Mr Newton (O/R)
to note + file

GRO-C

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File FT 4/2

Our Ref: HP412

Dr H Pickles
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4 December 1996

Dear Hilary

HAEMOPHILIA

Thank you for your letter of 14 November. We had previously discussed the topic on the telephone.

I agree with you that if one is going to consider "unknown viruses" then one really also ought to consider whether the use of a recombinant product poses other risks which are not found in plasma derived products. You will be aware that the Haemophilia Directors have an "orange card" alert system whereby they write to Oxford with any adverse reactions that they identify when using coagulation products. In theory this information also is supposed to go on yellow card to the MCA.. An important component of these adverse reactions is the incidence of inhibitors. However, it is likely that some of the reactions are not reported.

As regards the situation in Scotland, my understanding is that the Scottish Office have decided to make available funding in the current year because of the fundamentally different situation there. In Scotland, the Scottish National Blood Transfusion Service supplies plasma derived Factor VIII without charge. In consequence, health boards have been accustomed to paying nothing for Factor VIII.

Under current circumstances it is highly unlikely that the Department will agree to prescribing local purchasing decisions, or to central purchasing arrangements. The arguments for either ring-fenced funding, or for designating haemophilia care as a nationally commissioned service, are no more compelling than for any of a large number of other clinical services. I attach, for information, 2 recent letters from PS(H) to the Haemophilia Society.

Turning to your interesting paper, I have the following suggestions. I must stress that there are some aspects of the paper with which the Department does not agree, but I do not feel it appropriate to go into each and every detail. I have limited myself mainly to scientific facts of which you might be unaware.

Page 1, para 3 - both in the section on efficacy and safety, I think it is important to state that the Factor VIII products which you are discussing are those currently licensed in the UK.

In para 3, the 4 bullet points - could I suggest that in donor selection, risk factors for other infections are also identified. In between the testing of donors and viral inactivation, plasma pools are tested for HCV, HIV and hepatitis B both by the manufacturers and also independently by NIBSC.

Viral inactivation, currently is for non-enveloped viruses ie hepatitis C, HIV and hepatitis B, and the CPMP is asking manufacturers to develop methods which will also destroy non-enveloped viruses such as hepatitis A. Some manufacturers have already achieved this.

I think in the section about development of inhibitors, it is important to indicate how very expensive it is to eliminate inhibitors by immune tolerance techniques. The cost involved can quite easily reach £½m, since these protocols involve not only porcine Factor VIII, but also recombinant Factor VII, FEIBA, etc.

In the section on cost, I think it is important that the reader realises that prophylaxis is only recommended up to the age of 18-21. There is no suggestion that adults throughout their lives should remain on prophylaxis.

Page 2, para 4 - it may be worth reinforcing that it is the naive patients who are the most likely to develop inhibitors. This led one major Haemophilia Centre Director to suggest that perhaps the scientific way forward would be to give haemophiliacs plasma derived Factor VIII first of all until they had got over the risk period for inhibitors and then change them to recombinant, ie the exact opposite of the present proposals. There appears to be little, if any, evidence in support of the views of the UKHCDO on the matter of recombinant Factor VIII.

Para 8, you will see from my letter that the Scottish situation is not as simple as indicated in the first bullet point in this paragraph.

With best wishes.

Yours sincerely

GRO-C

Dr A Rejman MD FRCP FRCPath
Senior Medical Officer

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