see pages 4-5 re HIV infected patients numbers

Contents Previous

# Health Committee

**{report number} {Year}**

**Hepatitis C**

SP Paper 398

1 (2001)

FOLLOW UP SUBMISSION BY THE SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE

**Response to the Request from the Health and Community Care Committee of the Scottish Parliament for further information following the 8th Meeting 2001, Session 1**

Following the session of the Committee on March 14, 2001 at which evidence was given by SNBTS, the Senior Assistant Clerk to the Committee requested that SNBTS provide further information on issues raised at the meeting. Information was sought on the documents that had been submitted to the Committee by the Haemophilia Society, on the decisions taken at the time and whether these were driven by clinical or resource considerations and also on the use of imported US blood.

With reference to page 1614 of the transcript of the above meeting, the main focus of this response is on the matters that relate to the safety of products for the treatment of patients with Haemophilia in particular during the period up to 1987 after which all Factor VIII supplied by SNBTS was heat treated to exclude transmission of Non A, Non B hepatitis.

For clarity this report is arranged in into sections as listed below:



1. Governance of transfusion services in the UK at the time and the provision of expert advice.

1.1 During the 1980's there were three separate blood transfusion services operating within the UK, the National Blood Transfusion Service (subsequently the National Blood Authority) covering

England and Wales, the Scottish National Blood Transfusion Service (SNBTS) and the Northern Ireland Blood Transfusion Service.

1.2 The SNBTS was [and is] a division of the Common Services Agency of the Scottish Health Service (CSA) responsible to the Secretary of State for Scotland and now to Scottish Ministers through the Board of the CSA.

1.3 Each of these services was organised, managed and operated independently and there was coordination by the Departments of Health which received advice from experts in the UK.

## 2. Blood donations and blood products

2.1 Two different categories of blood product are prepared from human blood donations. These are:

· Blood Components, such as platelets or red cells which are generally prepared from the blood of a single donor.

· Plasma Derivatives, such as Factor VIII concentrates, which are pharmaceutical products manufactured from pools of plasma from thousands of donors.

2.2 The safety of the final blood product with regard to transmission of infection depends on the combined effect of the overall system for:

· selecting donors,

· testing their blood and

· preparing the final product that is received by the patient.

2.3 In the case of Blood Components it has only been possible in the last 2 or 3 years to implement processes that would remove, kill or inactivate infective agents without also damaging the cells and proteins in the donor's blood. Such processes are still only available for one of the commonly used blood components.

2.4 For Plasma Derivatives, methods have been developed that are used during the manufacture of plasma derivatives that remove, kill or inactivate most infectious agents. These methods have been shown to eliminate the risk of transmitting Non A Non B hepatitis. Details of the introduction of these processes by SNBTS have been given in previous reports.

## 3. Information on the use of imported US blood for plasma derivatives manufacture

### 3.1 Introduction

3.1.1 There are a number of manufacturers of Human Plasma Derivatives world-wide. Some manufacturers operate on a commercial basis whilst others operate on a non-commercial or not-for-profit basis.

3.1.2 There are two manufacturers of Human Plasma Derivatives in the UK, the Bio-Products Laboratory, BPL (formally the Blood Products Laboratory) at Elstree and the SNBTS Protein Fractionation Centre.

3.1.3 Until 1998 all of the plasma processed at BPL and at PFC was provided by the UK blood transfusion services and was obtained from non-remunerated UK volunteer donors.

3.1.4 Commercial manufacturers prepare Plasma Derivatives using plasma obtained predominantly from paid donors. Most paid donor plasma is collected in the USA, where regulations allow more plasma to be taken from an individual than is allowed in other countries.

3.1.5 In the UK a typical donor of blood who donates twice a year provides about 0.5 litres of plasma per annum. In the USA, plasma donors are allowed to provide up to 0.6 litres of plasma by plasmapheresis twice a week, with each commercial donor being able to sell up to 60 litres of their plasma per annum.

3.1.6 The relatively large volume of plasma available from a commercial donor in the USA was critical in enabling commercial manufacturers to respond rapidly to sharp increases in demand for Factor VIII concentrate, not only in the USA, but also in the UK and elsewhere.

3.1.7 By 1980, the total volume of human plasma processed throughout the world reached 8 million litres, with about 85% of this being handled by the commercial sector. By 1990, this total volume had increased to 17 million litres, with about 70% of this being commercial[1].

3.1.8 Commercial Plasma Derivatives imported into the UK include albumin and immunoglobulins as well as coagulation factors for the treatment of haemophilia. In 1981, 43% of the total UK requirement for Plasma Derivatives was met by commercial imports; this increased to 50% in 1984 and to 67% in 1987, falling to 24% in 1990[2].

3.2 Supply of Factor VIII to People with Haemophilia in the UK

3.2.1 Plasma Derivatives, such as Factor VIII concentrate, are pharmaceutical products which are regulated in the UK by the Medicines Control Agency (MCA).

3.2.2 The MCA has authority over all manufacturers who distribute Plasma Derivatives in the UK, including BPL and PFC. Each manufacturer must obtain a Manufacturing Licence, a Product Licence and Marketing Authorisation from the MCA for every product which they wish to distribute.

3.2.3 During the 1970's it was the objective of the UK to be self-sufficient in blood and blood products. In order to achieve this, BPL was extended and modernised and a new manufacturing centre (PFC) was constructed in Edinburgh to process plasma collected in Scotland and northern England. PFC became operational in 1975/76 using plasma collected in Scotland; plans to process plasma from England did not come to fruition.

3.2.4 Subsequently additional funding was awarded to BPL in order to increase production of Factor VIII concentrate and in 1982 a decision was taken to construct a new centre at BPL to meet the requirements for Plasma Derivatives in England and Wales. This new centre became operational in 1987/88.

3.2.5 During the 1970's the use of Factor VIII concentrate in the UK grew rapidly, exceeding all projections. The UK blood transfusion services were unable to satisfy this demand and clinicians turned to commercial suppliers to make up the shortfall.

3.2.6 Throughout this period there was no centralised system of purchase or supply of Factor VIII concentrate; individual clinicians or their Health Authority obtained Factor VIII concentrate either from BPL/SNBTS or purchased commercial supplies directly from the manufacturer concerned. It was not the function of either SNBTS in Scotland nor BPL in England to import or distribute Plasma Derivatives on behalf of commercial manufacturers.

3.2.7 Information on the quantities of Factor VIII concentrate used in the UK from the NHS (SNBTS/BPL) and from commercial manufacturers (Appendix I) is available from the Haemophilia Centre at Oxford.

3.3 Commercial Factor VIII Concentrates Used in the UK (1980-1988)

3.3.1 Information on the purchase of commercial Factor VIII by Health Boards in Scotland can be found in the SNBTS response to questions put during the recent investigation by the Scottish Executive (section 2.3, Additional Information from SNBTS, February 2000).

3.3.2 In the period 1980-1983 about 20% of the Factor VIII concentrate used in Scotland was purchased from commercial sources whilst in England this averaged about 55%. SNBTS was not involved in the supply of Factor VIII concentrate from commercial sources.

3.3.3 Output of SNBTS Factor VIII concentrate from PFC increased sharply over this period and reached a level sufficient to meet Scottish demand during 1983.

3.3.4 In the period 1984-1988 purchase of commercial Factor VIII concentrate accounted for about 1% of the Factor VIII used in Scotland compared with about 60% in England.

3.3.5 Six commercial companies are understood to have had authorisation from the MCA to market human Factor VIII concentrate in the UK during this period. These were:

· Alpha Therapeutics Corp, USA

· Armour Pharmaceuticals Ltd, USA (now Aventis-Berhring)

· Baxter-Travenol Ltd, USA (now Baxter-Immuno Ltd)

· Bayer Ltd, USA

· Behringwerke Ltd, Germany (now Aventis-Behring)

· Immuno Ltd, Austria (now Baxter-Immuno Ltd).

3.3.6 Information on the Factor VIII products from these companies which were authorised for use in the UK during the period 1985-1988 is given in Appendix II, along with equivalent information on the products manufactured by BPL and PFC.

3.3.7 The relative contribution made by each of the different commercial products to the total usage of commercial Factor VIII, either in England or in Scotland, is not known to SNBTS.

3.4 HIV Infection in People with Haemophilia in the UK

3.4.1 There are approximately 6 500 individuals in the UK who suffer from Haemophilia. At 31/12/2000 the cumulative total number of HIV infected persons resident in the UK whose infection is believed to have been acquired by treatment with a blood coagulation factor (e.g. Factor VIII or Factor IX concentrate) was 1350 of whom 605 (45%) have died of AIDS[3].

3.4.2 Analysis of the dates at which 1227 of these individuals were infected has shown that the earliest date of infection was June 1979 and that the peak date for infection was October 1982[4].

3.4.3 A similar study of HIV-infected haemophilia patients in the USA found the earliest date of

infection to be April 1978 and the peak date of infection to be October 1982[5].

3.4.4 The close similarity between the dates at which haemophiliacs were infected in the UK and in the USA is consistent with a common source being responsible for most of these infections.

3.4.5 In a study of 584 UK haemophilia patients, the incidence of HIV infection was 68% in those exposed to commercial concentrates and 11% in those treated only with NHS concentrates[6].

3.4.6 Approximately 500 people in Scotland suffer from haemophilia. The cumulative total number of HIV infected persons resident in Scotland who are believed to have been infected by treatment with coagulation factors is 87, of whom 32 (37%) have died of AIDS[3].

3.4.7 SNBTS has been notified of 20 HIV-infected haemophiliacs in Scotland who were treated only with SNBTS products and who are presumed to have been infected via this route.

3.4.8 How the remaining 67 individuals resident in Scotland were infected with HIV is not know to SNBTS.

3.4.9 In an early study of HIV infected haemophiliacs in Scotland, 9 infected patients had been treated with both SNBTS and commercial products. A significant correlation was found between the quantity of commercial concentrates used and HIV infection, implying that this was the most likely source of HIV infection in these patients[7].

3.5 The Impact of variant Creutzfeldt-Jakob Disease (vCJD)

3.5.1 The transmission of classical CJD to patients being treated with growth hormone derived from human pituitary glands, led in the late-1980's to concern that CJD might also be transmitted to patients via blood products. Despite intensive investigations, no evidence of transmission by blood or blood products has been found[8].

3.5.2 Following the emergence of vCJD in the UK in 1996, concern was expressed that the agent responsible might be transmissible by blood products.

3.5.3 Subsequently the UK government decided to authorise the importation of plasma for fractionation[9], to ban the manufacture of Plasma Derivatives from plasma donated in the UK[10] and to subject all Blood Components obtained from UK donors to a process of leukocyte depletion[11].

