Health and Community Care Committee

8th Meeting, 2001 (Session 1)

Wednesday 14 March 2001

The Committee will meet at 9.30 am in Committee Room 1

1. **Item in Private:** The Committee will consider whether to take item 5 in private

2. **Subordinate Legislation:** The Committee will consider the following negative instrument—

   The Coffee Extracts and Chicory Extracts (Scotland) Regulations 2001 **(SSI 2001/38)**

3. **Hepatitis C:** The Committee will take evidence from—

   Scottish National Blood Transfusion Service

   The Haemophilia Society

4. **Regulation of Care (Scotland) Bill:** The Convener to move motion (S1M-1735)—

   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.

5. **Handling of Committee Business:** The Committee will consider the process for handling future business.

Jennifer Smart
Clerk to the Committee
Room 2.5
email jennifer.smart@scottish.parliament.uk

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The following papers are attached for this meeting:

Agenda Item 2

The Coffee Extracts and Chicory Extracts (Scotland) Regulations 2001 **(SSI 2001/38)**

HC/01/8/1

Abridged from the Subordinate Legislation Committee 10th Report 2001 **HC/01/8/2**

Agenda Item 3

Submission from the Scottish National Blood Transfusion Service **HC/01/8/3**

Submission from the Haemophilia Society **HC/01/8/4**

SPICE research note: Hepatitis C virus in blood and blood products **HC/01/8/5**

SPICE research note: Hepatitis C: Health Committee Questions and the Executive Report **HC/01/8/6**

Agenda Item 5

Paper on process for handling future business **HC/01/8/7**

Agenda item 2

Health & Community Care Committee

14 March 2001

The Scottish Parliament

Subordinate Legislation Committee

10th Report, 2001

ABRIDGED

Subordinate Legislation

The Committee reports to the Parliament as follows—

1. The Committee met on 27th February 2001 and determined that the attention of the Parliament need not be drawn to the instruments listed at Annexe A.

Health and Community Care	SSI 2001/38

Negative Instruments

The Coffee Extracts and Chicory Extracts (Scotland) Regulations 2001, (SSI 2001/38)

Agenda item 3

Health & Community Care Committee
14 March 2001

Hepatitis C and Heat Treatment of Blood Products for Haemophiliacs in the Mid-1980's.

Scottish National Blood Transfusion Service Submission to the Health and Community Care Committee of the Scottish Parliament.

1. Introduction

1.1 Haemophilia is a serious disorder of blood coagulation affecting about 1 in 10,000 of the population. Prior to the availability of effective treatment, haemophilia was a crippling and extremely painful condition with few patients surviving beyond childhood.

1.2 The very bleak outlook for people with haemophilia was transformed by the introduction (in the 1970's) of replacement therapy with Factor VIII concentrates prepared from plasma derived from human blood donations.

1.3 The risk of hepatitis was well known and its transmission by Factor VIII concentrates became apparent soon after their introduction. Nevertheless, the benefit to patients was so profound that therapy with Factor VIII concentrate became the standard treatment throughout the developed world.

1.4 In the early 1980's it was discovered that the human immunodeficiency virus (HIV) could be transmitted by via Factor VIII concentrates that had been prepared using donations from individuals infected with HIV.

1.5 The most significant advances to-date in the treatment of haemophilia in the developed world have been:

- Provision of Factor VIII in sufficient quantity to treat all patients adequately (although large numbers outside OECD countries remain only partially treated or not treated at all).

- Provision of Factor VIII free from transmission of HIV and hepatitis.

2. Scotland

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

2.2 Due to the efforts of the SNBTS and to the generosity of Scotland's blood donors, Scotland was the **first country in the world** to:

- Become self-sufficient in the provision of Factor VIII concentrate obtained from unpaid volunteer blood donors.

- Be able to treat all of its haemophiliacs with Factor VIII concentrate made safe from HIV transmission.

- Be able to treat all of its haemophiliacs with Factor VIII concentrate made safe

from hepatitis transmission.

3. Advanced (80°C) Heat Treatment of Factor VIII Concentrate

3.1 Factor VIII concentrate is a freeze dried powder which is very complex to prepare and consists of a fragile mixture of sensitive proteins which can be easily damaged.

3.2 During the early 1980's it was discovered that established products could tolerate heating at up to about 68°C in the dried state before becoming unsuitable for use. Heating Factor VIII concentrate in this manner successfully inactivated HIV, but not hepatitis viruses.

3.3 In 1985, colleagues at the Blood Products Laboratory (BPL)), our sister organisation in England and a division of the English Blood Service, succeeded in preparing Factor VIII concentrate in a form which would tolerate heating at 80°C in the dried state. BPL were the first in the world to achieve such an advanced level of dry heat treatment. This degree of heat treatment was subsequently found to be effective against hepatitis viruses as well as HIV.

3.4 England was not self-sufficient in Factor VIII and only a small proportion of England's needs could be met with the 80°C heated product. Imported concentrates, which could not be regarded as hepatitis-safe, continued to represent the main source of Factor VIII concentrate used in England.

3.5 SNBTS worked to develop an equivalent 80°C heated product and assisted colleagues at BPL in solving on-going difficulties that were being experienced with their own manufacturing operation at this time.

3.6 Further advances were made by SNBTS, contributing to the resolution of BPL's manufacturing problems and enabling SNBTS to become the second manufacturer in the world to achieve advanced (80°C) heat treatment of Factor VIII concentrate.

3.7 During 1987, Scotland became the first country in the world to produce sufficient hepatitis-safe Factor VIII concentrate to treat all of its haemophiliacs.

3.8 Preparing Factor VIII in a form which could survive heating at 80°C was a major scientific and technical challenge. It was not until some years later that this same achievement was realised by manufacturers out-with the UK.

4. Patient Concerns

4.1 SNBTS is a patient-centred public service which is open and accountable and which has an international reputation for excellence. Although we do not treat haemophilia patients ourselves, we have close formal and informal links with doctors treating haemophilia and are always very willing to assist physicians and patient organisations with any questions or concerns that they may have.

4.2 In August 1999, we were surprised to find allegations of negligence and incompetence being promulgated in the media without these concerns first being discussed with SNBTS. We were very disappointed that some parts of the media chose to report these allegations without question.

4.3 We believe that information given to patients should be accurate. Much of the

information concerning the development of heat treatment of Factor VIII concentrate by SNBTS was already published, albeit in specialist medical and scientific journals which may not have been easy to find. Therefore, SNBTS welcomed the decision by the Scottish Executive to undertake a full investigation of the facts surrounding this matter.

4.4 In November 1999, SNBTS met with the Haemophilia Society to explain the development of heat treated Factor VIII and to answer their questions. We answered the questions put to us to the best of our ability and offered to answer further questions should any arise. No further questions have since been put to us by the Haemophilia Society.

5. The Investigation by the Scottish Executive (SE)

5.1 In our evidence to the SE investigation, we provided a detailed overview of the development of heat treatment of Factor VIII by SNBTS. We also provided supporting documentation and written answers to questions put to us by the SE.

5.2 We believe that the report of the investigation by the SE provides an accurate if simplified account of the development of heat treated Factor VIII by SNBTS. Our principal concern about the SE report is that the progress and achievements made by SNBTS are somewhat understated. Consequently, the true contribution made by SNBTS may not be appreciated by those who have not examined all of the evidence submitted.

5.3 Despite being amongst the world's leaders in the development of safe Factor VIII concentrates, the SNBTS has been criticised in some parts of the media in a way we consider to be inaccurate and unfair. We are concerned that this erroneous picture of the SNBTS may deter the people of Scotland from giving blood and that ultimately patients will suffer as a consequence.

5.4 Many patients are dependent on blood products for the treatment of their illness or injuries and an adequate supply of blood is fundamental to modern health care. Our supply of many of these products depends on the generosity of the people of Scotland to give of their time and their blood altruistically.

