REPORT OF THE HEPATITIS C WORKING PARTY TO THE HAEMOPHILIA SOCIETY

June 2002

Executive Summary

1. The Hepatitis C Working Party was set up by the Haemophilia Society in September 2001 and comprises a QC specialising in medical negligence, a consultant actuary, several specialist haemophilia doctors with particular expertise in treatment of hepatitis, and the Chief Executive Officer of the Haemophilia Society. The Secretarial support was provided by the PR firm Weber Shandwick.

2. The Hepatitis C Working Party was asked by the Society to devise costed proposals for a financial assistance fund to recognise the loss and suffering of people with haemophilia resulting from their infection with hepatitis C (HCV).

3. Hepatitis C is an infectious virus affecting most people with haemophilia or a related bleeding disorder who received blood products as part of their NHS treatment before 1985 (1987 in Scotland). Most of these blood products were contaminated with the HCV virus and some were also contaminated with HIV. The infection of such a proportion of a patient community with HCV and HIV viruses is without parallel in the history of the NHS.

4. The brief for the working group was to develop proposals for a scheme which would provide financial assistance on the basis of medical need, and which would be relatively simple and swift to administer. The working group reviewed various schemes operating in the UK and abroad to find a suitable model. It was decided that the Canadian HCV Compensation Scheme provided the most suitable model and this was therefore used as the basis for our proposals. The working group also considered British common law principles of damages in adapting the Canadian model for the UK.

5. We used as a starting point the latest UK Haemophilia Centre Doctors Organisation (UKHCDO) figures for the number of people living with haemophilia and HCV at 1/1/2000, namely 2829.

6. We also used figures for the number of people with haemophilia and HCV estimated to be alive at 1/1/93, namely 3641.

7. The number of people with haemophilia and HCV who have died from liver disease prior to 1/1/2000 is 212 (UKHCDO figures).

8. In our model payments would be made according to the stage the liver disease has reached with a range of formulae being used to calculate the amount of award. This will allow the payments to broadly reflect individual circumstances and to be allocated via an administrative system rather than a possibly more, time-consuming and costly system of individual tribunals.

9. There is also allowance made for dependants and family, for loss of earnings, for inconvenience of drug therapy, for out-of-pocket expenses and towards costs of care. Our figures assume payments would be made to the dependants and family of those who have died, regardless of whether HCV was identified as the actual cause of death.

10. The estimated average cost of this scheme over a 10-year period is £52.26 million per year. By the inclusion or exclusion of various different elements of the scheme this total could vary significantly. For example, the ten year total would reduce by an amount in the order of £100+ million if only deaths from liver disease, rather than all deaths, were compensated.

11. All the external members of the Working Party gave their services free of charge.

12. The assumptions we have used in our calculations have been fairly pessimistic. We hope that in the next 10 years treatments will improve to such an extent as to significantly improve life for people with haemophilia and to reduce the costs of the scheme.

13. The working group recognises that adaptations could be made to the basic model set out in this report and that this would involve decisions of policy and principle by Government should it decide to take forward these proposals. Equally the group is aware that other models exist in this country and abroad which could be considered.

Report

1. The membership of the Working Party was as follows:

(1) Matthias Kelly Q.C. Chairman of the Working Party.
Chairman of the Personal Injuries Bar Association.

(2) Jonathan Checkley, Actuary of CheckleyFisher Actuaries.

(3) Professor Eric Preston, University of Sheffield.

(4) Dr. Mike Makris, University of Sheffield.

(5) Dr. Paul Giangrande, the Oxford Haemophilia Centre.

(6) Karin Pappenheim, the Haemophilia Society.

(7) David Peel, Weber Shandwick

2. Our remit:

To devise costed proposals for a financial assistance fund to recognise the loss and suffering endured by those who suffer from haemophilia and hepatitis C.

In particular, the object of any such scheme should be to recompense those who contracted hepatitis C prior to 1st March 1990. They, because they had contracted hepatitis C from infected blood products prior to that date, are not eligible to be compensated under the provisions of the Consumer Protection Act 1987 and the Product Liability Directive of 1985. Some, but not all, were parties to the HIV litigation which was compromised in 1990 when the Macfarlane Trust was used as a vehicle to provide financial assistance to people with haemophilia and HIV. At that time those who were parties to the litigation in England (but not in Scotland) waived their rights to seek damages in respect of any of the hepatitis viruses even though the litigation was not concerned with such viruses.