3.5.4 As a result of these precautionary measures, PFC and BPL ceased processing UK donor plasma in 1998 and replaced this with imported plasma in order to maintain a supply of essential products.

3.5.5 Currently PFC obtains normal plasma from unpaid donors in Germany and the USA, whilst plasma containing specific antibodies is obtained from paid plasma donors in the USA. BPL obtains all of its plasma from paid plasma donors in the USA.

3.5.6 As a result of the above decisions, plasma recovered from UK blood donations cannot be used for manufacture of plasma derivatives.

4. Decisions about testing of blood donations to reduce risks of transmission of Non A Non B hepatitis

4.1 Hepatitis was a well recognised complication of blood transfusion from the 1940's. In the USA,

where the risk was much higher than in the UK, it declined greatly in the early 1970's due to a shift to a voluntary unremunerated system for the donation of whole blood and to the introduction of tests to screen blood donations to exclude those with evidence of hepatitis B infection[12]. Testing for Hepatitis B was also introduced in the UK at this time.

4.2 Post-transfusion hepatitis did not disappear following the introduction of hepatitis B testing and after the discovery of the hepatitis A virus in 1973, the term non-A, non-B hepatitis came to be used for cases of post transfusion hepatitis that could not be attributed to either of these viruses[13].

4.3 Prospective studies in the early 1980's indicated considerable variation in the incidence of post-transfusion hepatitis with 3% in Australia, 7% in the USA and 44% in Japan[12] and 2.4% in the UK [14].

4.4 Although post-transfusion NANBH was believed to be of viral origin the causative agent(s) had not been isolated and no test for NANBH was available for screening blood donations. The lack of a test that accurately identified hepatitis due to a specific infective agent undoubtedly hindered the development if understanding of the condition and its importance.

4.5 In the absence of a test for NANBH, it was suggested that indirect tests might serve as a useful interim donor screening measure[15,16]. These tests, which are not specific for the viral agent or agents of NANBH are sometimes referred to as surrogate tests.

4.6 One such test, called ALT, detects an enzyme (alanine aminotransferase) that is present in normal liver cells and may be detected in the blood if there is damage to liver cells from any cause. The ALT test is a general test for liver damage. It does not indicate the cause of the damage which could be due to an infection, to alcohol, to obesity or to a drug such as the contraceptive pill.

4.7 There was controversy with numerous medical and scientific publications in the United States and elsewhere about the likely usefulness of introducing these tests to screen blood donors. Predictions were made that this would lead to some reduction in the incidence of post transfusion hepatitis, but opinions were strongly divided about the merits of introducing either or both as routine donor screening tests. A leading authority on the subject summarised the situation as follows[12]

*"At the very best the ALT testing of donors would result in a 30% reduction in PTH (post-transfusion hepatitis)...donor losses would be limited to 1.5 to 3.0%. ... In the worst case, ALT testing would not reduce PTH ... there would be ... a donor loss of 3-6%, ranging up to 15% in some donor populations"*

4.8 In the UK, a working party on transfusion - associated hepatitis was established in 1982. Its terms of reference were *"To promote the investigation of the epidemiology of transfusion-associated hepatitis, to promote research into modes of prevention and to make recommendations to the directors of the UK transfusion services regarding procedures and screening tests necessary for its prevention".*

4.9 This working party gave consideration at that time to a proposal for a prospective study on the incidence of hepatitis in recipients of blood component transfusion. Although this was eventually not pursued, a number of studies did establish that the rate of Non A Non B hepatitis in recipients of blood components in the UK appeared to be substantially less than that reported from the USA.

4.10 There is no doubt that for several years from 1982/3 transfusion services In the UK, the US and other countries became preoccupied with the emerging AIDS problem. However during 1986, the United States began the use of surrogate testing of donors. The issue of ALT and HBc testing was

again extensively discussed at meetings of the UK Transfusion Services.

4.11 The UK working party on transfusion associated hepatitis was reconvened in November 1986. It concluded at an early meeting that Non A Non B screening of donors should not be implemented immediately, in view of the US decision to postpone the start of Anti HBc testing, the reports of difficulties with the US ALT screening programme that had started earlier in the year and the level of uncertainty about the likely effectiveness of the measure.

4.12 However, to provide better information on which to base a decision about screening, a UK study of 10,000 donors in 4 centres was initiated. The purpose was to establish the true prevalence of ALT elevation in the UK donor population following the introduction of donor selection measures to reduce HIV risks. Clinical correlates of elevated ALT levels, using standardised methods, would be established. The prevalence of anti HBc using an agreed confirmatory test would also be determined. Samples would be stored for DNA testing.

4.13 A new prospective study of transfusion recipients was not pursued, as it was felt that this would take several years to yield useful results on the effectiveness of surrogate testing for Non A Non B hepatitis.

4.14 The preliminary results of a study on ALT and Anti HBc in Scottish Blood donors[17] were presented to the working party in 1986 and later published in 1988[18]. This paper, showing that a majority of donors with elevated ALT values had clinical causes for the raised enzyme level [obesity or high alcohol intake] contributed to the arguments against the introduction of surrogate testing: These arguments were as follows:

· The test was predicted to be at best only moderately effective in reducing the risk of post transfusion hepatitis.

· *There would be many false positive results and these would lead to a loss of blood donors and blood shortages that would put other patients at risk.*

· *Many healthy individuals who volunteered to donate would have to be informed that they had abnormalities in a laboratory test. There was good evidence that this could cause them to suffer distress and morbidity*

4.15 Despite these concerns, the SNBTS directors decided during 1987, to recommend to the SHHD that surrogate testing for NANB should be implemented with effect from 1 April 1988 as a national development. Steps were initiated to evaluate equipment and test systems in preparation for the introduction of donor screening.

4.16 The SNBTS directors later in 1987 wrote to the Lancet[19] in expansion of the SNBTS view that surrogate marker testing of blood donations for Non A Non B hepatitis should be commenced. The arguments in favour of introducing testing were as follows:

· Although not fully effective, testing could lead to some reduction in hepatitis.

· Failure to test would lead to liability under the forthcoming Consumer Protection Act.

· There was a risk of a double standard if some imported products were tested.

· Testing might have a cost effectiveness comparable with some other established donor screening procedures.

4.17 The directors acknowledged that other experts had written to the journal expressing the view that the introduction of surrogate testing was not justified on scientific grounds, and indeed there continued to be intense professional controversy about this issue.

4.18 Early in 1988 it was learnt that a virus had been discovered using novel genetic techniques. This was believed to be the cause of NANBH and it was evident that a specific test for evidence infection with NANBH (hepatitis C) would soon be available.

4.19 The UK Advisory Committee on Virological Safety of Blood [ACVSB] was established in 1989. Surrogate testing of blood donations in relation to Non A Non B hepatitis formed an important part of its business. However, given the considerable advantages offered by a reliable and specific test, the conclusion was reached by the committee that efforts should be focussed on the specific test rather than on the introduction of surrogate testing.

5. Implications for the safety of Factor VII concentrate

5.1 From August 1986, SNBTS ceased manufacture of its 68-C heat treated Factor VIII concentrate, so that the risk of the product transmitting Non A Non B hepatitis was removed.

The surrogate tests were not sufficiently accurate to reduce the risk of a batch being contaminated with NANBH because of .the large number of donations from which each batch of Factor VIII concentrate was manufactured.

5.3 This is illustrated in the attached figure [Appendix III] in which the effect of exposure to a large number of donations on the probability of a recipient being infected with NANBH is estimated, both with and without ALT testing.

5.4 In the mid-1980's, the SNBTS manufactured over 50 batches of Factor VIII concentrate per annum with each batch being prepared from about 4 000 donations. From these calculations it is evident that every pool of plasma would have been expected to contain at least one donation from an individual infected with NANBH whether or not surrogate testing was employed.

5.5 Although Scotland achieved self-sufficiency in the supply of Factor VIII in 1983, demand for Factor VIII concentrate continued to rise throughout the 1980's resulting in continued pressure on SNBTS to further increase blood supplies.

5.6 If the UK had decided to introduce surrogate tests for screening blood donors, less Factor VIII would have been produced by SNBTS. It is likely that a shortfall in supply would have been made up by importation of Factor VIII from the USA with a possible increased risk of HIV infection.

6. Comments on the documents submitted to the Committee by the Haemophilia Society

6.1 We have the papers that have been received from the Senior Assistant Clerk to the Committee. We have difficulty in establishing the exact provenance of the documents. Most appear to be minutes [extracts of minutes] of meetings of the National Blood Transfusion Service England and Wales but these are not in their original form, and contain some obvious errors such as misspelling of names of NBTS personnel.

6.2 The papers supplied appear to be substantially the same as documents that were posted on a website that came to the attention of SNBTS in 1999. The website was headed "Haemophiliacs fight for Justice", and appeared at http://www.manor.dircom.co.uk/.uk. Several documents from this site are headed as Minutes of the Regional Transfusion Directors Meeting. Those listed would have attended meetings of the directors of the then National Blood Transfusion Service [England and Wales]. The papers displayed on this website were interspersed with editorial comments. The file of

papers received from the Clerk appears to contain the same documents, but with the editorial comments removed.

6.3 The Committee may wish to establish the provenance of the documents since it appears to SNBTS that they are not facsimiles.

May 2001

7. References

1. Foster PR. Blood plasma fractionation. In: Howe-Grant M, ed. *Kirk-Othmer Encyclopedia of Chemical Technology,* 4th edition, volume 11. New York: Wiley, 1994: 990-1021.

2. Reasor JM. The Plasma Fractions Market in Europe - 1990. The Marketing Research Bureau. Laguna Beach, California, 1991.

3. Scottish Centre for Infection and Environmental Health. HIV infection and AIDS: quarterly report to 31 December 2000. *SCIEH Weekly Report* 2001; 35(3): 18-26.

4. Darby SC, Ewart DW, Giangrande PL, Dolin PJ, Spooner RJ, Rizza CR. Mortality before and after HIV infection in the complete UK population of haemophiliacs. *Nature* 1995; 377: 79-82.

5. Kroner BL, Rosenberg PS, Aledort LM, Alvord WG, Goedert JJ.

HIV-1 infection incidence among persons with hemophilia in the United States and Western Europe, 1978-1990. *Journal of Acquired Immune Deficiency Syndromes* 1994; 7: 279-286.

6. Cheinsong-Popov R, Tedder RS, O'Connor T, *et al.* Retrovirus infections among patients treated in Britain with various clotting factors. *British Medical Journal* 1986; 293: 168-169.

7. Melbye M, Froebel KS, Madhok R, *et al.* HTLV-III seropositivity in European haemophiliacs exposed to factor VIII concentrate imported from the USA. *Lancet* 1984; ii: 1444-1446.