Scottish National Blood Transfusion Service, Edinburgh. February 2001

Agenda item 3

Health & Community Care Committee
14 March 2001

HAEMOPHILIA SOCIETY

SCOTTISH GROUPS FORUM

RESPONSE TO THE REPORT INTO HEAT TREATMENT OF BLOOD PRODUCTS AND INFECTION OF SCOTTISH HAEMOPHILIACS WITH HEPATITIS C

COMMISSIONED BY SUSAN DEACON – HEALTH MINISTER

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Further to your recent invitation to provide a written submission to the Health Committee due to meet on the 14th March 2001 we submit the following. The Haemophilia Society has already responded to the report (copy attached) The Haemophilia Society in Scotland are supplementing this valuable advice which is based on experience drawn from across the UK. Our main concerns are

1 At a meeting with the Haemophilia Society in September 1999 Susan Deacon gave a commitment to a full enquiry into the issue of infection of Scottish haemophiliacs with Hepatitis C (HCV). The Report does not deliver on this commitment. Issues and decisions prior to approximate 1984 were not addressed, despite evidence being presented indicating that this is the crucial period. Further, the decisions of government and civil service officials were not scrutinised. This failure is particularly alarming since the Scottish Health Department conducted the investigation itself. Official policy and funding decisions are crucial to the understanding of this tragedy particularly given the potential conflict if interest when government officials who decided on policy operate on the board of the Scottish National Blood Transfusion Service (SNBTS) at the same time.

2 Despite a commitment to listen to and giving a voice to the experiences of haemophiliacs infected with HCV and their families, publication of the report was repeatedly delayed yet even then only one paragraph out of 22 pages refers to this. This is unacceptable. Little credence appears to have been given to our evidence when weighed against the submissions of other interested parties. Specifically, many of us were never informed that there was a risk of viral infection from our factor treatment and also many of us were certainly tested for HCV without our knowledge. This is in direct conflict with the report.

3 Despite meeting on at least two occasions with both the doctors and SNBTS, patients and patients groups were not invited to meet with the committee of enquiry. There was therefore no mention of the impact that HCV has on the life of the person infected and their family. Also, the number of submissions quoted suggest that this is a small problem but fails to contextualise this. Firstly, by failing to en-numerate that the consequences are actually in some cases fatal. (More haemophiliacs in UK have died from HCV than fatalities due to CJD, E-coli0157 or any single rail disaster). Secondly by failing to mention that the stigma associated with this disease is such that many people are not willing to come forward, even in an anonymous capacity.

4 The evidence submitted by doctors and medical professionals has not been published within the complete report. This is unacceptable – how can we challenge their conclusions without seeing their evidence – and cast doubts on the transparency of the process.

5 Evidence submitted by infected haemophiliacs who gave their permission for it to be published does not appear in the full report. What has happened to this evidence and why was it not published? We are concerned that there was no real commitment to hearing our story.

6 There is very little mention of donor screening or screening of donated blood. Specifically, why was the ALT test not used to screen blood in the UK when several other countries thought it appropriate? The decision not to instigate screening when a screening protocol could easily have been developed suggests that the government, or its officials, knowingly exposed patients to potentially dangerous blood and blood products. It appears there has been no consideration of the Blood Bank Minutes submitted to the committee of enquiry and to Susan Deacon. These minutes clearly demonstrate the culture of secrecy and parsimony that exist within the system. It also shows that officials were aware of the potential danger to patients but chose not to adopt the best practices employed in other countries. (This places them in a similar position to the case of the man currently on trial who knowingly infected his ex-partner with HIV).

7 These points demonstrate that the only way to find the truth about this sorry affair is for the Scottish Executive to instigate a full independent Public Enquiry into the infection of haemophiliacs with Hepatitis C. Only in this way will we get the transparent process required to uncover how this tragedy was allowed to happen and learn what we need to prevent similar events in the future.

8 The issue of financial compensation for haemophiliacs infected with Hepatitis C was dismissed by the Report without any explanation and we make the following points

- Why is it an important principle that the NHS does not pay its own users no-fault compensation? Other precedents already exist in agriculture and industry.

- Why does our government hold its citizens in less regard than the governments of either the Republic of Ireland or Canada to name but two? Other states have accepted that they are responsible for the well-being of their citizens and have fully engaged with victims and put compensation procedures in place – as well as instituting full public enquires. Are we somehow less deserving?

- If the government is willing to pay compensation to people who develop vCJD on moral grounds, why is it immoral to do the same for those of us infected with Hepatitis C? The argument used by the Health Minister means that if we develop vCJD from eating a burger then we would be eligible for compensation. If, however, we were infected through our NHS treatment, it would be “an important principle” that we were not compensated. Why?

- We are not seeking compensation from the NHS but from the government. As citizens of the state we entrust ourselves to the state’s care through the NHS. Through no fault of ours we have been infected with a deadly disease through treatment supplied by the NHS. The state thus has an obligation to compensate us for the harm that we have suffered as it is obliged to ensure the well-being of its entire people. Given the current emphasis on self-reliance and personal responsibility for pensions etc. it should be noted that those infected with Hepatitis C are unable to secure mortgages or life assurance due to their infection and are thus unable to make any such arrangements. We feel that regardless of any other considerations, the government has a moral obligation to set up an adequate compensation scheme.

We look forward to appearing before the Health Committee to give our evidence in person and clarify any issues arising from our submissions.

Philip Dolan – Chairman
On behalf of the Scottish Haemophilia Society Groups Forum
20th February 2001

APPENDIX A

Haemophilia Society (UK) submission to Health and Social Care Committee

HEPATITIS C AND HEAT TREATMENT OF BLOOD PRODUCTS FOR HAEMOPHILIACS IN THE MID 1980s

The Haemophilia Society is the only UK wide patient group for people with haemophilia and related bleeding disorders and their families. Originally established as a 'self help' group by patients in 1950, the Society today is a membership organisation in which people with haemophilia and their relatives are involved as volunteers at every level from trustee board to local groups.

The Society has five volunteer led groups in Scotland and approx. 600 individuals in Scotland on our membership database. Their experiences and views have informed this submission. The Society welcomes the Committee's decision to focus on the issues of hepatitis C infection within the haemophilia community in Scotland. **We believe the enquiry and report carried out by the Health Department of the Scottish Executive is an inadequate response to the impact of the infection in Scotland, and we set out below our specific concerns and criticisms with regard to the Executive's investigation.**

The Haemophilia Society made a submission to the Executive's investigation which is available for Committee members. We remain extremely unhappy that so many of the issues in that submission have not been addressed by the Executive's report.

1) The Executive's investigation and final report are too limited in scope

A full inquiry is needed to properly answer all the questions which remain about accountability and the official decision making process during the era (the 1970s and 80s) when patients with haemophilia were exposed to contaminated blood products. **The Society wishes to draw the attention of the Committee to the statement issued recently by Dr Peter Jones, a leading international and UK haemophilia expert, supporting the call for a public inquiry (to be tabled).** Dr Jones was involved in treating patients with haemophilia throughout the period, and saw many of his patients die from HIV contracted from contaminated blood products, and is an Executive Member of the World Federation of Haemophilia.

2) Inquiry process flawed – not open and transparent

In our submission to the Scottish Executive in December 1999, the Society stated that the inquiry carried out in Scotland into contaminated blood products must 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 for a Government body to be investigating the use of contaminated blood products in the NHS. **We recommended the establishment of an independent task force to undertake the inquiry including patient representatives, scientists and medical experts.**

This was ignored; the conflict of interest issue has never been addressed by the Minister or her department. An internal inquiry has been carried out behind closed doors in a manner which has not been open and transparent, despite assurances given when we first met with ministers and officials in September 1999.

3) Patient perspective and views ignored

The Executive's team appears to have reached its conclusions about the information given to patients without talking to patients themselves. Whilst the authors of the report evidently had discussions with both SNBTS and haemophilia centre doctors in preparing the report, no discussions were held with patients and the experiences of patients are only referred to in one paragraph (page 5/6 of the Executive's report). This is particularly serious given that one of the two central areas the report sets out to address was the information given to patients at the time – the report's conclusions on this are based solely on what doctors have said – no attempt has been made by the report's authors to find out from patients themselves what they were told.

The report claims that all patients were fully informed about the risks of hepatitis. This directly contradicts the evidence put forward by the Society and our members that patients were not clearly informed of the risks and that many were informed of their diagnoses late or by accident.

4) What steps could have been taken to prevent almost universal hepatitis infection of this patient group? Who is accountable?