3. <u>The Impact of Hepatitis</u>

'Hepatitis' means inflammation of the liver. Hepatitis C –often shortened to HCV- is an infectious virus which was first identified in 1989 although its existence was known about for many years before through cases of 'non-A non-B' hepatitis. Hepatitis C affects most people with haemophilia or related bleeding disorders who received clotting factor concentrates from any source before 1985, the year when effective heat treatment was first introduced in the UK for state-produced products (1987 in Scotland). Before this most

concentrates were contaminated with HCV because blood clotting factors came from pooled blood donations received from up to 30,000 different donors.

4. An effective test for HCV was only developed in 1991. When people with haemophilia were tested for HCV it was found that about 95% of those treated with clotting factor concentrates before 1985/7 were 'antibody positive' for HCV, indicating that they had been exposed to the virus. It is estimated that after infection about 15% of people 'clear the virus' naturally, i.e. without treatment. This means that although this group of people is antibody positive, the virus is undetectable in their blood using PCR tests (i.e. they are PCR negative). When someone does not clear the virus naturally within six months of infection (i.e. they are PCR positive) the HCV infection is called 'chronic'.

5. There are still gaps in our knowledge about the disease and how it progresses, but for the remaining 85% of people with chronic HCV current medical opinion suggests that after 20-40 years of infection most will have some degree of liver damage, and about 20-30% of these will have such severe scarring that a diagnosis of cirrhosis is made. Most people with haemophilia have been infected for over 20 years and consequently many are now experiencing more severe liver problems, including cirrhosis. If cirrhosis progresses someone may develop liver cancer or decompensated liver disease which may be indicated by one or more of the following more severe symptoms: jaundice (skin yellowing), encephalopathy (impaired mental function), oedema (accumulation of fluid), or oesophageal varices (like varicose veins in the gullet).

6. There are treatments for HCV, namely interferon and ribavirin therapy (recommended by NICE[1] October 2000). Recently pegylated interferon and ribavirin has also been licensed in Europe. These treatments have a limited success rate of around 40% for people with genotype 1, which is the most common strain of the virus affecting people with haemophilia, and they are unpleasant to take with important side effects. About 1 in 10 people have to stop the course of the treatment (which usually lasts a year) because of the degree of side effects[2]. Many are also forced to stop work, or reduce their hours whilst on treatment.

7. Some of those with whom we are concerned are co-infected with HCV and HIV. Significant advances in the treatment of HIV in recent years have resulted in many of those co-infected with HIV living longer and fuller lives than they were expected to in 1990. The progression of HCV is accelerated by the presence of HIV. Liver failure progresses more rapidly in HIV/HCV co-infected patients and is now one of the commonest causes of death in this group.

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[1] National Institute for Clinical Excellence

[2] See Review of Side Effects of Interferon Alpha in Viral Hepatitis by Professor Geoffrey Dusheiko on the Hepatitis Central website http://hepatitis-central.com/hcv/ifn/sideeffects.html

8. How the financial assistance proposals were developed

In order to develop costed proposals for a possible scheme the working group had to agree a suitable framework or model which could be used to determine eligibility for financial assistance according to differing levels of need, which was a principle agreed by the Society's trustees. The group therefore considered a number of existing schemes from around the world and also took account of the methods of calculating damages in the UK courts.

9. Generally, in England, compensation is calculated on common law principles. Until the arrival of the revised Criminal Injuries Compensation Authority even schemes for ex gratia payments were still calculated on that model. We applied some common law principles of damages to the scheme we adopted

Those were also the principles applied by Mr. Justice Burton in S and Others v. National Blood Transfusion Authority and Others (unreported, 26/3/2001).

10. A number of countries have HCV compensation schemes. The schemes are described in the Spring Update of the 'Status of Financial Assistance for HCV-infected Persons with Haemophilia in WFH Member Countries'. The working party considered these schemes and also the Macfarlane Trust model and agreed that the best available model was the Canadian model adapted and applied to the United Kingdom. This is because the scheme is comprehensive and fairly straightforward to administer as the awards suggested are based on degree of illness using clear, fixed and easily verifiable categories. The scheme would be easier to implement than a tribunal where the circumstances of individuals are looked at in some detail in a court-style setting when deciding on awards. The Canadian model is at Appendix A.

