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From the Private Secretary

26 June 2001

Dear Mr Hodgson,

The Prime Minister has asked me to thank you for your letter of 20 April about National Health Service treatments for people with haemophilia. I am sorry for the very long delay in replying.

You raise the use of imported blood products from the USA in the early 1970s and its impact on the transmission of blood-borne viruses, in particular hepatitis C, to people with haemophilia in the UK. At that time, the benefits of freeze dried pooled blood products were being widely and rapidly adopted into clinical practice in all countries with well-developed haemophilia services. These products were easier to use compared to cyroprecipitate from a single donor which required a lengthy process that had to take place in hospital, and was less convenient for children. As a result, there was pressure from all sides for pooled blood products. However, as you know, making these blood products successfully, to preserve the active clotting factors, required the pooling of plasma from thousands of donors. This is still the case, and pool size – while it has reduced over time – remains in the thousands. It is for this reason that the UK could not hope to be self-sufficient in treatment production, as you suggest in your letter. Unfortunately, because of the need for pooling and the incidence of the virus in blood donor populations around the world, the risk at that time of them transmitting hepatitis C was almost 100%. It is deeply regrettable that, by the time viral inactivation technology was introduced in the mid-1980s, almost all people with haemophilia receiving treatment had unwittingly been infected.

You question the basis of decision to use pooled blood products. Since 1971 all products made in or imported to the UK for medicinal use, including clotting factors from the US, have needed a product licence under the Medicines Act 1968. The Committee on the Safety of Medicines provides advice to the Health Secretary on the quality, safety, and efficacy of the product, and this is the basis for granting a product licence. These products were therefore

independently judged at the time to be the best products available. With hindsight, we now know that had all doctors only used single unit cryoprecipitate, fewer people with haemophilia would have become infected with hepatitis C. I am afraid that this did not happen for the reasons explained above.

When hepatitis A and B were defined in the early 70s, the risk of transmitting hepatitis through blood transfusion and blood products was significantly reduced, but still remained – mainly in the form of non-A non-B hepatitis, or hepatitis C. People with haemophilia therefore continued to be at increased risk of hepatitis because of the volume of material, both cryoprecipitate and pooled blood products, that they needed to manage their bleeding problems. In the mid-1980s this risk was eliminated by the introduction of heat treatment, and later of chemical treatment with solvent detergent. I am assured that these techniques were introduced as soon as they became available.

You raise the issue of recombinant product provision. The Government is currently giving careful consideration to the case for extending the provision of recombinant clotting factors to all haemophiliac patients in England. As you know, there is a world-wide shortage of recombinant products and the current priority is to ensure that there are sufficient supplies for those new patients and those aged under 16. The Department of Health is working with the UK Haemophilia Centre Doctors Organisation and Industry to help ensure that the needs of haemophilia patients are met, and especially that those for whom recombinant coagulation factors are required, receive them.

To respond to your point about the remit of the Macfarlane Trust, I understand that the work of the Trust is specifically targeted at haemophiliacs with HIV and their particular needs, and that this focus will remain.

You refer in your letter to the Government's decision not to hold a public inquiry into this issue. The Government has explained its reasoning on this on a number of occasions through debates in both Houses, meetings with Department of Health Ministers and in correspondence.

The Department of Health did not seek leave to appeal against the Judgement from Lord Justice Burton. This was not because the Department considered that the grounds for the Judgement were correct. An appeal would have provided an opportunity to seek clarification on some aspects of the Judgement that may have a bearing on the future liability of the NHS. However, the Government did not wish to subject the claimants to a further period of uncertainty while an appeal was underway.

I am afraid that the Prime Minister's commitments mean that he is unable to meet you in the near future, but I do hope that this letter goes some way towards answering the points you have raised.

Yours sincerely,

GRO-C

DAVID NORTH

Chris Hodgson Esq