21st September 2003

GRO-C

Tel GRO-C

RE- COVER-UP OVER HEPATITIS C

Dear Baroness Andrews,

I am writing with regard to your response to politicians' questions on the hepatitis C/financial assistance issue as documented in Hansard 16th September 2003. I am unable to decide at this stage whether you are genuinely ignorant on the subject or part of the ever-growing Government propaganda machine on hepatitis C!

I am very disturbed by your comments, and note that you state that, quote, "there was no test until 1991 for hepatitis C." Yes, that is the official line, but perhaps you can explain why we now have evidence from medical records that haemophiliacs WERE tested for hepatitis C prior to 1991, without haemophiliacs' knowledge and permission, against General Medical Council procedure, and that these positive test results were withheld sometimes for years. Are you aware of the current GMC investigation into this and also the state of knowledge amongst the medical profession on hepatitis C going back to the 1970s? Are you aware of the GMC booklet on testing for infectious diseases such as HIV and hepatitis C which reads, "doctors who test patients for infectious diseases without their knowledge and permission can be held to account in a criminal court." The issue is not the accuracy of a test but that the patient is aware that he/she is being tested in line with GMC rules and human rights legislation. There are very specific rules with regard to HIV/HCV. Haemophiliacs give blood all the time for clotting factor levels and to monitor for inhibitors but this blood CANNOT then be used secretly to test for infectious diseases.

You must surely be aware of the whole-blood hepatitis C cases that were won where the judge stated that testing/ screening of blood donors for hepatitis C should have been introduced prior to 1991, and that this country should have acted as other European countries did and adopted testing earlier, erring on the side of caution even if there were some false positive test results.

With regard to the state of knowledge on the hepatitis C virus, I congratulate successive Governments on how clever they have been with the play on words with regard to the terms non-A, non-B/ hepatitis C. I enclose recent press articles however written using documents I acquired from litigation files. They show that far from doctors, the Government, and the Haemophilia Society "not knowing" (as you state) what was happening in the early 1970s with regard to non-A, non-B, hepatitis (hepatitis C), the blood of haemophiliacs was being carefully monitored for hepatitis viruses without their knowledge and permission.

How can the Government claim ignorance when they were warned NOT to use U.S. plasma in a letter from an American expert, Dr J Garrott Allen dated January 6th 1975. Dr Garrott Allen wrote to Dr William Maycock, of the Blood Products Laboratory raising his concerns over another form of hepatitis, (non-A, non-B) calling American plasma quote:-

"extraordinarily hazardous, with a 50 to 90% rate of icteric hepatitis developing from it. About half of these cases prove fatal. Cutter's source of blood is 100 percent from skid-row derelicts".

"it seems to be more frequently encountered in the lower socio-economic groups of paid and prison donors. It is minimal among volunteer donors. It seems that the most certain method we have for reducing the number of carrier donors at the present time, is still to determine whether or not the donor has been paid in money or in reduction of his prison sentence. Until we understand this problem better, I would hope that Great Britain would give some thought to what the purchase of Factor VIII and IX tends to do to our attempts to form a volunteer program. Commercial blood banking perpetuates the high-risk rates we encounter with their products, and it attempts these same commercial firms to sell the residual products of these high-risk donors (red cells, patelets, leucocytes, etc to non-immunised patients who tend to be more susceptible to post-transfusion hepatitis than is so far the non-virgin haemophiliac."

I want to know why my husband and his younger brother (now dead), alongside many other haemophiliacs, were given U.S, products made by Cutter as documented in medical records for a period of years when the Government knew of the high hepatitis risks? Why weren't patients informed of the risks?

I recently came across the haematologists study on Factor VIII/IX associated hepatitis including non-A, non-B hepatitis in haemophiliacs with figures from 1974 to 1979, cases associated with different brands which was presented to fellow doctors, representatives of the Government, and the Haemophilia Society in 1982.

"A total of 283 episodes of hepatitis were reported involving 253 patients. 26 patients had two attacks of hepatitis and 4 patients had three attacks. There were 197 cases of non-A, non-B hepatitis and 86 cases of hepatitis B".

There were more cases of hepatitis than the number of haemophiliacs studied. This is why many haemophiliacs have argued that haemophiliacs should be seen as a separate case from whole blood cases as haemophiliacs were exposed to multiple hepatitis viruses and to different genotypes over and over again throughout the years. Haemophiliacs only now realise know that exposure was virtually guaranteed!

The then, DHSS went so far as to fund a three year retrospective study on hepatitis, (including non-A, non-B hepatitis) in 1981. Hepatitis surveillance included recording of "suspect" batch numbers for hepatitis. Although an "official" hepatitis C test was not available until 1989, this did not stop doctors writing in medical journals about how they were able to identify cases of non-A, non-B by a test of elimination. For example if a virgin patient developed hepatitis and was glowing yellow, doctors would test for hepatitis A and B and elimate those forms of hepatitis, they would also monitor liver function tests to see if they were raised. If a virgin patient tested negative for hepatitis A and B, then it was obvious that another form of hepatitis (hepatitis non-A, non-B) was causing the problem. Doctors could then collect information on other patients who had received the same plasma batch number, particularly where outbreaks of hepatitis had occurred in these other patients.

For example between 1974 and 1979 the American product Hemofil, was associated with 87 cases of non-A, non-B hepatitis alone , as well as 32 cases of hepatitis B. Quote "It shows that there is a 4 to 20 times higher incidence of overt,

non-A, non-B hepatitis associated with U.S. Commercial concentrate compared with NHS."