In para 9 the report identifies that "*It is possible nowadays to identify the presence of the virus in pools or in individual donations. Up to around 89-90, it was not possible to do so with* ***any certainty*** *---."* This ignores the fact that surrogate testing to try to eliminate hepatitis-infected blood had been available for some years. Surrogate testing involves testing blood donations to measure the levels of an enzyme, alanine aminotransferase (ALT). Where ALT levels are high this indicates inflammation of the liver, i.e. hepatitis, and blood donations are discarded thus reducing levels of contamination in the blood supply.

The report totally fails to reveal what consideration was given to surrogate screening. It also fails to consider the international comparisons which the Society asked them to examine which might have helped in forming a view as to whether everything that could have been done was actually done as soon as possible to try to eliminate hepatitis–infected blood from the blood supply. For example *surrogate screening was used in Germany and Italy from the late 60s and early 70s*. Who made the decision not to test each pint of blood and what pressures were brought to bear upon scientists and clinicians by officials and politicians?

5) Failure to address follow up action

The Society has continually highlighted the lack of any official follow up strategy to ensure that all people who may have been affected by HCV have been properly traced, tested, counselled and if appropriate offered treatment. In producing the report the Scottish Executive has failed to address this very important issue and in its findings/recommendations has not even taken the basic step of making sure that every person with haemophilia who may have contracted HCV has been traced and offered a test. Because of this lack of follow up, there is still no accurate official figure for the number of people with haemophilia in Scotland who have contracted HCV.

6) Unreasonable rejection of financial assistance

The issue of financial assistance is not properly considered within the content of the report. In fact, as the question of financial assistance was not within the original remit of the investigation the Society believes that the report and its findings should not be used as the basis to form any conclusions about the case for financial assistance. We are extremely concerned that the Executive's report has been used by Ministers and the Health Department to justify their rejection of the case for financial assistance.

As the report failed to address the impact of hepatitis C fully on the whole haemophilia community -–and only refers in one paragraph to the health and social consequences of the infection – it actually provides no substantive evidence to support the arguments either for or against financial assistance.

The fact is that precedents in the UK and abroad already exist for providing Government financial assistance to offset the impact of contaminated blood products on the haemophilia community. In Ireland, Canada and Italy patients with haemophilia who contracted both HIV and hepatitis from contaminated blood products receive financial assistance or compensation.

Within the UK a precedent was set in 1987 when the Conservative Government of the time accepted a moral responsibility and agreed to provide an ex gratia financial assistance scheme for people with haemophilia infected with HIV through contaminated blood products.

Recently it has been announced that an ex gratia financial assistance scheme is to be set up by Government for victims of new variant CJD. Again this step has apparently been taken on moral grounds – how then can Ministers justify not taking a similarly compassionate approach for this very small group of people with haemophilia who have suffered hepatitis C infection?

The Haemophilia Society believes that as a minimum a hardship fund should be established in Scotland to assist those people with haemophilia for whom hepatitis C has caused evident damage to health and consequent hardship. This could be assessed on medical and other evidence of need, as already happens with the hardship fund established for people with haemophilia who contracted HIV from contaminated blood products. Such a fund could be established on a 'no fault' basis – as is the case for the HIV fund.

A 'no fault' scheme of this kind would stand outside the usual NHS fault-based legal compensation arrangements, a point which has been ignored in comments made by Ministers following publication of the report.

The Society believes this step is justified by the exceptional circumstances. The haemophilia community is a very small one, already facing an incurable and very serious medical condition, to which was added infection by two potentially deadly viruses, HIV and hepatitis C. Nationally, some 95% of the haemophilia patient population were infected with one or both of these viruses through contaminated blood products used in their NHS treatment. Many have lost their lives to these viruses.

The Society maintains that the exceptional situation of the haemophilia community calls for a special response from the Scottish Parliament, and we hope the Health and Community Care Committee will call for a proper and fair examination of the case for financial assistance.

Karin Pappenheim, Chief Executive
Haemophilia Society UK
(karin@haemophilia.org.uk/www.haemophilia.org.uk)
February 2001

References

Medical Literature

- Hepatitis and Clotting Factor Concentrates; C. K. Kasper and S. A. Kipnis (1972*), Journal of the American Medical Association; 221:510*
- An Outbreak of Hepatitis Associated with Intravenous Injection of Factor VIII Concentrate; J. Craske, N. Dilling and D. Stern, (1975), *The Lancet; ii: 221-223*
- Non-A, Non-B Hepatitis After Transfusion of Factor VIII in Infrequently Treated Patients; M. L. Fletcher, J. M. Trowell, J. Craske, K. Pavier and . R. Rizza (1983), *British Medical Journal; 287: 1754-1757*
- Transmission of Non-A, Non-B Hepatitis by Heat-Treated Factor VIII Concentrate; M. Colombo, P. M. Mannucci, V. Carnelli, G. F. Savidge, C. Gazengel, K. Schimpf and the European Study Group, (1985), *The Lancet; ii: 1-4*
- Progressive Liver Disease in Haemophilia: An Understated Problem?; C. R. M. Hay, F. E. Preston, D. R. Trigger and J.C.E. Underwood, (1985), *The Lancet; I: 1495-1498*

Other sources

- Dail Eireann, 2 June 1999, Motion to establish Tribunal of Inquiry on haemophilia and hepatitis C.

Publications/reports from the Haemophilia Society

- *Haemophilia and Hepatitis C*; research report, Mandy Cheetham 1996, The Haemophilia Society
- *Haemophilia Society Submission to the Health Committee Inquiry into Procedures Related to Adverse Clinical Incidents and Outcomes in Medical Care, 1999.*
- Sarah Bond and Jennifer Roberts*; Hepatitis C and Haemophilia; the Social and Economic Impact,* report of a pilot study prepared to the Haemophilia Society 1999 (unpublished)
- Haemophilia Society submission to the Scottish Executive's investigation into hepatitis C infection within the haemophilia community (December 1999)
- Dr Linda Garvican*, National provision of care for patients with HIV and hepatitis by haemophilia centres* (for publication April 2001)

Agenda item 3

Health & Community Care Committee
14 March 2001

The Scottish Parliament

The Information Centre

Research Note for the Health and Community Care Committee

HC/01/8/5
RN 00/85 (REVISED)
6 November 2000

HEPATITIS C VIRUS IN BLOOD AND BLOOD PRODUCTS

MURRAY EARLE

This Research Note provides information to the Health and Community Care Committee on Hepatitis C infection by contaminated blood and blood products. It is intended to serve as background information on the Executive's Report on the matter. It also considers Petition PE185 on the same issue.

BACKGROUND

Petition PE 185:

The petition was made by Thomas McKissock and called 'for the Scottish Parliament [to] take the necessary steps to establish a scheme of compensation to assist people in Scotland who have contracted Hepatitis C infection as a consequence of infected blood transfusions.'

Petition PE45 was brought by Mr P Ferguson and called, 'for the Scottish Parliament to hold an independent inquiry into Hepatitis C and other infections of people with haemophilia.' The Parliament's Public Petitions Committee met on Tuesday 9 May 2000 and noted that, '[t]he issue is similar to that which was addressed by petition PE45.' The Petitions Committee agreed with the suggestion that the Health and Community Care Committee be asked to consider both petitions together with their response to the Executive inquiry.

On 21 June 2000 the Health and Community Care Committee considered the issue and the petition and sought further information on when it was established that Hepatitis C was a problem in blood products as well as 'questions surrounding the treatment and examination of blood and whether it was done timeously.'[1] Background information was also sought on Hepatitis infection itself, factor VIII, the processes of screening and sterilisation of blood products, the importation of blood and blood products and the issue of compensation. Information was also sought on the extent to which the Executive Inquiry set out to address these issues.

There have been several Parliamentary Questions on the matter, as set out in Annex A, which should further remind members of the background to this Research Note.

GLOSSARY

Before considering the substantive issues in the present debate, it might be useful to outline some of the medical terms used in this Research Note as well as within the forthcoming Executive Report.

Hepatitis C: a virus which was first named in the late nineteen eighties, having previously been known as non-A and non-B Hepatitis. This is a virus which attacks the liver and can be transmitted by the faeco-oral route, usually in outbreaks via a contaminated water source, or through(transfused) blood products. It is the most common form of blood transfusion acquired Hepatitis. It is also transmitted through sexual contact, though this is considered rare. Risk factors include recent blood transfusion, intravenous drug use or occupational exposure to blood products. There is no specific treatment, but there is a test for Hepatitis C antibody which indicates prior exposure.