8. Foster PR. Prions and blood products. *Annals of Medicine* 2000; 32: 501-513.

9. UK Department of Health. Further precautionary measures in blood products announced. *Press Release 98/076*; London:1998 Feb 26.

10. UK Department of Health. Committee on Safety of Medicines completes review of blood products. *Press Release 98/182;* London:1998 May 1.

11. UK Department of Health. Government accepts advice on leucodepletion from Spongiform Encephalopathy Advisory Committee. *Press Release 98/295*; London:1998 July 17.

12. Alter HJ. Post transfusion hepatitis: clinical features, risk and donor testing. *Progress in Clinical and Biological Research* 1985; 182: 47-61.

13. Feinstone SM, Kapikian AZ, Purcell RH, Alter HJ, Holland PV.

Transfusion-associated hepatitis not due to viral hepatitis type A or B.

*New England Journal of Medicine* 1975; 292: 767-770.

14. Collins JD, Bassendine MF, Codd MF, Collins A, Ferner RE, JamesOFW. Prospective study of post-transfusion hepatitis after cardiac surgery in a British centre. *British Medical Journal* 1983; 287: 1422-1424.

15. Aach RD, Szmuness W, Mosley JW, Hollinger FB, Kahn RA, Stevens CE, et al. Serum alanine amino-transferase of donors in relation to the risk of non A, non-B hepatitis in recipients. *New England Journal of Medicine* 1981; 304: 989-994.

16. Koziol DE, Holland PV, Alling DW, Melpolder JC, Solomon RE, Purcell RH, et al. Antibody to hepatitis B core antigen as a paradoxical marker for non-A, non-B hepatitis agents in donated blood. *Annals of internal Medicine* 1986; 104: 488-495.

17. Gillon J, Hussey AJ, Howe SP, Beckett GJ, Prescott RJ. Non-A, non-B hepatitis surrogate testing of blood donations. *Lancet* 1987; i: 1366-1367.

18. Gillon, J, Hussey AJ, Howe SP, Beckett GJ, Prescott RJ. PosT transfusion non-A, non-B hepatitis: significance of raised ALT and anti-HBc in blood donors. *Vox Sanguinis* 1988; 54: 148-153.

19. McClelland DBL, Cash JD, Mitchell R, et al. Testing blood donors for non-A, non-B hepatitis: irrational, perhaps, but inescapable. *Lancet* 1987; ii: 36-37.

20. Kasper CK, Lusher JM. Recent evolution of clotting factor concentrates for hemophilia A and B. *Transfusion* 1993; 33: 422-434.

21. Carnelli V, Gomperts ED, Friedman A, *et al.* Assessment for evidence of non-A, non-B hepatitis in patients given n-heptane suspended heat treated clotting factor concentrates. *Thrombosis Research* 1987; 46: 827-834.

22. Kernoff PBA, Miller EJ, Savidge GF, *et al.* Reduced risk of non-A, non-B hepatitis after a first exposure to `wet heat' factor VIII concentrate. *British Journal of Haematology* 1987; 67: 207-211.

23. Preston FE, Hay CRM, Dewar MS, Greaves M, Triger DR. Non-A, non-B hepatitis and heat-treated factor VIII concentrates. *Lancet* 1985; ii: 213.

24. Wolfs TF, Breederveld C, Krone WJ, *et al.* HIV-antibody seroconversions in Dutch haemophiliacs using heat-treated and non-heat-treated coagulation factor concentrates. *Thrombosis and Haemostasis* 1988; 59: 396-399.

25. Dietrich SL, Mosley JW, Lusher JM, *et al.* Transmission of human immunodeficiency virus type I by dry-heated clotting factor concentrates *Vox Sanguinis* 1990; 59: 129-135.

26. Remis RS, O'Shaughnessy M, Tsoukas C, *et al.* HIV transmission to patients with hemophilia by heat-treated donor screened factor concentrate. *Canadian Medical Association Journal* 1990; 142: 1247-1254.

27. Williams MD, Skidmore SJ, Hill FGH. HIV seroconversion in haemophilia boys receiving heat treated factor VIII concentrate. *Vox Sanguinis* 1990; 58: 135-136.

28. Berntorp E, Nilsson IM, Ljung R, et al. Hepatitis C virus transmission by monoclonal purified factor VIII concentrate. *Lancet* 1990; 335: 1531-1532.

29. Columbo M, Mannucci PM, Carnelli V, *et al.* Transmission of non-A, non-B hepatitis by heat treated factor VIII concentrate. *Lancet* 1985; ii: 1-4.

30. Mariani G, Ghirardini A, Mandelli F, *et al.* Heated clotting factors and seroconversion for human immunodeficiency virus in three hemophilic patients. *Annals of Internal Medicine* 1987: 107; 113.

31. Epstein JS, Fricke WA. Current safety of clotting factor concentrates. *Archives of Pathology and Laboratory Medicine* 1990; 114: 335-340.

32. Brackman HH, Egli H. Acute hepatitis B infection after treatment with heat inactivated factor VIII concentrate. *Lancet* 1988; ii: 967.

33. Gerritzen A, Scholt B, Kaiser R, *et al.* Acute hepatitis C in haemophiliacs due to "virus inactivated" clotting factor concentrates *Thrombosis and Haemostasis* 1992; 68: 781.

34. Schulman S, Lindgren AC, Petrini P, Allander T. Transmission of hepatitis C with pasteurised factor VIII. *Lancet* 1992; 340: 305-306.

35. Koehler-Vajta K, Guertler L, Schaetzl H. Frequency of HCV-RNA in anti-HCV positive hemophiliac children and young adults *Thrombosis and Haemostasis* 1993: 69; 853.

36. Klarmann D, Kreuz W, Auerswald G, *et al.* Hepatitis C and pasteurised factor VIII and IX concentrates. *Thrombosis and Haemostasis* 1995; 73: 736-737.

37. Jantsch-Plunger V, Beck G, Maurer W. PCR detection of a low viral load in a prothrombin complex concentrate that transmitted hepatitis B virus. *Vox Sanguinis* 1995; 69: 352-354.

38. Mannucci PM, Zanetti AR, Colombo M, *et al.* Antibody to hepatitis C virus after a vapour-heated factor VIII concentrate. *Thrombosis and Haemostasis* 1990; 64; 232-234.

39. Mannucci PM, Colombo M, Zanetti AR, *et al.* Antibody to hepatitis C virus after a vapour-heated factor VIII concentrate - lack of evidence - rebuttal. *Thrombosis and Haemostasis* 1991; 66: 621-622.

40. Colvin BT, Rizza CR, Hill FGH, *et al.* Effect of dry-heating of coagulation factor concentrates at 80-C for 72 hours on transmission of non-A, non-B hepatitis. *Lancet* 1988; ii: 814-816.

41. Rizza CR, Fletcher ML, Kernoff PBA. Confirmation of viral safety of dry heat treated factor VIII concentrate (8Y) prepared by Bio Products Laboratory: a report on behalf of the UK Haemophilia Centre Directors. *British Journal of Haematology* 1993; 84: 269-272.

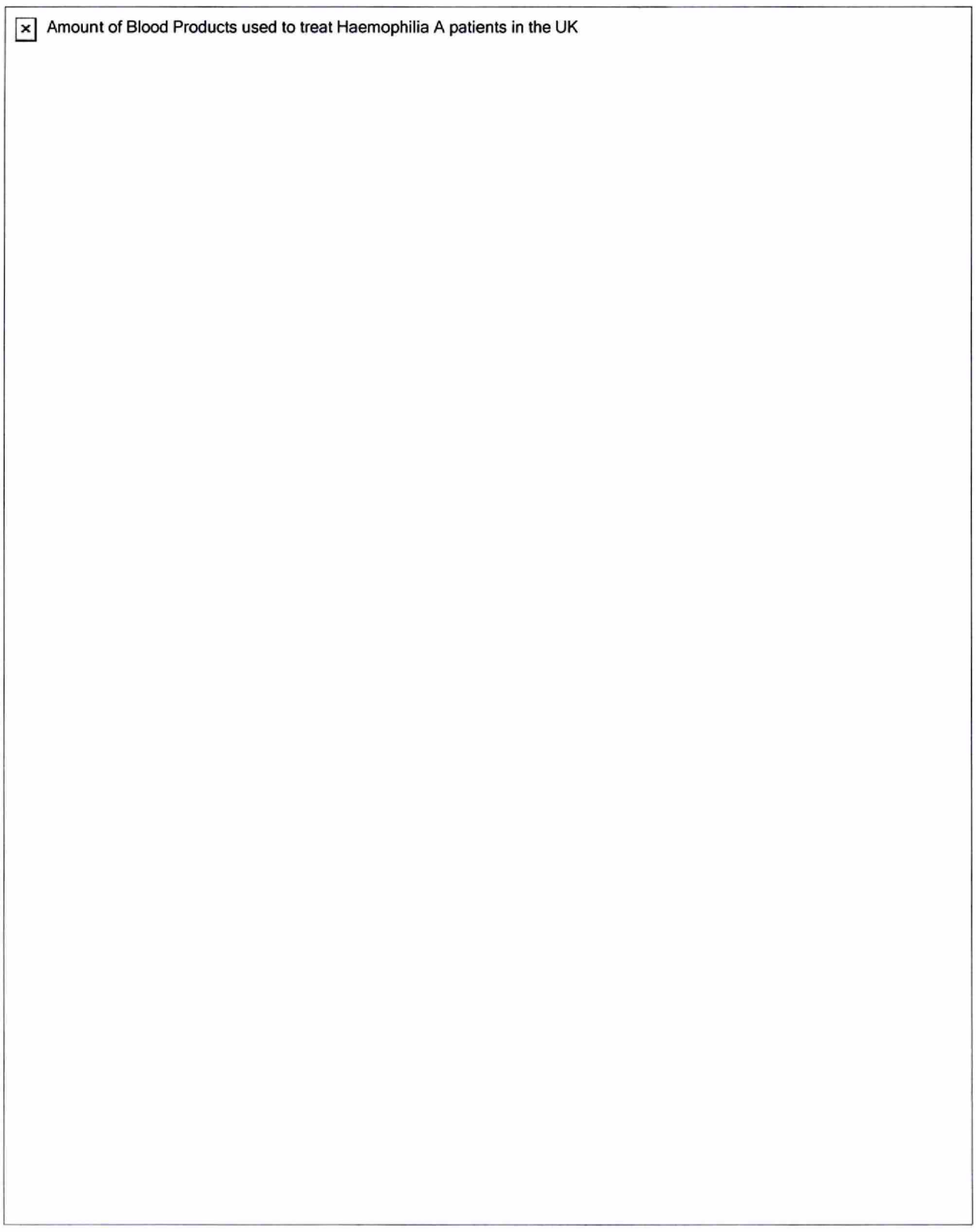
42. Cuthbertson, RJG, Ludlam CA, Brookes E, McClelland DBL. Efficacy of heat treatment of factor VIII concentrate. *Vox Sanguinis* 1988; 54: 199-200.

