolyn Leckie: I agree with Duncan McNeil that both sides of the story need to be heard. That is why we need an independent public inquiry because, so far, we have been asked to accept the judgment of the current Minister for Health and Community Care, previous health ministers and previous Governments that everything is okay, lessons have been learned and there is no need for an independent public inquiry. The only way that people can trust that judgment is by having an inquiry with independent analysis of the evidence and an independent judgment on it.

It is not about coming to a conclusion or judgment today, because that is impossible, to be frank. The large sheaf of papers that I have with me contains only the papers that are associated with the third bullet point in my letter. I extracted a few of those papers and circulated them to the committee. The reason why committee members got them only this morning is that I read them only yesterday afternoon; I moved as quickly as possible to circulate them to the committee. They are an example of the many questions that surround the issue and of why there is a lack of trust and confidence in all the Government departments and NHS services, such as the blood transfusion service, that have been involved in the story.

I will concentrate on my third bullet point, because it relates to some of the evidence that Frank Maguire submitted, which is part of the documents that the Scottish Executive has released. I have many other documents that have been obtained from other sources and I have told the committee previously that it can access them. The letter from the Scottish National Blood Transfusion Service to the northern region of the National Blood Transfusion Service to which Jean Turner referred says, in effect, that the northern region of the NBTS needs to come into line. Defensive medicine was being practised and, if one arm of the blood transfusion service did one thing, the rest of the service would be exposed to the risk of litigation.

That came at the end of a protracted discussion and debate about the availability and efficacy of a non-specific test—an alanine amino-transferase test—to identify non-A, non-B hepatitis in the period before 1991. The test was available and accurate in five cases out of six in America and in other European countries from 1986. The Scottish National Blood Transfusion Service wanted to introduce it but was prevented from doing so by

the Scottish Office home and health department and the Westminster Government. That information is contained in the documents.

More astonishingly, instead of introducing the routine screening that was the best available at the time and which could over five years have reduced the risk of infection by what was known at the time as non-A, non-B hepatitis, the working party advocated a research project. One paragraph of the documents that have been submitted states:

"The position explicitly reached at the meeting is to recommend research of no great significance or scientific interest because the prospect of research would serve to counter pressure from for example haemophiliacs and Haemophilia Directors to embark on an indirect and largely ineffective form of screening".

Rather than introduce the only routine screening that was available to them, they substituted research for it and procrastinated for more than five years.

In the research, the working party identified the blood from donors that was prospectively at risk and had the markers that could be identified by the ALT test. The documents that I have supplied indicate that it knowingly allowed that blood to be received by people without their knowledge and that it followed up the matter in only a small way. Knowingly, it put those people at higher risk of transmission of non-A, non-B hepatitis, in order to conduct research that the Medical Research Council did not even support and that was a substitute for introducing the only screening available, which the Scottish National Blood Transfusion Service wanted to introduce but did not under Government and political pressure. That is where the letter comes in. The Scottish National Blood Transfusion Service abided by the political will of the Government departments of the day, but the northern region of the National Blood Transfusion Service stepped out of line and unilaterally introduced the ALT test. That is why the SNBTS was angry.

I have my judgment on the morality of what happened and what it says about how the process was conducted. I have provided just one example of many controversial developments associated with the issue. I am not asking the committee to form a judgment today or asking Duncan McNeil to accept my version of events without having seen the documents. However, what I have described shows that there needs to be an independent analysis and trial of the evidence, so that an independent judgment can be reached on it. We are having to fight tooth and nail to get every wee scrap of information. Documents have been withheld from the Executive. We have letters from the blood transfusion service to Government departments—the Department of Health and Social Security and the Scottish Office home and health department—but there are no replies. Where are the replies? The fact that there are loads of questions demonstrates the need for an inquiry. Only then will both Duncan McNeil and I be satisfied.

Kate Maclean: I feel at a disadvantage, because I have not been in my office in Edinburgh today. I do not have staff through here, so if papers were delivered to my office I have not had access to or been able to read them. Carolyn Leckie referred to information contained in certain documents. Can the clerk or Carolyn refer to papers that we have already received that include that information?

Carolyn Leckie: It is in the Scottish Executive documents that were released under the freedom of information regime.

Kate Maclean: I am talking about papers to which I have had access. I am wondering whether some of the documents that Carolyn Leckie has distributed are included in the papers that we have received already. I find it difficult when Carolyn keeps referring to documents that I have not seen. Three members of the committee have not seen those documents.

The Convener: Some of the issues to which Carolyn Leckie has referred are contained in the papers that members have seen. They might be presented in a slightly different way, but the information is in our papers.

Kate Maclean: The situation is not satisfactory.

15:30

The Convener: It is not satisfactory, as I said at the beginning.

We decided that we would reach some kind of decision today. We have several options to consider, which may or may not be formalised into a decision. The first option is to call for an independent inquiry. Both an independent inquiry and an independent public inquiry, which are not the same, have been mentioned. That matter would have to be clarified if an inquiry were proposed. We could argue for a debate in Parliament, although we had one in December and we would need to think what we wanted the debate to be about and how it would be different from the debate in December. I will ask Helen Eadie to formalise her comments, but she suggested some form of committee inquiry, with a small i rather than a large one. Alternatively, we could have a committee inquiry with a large i or decide to take no further action. We have several options. I want to bring the discussion to a close and, ideally, have the committee agree on future action.