11. In order to determine the overall cost we have used the best possible estimate of the current number of people with haemophilia and HCV (infected before 1990) and estimated the likely mortality. We also carried out a survey[3] to establish the age brackets of sufferers, the nature of their symptoms, the date they were informed, tests and treatments undertaken, the marital status, household structure, work and social impact of the infection. The results of the survey are at Appendix B. The actuarial calculations are at Appendix C. A table of awards in the hepatitis litigation is at Appendix D.

[3] Oxford/Sheffield Survey 2001 (see Appendix B)

12. The relevant population:

We used as a starting point latest UKHCDO[4] figures for the number of people with haemophilia living with HCV as at 1 January 2000, namely 2829 people. We also took into account previous attempts to ascertain the number of people with haemophilia infected with HCV which were carried out by Sarah Darby et al[5], specifically the following:

- No of men and boys in the UK who were treated between1969 and 1985 with blood products "carrying a high risk of HCV infection" **4865**
  (Darby et al 1997)
- No of men and boys with haemophilia in UK at 1/1/93 **3641**
  (Darby et al 1997)- *assumes a 100% infection rate for HCV*

The number living with haemophilia and HCV as at the 1st of January 2000 was 2829 of whom 469 were also HIV positive as a result of being given the same contaminated blood products. Dr Mike Makris has produced an analysis estimating the number of people in different stages of HCV disease (Appendix E). The UKHCDO supplied a figure of 212 as the number of people known to have died from liver disease up until 1/1/2000.

13. The impact of HCV on this population, in terms of health, personal circumstances, education, employment and the impact on social and work opportunities was studied (see Appendix B). A special survey was conducted amongst the patients at the Oxford and Sheffield haemophilia Centres in July and August 2001 with the aim of finding out more about the impact of HCV on the lives of people with haemophilia. Ninety-three people (38%) responded to the questionnaire, and a large majority (73%) said that HCV had adversely affected their family and social life in a variety of different ways including anxiety problems, problems with intimate relationships including sexual relationships, problems with communication within the family, tiredness and lethargy etc.

14. In terms of health issues the biggest problem reported was fatigue. This affected both people with known severe liver disease, and people with mild disease/unknown level of disease. Nearly 50% of people responding to the survey had had to cut down/give up work due to health problems, and a significant minority also stated that hepatitis had had an impact on their regular earnings or their choice of career (29% or 27%). Many had also had problems obtaining life assurance (40%), travel insurance (17%), mortgages (14%) and pensions (11%). Many were glad that they had arranged their mortgages before the diagnosis of HCV. In summary the survey results gave a clear indication that the HCV virus has had a significant detrimental effect on the lives of people with haemophilia in medical and non-medical ways. These findings are consistent with other pieces of research commissioned by the Society

[4] United Kingdom Haemophilia Centre Doctors' Organisation
[5] Darby SC, Ewart DW, Giangrande PLF, Spooner RJD, Rizza CR, Dusheiko GM, Lee CA, Ludlam CA, Preston FE, for the UKHCDO . Mortality from liver cancer and liver disease in haemophilic men and boys in UK given blood products contaminated with hepatitis C. *The Lancet* 1997; **350**: 1425-1431

(Cheetham 1996[6], Roberts 2000[7]). These more qualitative studies also showed that people experienced problems in accessing information about HCV and support in dealing with living with the illness, and that many faced discrimination and ostracism at work, school and in society in general. Foster and colleagues[8] similarly confirm that chronic HCV has a severe impact on quality of life, even in the absence of cirrhosis.

15. The results of the study have been used in several ways in our calculations, e.g. in calculating the estimated loss of earnings through ill-health.

16. A computer model which simulated the progress of hepatitis C "A Health Economic Analysis of Chronic Hepatitis C Infection"[9] was used to predict the number at different levels of severity over a period of 10 years into the future. That model relates only to those with hepatitis C and not haemophilia as well but nevertheless gives the best available evidence as to the future of the 2,829 lives with which we are concerned.