43. Bennet B, Dawson AA, Gibson BS, *et al.* Study of viral safety of Scottish National Blood Transfusion Service factor VIII/IX concentrate. *Transfusion Medicine* 1993; 3: 295-298.

8. Appendices

APPENDIX I

Amount of Blood Products used to treat Haemophilia A patients in the UK



APPENDIX II

HUMAN FACTOR VIII CONCENTRATES AUTHORISED FOR USE IN THE UK, 1985-1988

AUTHORISED MANUFACTURERS

COMMERCIAL

Alpha Therapeutics Corporation, USA

Armour Pharmaceuticals Ltd, USA (now Aventis Behring)

Baxter Ltd, USA (now Baxter-Immuno Ltd)

Bayer Ltd, USA

Behringwerke Ltd, Germany (now Aventis Behring)

Immuno Ltd, Austria (now Baxter-Immuno Ltd)

NON-COMMERCIAL (NHS)

Blood Products Laboratory, Elstree (now Bio-Products Laboratory)

SNBTS Protein Fractionation Centre, Edinburgh

ALPHA THERAPEUTICS CORPORATION (USA)

5555 Valley Blvd

Los Angeles

California 90032

USA

Phone: 001 323 225 2221

Fax: 001 323 227 9053

Factor VIII Concentrates Marketed in the UK, 1985-1988

(a) Profilate

Not treated to inactivate viruses

UK withdrawal date not known

(b) Profilate-HT

Dried powder heated at 60-C for 24 hours suspended in an organic solvent

FDA licence February 1984[20]

Hepatitis transmissions published 1987[21,22]

(c) HT-Profilate

Dried product heated at 60-C for 24 hours

FDA licence September 1985[20]

UK marketing authorisation for (a)/(b) ceased August 1989

ARMOUR PHARMACEUTICAL CO. (USA)

*Aventis Behring*

1020 First Avenue

King of Prussia

Pennsylvania 19406

USA

Phone: 001 610 878 4000

Fax: 001 610 878 4178

Factor VIII Concentrates Marketed in the UK, 1985-1988

(a) Factorate / Factorate Generation II

Not treated to inactivate viruses

Last USA release 1985[20]

UK withdrawal dates not known

(b) HT Factorate/ HT Factorate Generation II

Dried product heated at 60°C for 36 hours

Hepatitis transmissions published 1985[23]

HIV transmissions published in 1988[24] and 1990[25,26,27]

Last USA release 1988[20]

Withdrawn from UK October 1986

(c) Monoclate

Immunopurified, dried product heated at 60-C for 36 hours

Hepatitis transmission published 1990[28]

FDA licence 1987, last USA release 1991[20]

UK entry/withdrawal dates not known

BAXTER LTD (USA)

Baxter Hyland Immuno Division

550 N Brand Avenue

Glendale

California 91203

USA

Phone: 001 818 956 3200

Fax: 001 818 507 5596

Factor VIII Concentrate Marketed in the UK, 1985-1988

Hemophil T

Dried product heated at 60-C for 72 hours

Hepatitis transmissions published in 1985[29]

FDA licence March 1983[20]

UK marketing authorisation ceased February 1989

BAYER LTD (USA)

Bayer, Pharmaceutical Division, Biologic Products

Building 4101

85 T W Alexander Drive

P O Box 13887

Research Triangle Park

North Carolina 27709-3887

USA

Phone: 001 919 316 6075

Fax: 001 919 316 6065

Factor VIII Concentrates Marketed in the UK, 1985-1988

(a) Koate

Not treated to inactivate viruses

Last USA release October 1984[20]

UK marketing authorisation ceased August 1988

(b) Koate HT

Dried product heated at 68-C for 72 hours

Association with HIV transmission reported 1987[30]

Hepatitis transmission reported 1990[31]

FDA licence February 1984, Last USA release August 1990[20]

UK marketing authorisation ceased October 1992

BEHRINGWERKE LTD (GERMANY)

Aventis Behring

P O Box 1230

76 Emil-von-Behring Str.

D-35002 Marburg

Hessen

Germany

Phone: 049 6421 3912

Fax: 049 6421 3948 25

Factor VIII Concentrates Marketed in the UK, 1985-1988

Haemate HS/Haemate P

Intermediate products heated in solution (pasteurised) at 60-C for 10 hours.

Hepatitis transmissions published in 1988[32], 1992[33,34], 1993[35] and 1995[27]

Hepatitis transmissions by pasteurised Factor IX concentrate[37]

UK marketing authorisation ceased April 1996

IMMUNO LTD (AUSTRIA)

Baxter- Immuno Ltd

Industriestrasse 67

A-1220 Vienna

Austria

Phone: 043 1 201 000

Fax: 043 1 203 71 24

Factor VIII Concentrates Marketed in the UK, 1985-1988

Kryobulin TIM

Dried powder heated at 60-C for 10 hours in the presence of steam under pressure

Hepatitis transmission published 1990[38,39]

UK marketing authorisation ceased March 1992

Bio-Products Laboratory, UK (NHS)

Bio-Products Laboratory

Dagger Lane

Elstree

Hertfordshire WD6 3BX

UK

Phone: 0181 258 2200

Fax: 0181 207 4824

Factor VIII Concentrates Distributed in the UK, 1985-1988

(a) 8A

Not treated to inactivate viruses

Last issued May 1985

(b) 8Y

Dried product heated at 80-C for 72 hours

Studies on hepatitis safety published 1988[40] and 1992[41]

SNBTS Protein Fractionation Centre , UK (NHS)

SNBTS Protein Fractionation Centre

21 Ellen's Glen Road

Edinburgh EH17 7QT

UK

Phone: 0131 536 5700

Fax: 0131 536 5781

Factor VIII Concentrates Distributed in the UK, 1985-1988

(a) NY-HT, mark I

Dried product heated at 68-C for 2 hours

No HIV transmission[42]

Last issued Autumn 1985

(b) NT-HT, mark II

Dried product heated at 68-C for 24 hours

No HIV transmission[42]

Last issued March 1987

(c) Z8

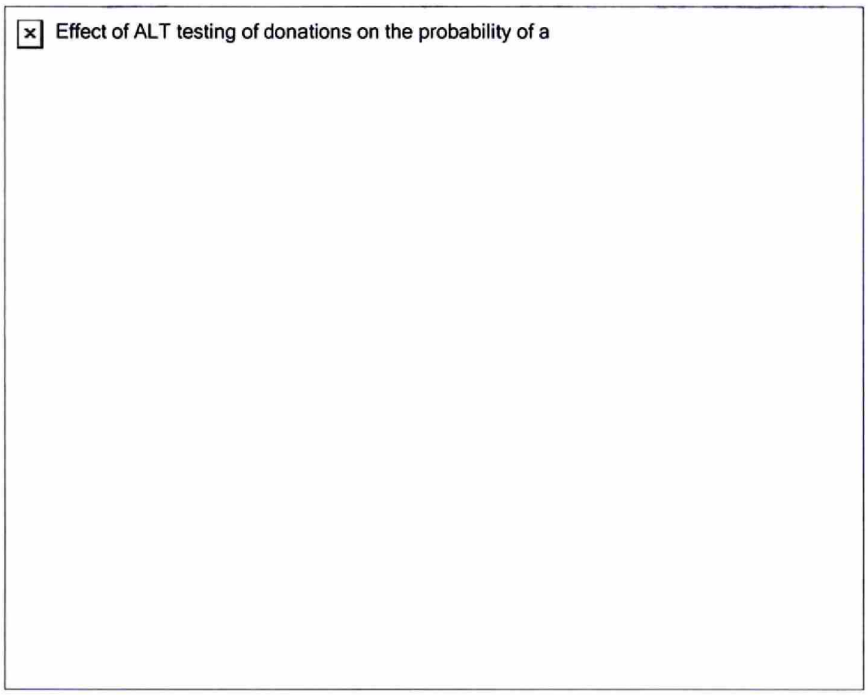
Dried product heated at 80-C for 72 hours

First routine issue April 1987

Study on hepatitis safety published 1992[43].

APPENDIX III

Effect of ALT testing of donations on the probability of a recipient being infected with Hepatitis C.




SCOTTISH EXECUTIVE PRESS RELEASE

29 August 2001

EXECUTIVE MOVES TO SETTLE WITH SOME PATIENTS INFECTED WITH HEP C

- Deacon outlines plans to settle more NHS disputes outside the courts -

NHSScotland lawyers have today been instructed by Scottish Health Minister Susan Deacon to begin talks aimed at settling outstanding legal actions that are directly analogous to those considered in a recent ruling by Mr Justice Burton in the English High Court.

These were actions raised under the Consumer Protection Act 1988 (CPA) whereby certain individuals alleged that blood they received by transfusion was a defective `product' as it carried Hepatitis C.

The Minister's decision follows careful consideration of the English judgement and its likely implications for similar Scottish cases. While the High Court decision is not binding on Scottish courts, a Scottish court would be likely to have regard to a relevant judgement reached elsewhere. For this reason, the Minister is keen to avoid individuals in similar circumstances facing the cost and distress of fighting their cases through the Scottish courts.

She also announced that the Executive was exploring ways of achieving faster, fairer resolution of disputes between patients and the NHS. This `middle way' will seek to resolve more disputes outside the courts through:

- a comprehensive new NHS complaints system in Scotland, to be implemented in 2002, which will include the use of conciliation to settle NHS disputes;

- and consideration of new work by the independent Royal Society of Edinburgh on the scope for

using mediation to resolve disputes in NHSScotland.

The Executive will also continue to consider the most effective and sensitive way of dealing with cases of clinical negligence and will monitor carefully any parallel developments in England.

Ms Deacon said:

**"The issues involved here are both sensitive and complex. Our aim is to adopt an approach which is sensitive to the concerns of individuals while recognising the wider implications of any decision for future patient care. We have sought also to be responsive to the developing legal position in this complex area.**

"Over the years, significant advances in science and medicine have taken place. Blood and blood products are now considerably safer than in the past. Sadly, many people, were unknowingly infected by hepatitis C during the 1980's before the virus itself was identified and isolated, and before the procedures existed to eliminate it.