All blood products are screened for Hepatitis C. The risk of transmission following transfusion is small though not absent. Most manufactured products (such as cryoprecipitate, which contains the Factor VIII which haemophiliacs lack) are produced in such a way that viruses are destroyed, for example using heat treatment.

Blood and Blood Products

Blood: a circulating tissue composed of a fluid portion (plasma) with suspended formed elements (red blood cells, white blood cells, platelets).
Blood Products: biopharmaceutical products purified from human blood, such as the blood clotting factor VIII used to treat haemophiliacs (Recombitant factor VIII is also on the market.)

Recombinant: a cell or an individual with a new combination of genes not found together in either parent

[1] Dr Richard Simpson MSP at the meeting of 21 June 2000, Col. 1068.

Hepatitis C & Factor VIII: a coagulation or clotting factor, which is missing in haemophiliacs due to a congenital deficiency in either the amount or activity of factor VIII.

Factor VIII deficiency: an X-linked deficiency, such that females can be carriers and males can be haemophiliacs, it results from a deficiency of clotting factor VIII, a protein factor that is required for normal blood clotting. Symptoms include easy bruising, bleeding gums and nose as well as bleeding into muscle tissue (haematoma) or joint space (haemoarthrosis). Treatment includes the infusion of factor VIII to normalise blood coagulation.

Autoclaving (and the surrounding controversy): a mechanical sterilisation process using pressure and heat or pressurised steam.

Fractionation: a term used to describe any method for separating and purifying biological molecules.

TWO SIDES OF THE ARGUMENT

The Department of Health position

The Department of Health (UK) emphasised that the difference between blood *per se* and blood products is an important one, not least because in the case of the latter, the Consumer Protection Act 1987 (discussed below) is applicable.

It is also noteworthy that England has never been self-sufficient in respect of blood products (which are plasma-based, such as clotting factors [factor VIII] and immunoglobin). While these products are acquired from the USA, Scotland's are acquired from USA and Germany. The same is not true of blood itself; it is not logistically possible to import blood because it must come from a CJD-free state.

Considering the matter of elimination of Hepatitis C from blood products, chronology is very important. The spur for development of heat treatment in the early 1980s was HIV. At the time, different manufacturers used different time/temperature combinations in the autoclaving / fractionation process. There was no particular standardisation and use was made of dry heat, wet heat and pasteurisation. The processes employed are not so straight-forward as to be able to say which is the most effective.

At the time, Bio Products Laboratories (England) used a time/temperature fractionation which fortuitously in-activated Hepatitis C as well as HIV. 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. At that stage (1985) neither company was actively considering Hepatitis C.

At the same time, the NHS would have been importing blood products which would have come with a range of time/temperature combinations favoured by different pharmaceutical multinationals.

The discovery of Hepatitis C as an entity occurred in May 1988. Before that there was only non A non B Hepatitis.[2] The Department argued that only after that was it feasible to develop a test, then a screening process for Hepatitis C. This was first available in January 1990 and various countries introduced it subsequently (France in March 1990, USA in early 1990). Thereafter a so-called 'second generation' test was developed in spring 1991. This development was necessary due to a high proportion of both false negative and false positive results.

This screening test was introduced in the United Kingdom in September 1991, which made the UK one of the last countries in the Western world to introduce any test at all. Should it come to that, the question for any court will be at what point *should* the UK [health authorities] have introduced a test for Hepatitis C?

Not all aspects of this position are agreed with by the Haemophilia Society.

The Haemophilia Society Position

The Haemophilia Society gave evidence to the Executive Inquiry.[3] In it the Society argued that Scots manufactured blood products were not inactivated against Hepatitis C until after those manufactured in England were inactivated. This would appear to accord with the Department of Health position. These products were not fully in use in Scotland until 1988.

While the Department of Health would argue that because Hepatitis C did not exist as such, there was therefore no test for it, the Haemophilia Society argues that the test existed, but did not have a name. This would appear to be backed by the medical literature. In particular, the society points to an article published in *the Lancet* in 1985 which pointed to the transmission of non-A, non-B Hepatitis by heat treated Factor VIII Concentrate.[4]

The society stressed the need for an independent inquiry into the issue, expressing scepticism of the nature of the present inquiry (by the Executive into the activities of one of its agencies,[5] i.e. the Scottish National Blood Transfusion Service, which is part of the National Health Service) and noting that 48 MSPs

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[2] This is backed up by the medical literature: See Tabor et al 'Additional Evidence for more than one agent of human non-A, non-B Hepatitis. Transmission and Passage Studies in Chimpanzees.' (1984) 24 *Transfusion* 224-236:

[3] *Response to the Scottish investigation into hepatitis C infection via contaminated blood within the haemophilia community.* December 1999.

[4] See Colombo *et al*, 'Transmission of Non-A, Non-B Hepatitis by Heat Treated Factor VIII Concentrate', (1985 *The Lancet* ii: 1-4.

[5] Haemophilia Society submission paragraph 2.6

have signed motion S1M 323 calling for an independent inquiry by the Scottish Parliament.[6]

The main issues to which attention was drawn by the Society were:

- whether Scottish patients were exposed to risks longer than they ought to have been given the extent of knowledge in the field
- why Scottish blood products were not made safe from Hepatitis C until two years after the English equivalents
- which authority bore responsibility for decisions on importation and screening of blood products
- that it is a red herring to say that Hepatitis C was unknown, as it was known, but as Non-A, Non-B Hepatitis
- whether patients were given appropriate information on the risks inherent in the use of the products in question (this was supported by anecdotal evidence of adverse outcomes and insufficient information given to particular patients).
- socio-economic issues surrounding infection with Hepatitis C and haemophilia.

WESTMINSTER

The issues considered in this Research Note have also been debated at Westminster, in both the House of Commons and the House of Lords. Some recent government responses germane to this Note have been appended as Annex B.

THE EXECUTIVE INQUIRY[7]

The Inquiry set out to produce a Report on Hepatitis C and Heat Treatment of Blood Products for Haemophiliacs in the mid 1980s. It was undertaken following media speculation that 'a Hepatitis C inactivated Factor VIII product had become available in England in 1985 through the Bio Products Laboratory (BPL), whereas it had taken until late 1987 for the Scottish National Blood Transfusion Service (SNBTS) to produce a comparable product in Scotland.' This led to concern that those in Scotland were at risk for longer than they ought to have been.

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[6] S1M-323 Brian Adam: Hepatitis C Inquiry—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. Supported by: Hugh Henry, Margaret Jamieson, Ian Jenkins, Mary Scanlon, Mr John Swinney, Ms Irene Oldfather, Mr John McAllion, Kay Ullrich, Tommy Sheridan, Alex Fergusson, Michael Russell, Nick Johnston, Bristow Muldoon, Dorothy-Grace Elder, Dr Winnie Ewing, Richard Lochhead, Cathy Jamieson, Lord James Douglas-Hamilton, Mrs Lyndsay McIntosh, Fiona Hyslop, Donald Gorrie, Roseanna Cunningham, Alasdair Morgan, Colin Campbell, Michael Matheson, Patricia Ferguson, Mike Watson, Mr Kenneth Gibson, Fergus Ewing, Karen Whitefield, Mr Brian Monteith, Mr Duncan Hamilton, Fiona McLeod, Ben Wallace, Mr Keith Raffan, Mr David Davidson, Cathie Craigie, Kate Maclean, Shona Robison, Andrew Wilson, Alex Neil, Trish Godman, Maureen Macmillan, Mr Kenny MacAskill, Tavish Scott, Ms Margo MacDonald, Nicola Sturgeon, David McLetchie, Rhoda Grant, Robin Harper, Irene McGugan, Mr Gil Paterson, Mr Adam Ingram, Phil Gallie, Janis Hughes, Mr John Munro, Mr Mike Rumbles, Pauline McNeill, Alex Johnstone, Johann Lamont, Mr Murray Tosh, Ms Margaret Curran, David Mundell, Mr Duncan McNeil, Christine Grahame, Dennis Canavan.

[7] Available on http://www.scotland.gov.uk/library3/health/hepatitis_c.pdf

The remit if the inquiry was to

1. 'examine evidence about the introduction of heat treatment in Scotland for Factor VIII in the mid 1980s, to assess whether patients in Scotland with haemophilia were exposed to the risks of the Hepatitis C virus longer than they should have been, given the state of knowledge at the time' and
2. to 'examine evidence about the information given to patients with haemophilia in the 1980s about the risks of contracting the Hepatitis C virus from blood products.'