Janis Hughes: I accept that there are a few options, but I agree with Kate Maclean and

Duncan McNeil about the further evidence that has been submitted—I was given it literally as I left to come to the meeting and, like other members, I have not read anything other than the covering letter. I accept the convener's point that some of the information is contained in the evidence that we already have, but Carolyn Leckie has referred to evidence that the majority of members have not considered. I hesitate to make a final decision today on the basis of papers that we have been given but not had the chance to read. I urge caution in making a final decision.

The Convener: It is a matter for members whether they make a decision on the basis of the papers or on the basis of the evidence that was already before us, which is what we should do. I do not want a roundabout discussion to go on for a great deal of time. I want some formal proposals that the committee can either agree to or not agree to.

Mrs Milne: I seek clarification on one issue, convener. You referred to an independent inquiry and an independent public inquiry, but you did not use the word "judicial" at any stage.

The Convener: No, because nobody around the table has used the term "judicial".

Mrs Milne: If memory serves me right, that was what was called for when we took evidence.

The Convener: I am asking for the various positions to be clarified.

Helen Eadie: Before we do that, could we have some clarification? The Inquiries Act 2005 was passed in April last year. I want to know whether that act affects Scotland and, if so, what the implications would be if we went down the route of an inquiry. Can the committee clerks find that out for us?

The Convener: I do not know when you knew about the Inquiries Act 2005, but some of the comments that applied to Carolyn Leckie apply also to you.

Helen Eadie: I found out about the act during last-minute reading before I retired for the evening last night.

The Convener: Decisions about inquiries go on all the time.

Helen Eadie: We have just had a recess, during which I was in Coventry. I came back late on Sunday night, did my work yesterday and then found out about the Inquiries Act 2005. I want to know what a public inquiry would achieve. If a public inquiry would be the appropriate route, members might wish to opt for it, but if we want to safeguard the people of Scotland, other action might be more appropriate.

The Convener: No reference was made to the Inquiries Act 2005 at any stage during the many debates about the McKie case, which suggests to me that the legislation is not particularly germane to the present situation. I would like some clarified positions to be made so that the committee can, if necessary, vote on them. If Helen Eadie wants to delay a decision further, the committee as a whole can decide on her proposal.

Shona, do you want to go first?

Shona Robison: Before I do that, would it be helpful to clarify something that Helen Eadie asked about?

The Convener: Yes, please.

Shona Robison: Let us be clear about the look-back exercise, which Helen Eadie has raised. It took place between 1995 and 1997, and the minister's evidence makes the situation clear:

"Where a returning donor was identified with Hepatitis C after 1991, records were identified for any donations made prior to September 1991 and for each blood component made from these donations".

Only those returning donors during that period were considered, which is why the look-back exercise was inadequate.

Despite the information that Kate Maclean has talked about Carolyn Leckie producing, the bulk of the evidence that concerns the committee is within the existing papers, especially those from Thompsons Solicitors. Having seen the stuff that Carolyn Leckie has submitted, I assure the committee that the most important element of her paper is already in the Thompsons Solicitors paper, so we can come to a conclusion today. My proposal is simple: the Health Committee should call on the Scottish Executive to establish an independent public inquiry into the infection of people with hepatitis C through NHS treatment. Helen Eadie has mentioned the Inquiries Act 2005. Frankly, even if what she says is true—the minister would appoint the chair and the independent inquiry would report to him—it would be better than having no inquiry at all. Having been a member of the previous Health Committee and having heard all the evidence, I think that we owe it to the people who are affected to come to a decision today, and I put that forward as a proposal to the committee.

Kate Maclean: I ask for clarification of what Shona Robison has said. Carolyn, have you not submitted any new evidence to the committee today?

Carolyn Leckie: I have circulated papers that have already been released by the Scottish Executive under the Freedom of Information Act 2000. Their relevance became apparent to me only yesterday, and I quickly gathered them together for the benefit of the committee. The issue that I am highlighting has not, to my

knowledge, been highlighted before, but the evidence is not new. The Scottish Executive has known about it, as it has had the documents. Information on the ALT testing has been submitted in Frank Maguire's documents.

Kate Maclean: That does not really answer the question that I am asking. Is there any evidence that the committee has not already seen? Have you submitted new evidence or not?

Carolyn Leckie: I do not know whether you have read the documents that have been released by the Scottish Executive—

The Convener: Leave your documents out of it.

Kate Maclean: I am talking about the papers that have been circulated to the committee. Have you today circulated evidence that is new to the committee?

Carolyn Leckie: If you have not read all the documents that have been released by the Scottish Executive, the answer is probably yes.

The Convener: I detect that Helen Eadie and Janis Hughes take a different position from Shona Robison. I do not know whether you want to formalise it in some way.