17. Having estimated the number of affected people who would be covered by a financial assistance scheme and analysed the impact of HCV on their lives, the working group then had to put monetary values to the levels of awards for which they might eligible. Here we were influenced by English legal principles. The only mechanism by which society can be seen to compensate a person who has suffered loss or damage in consequence of a wrong done to him is to award monetary compensation. In personal injury cases the element of damage which is common to all, physical injury, cannot be eliminated or ameliorated merely by an award of money. Nevertheless, the object of such an award has long been accepted in England and throughout the rest of the common law world. It is to award "full compensation"[10]. As Viscount Dunedin expressed it the object is to award such sum in "damages which, so far as money can compensate, will give the injured party reparation for the wrongful act".[11] The principle has recently been reaffirmed by the Judicial Committee of the House of Lords.[12]

18. The Court of Appeal in Heil v. Rankin and Associated Appeals (2000 P.I.Q.R. Q.187) comprehensively reviewed the level of general damages in England. It concluded that an award for pain, suffering and loss of amenity in respect of the more serious injuries should be increased by a third.

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[6] Cheetham M; **Haemophilia and Hepatitis C Research Report.** The Haemophilia Society 1996
[7] Roberts JA, Bond S; **The social and economic impact of hepatitis C in people with haemophilia.** Report for Haemophilia Society 2000
[8] Foster GR, Goldin RD, Thomas HC; Chronic hepatitis C virus infection causes a significant reduction in quality of life in the absence of cirrhosis. Hepatology 1998;**27**;209-212
[9] Developed by pH Consulting (under sponsorship by Roche Products Limited)
[10] See Lord Blackburn in Livingstone v. Rawyards Coal Company 1885 App. Cas. 25.
[11] Admiral Decommissioners v. SS Susquehala (1926) A.C. 655.
[12] Wells v. Wells (1999) 1 A.C. 345.

19. Traditionally an award of damages in England can be classified under a number of different headings which, added together, make up the total award:

(1) General damages for pain, suffering and loss of amenity. This is a sum of money awarded to compensate the injured person for the physical or mental injury which they have suffered and is entirely independent on any compensation for loss or expense past, future or present which may also be claimed. At the top end of the scale awards can be of the order of £200,000 for quadriplegia down to £250 for a very minor injury. In looking at the level of compensation that ought to be awarded for the pain, suffering and loss of amenity endured by the subject population we have borne in mind the JSB Guidelines (5th Edition) and the very detailed and thoughtful judgment of Mr. Justice Burton in S and Others v. The National Blood Transfusion Authority and Others[13].

(2) Out of pocket expenses such as, for example, travel, telephone calls, payments to others who, for example, undertake domestic tasks that the person would otherwise undertake themselves.

(3) Past loss such as, for example, loss of earnings.

(4) Increased expenditure such as, for example, medical treatment, therapy, prescription costs etc.

(5) Future losses such as, for example, loss of earnings.

(6) Medical costs though these are likely to be funded by the NHS.

(7) Future losses such as, for example, handicap on the labour market. This is a head of damage which attempts to compensate the injured person where he or she will find it more difficult to obtain work in the future, or if they are in work at the time of the assessment of damages, are more likely than a non-infected person to lose their job and find it more difficult to obtain alternative employment.

20. The payments:

We concluded that it would be appropriate to divide the population into five categories reflecting the progressive impact of HCV on those who were infected:

(1) HCV anti-body test positive, HCV PCR-test negative.

[13] *Unreported, decided on 26th March 2001*

(2) HCV anti-body test positive, HCV PCR- test positive.

(3) Those whose liver shows fibrous changes or who have received drug therapy or meet the criteria for such therapy.

(4) Those in respect of whom there is clinical proof of liver cirrhosis. Proof can be established other than by means of biopsy.

(5) Those who have decompensation of the liver or liver cancer or those who have undergone a liver transplant.

21. In order to determine how many fell into each category based on the population of 2,829 as at the 1st of January 2000 we used an estimate supplied by Dr Mike Makris (Appendix E)

22. The figures in Appendix E have then been used to produce a table to show those who are at or beyond each level. The population of 2,829 can be projected forwarded according to degree of severity and from this it can be calculated what the true cost of each stage payment is as the disease progresses. We calculate that as £89.0 million.