The Inquiry received submissions from the Haemophilia Society, the Scottish National Blood Transfusion Service, Scottish Haemophilia Directors and the Department of Health in England, as well as taking evidence from members of the Haemophilia Society.

Findings

The Executive Inquiry concluded that the Scottish National Blood Transfusion Service were indeed 'around 18 months behind the Bio Products Laboratory in England' in producing a heat-treated product which had eliminated Hepatitis C. However, the Inquiry found that this time delay was justified for technical reasons: there was at the time no test to identify the virus itself and there were different (blood product) treatment processes undergoing assessment at the time. The Report also pointed out that as soon as a suitable process had been found, the SNBTS was quick to implement it. In addition, it was found that no attempt was made to mislead patients on the risks of contracting Hepatitis C.

THE ISSUE OF COMPENSATION

Petition PE185 calls on the Scottish parliament to offer compensation to those who have contracted Hepatitis C from contaminated blood products. This section outlines current approaches to the issue of compensation in the medico-legal context.

The Haemophilia Society, in its response to the Executive Inquiry pointed out that that Hepatitis C infection causes stigmatisation, anguish, ill health and hardship, and may force sufferers to cut down on work obligations. The Society argued that a precedent in fact exists for financial assistance for those infected with HIV through blood products administered as a result of NHS treatment, noting that, *the Conservative Government in 1987 accepted moral responsibility … and provided £10 million for the Society to set up the MacFarlane Trust in 1988*.[8] The Society recommended a similar regime for sufferers of HCV.

In the Scottish context, *The Society strongly urges the Scottish Parliament to offer a more equitable and just response to the tragedy the haemophilia community has suffered by establishing a financial assistance scheme / hardship fund for those*

[8] Haemophilia Society Submission paragraph 4.6.

with HCV to run alongside that available from the MacFarlane Trust to those with HIV.[9]

As was pointed out in the House of Commons (see Annex B), compensation is ordinarily paid in such circumstances only where the Health Authority or the National Health Service has been negligent. Other than the setting up of a trust such as the MacFarlane Trust or the making of an *ex gratia* out of court payment to claimants, there are a number of methods through which payments may be sought.

Parliament may enact legislation to that effect, similar to the Vaccine Payments Damage Act 1979, but specific to Hepatitis C, such that recognised sufferers who can prove a specified level of disability and an attributable cause, may receive certain levels of compensation.

Alternatively, compensation could be sought through the courts in one of two ways. Claimants may allege that the Health Service was negligent in not screening for Hepatitis C in blood products administered to sufferers. This would involve proving that the reasonably competent blood transfusion service would have screened for the virus given the state of available technology and knowledge at the time. It also involved proving that infection with HCV was cause by the transfusion administered by the defender.

Finally, pursuers may pursue a claim under the Consumer Protection Act 1987. This is the method being employed in England at present.

Group Action in England[10]

Litigation commenced in the High Court on the 10th of October 2000, involving 112 patients who have allegedly been infected with Hepatitis C through contaminated blood, blood products or transplanted organs in the course of medical treatment. The case for the plaintiffs will use 6 'lead' cases, and will be brought against the National Blood Authority in England and the Velindre NHS Trust in Wales.

This is one of the first cases to be brought under the Consumer Protection Act 1987 and the first group action to be brought under the 1987 Act. It will be contested on the basis of actual liability rather than correct implementation of a European directive by the UK. The case is expected to last for three months.

The Consumer Protection Act 1987 was enacted following a 1985 European Directive on Product Liability.[11] For this reason, and under the act, claims will be made for injuries sustained after 1988. The Act itself set up a system of strict liability to provide compensation to those injured by defective products - in this case human blood. To say that the Consumer Protection Act 1987 is an instrument of strict liability means that negligence need not be established for a

[9] Ibid. paragraph 4.10.
[10] See *The Guardian*, October 11 2000: http://www.guardianunlimited.co.uk/Archive/Article/0,4273,4074769,00.html.
[11] 85/374/EEC: http://www.europa.eu.int/eur-lex/en/lif/dat/1985/en_385L0374.html.

claim to be successful, though a causal link between the blood or blood product used and the actual injury suffered, must be established. It is on this point that claimants are usually likely to encounter difficulties, though less so in the case of blood **products** containing Hepatitis C.

Litigants will first have to prove that the product was 'defective', the standard for which is that the product in question failed to meet the standard that 'persons generally are entitled to expect'. To answer this question, courts will ask whether it is reasonable in the circumstances for 'persons generally' to expect blood and blood products to be free of Hepatitis C virus. This will entail a judicial consideration of the date of transfusion and infection and the state of scientific knowledge (in screening for and eliminating Hepatitis C) at the time.

It must also be established that the transfused blood or blood product was the most likely cause of the infection with Hepatitis C (that is, ruling out intravenous drug use and other possible causes. This is necessary because in *Kay v Ayrshire Health Board* [1987] 2 All ER417 (HL) it was held that where there was more than one possible cause of the injury suffered, the law could not presume in favour of the pursuer.

The Consumer Protection Act 1987, however, also incorporates a very strong defence known as the Development Risk defence. Section 4(1)(e) stipulates that it will be a defence that *the state of scientific and technical knowledge at the relevant time was not such that a producer of products of the same description as the product in question might be expected to have discovered the defect if it had existed in his products while they were under his control…*'. This is a *British defence* which is to be construed in the spirit of the directive.[12]

The date of injury will be important to the plaintiffs in establishing that the product was defective according to the above definition. It will also be important to the defence case, in rebutting the pursuer's case and, failing that, in proving that the state of the art at the time was such that it was not possible to avoid the injury.

CONCLUSION

This Research Note has considered the issues surrounding the transmission of Hepatitis C Virus by contaminated blood or blood products administered to haemophiliacs. It has sought to cover the medical and the legal angles and to inform Members of the current state of play both north and south of the border. It will be updated as and when further information comes to light.

If you have any comments or questions about this Research Note, please contact Murray Earle on extension 85377 or Murray.Earle@scottish.parliament.uk.

***Research Notes** are compiled for the benefit of Members of Parliament and their personal staff. Authors are available to discuss the contents of these papers with Members and their staff but cannot advise members of the general public.*

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[12] See, for example, *European Commission v United Kingdom (re the Product Liability Directive)* [1997] All ER (EC) 481, [1997] 3 CMLR 923 (Case C-300/95), in which the European Court of Justice held that it had not been established that Britain's section 4(1)(e) did not conflict with Europe's Article 7(1)(e), which the former was set to incorporate into UK law.

Annex A

Parliamentary Questions

Fergus Ewing (Inverness East, Nairn and Lochaber) (SNP): To ask the Scottish Executive whether it will set up a body, similar to the MacFarlane Trust which exists to provide help to people in the haemophilia community who incur extra costs of living arising from HIV or AIDS as a result of having received contaminated blood products in the UK, to provide such support for those who have contracted Hepatitis C in the same manner.

(S1W-823)

Fergus Ewing (Inverness East, Nairn and Lochaber) (SNP): To ask the Scottish Executive whether it will make representations to Her Majesty's Government recommending that the remit of the MacFarlane Trust be extended to allow haemophilia sufferers in Scotland inflicted with Hepatitis C as a result of receiving contaminated blood products in the UK to benefit from the work of the Trust.

(S1W-854)

Susan Deacon: The circumstances surrounding those who may have contracted Hepatitis C through treatment with blood products are tragic. I have met the Haemophilia Society to hear their concerns at first hand and officials within my Department are making enquiries into the circumstances surrounding this issue. I will be better placed to consider whether any further action on the part of the Scottish Executive is indicated when these enquiries are completed.

Mr John Swinney (North Tayside) (SNP): To ask the Scottish Executive when heat treatment procedures were introduced in Scotland to eliminate the Hepatitis C virus in blood products.

(S1W-839)

Susan Deacon: The question is among a number of points which I have asked my Department to look at in relation to the safety of blood products from Hepatitis C. I also met with the Haemophilia Society to hear their concerns at first hand.
I have noted the question and the points also raised in S1W-840, S1W-841 and S1W-842, and these will be taken into account in the Department's enquiries. I will keep you informed of the outcome of these enquiries as soon as they are completed**.**

Mr John Swinney (North Tayside) (SNP): To ask the Scottish Executive what clinical indicators among Scottish haemophilia sufferers led to the introduction of work on heat treatment of blood products with a view to sterilising the Hepatitis C virus.