A statement in 1981 from the Haemophilia Centre Directors Hepatitis Working Party Report for the year 1980-81, records, "there have been no further deaths directly or indirectly attributed to liver disease in the past year".

Why weren't haemophilia patients informed of these hepatitis risks associated with plasma concentrates? Why were haemophiliacs' human rights abused? A patient has the right to know of medium to high risks associated with treatment, especially a treatment decribed as "extraordinarily hazardous." Haemophiliacs had a right to know that deaths were occurring. Dr Craske was not only asking for "suspect" batch numbers to be CONTINUED to be reported in 1981 as it was thought that "it might be necessary in the future to again ask for details of all patients who had received treatment with a particular "suspect" batch number," but Craske also stated that, "he would be most interested to receive samples of liver from patients who came to autopsy where there was evidence of chronic liver disease."

Incidently, where are these "suspect" batch numbers now? Haemophiliacs want them for their U.S. lawyers for their cases against U.S. plasma companies. (You may be aware that I set up the contact with U.S. law firm, Leiff, Cabraser, Heimann, and Bernstein, LLP, and the first UK cases were filed against U.S. plasma companies on June 2nd 2003). Far from the Government statement that nothing could have been done to eliminate hepatitis until 1985 or thereabouts, our expert legal witnesses will testify to that fact that plasma companies were offered an effective way to eliminate hepatitis from plasma products years before this date but did not employ such elimination methods on the grounds of cost. We are talking alleged negligence here.

It was dangerous and unethical to introduce a "treatment" such as pooled commercial plasma (often from plasma pools of 60,000 high –risk donors) with a high risk of transmitting hepatitis before first eliminating hepatitis viruses. American studies in 1972, a year BEFORE the UK started to import U.S. plasma, identified outbreaks of hepatitis in U.S. patients using commercial factor concentrates. This treatment was experimental, haemophiliacs were used as guinea-pigs and commercial factor concentrates were highly dangerous!

Haemophiliacs were kept in ignorance of the fact that they were being so carefully monitored for hepatitis viruses, including non-A, non-B hepatitis, and were denied a patient's right to make an "informed choice" on whether to risk taking the factor concentrates. A patient refusing such treatment may be controversial but it is a patient's right to refuse treatment if they perceive "the risks of the treatment outweigh the benefits". This was always a patient's right.

My husband has refused to take human factor concentrates for over 3 years, arguing his refusal on safety grounds having been infected with HIV, hepatitis B and C and more recently exposed to vCJD, and now has a test case in the High Court in November to fight for recombinant, synthetic treatment. He is also arguing on moral grounds against the exploitative and dangerous practice of using paid donors which still happens with regard to collection of U.S. plasma to make factor concentrates. It seems no-one has learnt any lessons and I have evidence of very recent safety violations.

It is extremely disturbing that the Government knew so much about the dangers of hepatitis C in 1991 when it forced haemophiliacs to sign a hepatitis waiver as part of the HIV litigation, signing away their legal rights. John Horam wrote a letter to me in

1996 where he states, "at the time of the signing of the waiver, the Government knew that haemophiliacs had died from hepatitis C and others were seriously ill." No wonder haemophiliacs were tested without their knowledge and permission prior to the signing of the 1991 waiver and their test results withheld! It is also very disturbing that the Haemophilia Society (that has a long-standing history of receiving funding from the same U.S. plasma companies that contaminated haemophiliacs) should write in its minutes of 1991 that hepatitis C was not a problem for haemophiliacs, especially considering that Society members were present in 1982 when the haematologists, (Government funded), hepatitis study into haemophiliacs was discussed.

The reason haemophiliacs have never been granted a full and open public inquiry is that so many professionals are involved in a cover-up, including Government, doctors, the Haemophilia Society, and even the original UK HIV lawyers, for haemophiliacs. A legal opinion last year stated that HIV lawyers for haemophiliacs had quote "even lied", (I have this in writing), yet the eminent QC, now head of the Bar, and Chairman of Working Party for recompense with the Haemophilia Society, that proposed an "ex-gratia" payment to Government for haemophiliacs is staying silent on this matter.

Is it any wonder that the Government claimed "public interest immunity" with regard to blood/health documents at the time of the HIV litigation, and only decided to pay out when this was overturned and documents including Lord Owen's documents when he was Health Minister, were about to be shown in court. Of course this never happened and attempts were made to seal files, and Lord Owen's documents we now know were pulped. Lord Owen stated in the press that this was "unprecedented", as these documents were supposed to be kept for 30 years. He stated in the press that this was unprecedented. Lord Owen, you may recall accused the Government of "gross maladministration," which led to the contamination of the haemophilia community with HIV/HCV. What happened with the Government's recent so-called investigation into Lord Owen's pulped files? We have not received any satisfactory answers on this matter. The Department of Health promised me an answer to my letter of January 2003 within 20 days. I AM STILL WAITING!

I WILL expose the truth on this matter, and I expect a proper response to this letter. The Convenor of the Scottish Health Committee has written to Malcolm Chisholm with regard to the enclosed press articles and is currently asking questions on this matter. Let's hope the Scottish Executive can see what Westminster has been up to with regard to covering-up this matter!

If there is no independent full and open public inquiry, I will use my documents to fight through the European Courts for justice and write a book using this evidence. Haemophiliacs will not stay silent!

Yours sincerely

Carol Grayson (Haemophilia Action UK)

Cc Lord Morris of Manchester
Lord Campbell of Croy
Lord Ackner
Lord Clement- Jones
Jim Cousins MP
John Reid (Health, England)
Malcolm Chisholm (Health, Scotland)

Convenor Health Committee, Scotland
Press -various
Campaigners- various
U.S. lawyers -LCHB