**"As I have said repeatedly, Executive Ministers and the wider NHS have the greatest sympathy for those who have been infected with the hepatitis C virus as a result of blood transfusions and other procedures carried out in the NHS.**

"I realise too that for many that human cost has also translated into financial costs. For some it is also a question of recompense for the pain and suffering endured. I understand the strength of feeling that exists.

"The NHS is a caring organisation staffed by competent well-trained professionals. But sometimes, somewhere, something will go wrong. In cases of negligence, clear arrangements already exist to provide compensation where an error or injury occurs.

"However, prior to Mr Justice Burton's judgement, the NHS has held to the general principle that individuals are not compensated in cases of non-negligent harm. This approach has been adopted by successive UK Governments and is in line with the practice in almost every other major developed country.

"The reason for this approach is sound. Every drug, treatment, therapy and medical procedure carries a degree of risk. Every day medical professionals must reach judgements about how best to treat an individual patient. A life saving operation or blood transfusion can, on occasion, have adverse consequences.

"The issue here is how we manage that risk. It would not be in the interests of the NHS or, more importantly patients, to create a climate whereby doctors and other health professionals were more likely to opt not to administer a treatment because of the consequences it might have. A `risk averse' NHS is one which may not be able to deliver the best outcomes for patients.

"Similarly, widespread compensation for every adverse consequence of non-negligent harm would divert substantial amounts of vital NHS resources away from frontline patient care and could ultimately harm significantly more people than it benefits.

"However, I believe we must be sensitive to changes in public expectations. Individuals should, as far as possible, be made aware of the risks involved in their treatment, where these are known. Better information and greater dialogue with patients must be central to a modern patient-centred NHS.

"The law is also evolving in this area. The recent English High Court judgement was significant in

that it ruled that, under the terms of the CPA, certain patients infected by Hepatitis C through blood transfusions should be compensated as the blood was deemed to be a defective `product'.

"The ruling applies to limited number of people in very specific circumstances and within a limited time period. However, I have no wish to see individuals in a similar position here in Scotland be dragged through the courts. That is why I have decided to move towards a settlement in such cases.

"We have now begun that process with the small number of Scottish patients in a similar position to those affected by the English ruling. Solicitors acting for NHSScotland have today contacted the legal representatives of those patients involved. Discussions and investigations on individual settlements will begin almost immediately. This will necessarily involve checking that the actions are legally competent and the relevant facts can be proved.

"Our decision will not please everybody. There are many others who have been similarly affected by this debilitating disease but who fall outside the scope of the recent English court ruling. No doubt some will choose to raise actions through the Courts. Others - including individual patients, patients' groups and politicians - will ask us to go further. But the question is how far?

"This is a legitimate area for public debate. The fact is that the law, policy and practice is continually evolving and developing and I welcome open and constructive debate around this issue. Much has been made, not least in the Parliamentary Health Committee, around the debate on `where to draw the line' on compensation in the NHS. No consensus exists and I believe, as politicians, we must be careful not to reach judgements which might seem `fair' to some but manifestly `unfair' to many. We must also avoid taking short-term decisions without thinking through the long term implications.

Today's announcement seeks to strike a balance. I believe it is the right one."

The Minister also announced plans to improve the way that patients can seek redress when they are dissatisfied with their treatment or care in the NHS.

"At present we have a complaints system that too many find too cumbersome to use. Apart from that, patients have recourse to the law, which can be just as cumbersome, much more expensive in terms of legal fees, and far more stressful.

"I want to explore new ways of making the system faster and fairer where the people affected have a legitimate legal claim, for example where there has been negligence by NHSScotland or a breach of the legal duties imposed by the Consumer Protection Act. A middle way where we look at conciliation and mediation as serious alternatives to the courts.

"We will shortly publish a major evaluation of the NHS complaints system, with a view to bringing in a new and more flexible system next year. One central strand of that new system will be enhanced conciliation services within the NHS complaints framework. The Executive is also supporting the current work of the Royal Society of Edinburgh to explore the scope for using mediation to resolve patient disputes."

NOTES FOR NEWS EDITORS

1. A fact sheet on this issue is available for the media by telephoning 0131-244 2968.

2. All those claimants who have raised an action under the CPA alleging that they received blood from the Scottish National Blood Transfusion Service (SNBTS) after 1 March 1988 that was contaminated with Hep C will today be contacted through their solicitors.

3. An evaluation of the current NHS complaints system is being carried out on a UK basis and will be published shortly. As set out in the Scottish Health Plan, Our National Health, a reformed NHS complaints system will be introduced in Scotland in 2002. It will include, for the first time, conciliation measures to help resolve disputes.

4. The Royal Society of Edinburgh has drawn together a wide-ranging group to review the use of mediation in the NHS in Scotland. The group, which includes representation from NHSScotland, the BMA, the voluntary sector, and the legal community will report with recommendations by end January 2002.

SUBMISSION BY THE HEAMOPHILIA SOCIETY TO THE WESTMINSTER HEALTH COMMITTEE INQUIRY INTO PROCEDURES RELATED TO ADVERSE CLINICAL INCIDENTS AND OUTCOMES IN MEDICAL CARE

**Executive Summary**

**About the Haemophilia Society: subject of this submission**

The Haemophilia Society is the national patient group for people with haemophilia, von Willebrand's disease and other bleeding disorders. Our submission is on the infection of haemophilia patients with HIV and hepatitis A, B and C viruses transmitted through contaminated blood products used in their NHS treatment prior to 1985/6. Over 95% of patients treated were infected in this way: an adverse clinical outcome on a very wide scale. It draws on evidence collected from patients through three formal research studies and our day-to-day contact with our members and service users. It is therefore based on the actual experiences of patients themselves. (paras. 1.1 to 1.4)

**History of contaminated blood products**

Blood products were first introduced to haemophilia treatment in the late 1960s, and were then widely used in the 70s and 80s. Viral inactivation processes were introduced in 1985/6 to prevent blood borne viruses from contaminating the products, but by then an estimated 4,800 people with haemophilia had suffered hepatitis C infection; of these 1,200 were also infected with HIV. Much, but not all of the infection, can be traced to use of commercial imported products from the USA where blood was collected from so-called `skid row' and other paid donors from high risk groups. (paras. 2.1 to 2.4)

**Adverse treatment outcomes suffered**

Patients with haemophilia have suffered serious adverse outcomes as a result: over 700 have died of AIDS; at least 90 have died of hepatitis related liver disease. Both HIV and hepatitis C (HCV) are life threatening viruses, which are very difficult to treat. There are additional complications for people who are co-infected with both. Treatment regimes are very demanding with unpleasant side effects and uncertain outcomes. (paras. 3.2 to 3.5)

Social and economic impacts of these viruses include stigma, affecting relationships and employment; fears of transmission; and actual loss of earnings due to impaired health. Many have become dependent on social security benefits which cannot compensate for these financial losses nor the additional costs arising from their medical condition. Life insurance and mortgage protection are a major problem for those with HIV and/or hepatitis: many companies will not provide cover or only at prohibitively high premiums. (paras. 3.6 to 3.11).

**Investigation of the occurrence**

Unlike other countries (Canada and Ireland) where patients with haemophilia were also infected through contaminated blood, in the UK there has been no full investigation of the occurrence, and no systematic national follow up of patients. Only some health authorities and trusts appear to have investigated.

The Society's evidence is that approaches to tracing, testing, and counselling patients varied widely between haemophilia treatment centres; in many cases patients were tested without consent and/or not informed of the results. This meant that infected patients could not take appropriate precautions to prevent infecting those close to them or to make lifestyle changes to safeguard their own health (e.g. reducing alcohol in the case of HCV). Nor were steps taken to ensure all those infected were provided with the best treatment for the viruses. The Society has examples of patients denied necessary treatment (i.e. interferon for HCV) on grounds of cost.

By contrast with the approach adopted by the Department of Health with respect to patients infected with hepatitis C through blood transfusion, there was no national follow up strategy on patients with haemophilia. It was apparently assumed all haemophilia patients would be traced by their haemophilia centres, yet the Society still has cases today of individuals who are only just being tested for HCV. One result of the failure to trace all those people with haemophilia infected with HCV is that there is no official figure for the precise number infected, and of those suffering impaired health and receiving treatment for the virus. (paras. 4.1 to 4.8)

Good practice has not been followed routinely with regard to testing patients with haemophilia for HIV and/or HCV: in many cases pre and post test counselling was not offered, information was not given on the medical and social implications of these viruses, minors were sometimes informed without their parents being present. (paras 4.9 to 4.13).

**Legal issues and Government response**

The infected patient group has had to battle through the courts and to use public campaigning to seek redress. A group legal action against Government for some 900 of those infected with HIV eventually led to an ex gratia out of court settlement. The Government continues to deny formal liability for the occurrence. Others with HIV and HCV have pursued legal actions against individual health authorities; some action is ongoing against the National Blood Authority.

Campaigning by the Haemophilia Society supported by public opinion persuaded the previous Government to set up a financial assistance scheme for those infected with HIV. The Macfarlane Trust was set up as a result in 1988 with £10 million from Government (subsequently topped up with further Government grants).

The situation for those with hepatitis C is very different: legal action offers very little hope for the majority of this group The Government has refused the Society's appeal for financial assistance for them on the grounds that the harm was inadvertent or non-negligent. This leaves the majority of this infected patient group with no means of seeking redress, and, because of the different response to those infected with HIV, is widely felt as unjust and discriminatory within the haemophilia community.

The Society questions whether this is an appropriate response to such a large scale adverse treatment outcome and wishes the Committee to consider whether in such a situation a `no fault' compensation system should apply (paras. 4.14 to 4.21)

**Mechanisms to support and advise patients and their families**

Much of the task of providing information, advice and support has been undertaken by the Haemophilia Society. The management of patients after diagnosis with HIV and/or HCV has varied greatly within the NHS with varying standards of clinical care.

There has been a reluctance in some haemophilia centres to encourage patients to seek expert HIV care/support: a recent report found patients with haemophilia and HIV were less informed about their condition than any other HIV patient group studied.

A study for the Society in 1996 found the need for up-to-date information on HCV was `by far and away the biggest single need' amongst patients with haemophilia. (paras 4.22 to 4.24)

**Legal and professional obligations on doctors and institutions to disclose information**

The experience of patients with haemophilia infected over a long period of time by their NHS treatment raises the question of whose responsibility it should be to pick up and act on early warning signs of adverse treatment outcomes. We hope the Committee will examine the future role of NICE and CHI in such circumstances.

Patients were not routinely warned of the risks of blood borne viruses in haemophilia treatment products at the time: this is a particular issue for those with mild haemophilia who might have chosen not to accept treatment or parents who gave consent to treatment for minors. Those infected now want to know why they were not warned, why action was not taken sooner to prevent transmission of blood borne viruses.