(S1W-840)

Mr John Swinney (North Tayside) (SNP): To ask the Scottish Executive whether blood products carrying the risk of Hepatitis C virus transmission were still in use in Scotland in 1987, when the use of such products was discontinued in England and Wales in 1985.

(S1W-841)

Mr John Swinney (North Tayside) (SNP): To ask the Scottish Executive how many haemophilia sufferers have been infected with the Hepatitis C virus after receiving contaminated blood products: (a) manufactured in Scotland, and (b) imported from abroad.

(S1W-842)

Susan Deacon: I refer the member to the answer given to S1W-839.

Mr Kenneth Gibson (Glasgow) (SNP): To ask the Scottish Executive what action it is taking to improve standards of care and access to treatment for Hepatitis C positive individuals.

(S1W-1644)

Susan Deacon: It is the responsibility of health boards to assess local needs for patients with Hepatitis C, and arrange provision of appropriate treatment and care services. Last year, the Scottish Office commissioned the Scottish Needs Assessment Programme to establish a working group to consider all aspects of Hepatitis C including epidemiology, prevention, investigations, and treatment, and to estimate future implications for the Scottish population and for service needs. This working group is expected to report early in 2000.

Mr Kenneth Gibson (Glasgow) (SNP): To ask the Scottish Executive what its plans are for the introduction of treatment guidelines for patients suffering from Hepatitis C.

(S1W-1645)

Susan Deacon: There are no plans at present to introduce national guidelines. It is for health boards to assess the local needs for patients with Hepatitis C, and many health boards have developed local treatment guidelines and protocols.

Mr Kenneth Gibson (Glasgow) (SNP): To ask the Scottish Executive what its plans are for introducing Interferon and Ribavirin combination treatment for patients suffering from Hepatitis C.

(S1W-1646)

Susan Deacon: The Scottish Health Purchasing Information Centre (SHPIC) published a report on Hepatitis C in September 1998. This report was updated to include recommendations on the use of combination treatment with interferon alfa and ribavirin and disseminated to the NHS in Scotland in February 1999. The working group set up under The Scottish Needs Assessment Programme will be further considering interferon alfa and ribavirin treatment. The National Institute for Clinical Excellence in England is also to consider the issue of antiviral combination treatment for Hepatitis C early in 2000. The conclusions of these bodies will help to inform decisions about the provision of this treatment within the NHS in Scotland.

Fergus Ewing (Inverness East, Nairn and Lochaber) (SNP): To ask the Scottish Executive what the rate of Hepatitis was in whole blood recipients at the time haemophilia treatment with blood products factors VIII and IX was introduced.

(S1W-2377)

Fergus Ewing (Inverness East, Nairn and Lochaber) (SNP): To ask the Scottish Executive whether there were any cases of undiagnosable Hepatitis noticed in haemophiliacs in Scotland before 1987 and, if so, how many.

(S1W-2379)

Susan Deacon: This information is not held centrally. I have noted the question however and the points also raised in S1W-2379 and S1W-2380, and these will be taken into account in the Department's enquiries into the circumstances surrounding the safety of blood products from Hepatitis C. I will keep you informed of the outcome of my enquiries as soon as they are completed.

Fergus Ewing (Inverness East, Nairn and Lochaber) (SNP): To ask the Scottish Executive what is the current recorded death rate of haemophiliacs from Hepatitis C and up to what date was that number last reviewed.

(S1W-2380)

Susan Deacon: I refer to the answer given to question S1W-2377.

Annex B

Recent Westminster Questions germane to the present Research Note.

11.01.2000
Lord Lester of Herne Hill / Lord Hunt of Kings Heath
Whether they will publish documents relevant to the death of haemophiliacs from Hepatitis C after being given Factor 8, referred to in the Observer on 21 November; and if not, why not. [HL 69]. - Includes ref to a letter about manufacturing practice dated 2 May 1979 from Dr Richard Lane and a paper written by officials on 21 December 1979 in Library.

21.12.1999
Chris Ruane: To ask the Secretary of State for Health, how many haemophiliacs there are infected by blood containing Hepatitis C in each health authority area. - Including figure and fact that do not hold this information centrally for individual health authorities.
Mr. Denham: We do not hold this information centrally for individual health authorities. We estimate that 4,000 people with haemophilia were infected with Hepatitis C before blood products were virally inactivated.

16.12.1999
Paul Marsden: To ask the Secretary of State for Health, if he will compensate those haemophiliacs infected with Hepatitis C through contaminated blood products; and if he will make a statement.
Mr. Denham: It remains our policy that compensation or other financial help to patients is given only when the National Health Service has been at fault. We do not believe we should make an exception to that general rule in the case of people with haemophilia infected with Hepatitis C.

29.11.1999
Betty Williams: That this House is concerned for the well-being of people who contracted Hepatitis C from contaminated blood products given to them under NHS treatment up until the mid-1980s; regrets that to date 113 such people have died from Hepatitis C; supports the campaign of the Haemophilia Society to obtain financial assistance for those affected in line with assistance received by those infected with HIV; and while recognising that the NHS was not negligent, asks the Government to consider how these people can be helped financially to enable them to live normal lives.

13.10.1999
RtHon Lord Morris of Manchester / Lord Hunt of Kings Heath: What consideration they have given to the implications of the recent disclosure that, while processes to eliminate the Hepatitis C virus through heat-treating NHS blood products used by patients with haemophilia were introduced in England in 1985, this did not happen in Scotland until 1987; and whether they will now review their

policy in relation to new financial help from patients infected with the virus by NHS treatment and the dependants of those who have since died. [HL 4115].

10.05.1999
Roger Godsiff: To ask the Secretary of State for Health for what reason the study tracing people who might have contracted Hepatitis C from blood transfusions did not also trace those people with haemophilia who contracted Hepatitis C through blood product treatments. [82885]
Mr. Hutton: The study to trace people who might have developed Hepatitis C following blood transfusion focused on those who were unlikely to have remained under clinical care and who could benefit from treatment which had then become available. As haemophiliacs are in constant contact with their clinicians, the need to include them in the tracing exercise did not arise as they would have already been known to the service. It was implicit in the Hepatitis C exercise that anyone who was concerned about their Hepatitis C virus status could request a test.

06.05.1999
Roger Godsiff: To ask the Secretary of State for Health if he will assess the benefits of providing financial assistance schemes for people who contracted Hepatitis C through contaminated blood products as a result of NHS treatment. [82860]
Mr. Hutton: We carried out a thorough assessment in 1998 of whether it would be right to introduce a special payment scheme for people infected with Hepatitis C through National Health Service treatment. We concluded that this would not be appropriate and that such patients should continue to obtain support through the benefits system in the same way as other NHS patients who have suffered non negligent harm.

30.04.1999
Geoffrey Johnson Smith: To ask the Secretary of State for Health on what number of people with haemophilia and Hepatitis C the assumptions are based on which his estimate of the cost of a financial assistance scheme is founded; if his estimate of the costs of such a scheme includes amounts of money for (a) payments for all and (b) a hardship fund; and how much he has assumed would be applied for each; over how many years such expenditure would be spread; what are the estimated costs in the first year; and what figure for first year start up costs he has included in his estimate. [80463]
Mr. Hutton: The estimate was based on approximately 3,000 people and the overall expenditure to date on the special payment scheme for those with haemophilia infected with HIV through national Health Service treatment with blood products. The estimates did not include start-up costs or the costs of managing the process.

29.04.1999
Roger Berry: To ask the Secretary of State for Health (1) what estimate he has made of the number of people with haemophilia infected with Hepatitis C by

contaminated blood products who are now suffering (a) chronic liver disease and (b) other significant health problems as a result of their infection; [80909]
(2) what estimates he has made of the number of people with haemophilia who were infected with Hepatitis C as a result of their NHS treatment before 1986 and the number of these who are alive today. [80908]
Mr. Hutton: We estimate that 4,000 people with haemophilia were infected with Hepatitis C through their National Health Service treatment with blood products before the introduction of viral inactivation processes in 1985. The Haemophilia Society assesses that more than ninety patients have died. We do not have information on the number of people with chronic liver disease or other significant health problems, but all identified cases of Hepatitis C infection through blood or blood products are referred to a specialist for further assessment, and drug therapy as appropriate. We believe that 6 or 7 people with haemophilia are on the United Kingdom Transplant Support Service Authority's list of people awaiting liver transplants.