Janis Hughes: On the basis that Carolyn Leckie has said that there is evidence that we have not seen—

The Convener: I am trying to move us on, Janis.

Janis Hughes: On the basis that she has said that she has submitted evidence that she has received under the Freedom of Information Act 2000 that we have not seen, because it has not been submitted to us—

Carolyn Leckie: It is in the Scottish Parliament information centre.

Janis Hughes: But it has not been submitted to us in the papers that we have received for today's meeting. I would like to be able to see—

Carolyn Leckie: It is not a—

The Convener: Carolyn, could you please be quiet at this stage and let Janis Hughes formalise her position?

Janis Hughes: I would like the opportunity to see that evidence.

The Convener: So, you move that we continue the discussion to a future date to allow us to consider further papers.

Janis Hughes: Yes.

The Convener: Is there any other position that anybody wishes to formalise at this stage?

Helen Eadie: Could I add an amendment to Janis Hughes's position? I also wish to have that further information to clarify precisely what the impact of the Inquiries Act 2005 will be for Scotland and what benefit an inquiry under that act would have in contrast to an action strategy delivered by the minister. Undoubtedly, we have been given information that demands action.

The Convener: We can take it as read that the clerks will look at the Inquiries Act 2005 issue. If the committee's decision is to continue the discussion, that is one of the issues that will be looked at.

Dr Turner: I made my decision on the basis of the material that was submitted to the committee. I got Carolyn Leckie's papers as I was coming down the stairs to the meeting and had time only to open and glance through them. If there were to be an inquiry, her detailed information, which we have not been able to read as yet, would come out.

It would take an awful lot of time to take in all the material that she has presented, but only a short time is available to us. As I said, I made my decision on the material that we had in front of us and on the fact that the look-back exercise did not look back far enough. Not only were many areas missed out but there were a number of discrepancies, for example in communications between our system in Scotland and the system in England. Also, at the time the powers that be were the Westminster Government and the Scottish Office, not the Scottish Executive. I am in favour of this—

The Convener: I think that we understand your position, Jean. Do you want to come in at this point, Nanette?

Mrs Milne: I am in favour of an inquiry of some sort. Again, I apologise for my ignorance of legal matters, but is Shona Robison's proposal for a public inquiry significantly different from a call for a judicial inquiry?

The Convener: A judicial inquiry would be remitted to a named judge who would operate it on the basis of taking evidence. We have seen many such inquiries in the past. Strictly speaking, public inquiries do not have to be heard in front of a judge, but they usually are. The difference may simply be semantic. Perhaps Shona Robison will clarify whether she sees her proposal in terms of a judicial inquiry.

Shona Robison: Yes.

The Convener: Perhaps it would be better to actually say that.

Shona Robison: I am happy to say that.

The Convener: Right. That needs to be said; the purpose is for everyone to be comfortable.

Shona Robison: In custom and practice, it is the same thing.

The Convener: The situation appears to be that two proposals are on the table. The first is that, as a result of the evidence that has been before us, the committee calls for a public inquiry into all matters pertaining to hep C that was acquired through contaminated blood, but with particular reference to the issue of traceability, which has arisen in new form.

The second proposal, which Helen Eadie and Janis Hughes have jointly proposed, is that the committee's consideration of the issue be continued to allow for a further look at, among other things, the paperwork that Carolyn Leckie attempted to circulate today and the issue that Helen Eadie raised on the Inquiries Act 2005. Is that a fair summation of the two positions?

Members *indicated agreement.*

The Convener: Okay. If it comes to it, our standing orders require me to use my casting vote; I am not permitted to dodge the issue. Given that the committee now has an even number of members, I thought it would be helpful to say that in advance of any vote. Two proposals are on the table. We will have to take a vote. Will those members in favour of Shona Robison's proposal indicate their support?

FOR

Cunningham, Roseanna (Perth) (SNP)
Milne, Mrs Nanette (North East Scotland) (Con)
Robison, Shona (Dundee East) (SNP)
Turner, Dr Jean (Strathkelvin and Bearsden) (Ind)

The Convener: Will those members in favour of Helen Eadie and Janis Hughes's joint proposal indicate their support?

FOR

Eadie, Helen (Dunfermline East) (Lab)
Hughes, Janis (Glasgow Rutherglen) (Lab)
Maclean, Kate (Dundee West) (Lab)
McNeil, Mr Duncan (Greenock and Inverclyde) (Lab)

The Convener: I was afraid that that would happen. The situation is not one in which the status quo is the imperative. As I voted for the inquiry, I will use my casting vote for Shona Robison's proposal. It would have been preferable to come to a broader agreement, but if that is not the case, it is not the case.

The committee has agreed to call for an independent public inquiry into the issues that have been before us until now. That will be communicated forthwith to the Minister for Health and Community Care. I thank everyone for their forbearance.

Item in Private

15:45

The Convener: The final item on our agenda is consideration of matters in private. At our meeting next week, we will discuss our work programme. I seek the committee's agreement to consider it in private. Are we agreed?

Members *indicated agreement.*

Meeting closed at 15:45.