The issue of informed consent is central with regard to both treatment and HIV/HCV testing: we hope the Committee will look closely at this, particularly at professional and NHS guidelines.

It also appears that patients were not provided with information about the possibility of complaining or taking legal action when they were told that they had been infected via their NHS treatment. (paras. 4.25 to 4.33)

**RECOMMENDATIONS [Section 5]**

**Specific to people with haemophilia**

1) The UK Government should ensure that a full inquiry is conducted into the way in which patients with haemophilia were infected with viruses through contaminated blood, the impact this has had on their health, social and economic circumstances and that of their families, and whether adequate support has been provided. This inquiry should look carefully at how other countries such as Canada, Ireland and Italy have responded to the tragedy of contaminated blood, and how similar approaches could be adopted in the UK.

2) The Government should ensure that all patients with haemophilia - not only those aged up to 16 years -have access to recombinant treatment products to avoid the risks of CJD and other blood borne viruses.

3) Financial assistance should be offered to people with haemophilia infected with hepatitis C via their NHS treatment and not only those with HIV as is the case at present. This is the approach in Ireland and Italy where financial assistance is provided for both HIV and HCV.

4) Government funding for the Macfarlane Trust should be continued to enable the Trust to carry on providing financial help for people with haemophilia infected with HIV.

5) Government should continue to fund the Haemophilia Society and other relevant bodies to

provide information, advice and support to people with bleeding disorders infected with HIV, hepatitis C or both via their NHS treatment.

6) Government should ensure that social work posts are maintained or re-established in all larger haemophilia centres to provide advice, support and access to social services support for all those who were infected via their NHS treatment.

7) Government should ensure that no people with haemophilia infected with HIV or hepatitis through their NHS treatment should be denied treatment which is clinically essential for the virus infection on grounds of cost. Guidance should be issued urgently to health authorities and trusts to ensure that interferon treatment for HCV is provided whenever clinically required.

8) Government should carry out an urgent exercise to ensure that all patients with haemophilia infected with hepatitis C have been traced, tested, counseled and, if necessary, treated in view of evidence that this is not currently the case.

9) The Health Select Committee should conduct an in-depth inquiry into contaminated blood, as has previously been requested by the Society, looking not only at the history and outcomes, but also the issues of blood safety now and in the future, which is a major public health concern.

**General**

1) It should be the responsibility of Government in future to make sure that a full public investigation and appropriate follow up is carried out when there is a wide-scale adverse outcome of the kind experienced by people with haemophilia.

2) Some mechanism must be put in place to offer redress to patients harmed `inadvertently' or `non-negligently' through their NHS treatment, such as those with haemophilia who have suffered as a result of contaminated treatment products used nationally throughout the NHS. Neither the legal system nor the normal NHS complaints procedures meet this need, and consideration should be given to a `no fault' compensation scheme to cover this sort of exceptional occurrence.

3) The role of NICE, CHI and the relevant health professional bodies should be reviewed to ensure that more effective early warning mechanisms are in place to pick up and act upon the signs of widespread adverse outcomes such as that experienced by people with haemophilia.

4) There must be more effective systems to inform, advise and support patients affected by adverse treatment outcomes and clear responsibilities laid down for health professionals, and institutions.

**1. Introduction**

**About the Haemophilia Society**

1.1 The UK Haemophilia Society is the national patient group for people with haemophilia, von Willebrand's disease and other related bleeding disorders. Our aim is to secure the best possible treatment, care and support for all people with these bleeding disorders and their families. Founded in 1950, the Society is an organisation of and for people with bleeding disorders who are involved and active at every level from the Trustee board to our 23 local volunteer-run groups throughout the UK.

**Subject of this submission**

1.2 The Society welcomes this opportunity to present evidence on the infection of patients with haemophilia and other bleeding disorders with HIV and hepatitis via contaminated blood products

used in their NHS treatment. This is an adverse clinical outcome on a very large scale: over 95% of patients with haemophilia treated before 1986 were infected with HIV, hepatitis C or both. This means almost every patient now aged 13 years and over has been exposed to one or other of these life-threatening viruses.

1.3 As such there are many questions raised by this occurrence, and lessons to be learned about the Government, NHS and legal responses to a large-scale adverse clinical outcome of this type, which we hope the inquiry will consider carefully.

1.4 This submission focuses on the two life threatening viruses HIV and hepatitis C (HCV) which were passed on through contaminated blood products, but it should not be forgotten that people with haemophilia have also been infected with many different types of hepatitis, including hepatitis B, which can also be life threatening, and possibly other blood borne viruses not yet identified. Despite modern viral inactivation techniques introduced from 1986 to the manufacture of plasma derived treatment products, at least three viruses (parvovirus, hepatitis A and TTV) have been found to escape the process. The evidence presented is drawn from the reported experiences of people who were infected, collected via research studies for the Society and our day to day contact with members.

**2. Background information**

**About haemophilia**

2.1 Haemophilia itself is an inherited medical condition for which there is still no cure. It is rare: some 11,000 people in the UK are registered as having either haemophilia or von Willebrand's disease. For those with the conditions the blood fails to clot properly, leading to painful, disabling and even life-threatening internal bleeding if not effectively treated. Thus people with haemophilia and other bleeding disorders are reliant throughout their lives on NHS treatment, which is generally provided through 100 specialist haemophilia centres located in hospitals. Modern treatment involves injections of the missing blood clotting factors to prevent such bleeding and minimise the risks of joint damage and other problems.

**The history of contaminated blood products**

2.2 Clotting factor treatment products have been manufactured from human blood since the late 1960s. Only very recently, genetically engineered synthetic products (recombinants), which do not rely on human plasma, have become available. In the `60s, `70s and `80s, when the first plasma derived clotting factors were introduced, the majority of haemophilia patients treated were infected with blood borne viruses, including HIV and hepatitis A, B, and C, passed on through contaminated blood products. At that time the UK was unable to produce enough home manufactured product to meet demand, and large quantities were imported from the USA. Much, but not all, of the infection has been traced back to the use of so-called `skid row' and other paid donors from high-risk groups in the USA.

2.3 Viral inactivation processes were implemented in 1985/6 to prevent such contamination but by then an estimated 4800 people with haemophilia had been infected with hepatitis C and 1,200 of these co-infected with HIV. Over 700 of those infected with HIV have now died, and of the 475 survivors almost all are HCV/HIV co-infected. Over 90 people with haemophilia are estimated to have died of liver disease, although in the absence of an official Government figure the total may well be higher.

2.4 The infection of 95% of haemophilia patients with HIV and/or hepatitis has been described as one of the greatest treatment disasters in the history of the NHS. In response the Haemophilia Society has consistently campaigned for all patients to have access to recombinants to reduce the

risks of blood borne viruses. Since 1998 the Government has required all haemophilic children under 16 to be treated with recombinant products which are regarded as safer with regard to blood borne viruses and the `theoretical risks' of CJD. There is still no screening test for CJD, and it is also known that certain viruses (parvovirus, hepatitis A and TTV) escape the inactivation procedures. Nevertheless the majority of adults and teenagers over 16 years are still being treated with plasma derived products.

3. The adverse treatment outcomes suffered by people with haemophilia: health, social and economic impacts of the viruses

3.1 The impact of contaminated blood products on the haemophilia community has been devastating, and the aftermath is still being coped with today. Within such a small and often close knit patient group, few families have been left unscathed. This section briefly describes the medical, social and economic impacts of the HIV and HCV infection suffered by people with haemophilia. All these can be seen as adverse outcomes of the treatment with contaminated blood products.

**Medical**

3.2 One of the major problems for those infected has been uncertainty. Knowledge about both HIV and hepatitis C is still evolving. Both viruses have been only relatively recently identified, and treatment methods are still developing. It is often not possible therefore for clinicians to tell those infected exactly what their prognosis is. Added to the knowledge the fact that many have lost friends and relations to these viruses, this creates considerable stress and anxiety.

3.3 What is clear is that when most people with haemophilia received their HIV diagnosis the condition was seen as inevitably fatal. They did not expect to live. For the minority who have survived, their co-infection with HCV presents particular medical difficulties. Combination therapy is proving successful for some in extending life, but the treatment regime is extremely demanding, and has unpleasant side effects, one of which is that it places great strain on the liver, hence worsening the effects of HCV.

3.4 For those with HCV, up to 80% may go on to develop chronic liver disease and up to 20% of these will develop cirrhosis, possibly leading to liver cancer. This progression can take between 20 and 40 years, however many with haemophilia have been infected now for over 25 years. Symptoms of HCV include extreme fatigue, skin and digestive problems.

3.5 Interferon was until recently the only licensed treatment for hepatitis C. The success rates among people with haemophilia are around 10%. In clinical trials improved success rates have been achieved with a combination of interferon and ribavarin, only just licensed in this country, but still only about 40%. Again the treatment regime is demanding, with unpleasant and debilitating side effects, which some cannot tolerate, and the treatment is contra-indicated for some patients. The treatment of last resort is liver transplant, and there are currently 6 or 7 people with haemophilia on the waiting list for transplants. No special priority is afforded to this group despite the fact that they have developed their liver disease as a result of NHS treatment.

**Social**

3.6 Both HIV and hepatitis B and C viruses carry considerable social stigma. Research carried out for the Society documents many experiences of infected people, which provide evidence of that stigma. Many of those infected continue to keep this secret from friends, neighbours and work colleagues for fear of negative reactions.

3.7 Relationships and family life are affected by both HIV and hepatitis. Fears of transmission are great, and this puts pressure on relationships. In a number of cases wives and partners have become

infected with HIV or hepatitis. For younger couples who wish to have children the fear of viral transmission can cause difficulties and distress.

**Economic**

3.8 Deteriorating health has forced many of those infected either to give up or cut down on work. It is not only the symptoms of the infection which are debilitating; both combination therapy for HIV and interferon/ ribavarin treatment for hepatitis C can have extreme side effects which make it difficult or impossible to carry on working. The Society knows of individuals with family responsibilities who have postponed accepting interferon treatment because they cannot afford to take the financial risk of being forced to give up work by the side effects of the treatment.

3.9 Many have already suffered loss of earnings and employment prospects and have been forced into dependency on welfare benefits. The social security benefits available, however, cannot compensate for these financial losses and hence many individuals and families face a severely reduced standard of living.

3.10 In addition, infected people face added costs due to their medical condition. This may be due to special dietary requirements, or the need for adaptations to the home, to expenditure on medication.

3.11 Life insurance and mortgage protection policies present a major problem for those with HIV or hepatitis C infection. Many companies will not offer life insurance to people with these viruses, or only at prohibitively high premiums. Those with family responsibilities are thus unable to provide properly for their financial security in the future.