13.04.1999
Andrew Stunell: To ask the Secretary of State for Health what further representations he has received on help for patients with Hepatitis C since 28 July; and if he will make a statement. [79719]
Mr. Hutton: Since 28 July 1998, hon. Members have asked 18 Parliamentary Questions (in addition to this one) and we have received 140 letters about help for people infected with Hepatitis C through National Health Service treatment.

12.03.1999
Dafydd Wigley: To ask the Secretary of State for Health if he will make a statement on the basis of the compensation entitlement for those suffering from (a) the AIDS virus and (b) Hepatitis C through contaminated blood products. [75559]
Mr. Hutton: As a general rule compensation or other financial assistance is only paid when the NHS, or individuals working in it, has been at fault. This is not the case with infection by HIV or Hepatitis C through blood products before viral screening tests and inactivation processes were available. An exception to this general rule was the special payment scheme for people infected with HIV through NHS treatment with blood or blood products. This reflected the widespread public fear of the disease at the time, when the infection was rapidly fatal and associated with sexual transmission.

Agenda item 3

Health & Community Care Committee
14 March 2001

The Scottish Parliament

The Information Centre

Research Note for the Health and Community Care Committee

HC/01/8/6
RN 00/99
21 November 2000

HEPATITIS C: HEALTH COMMITTEE QUESTIONS AND THE EXECUTIVE REPORT

MURRAY EARLE

This note considers issues raised by members of the Health and Community Care Committee on the matter of contracting Hepatitis C from transfusions of blood products, and the extent to which these issues were addressed by the Executive Report[1] into the matter. This Note should be read in conjunction with RN 00-85 Hepatitis C Virus in Blood and Blood Products,[2] which was based on Petitions PE 185 and PE 45.

Petitions PE 185 and PE 45:

PE 185 was raised by Thomas McKissock and called 'for the Scottish Parliament [to] take the necessary steps to establish a scheme of compensation to assist people in Scotland who have contracted Hepatitis C infection as a consequence of infected blood transfusions.' The Parliament's Public Petitions Committee met on Tuesday 9 May 2000 and noted that, '[t]he issue is similar to that which was addressed by petition PE45.'

PE45 was raised by Mr P Ferguson and called, 'for the Scottish Parliament to hold an independent inquiry into Hepatitis C and other infections of people with haemophilia.' The Petitions Committee agreed with the suggestion that the

[1] Available on the Scottish Executive Website: http://www.scotland.gov.uk/library3/health/hepatitis_c.pdf
[2] http://www.scottish.parliament.uk/whats_happening/research/pdf_res_notes/rn00-85.pdf

Health and Community Care Committee be asked to consider both petitions together with their response to the Executive inquiry.

On 21 June 2000 the Health and Community Care Committee considered the issue and the petition and sought further information on several points. These have been tabulated below and plotted against the extent to which the Executive Report answered those issues raised.

Issues Raised by the Committee	Executive Report
1. Was Scotland Behind England in screening blood products for Hepatitis C?	The Executive Inquiry concluded that the Scottish National Blood Transfusion Service was indeed 'around 18 months behind the Bio Products Laboratory in England' in producing a heat-treated product which had eliminated Hepatitis C - though not necessarily in its use (see point 3 below). However, the Inquiry found that this time delay was justified for technical reasons: there was at the time no test to identify the virus itself and there were different (blood product) treatment processes undergoing assessment at the time. The Report also pointed out that as soon as a suitable process had been found, the SNBTS was quick to implement it. In addition, it was found that no attempt was made to mislead patients on the risks of contracting Hepatitis C.
2. When was it established that Hepatitis C was a problem in blood products?	The chronology of the issue is set out on page 2 of the report, and a 'full chronology' is given as Annex A to the Report. From that Annex, it is apparent that in the scientific literature from 1975 the *possibility*,[3] and from 1978 the *probability*[4] became apparent that hepatitis incidence was related to blood products. In 1980, German scientists published a report suggesting that pasteurising Factor VIII at 60^{o}C for 10 hours alleviated risk of Hepatitis B. The chronology of the development of pasteurisation techniques thereafter concentrated on HIV and hepatitis B, as at that time what is now known as hepatitis C, was known as non-A, non-B hepatitis. Only in 1988, did a French study of 60-68 ^{o}C dry heat reduce non-A non-B hepatitis by 75%; i.e. by that time scientists were interested in using pasteurisation to reduce the risk of what later became known as hepatitis C. In 1989, the Hepatitis C DNA code was isolated.

[3] Italian study.
[4] American paper.

3. 'questions surrounding the treatment & examination of blood and whether it was done timeously.'[5]	The above references to the chronology would suggest that work was done as soon as problems were flagged up by the scientific progress made. On page 6, the Report discusses in greater detail than the chronology in Annex A, the Development of Heat Treated Products. From that, the point is made that the remit of the Scottish National Blood Transfusion Service was to use pasteurisation techniques to eliminated HIV from Factor VIII (1984). In March 1985, 80°C dry-heated Factor VIII was produced. It was found to be effective against Non-A Non-B Hepatitis (NANBH) in a clinical report issued in September 1986.[6] The Report then points out that 'they could not know for sure that this form of heat treatment would be effective until after the product had been in clinical use. The full results of this trial were published only in October 1988, but within the SNBTS, it 'had been in routine clinical use from April 1987, supplying 89% of Scotland's needs.'[7] All of Scotland's needs were catered for in 1988, though, 'outwith Scotland, over half the UK's Factor VIII concentrate requirement in 1988 was still being supplied with products being heat treated at 60-68 °C.'
4. Background Information on:	
a. Hepatitis infection itself	Given on Page 4 of the Report. The Report goes on to consider haemophilia and then the effect of HCV on Haemophiliacs (p5).
b. Factor VIII	No specific scientific background information on Factor VIII is given, though it is clear that this is a plasma product, which is manufactured from the donations of thousands of people (pp4-5). It is also clear that Factor VIII is useful in the treatment of haemophilia.
c. Screening and sterilisation processes	At pp.6-8, the Report sets out the Development of Heat Treated Products, making it clear that the very development of this process set out to eliminate HIV, Hepatitis B, NANBH, and *then* Hepatitis C. The Report stresses throughout that chronology is of critical importance.
d. Importing blood & blood products[8]	Not discussed in the Report as it did not form part of its remit (set out on p.1).
e. Compensation.[9]	Not discussed in the Report as it did not form part of its remit (set out on p.1).

[5] Dr Richard Simpson MSP at the meeting of 21 June 2000, Col. 1068.
[6] Report, para. 27.
[7] Ibid.
[8] Dorothy Grace Elder, Ibid. Col 1071. The issue was again raised on 20 September at Committee by Margaret Jamieson (by Col. 1216).
[9] inter alia, Dr Richard Simpson, Ibid. Col. 1068

5. The extent to which the Executive Inquiry set out to address these issues, in particular the class(es) of patient covered by the report, and whether it would be confined to haemophiliacs and Factor VIII. [10]	This Note considers the extent to which the Executive Inquiry set out to cover the issues in this table. On the matter of the remit of the Inquiry, this is set out in the Executive press release which accompanied the publication of the Report and on the first page of the report. From that it is clear that the Inquiry covered those haemophiliacs who contracted Hepatitis C from blood products (i.e. Factor VIII).
6. Conservative Government not supplying enough money to SNBTS (to set up fractionation centre for Factor VIII).	Not discussed in the Report as it did not form part of its remit (set out on p.1).
7. 'During the recess, I heard an announcement to the effect that people in Scotland with hepatitis C will be treated differently from those in England, who will get legal aid for their cases.'[11]	Not discussed in the Report as it did not form part of its remit (set out on p.1).

