

Ms C A Grayson

GRO-C

Newcastle Upon Tyne

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17 May 1996

Dear Ms Grayson

Thank you for your letter of 2 May to the Secretary of State about those patients with haemophilia who have been infected with hepatitis C. I have been asked to reply to that letter and to your letter of 19 March to Mr Horam which, unfortunately, did not reach this Department at the time.

I am aware that people who are dually infected with both the HIV and the hepatitis C viruses have additional problems, and was sorry to read about those faced by your partner.

The HIV, hepatitis B and hepatitis C viruses have been inactivated in blood products since 1985, so the timing of the introduction of hepatitis C testing was not relevant to haemophilia patients. Research into possible ways of inactivating viruses was going on for several years before satisfactory results became available.

It is our understanding that in 1979 a German company produced heat treated Factor VIII, but in quantities which were insufficient to satisfy the West German market, let alone allow any export. Details of the process which led to a significant loss of Factor VIII were not made available to competitors. In 1982-84 other companies started to supply heat treated Factor VIII. This was used in several trials, and by early 1984 it was obvious that despite heat treatment non-A non-B hepatitis was still being transmitted. Some patients in the UK were involved in these trials. Unfortunately, there was no definite way in which to prove that non-A non-B hepatitis transmission was being prevented. For instance, it was not until 1987 that it became established that the German product did indeed not transmit hepatitis. In September 1984 a paper appeared that suggested heat treatment would prevent transmission of HIV. In 1985 UK fractionators produced heat treated Factor VIII from UK voluntary unpaid donors.

Knowledge of non-A non-B hepatitis, now called hepatitis C, developed over the years. Solicitors acting for the haemophilia patients proposed the settlement terms, since it was known that the risk of dying from AIDS was much greater than from hepatitis C. In your letter you mentioned that your mother-in-law received £23,000 from the Macfarlane Trust; I think this would have been in addition to £20,000 received a year earlier. Intimate partners infected by HIV from haemophilia patients are also covered by the payment scheme.

The National Blood Service does not collect surplus blood, but collecting sufficient blood to meet domestic demand may result in a surplus of plasma and plasma-based products. When a surplus arises, it is exported on the basis of cost recovery. The alternative would be to destroy it. Receipts from sales reduce the cost of blood supplies. All imported blood products must satisfy the requirements of the European Union, including testing for hepatitis B, hepatitis C, and HIV and additionally all blood products are tested at NIBSC (the National Institute for Biological Standards and Control). The majority also undergo virucidal procedures to destroy any virus not detected. Clinicians decide which blood product to use for individual patients. They must decide whether it is appropriate to use blood products derived from voluntary unpaid British donors or from paid donors overseas. The Government promotes the use of products from unpaid donors.

The funding of a settlement to haemophilia patients abroad by pharmaceutical companies was solely about HIV and made no reference to hepatitis C. The UK settled the HIV cases some years ago. The involvement of commercial companies in the proposed payment schemes in some other countries reflects the difference between healthcare systems in different countries and the way that blood products are supplied. It provides no basis for an approach to commercial companies in the context of the current claims for hepatitis C compensation even if this were thought appropriate.

The advice that this Department has received suggests that there is no evidence that recombinant Factor VIII is any safer than Factor VIII derived from plasma at the present time. Recombinant factor VIII contains albumin derived from plasma as a carrier. We also understand that recombinant products themselves are not without side effects. This Department has issued guidance to medical purchasers to help them in placing contracts for the care of haemophilia patients. Purchasers are guided by expert advice. However, they must be assured that the money they spend is determined by the effectiveness of the treatment, as well as value for money. This is to ensure that the best health care is obtained for the resources available, and that clear benefit must be seen if extra costs are to be spent on one group of patients with less available for others.

Yours sincerely

GRO-C

*Leonard Levy*