23. The Canadian model also provides compensation for drug therapy, medication, care, out of pocket expenses, HIV in addition, those who died before the scheme came into force, their dependants and family. The working group concluded that some of these may be inappropriate in the UK context.

24. The full actuarial calculations are at Appendix C.

25. Levels of payment:
Our model diverges from the Canadian model in terms of levels of payment depending on severity of HCV disease. The Canadian model envisages the payment to be staged. We do not. We recommend that payment be determined by the level of injury at the time the compensation is determined. Subsequently, if the compensated person moves on to another level they ought to be able to return and seek assistance appropriate to that level. In determining the size of award at that stage (where the damage has become worse) credit should be given in the calculation of the award to the payment previously received. That will have the effect of avoiding double compensation and will reduce the overall cost to the State.

26. Level 1. We concluded that the appropriate level here was £7,500 for general damages[14].

27. In our model all of the group are antibody positive for HCV but only those who have not progressed to a higher level/stage of the illness are eligible for such a payment The estimated number of people at payment level 1 who have not progressed to a higher payment level is 424 at 1/1/2000.

28. Payment level 2: We concluded that the appropriate level here was £10,000. The estimated numbers involved here are 361 at 1/1/2000.

29. Payment level 3 we concluded should be set at £20,000. By that stage the liver is already showing fibrous change or the claimant has received substantial drug therapy or meets the criteria for such therapy. It is a debilitating condition which must also carry with it substantial psychological trauma. The estimated numbers involved here we are 1,563 at 1/1/2000.

30. Payment level 4 we believe should be set at £40,000. At this level the infected person will have clinical proof of liver cirrhosis and therefore have a very serious injury[15]. The estimated numbers involved here are 361 at 1/1/2000.

31. Payment level 5 we believe should be set at £60,000. At this level decompensation of the liver or liver cancer will already have set in or there may have been a liver transplant already with a high probability of re-infection with HCV. The estimated number involved here is 120 at 1/1/2000.

32. We have included an element to compensate those who have had drug therapy as this can be unpleasant and cause strain on an individual. We have not allowed any costs for medication on the basis that this will be provided by the NHS. We have also calculated, on the basis of the Oxford/Sheffield survey, a likely award for out of pocket expenses.

33. We have assumed that people with HIV and HCV will receive the same levels of compensation as those with HCV alone together with an additional one-off payment of £25,000 in recognition that they are also living with HIV. Given the existence of the Macfarlane Trust in the UK, this provision may be unnecessary.

34. We have assumed that any scheme should also make provision to compensate the estate of those who died prior to its implementation because they and their families, during the relevant period, have suffered emotionally, physically and financially as well as enduring the stigma that so often sadly accompanies the infection. This is an assumption made in the Canadian

[14] This is supported by the case of Mr. S. in the hepatitis litigation who, having tested positive, cleared the virus but suffered an adjustment order. See Appendix D.
[15] We note that Mrs. X in the hepatitis litigation was awarded £45,000 at this stage. See Appendix D.

scheme. If only deaths from liver disease were compensated, rather than all deaths, this would significantly reduce the overall cost of the scheme.

35. The overall compensation package we have calculated would cost £522.6 million over ten years. This is based on the estimate of 3641 people with haemophilia and HCV as at the 1st of January 1993[16] by Darby and assumes that the estates of all those who have died since 1993 receive some compensation. This gives an average of £144,000 per person. For the Canadian scheme which spread across 1,408 individuals the average cost was £71,000 per person. If only the estates of those who actually died from HCV received compensation, the overall figure would reduce by an amount in the order of £100 million.

36. Summary:

We have attempted to address the issue of what the likely overall cost of a scheme to provide financial recompense for HCV to people with haemophilia might be. In doing so we have had to make a number of assumptions, some of which may have been unduly pessimistic. It will be noted that the biggest element of this is cost of lost earnings.

MATTHIAS KELLY Q.C.

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16 Darby SC, Ewart DW, Giangrande PLF, Spooner RJD, Rizza CR, Dusheiko GM, Lee CA, Ludlam CA, Preston FE, for the UKHCDO. Mortality from liver cancer and liver disease in haemophilic men and boys in UK given blood products contaminated with hepatitis C. *The Lancet* 1997; **350**: 1425-1431