4. Issues relevant to the Inquiry

In this section we cover issues relating to the Inquiry's three areas of interest.

**How was the contaminated blood products occurrence investigated?**

4.1 Unlike other countries where patients with haemophilia were also infected with HIV and hepatitis C through contaminated blood products, there has been no full investigation into the occurrence in the UK. Canada has held a four year full public inquiry, whilst the Irish Government has recently voted to do the same.. In this country, despite the fact that almost the entire patient group was infected, and concerns about blood safety persist in the light of CJD, there has been no systematic national approach to investigation and follow up as might have been expected when such a large scale adverse clinical outcome had taken place. Only some individual health authorities or hospital trusts appear to have investigated and implemented systematic follow up procedures.

4.2 The Society's evidence, gathered through a number of research projects and illustrated in the case histories attached at appendix one, is that

· approaches to tracing, testing and counseling infected patients varied widely between haemophilia centres

· in many cases patients were tested without their knowledge or consent and not informed as to the results.

· This failure to inform meant that patients could not take appropriate precautions to prevent infecting those close to them and as a result some partners and wives were infected and also meant they were not able to make lifestyle changes to safeguard their own health (e.g. reducing alcohol consumption in the case of hepatitis C). Some 80 partners were infected with HIV in this way; no

figures are collected for HCV.

· Equally there has been no systematic attempt to ensure that all patients infected with HIV or HCV through their NHS treatment were provided with the best possible treatment for their HIV or HCV. In fact there have been instances where people with haemophilia have been denied appropriate treatment on grounds of cost, and campaigning by the Haemophilia Society has been necessary to secure this.

4.3 The Society wishes to draw particular attention to the following key points which illustrate the patchy and uncoordinated response to the HIV and hepatitis infection of people with haemophilia, and the lack of an effective national follow up strategy to ensure that patients who had been infected through their NHS treatment were properly traced, counseled and treated to minimize the adverse outcomes for their own health and that of their families.

**Tracing those infected by contaminated blood**

4.4 Patients with haemophilia were not the only patients to be infected with HIV and hepatitis via contaminated blood. However, whilst the last Government in 1995 ordered a look back exercise to trace those infected with hepatitis C by blood transfusions, no action was taken to ensure all those with haemophilia who might have been infected with hepatitis C were also traced.

4.5 *In a recent parliamentary answer Health Minister John Hutton justified this decision of the previous Government by stating that: `...haemophiliacs are in constant contact with their clinicians (so) the need to include them in the tracing exercise did not arise as they would already have been known to the service'* (written answer 10.5.99).

4.6 Unfortunately whilst this argument might hold true for those with severe haemophilia, those with mild haemophilia may only require treatment very occasionally in a lifetime. We include in appendix A the case history of a man of 28 who has only been treated three times in his life, one of those treatments in 1981 infected him with hepatitis and he has only been informed of this within the last 10 months. Thus for a 17 year period he has been infected and unknowingly may have passed on this infection, and was given no counseling, information, advice on his condition.

4.7 This is not an isolated instance: the Society still receives a few calls each year from people with haemophilia and hepatitis C who have only just found out about their infection. As recently as 4 June 1999, the Society received a call from the very distressed sister-in-law of a man with moderate haemophilia whose family had only just been notified of his diagnosis. The results of a positive hepatitis C test had apparently been given to this man and his wife without any further information or advice being given on the condition leaving them to cope in extreme distress and shock.

4.8 One of the results of the failure to trace and identify all people with haemophilia who were infected with hepatitis C is that to date there is still no accurate official figure for the precise number infected, nor any official figures to indicate how many of these are receiving treatment for their hepatitis, how many have advanced liver disease. Even the national clinicians organisation the UK Haemophilia Centre Directors Organisation (UKHCDO) which publishes annual statistics on haemophilia patients does not include in this statistics for those with hepatitis.

**Testing for HIV and HCV**

4.9 Following from the fact that there was no national strategy to trace, test, counsel and if necessary treat people with haemophilia who had been infected, the approach to testing varied widely between haemophilia centres. By contrast with the look back initiative ordered for those infected via blood transfusions, no national guidelines were issued by the Department of Health to instruct clinicians and health authorities on best practice.

4.10 The following particular problems are identified in research carried out for the Haemophilia Society and are illustrated in the case histories presented at appendix A.

· Testing people with haemophilia, or a related bleeding disorder, for both HIV and hepatitis C frequently took place without individual consent *(Sexton 1995, Cheetham 1996, Roberts 1999).*

· In the case of hepatitis C people were often not informed of their results until several years after they had first been tested, and then often `accidentally' (Cheetham ,Roberts, and see case histories). This delay in informing people of their results prevented people from making active decisions to improve their health (e.g. going on interferon treatment to try to clear the virus, reducing alcohol consumption), and also increased risks of transmission of the virus to others *(Roberts 1999)*

· We have many examples of how the informing of minors of both HIV and hepatitis C infection was handled badly *(see case histories - Jan Hardy's example).* In some cases minors were informed without their parents being present. In other cases boys/young men with HIV were not told of their status until long after they became sexually active, and had infected partners.

· Several people with hepatitis C were only informed of their results by *post (Cheetham and see case history for Mr X)* - a situation, which caused a lot of distress and anxiety.

· Retrospectively, many centres said that pre- and post-test counselling would have been appropriate for both HIV and HCV. It appears that the mistakes made with HIV were repeated, or magnified, with HCV, perhaps because the impact of HIV was so great on the haemophilia community and its treaters, that there was a reluctance on the part of clinicians to face up to the seriousness of HCV.

4.11 The evidence gathered by the Haemophilia Society indicates serious failures to inform, advise and counsel individuals and their families about the impact of HIV and hepatitis on their health and life prospects. In the field of HIV it is now widely regarded as good practice to offer pre and post test counseling; however this practice has not been followed as the norm for people with haemophilia infected with either HIV or hepatitis.

4.12 Both HIV and hepatitis viruses have a considerable impact not only on an individual's health but on many aspects of their own and their family's life, and great distress has been caused in many cases by the way testing has been carried out and the results have been made known to patients.

4.13 In view of the fact that these patients had contracted the viruses through their NHS treatment it seems not unreasonable to expect that the Department of Health and NHS as a whole should have adopted a more pro-active strategy to ensure that all who might have been infected were properly tested and counseled. The difference in the approach adopted towards those infected via transfusions and those infected via haemophilia treatment cannot be justified, particularly in view of the experiences recorded by the Haemophilia Society.

**Legal issues and the Government response**

**4**.14 Following the discovery that patients with haemophilia had been infected via contaminated blood, the immediate focus was on HIV, for which at that time there was no treatment and the virus was regarded as being almost inevitably fatal. Public concern about HIV in general was at a very high level. The Haemophilia Society mounted a concerted campaign from the mid 1980s for compensation for the 1,200 people with haemophilia who had been infected with HIV, whilst at the same time some 900 HIV positive haemophiliacs pursued a group legal action against the Government on the basis that they had been infected by their NHS treatment. During this period people with haemophilia were dying of AIDS at a rapid rate, estimated at one a week.

4.15 The combination of public pressure, press and media publicity - the *Sunday Times* ran a high

2.9 Second, we want to see the establishment of an independent, expert task force to carry forward the investigation in Scotland, which should include a number of patient representatives, as well as medical and scientific experts. The issues and themes, which would need to be covered, are outlined in the next sections of this document, in which we indicate the very serious questions, which remain unanswered for the patient group.

**3. Concerning the issues raised by Susan Deacon**

A. The introduction of HCV viral inactivation for factor VIII

- Were patients with haemophilia in Scotland exposed to the risks of HCV for longer than they should have been?

3.1 The question of whether patients in Scotland were exposed to risks for longer than they should have been is very complex, and requires information on the actions taken during the 1970s and 1980s by a number of bodies, some UK wide and some with responsibilities for Scotland only. Largely because no official investigation and report have been produced, the information required to put together and assess this complex picture has not been gathered and debated in the public domain.

3.2 The process of investigation initiated by Susan Deacon is for the patient group the first and only time that we have had an opportunity to engage in any form of retrospective inquiry which might begin to answer this question. In order to establish the full picture, we believe the following key questions of crucial concern to patients must be investigated in Scotland.

- Why was Scottish blood product not made safe from hepatitis C until two years after that being produced in England?

- Why were more active steps not taken to protect the haemophilia patient group from the risks of hepatitis during an era when blood products were well known to be carrying the virus?

- Why did Scotland not follow the practice of other countries, which adopted surrogate testing (ALT testing) ahead of the UK?

- Were financial considerations put ahead of patient safety during this era?

3.3 These key concerns give rise to a host of detailed questions which we have attempted to set out below, bearing in mind that at this stage that the policies and actions of a number of bodies have to be examined to provide the necessary answers. *Among those which must be scrutinised are*

(i) actions of Scottish Office

(ii) actions of SNBTS

(iii) actions of haemophilia clinicians

(iv) UK national policies

(v) International actions/response.

**1. The need for accurate figures**

2. 3.4 There is still no official figure for the number of patients with haemophilia in Scotland who

were infected with hepatitis C during the 1970s and 1980s. No look back exercise has been undertaken in the UK to ensure that all those who may have been exposed to contaminated blood products have been traced, tested, counselled and treated if appropriate.

3.5 There is no published data on the number of Scots haemophilia patients with HCV, nor on the numbers who have been treated for HCV infection or those who have died from it. We need to know how many of the total infected group has mild, moderate or severe haemophilia; and how many were first treated between 1985 and 1988. An overview of the current state of health of the infected community should be produced showing how many have advanced liver disease.

3.6 The Society urges that this data should be collected immediately by the haemophilia centres and made available in the public domain. It is essential to know clearly how many have been infected in addition to learning how they were infected and whether this infection was preventable.

**Questions about treatment in the 1970s and 1980s**

3.7 Various clotting factor products were in use in Scotland in the 1970s and 1980s; both commercial and state produced. The SNBTS have told the Society that it was not their responsibility to decide which products should be imported for haemophilia treatment. Patients therefore wish to know whose responsibility this was and what assessment was made of the safety and efficacy of blood products being imported for use in the NHS in Scotland.

3.8 It is equally important to establish what infections the different products carried and how many Scots haemophilia patients were infected by each product in use at the time.

3.9 The risks of hepatitis as a blood borne virus were well known in the 1970s and before, and warnings about the use of blood products were published in the medical literature (some references are included on page 8). SNBTS representatives explained to the Society that efforts were being directed at eliminating HCV from blood products throughout the 1970s, well before HIV was identified and became the urgent focus in the 1980s.