From the above tabulation, it is apparent that the Executive Report did not address the issues raised in either of the petitions considered by the Health and Community Care Committee, being outwith the remit of the Inquiry. In a Press Release, however, the Minister announced:

> *Having studied all the facts, I have concluded that there is no evidence that the relevant authorities did anything other than their best for patients. As a result I do not believe that the NHS should pay compensation for non-negligent harm to those haemophiliacs who contracted Hepatitis C during the period covered by the report.*[12]

If you have any comments or questions about this Research Note, please contact Murray Earle on extension 85364 or Murray.Earle@scottish.parliament.uk.

[10] Ibid., Col. 1067 and by Malcolm Chisholm, at Col. 1070. The matter was again raised at Committee on 7 June 2000.

[11] Ben Wallace, Committee Meeting: 20 September. Col 1216.

[12] 24 October 2000: http://www.scotland.gov.uk/news/2000/10/se2726.asp

Table 2

Persons in Scotland reported to be Hepatitis C antibody-positive by health board, risk group, and year of earliest positive specimen (to 31 December 1999)

	Risk	Prior to 1991	1991	1992	1993	1994	1995	1996	1997	1998	1999	Total
ARGYLL & CLYDE	*IDU*	0	5	6	6	6	24	25	39	90	112	313
	Blood Factor	0	17	15	3	2	1	1	0	0	1	40
	Other	1	0	5	0	1	6	1	6	0	5	25
	No Info	2	11	15	7	20	24	21	38	35	50	223
	Total	***3***	***33***	***41***	***16***	***29***	***55***	***48***	***83***	***125***	***168***	***601***
AYRSHIRE & ARRAN	*IDU*	1	1	5	3	6	10	8	16	36	42	128
	Blood Factor	2	4	3	1	6	1	2	1	0	1	21
	Other	0	1	0	2	0	1	4	2	1	4	15
	No Info	0	1	2	2	15	19	20	36	47	78	220
	Total	***3***	***7***	***10***	***8***	***27***	***31***	***34***	***55***	***84***	***125***	***384***
BORDERS	*IDU*	0	0	0	2	4	6	3	4	2	0	21
	Blood Factor	0	1	0	0	0	0	0	0	0	0	1
	Other	0	1	1	1	0	1	0	0	0	0	4
	No Info	0	0	6	2	3	5	2	2	4	2	26
	Total	***0***	***2***	***7***	***5***	***7***	***12***	***5***	***6***	***6***	***2***	***52***
DUMFRIES & GALLOWAY	*IDU*	0	0	0	2	9	8	6	12	16	17	70
	Blood Factor	0	2	1	1	0	0	0	0	1	0	5
	Other	0	0	0	1	1	1	0	1	3	1	8
	No Info	0	0	0	1	8	13	7	9	10	16	64
	Total	***0***	***2***	***1***	***5***	***18***	***22***	***13***	***22***	***30***	***34***	***147***
FIFE	*IDU*	0	0	2	2	9	17	32	26	34	38	160
	Blood Factor	0	5	0	1	1	0	1	0	0	0	8
	Other	0	0	3	0	0	1	1	3	2	1	11
	No Info	1	1	1	8	3	6	14	9	14	18	75
	Total	***1***	***6***	***6***	***11***	***13***	***24***	***48***	***38***	***50***	***57***	***254***
FORTH VALLEY	*IDU*	0	3	3	8	14	16	20	24	38	39	165
	Blood Factor	0	7	0	0	1	3	0	0	0	0	11
	Other	0	2	1	1	1	1	0	3	1	2	12
	No Info	1	3	6	10	14	20	28	40	51	49	222
	Total	***1***	***15***	***10***	***19***	***30***	***40***	***48***	***67***	***90***	***90***	***410***
GRAMPIAN	*IDU*	0	0	9	8	36	98	137	124	183	191	786
	Blood Factor	2	5	4	3	2	5	1	1	1	0	24
	Other	0	0	1	3	5	11	5	6	7	5	43
	No Info	1	0	6	8	13	29	38	35	48	95	273
	Total	***3***	***5***	***20***	***22***	***56***	***143***	***181***	***166***	***239***	***291***	***1126***
GREATER GLASGOW	*IDU*	4	22	41	92	105	179	221	328	497	567	2056
	Blood Factor	2	29	20	9	7	5	1	4	1	2	80
	Other	1	2	12	7	6	12	12	17	14	29	112
	No Info	0	17	40	47	159	186	170	278	399	168	1464
	Total	***7***	***70***	***113***	***155***	***277***	***382***	***404***	***627***	***911***	***766***	***3712***
HIGHLAND	*IDU*	0	0	0	0	1	3	9	22	9	26	70
	Blood Factor	0	0	6	0	0	0	1	1	0	0	8
	Other	0	0	0	0	0	8	1	3	1	1	14
	No Info	0	0	3	1	6	19	11	24	26	16	106
	Total	***0***	***0***	***9***	***1***	***7***	***30***	***22***	***50***	***36***	***43***	***198***
LANARKSHIRE	*IDU*	1	0	3	7	9	23	37	41	78	43	242
	Blood Factor	0	6	8	1	1	4	1	0	0	1	22
	Other	0	1	4	4	0	1	6	2	1	2	21
	No Info	3	6	3	4	25	20	32	35	71	77	276
	Total	***4***	***13***	***18***	***16***	***35***	***48***	***76***	***78***	***150***	***123***	***561***
LOTHIAN	*IDU*	10	29	61	148	185	144	166	128	106	108	1085
	Blood Factor	1	39	14	5	1	1	2	0	2	2	67
	Other	4	3	7	12	15	16	18	17	15	7	114
	No Info	14	43	39	33	34	37	67	45	71	81	464
	Total	***29***	***114***	***121***	***198***	***235***	***198***	***253***	***190***	***194***	***198***	***1730***
ORKNEY	*IDU*	0	0	0	0	0	0	0	1	2	0	3
	Blood Factor	0	0	0	0	0	0	1	0	0	0	1
	Other	0	0	0	0	0	0	1	0	0	0	1
	No Info	0	0	0	1	0	1	0	0	1	0	3
	Total	***0***	***0***	***0***	***1***	***0***	***1***	***2***	***1***	***3***	***0***	***8***
SHETLAND	*IDU*	0	0	0	0	0	2	0	1	3	1	7
	Blood Factor	0	1	1	0	0	0	0	0	0	0	2
	Other	0	0	0	0	0	1	0	1	0	0	2
	No Info	0	0	1	0	1	0	2	0	0	0	4
	Total	***0***	***1***	***2***	***0***	***1***	***3***	***2***	***2***	***3***	***1***	***15***
TAYSIDE	*IDU*	0	1	13	47	66	94	74	81	62	67	505
	Blood Factor	13	3	3	1	0	3	1	1	3	0	28
	Other	0	1	1	3	8	12	10	3	8	5	51
	No Info	2	2	4	11	21	27	15	23	58	39	202
	Total	***15***	***7***	***21***	***62***	***95***	***136***	***100***	***108***	***131***	***111***	***786***
WESTERN ISLES	*IDU*	0	0	0	0	0	0	0	1	0	0	1
	Blood Factor	0	0	1	0	0	0	0	0	0	0	1
	Other	0	0	0	0	0	0	0	0	0	0	0
	No Info	0	0	1	0	0	0	0	0	0	0	1
	Total	***0***	***0***	***2***	***0***	***0***	***0***	***0***	***1***	***0***	***0***	***3***
SCOTLAND	***IDU***	**16**	**61**	**143**	**325**	**450**	**624**	**738**	**848**	**1156**	**1251**	**5612**
	Blood Factor	**20**	**119**	**76**	**25**	**21**	**23**	**12**	**8**	**8**	**7**	**319**
	Other	**6**	**11**	**35**	**34**	**37**	**72**	**59**	**64**	**53**	**62**	**433**
	No Info	**24**	**84**	**127**	**135**	**322**	**406**	**427**	**574**	**835**	**689**	**3623**
	Total	**66**	**275**	**381**	**519**	**830**	**1125**	**1236**	**1494**	**2052**	**2009**	**9987**

Notes:

Earliest positive specimens with specimen dates prior to 1991 were identified through retrospective testing of stored sera.

'Health Board' refers to the persons health board of residence, or where this is not known, the health board of source of specimen

'Other' includes sexual contact, tattoo/body piercing, needlestick, bite, blood spillage, blood transfusion, or perinatal risk.

Persons who acquired their hepatitis C infection in Scotland through blood factor will have become infected prior to the time, in the mid 1980's, when heat treatment was introduced to eradicate blood borne infection.