3.10 This raises many questions about whether effective and timely steps were taken to reduce patients' exposure to these risks. We wish to know what considerations led to the SNBTS/Scottish Office view that Scotland should be self sufficient in blood? When was this policy first stated and what steps were taken to implement it? What warnings were given to patients about the risks of blood products?

3.11 In the case of people with mild haemophilia who might have required treatment no more than once or twice in a lifetime, alternatives to the use of blood products were available i.e. not to treat or to use DDAVP instead. Why was this strategy not adopted comprehensively in Scotland? And why were many of these patients not informed of the risks of using these products?

3.12 Given the known viral risks of blood products in the 70s and 80s, we are concerned to learn what guidance was issued to clinicians about their use and particularly on which patients should not be treated with blood products. Such guidance should have included the recommendation not to treat those with mild haemophilia with blood products.

3.13 We understand from the SNBTS meeting that a Coagulation Factor Working party was in existence during the period in question together with an Advisory Committee on the Virological Safety of Blood.

What were the responsibilities and remits of these groups as regards ensuring the safety of blood products being used in the treatment of patients with haemophilia in Scotland? What was the role of the MCA or its precursor in this field?

3.14 What were the considerations that influenced the Scottish Office/Scottish haemophilia centre directors/SNBTS in selecting what blood products to import in the days before Scotland was self-sufficient? Were these considerations adequate and timely in trying to ensure that Scottish haemophiliacs were exposed to as few "risks" as possible?

3.15 We need to know far more about the steps taken by the various UK wide and Scottish bodies at the time to ensure that the safest possible blood supplies and treatment products were in use. In this context information is required on the blood donor selection policy used in Scotland in the '70s and `80s (selection, screening, testing)? In particular, since hepatitis transmission via blood products was known to take place, what measures were taken and when (and why) to screen out hepatitis from the blood supply. Were these measures adequate? How did they compare with measures taken internationally?

3.16 Looking at why Scotland took so much longer than England to produce clotting factor products which were safe from hepatitis C, we need to know what viral inactivation procedures were researched and introduced into the manufacture of haemophilia blood products in the `70s and `80s? And what was the rationale behind this research? How did Scottish R & D compare to what was being done internationally?

3.17 Whilst we appreciate that hepatitis C was only formally identified as such in 1989, it was well known as non-A, non-B hepatitis during the 1970s and the risks of hepatitis generally were well understood. In this context we understand that there was a transition phase from 1985 onwards when products inactivated against HCV began to be introduced first in England and later in Scotland.

3.18 Again looking at this from the perspective of how best patients might have been protected from risks, we need to know when products (home and commercial) were known/expected to have probably caused infection, what steps were taken to ensure these products were no longer used/recalled? Were these steps adequate? Were they timely?

3.19 This aspect needs to be considered particularly from the point of view of previously untreated patients (PUPs) i.e. children diagnosed after 1985 and adults with mild haemophilia who may not have required treatment before then. Were these patients given priority to ensure that they received the safest product available as a preventative measure to protect them from the risks of the virus?

**3.20 Follow up to the infection**

The Society has highlighted in a number of reports the fact that no follow up strategy was implemented by Government once it became known that large numbers of haemophilia patients had been infected with HCV. This contrasts with the action taken to follow up patients who might have been infected with HCV via blood transfusions for whom the Chief Medical Officer in 1995 ordered a `look back exercise.'

3.21 Without a planned follow up strategy nationally any action in response to the infection appears to have been left to the discretion of individual clinicians. At a national level, the Society has produced evidence to show that some patients are still only now being told of their HCV infection, well over a decade since they were probably infected. Others were tested but not told the results. In some centres testing has not been done effectively using the latest PCR tests.

3.22 Clearly if people were not told of their HCV infection they were not given the information necessary to make changes to lifestyle (i.e. cut down on alcohol, practice safer sex) to protect their own health and the health of those close to them.

3.23 These issues have been extensively described in the Society's recent submission to the Health

Committee at Westminster (some references are included on page 8) a copy of which has already been provided to Ms Deacon and officials. This is an area, which requires further investigation in Scotland. Very recently we have learned of an individual in Scotland who has only just been diagnosed with HCV, which leads us to believe that the problems outlined above are not confined solely to the rest of the UK. We have also heard from individuals in Scotland of failure by clinicians to inform patients of their diagnosis. In one instance the patient learned of his HCV status by taking a look at his own notes. In others Scottish patients have only become aware of the possibility that they might have HCV infection as a result information provided by the Society.

3.24 We need to know far more about the steps, which were taken in Scotland to follow up the known infection of patients with haemophilia with HCV. Where products were known to have caused, or probably caused, infection what steps were taken to identify and trace patients who were/had been at risk, to inform these patients that they may be/have been at risk and to offer them information, support, testing and counselling? Patients are clearly asking now whether enough was done, and whether it was done soon enough.

3.25 Again we are concerned to know which body was responsible for leading on these matters: the Department of Health, the Scottish Office, the clinicians, the SNBTS?

B. Were patients given enough information about the risks of HCV in the 1980s to enable them to make an informed choice?

3.26 As indicated above and in previous evidence submitted by the Society, patients generally appear to have been given no information about the risks of blood borne viruses in clotting factor treatment. Even those first treated as late as 1986 state that they were told nothing about the risks.

3.27 Many patients only became aware of the possibility of HCV infection through information provided to them by the Haemophilia Society. Whilst evidence was accumulating within the medical and scientific community about the risks of blood borne viruses in clotting factor treatment, this information was not shared with patients.

3.28 In this context, the Society wishes to know on behalf of patients how the Scottish authorities responded to the growing weight of evidence about the risks. For instance, the publication of a *Lancet* article in 1975 documenting the hepatitis infection of nine our of 18 haemophilia patients treated at Bournemouth Haemophilia Centre, and the publication in the *Journal of American Medical Association* in 1972 of further research on hepatitis and clotting factor concentrates which recommended avoiding the use of multi-donor products for those with mild haemophilia (Craske et all, 1975, Kasper and Kipnis, 1972).

3.29 The Society wishes to know which body in Scotland was responsible for providing information to patients, and what steps were taken from the 1970s onwards to warn patients and enable them to be able to make informed choices about accepting blood product treatment.

**4. Other Concerns**

**The social and economic impacts of the virus**

**4.1** The Society has well documented evidence of the social and economic impacts of HCV. We have commissioned two reports nationally (Cheetham, 1996; Roberts, 1999) which provide evidence of the stigma, strains on family and personal relationships, and the loss of income due to declining health.

**4.2** The most recent - as yet unpublished - study by Dr Jenny Roberts of the London School of Hygiene and Tropical Medicine aimed to assess the social and economic impacts of the virus. In the

course of the study, which involved structured interviews with 25 individuals affected by HCV, the researchers identified many unmet needs with regard to information, support and counselling, again drawing attention to the lack of follow up action targeting the infected haemophilia community.

4.3 The conclusions of that study are included at Appendix 2. It should be noted that this was a small-scale pilot intended to pave the way for a larger study. The Society recommends that such a study could be carried out within Scotland to gain a full assessment of the social and economic impacts of hepatitis C within the Scottish haemophilia population.

**The case for a financial assistance scheme**

**4.4** The infection of the haemophilia community with HCV has caused considerable anguish and hardship. Those infected are living with stigma, much uncertainty as to the likely progress of the disease, and in many cases impaired health due to HCV has forced people to give up or cut down on work. In addition to loss of earnings, living with hepatitis adds costs eg. For special dietary requirements and medication costs. As discussed previously, the virus has had serious health, social and economic impacts, particularly in a patient group already suffering a lifelong, disabling medical condition. As the study conducted by Dr Roberts indicated, it is possible to differentiate the impacts of the HCV virus from the effects of haemophilia itself. Especially for those with mild haemophilia, the virus has created far more problems than the haemophilia itself.

**4.5** Treatment prospects, whilst improving with the recent introduction of ribavirin/interferon combination therapy, are still not good. The treatment carries very severe side effects, which many cannot tolerate, and success rates range from 40% to as low as 10-20%. Undergoing a six to 12 month course of treatment is very onerous for patients particularly when the chances of success are so uncertain.

4.6 There is a precedent for the provision of financial assistance for members of the haemophilia community infected with HIV through contaminated blood products used in their NHS treatment. The Conservative Government in 1987 accepted a moral responsibility to provide financial assistance for this group, and provided £10 million for the Society to set up the Macfarlane Trust in 1988. The Trust continue to administer both regular payments and one off hardship grants to the HIV survivors in the UK haemophilia patient group.

4.7 This experience, together that of other countries such as Canada, Ireland, Italy, could be used to develop a financial assistance scheme for the Scottish haemophilia community who are suffering the impacts of HCV. We would recommend the establishment of a hardship fund which could provide financial help for those most seriously affected by the virus. A mix of medical/social criteria could be used to assess eligibility, the system already used by the Macfarlane Trust, with haemophilia centre doctors playing a leading role in assessing health status and need of individuals.

**4.8** In Canada, where financial assistance is being provided for those with HCV contracted from contaminated blood products, a series of graduated trigger points have been developed to determine the level of award depending on the seriousness of the individual's medical condition. These provide another model which could be adapted for Scotland.

**4.9** The current situation is highly inequitable in that patients who were infected in the same way at the same time through contaminated blood products used in their NHS treatment are not able to receive financial assistance in the same way. Those infected with HIV, most of whom are co-infected with HCV, are eligible for help from the Macfarlane Trust, whilst those who have HCV alone are not.

4.10 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 with HCV to run alongside that available from the Macfarlane Trust to those with HIV. The numbers involved in Scotland are relatively small, and were the fund to be available for those in most serious need as a priority, only a proportion of the total HCV infected haemophilia population would become eligible for help initially.

**Treatment access problems**

4.11 The Society is increasingly concerned that the only available treatment regime for those with HCV - ribavirin and/or interferon - is not being provided for patients in some parts of the UK on funding grounds. In effect, a treatment by postcode situation is developing with regard to interferon/ribavirin treatment. We have raised this issue with the Department of Health and have been assured that clinical need should determine the provision of this treatment i.e. it should not be denied on funding grounds alone.

4.12 It now appears that this is a problem in Scotland as well as other parts of the UK. We have evidence that patients in Scotland who have been recommended treatment based on clinical needs are having difficulty securing it because of funding constraints. This is unacceptable: at the very least patients who have been infected with HCV via NHS treatment should be entitled to receive the most effective treatment available for the virus.

4.13 The Society urges the Health Minister to remind health authorities and trusts in Scotland of this principle, and to ensure that all those HCV infected people with haemophilia who need the treatment are able to receive it.

**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*

**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)