

NORTHERN REGIONAL HAEMOPHILIA SERVICE

NEWCASTLE HAEMOPHILIA CENTRE

THE ROYAL VICTORIA INFIRMARY

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Ref: PJ/LM

18th March, 1985

IN CONFIDENCE

Mr. P. Hopley,
Pharmacy,
RVI.

Dear Peter,

Since you kindly gave me the information received from the 5 factor VIII importing commercial companies, I have discussed our requirements both within our own department and with other Reference Centre Directors in the United Kingdom.

Whilst pricing alone would appear to give Travenol a substantial advantage, especially if District bought 4 million units for the 12 month period, as we suspected the clinical position is very unclear. Overall, the best product presently available for clinical use is probably the Alpha one, Profilate. This is the only product in which heating of wet material occurs and preliminary results of a clinical trial being mounted by the company suggests that it is free of non A non B hepatitis, as well as AIDS. There is little to choose between the other 4 products, which all rely on dry heat. However, in the case of the Armour product, Factorate, there has been a recent outbreak of hepatitis B in Birmingham and two cases of hepatitis B have been confirmed at St. Thomas'. It is probable that their non-heat treated product is being recycled through Germany to avoid FDA regulations and that the heat treated material still contains hepatitis B.

The other product with which there have been problems is Hemofil from Travenol Laboratories. The Reference Centre Director at the Royal Free told me that he would not even consider using this product because the results of the recent trial of heat treated Hemofil in Europe showed an 80% hepatitis non A non B attack rate. The Director of the Treloar Centre confirmed worries about Hemofil saying that he had seen extremely high transaminase levels in two patients treated with Hemofil within the past few months. Like the other products, however, it is probably free of AIDS.

Given these opinions it would seem that the best option is to go for a proportion of the Travenol material but only for use in patients who have already had massive exposure to non A non B hepatitis, i.e. the older patients, and that we should use Alpha Profilate for patients without such exposure. The Armour product Factorate should only be used on patients who have a hepatitis B antibody.

We presently have 7 children on heat treated Koate and 8 on heat treated Profilate. Since heat treated material was introduced, these children have been on the single product and I would prefer to continue this policy so that we have at least some indication of how effective heat treatment is.

Cont'd . . .

In summary, I would not oppose District going for option B and obtaining 2 million units of Travenol Hemofil under the provisos which we have already discussed, i.e. ensuring that the product is available without delay and that pricing will be adhered to. The material we receive from Travenol will almost certainly be unscreened for HTLV III antibody in individual donations and as such will have been rejected by the West German market. Once this is taken up, Travenol are almost certain to go for price increase.)

I would prefer the remainder of our needs to be met from Alpha, Armour and Cutter Laboratories, given the provisos mentioned above. I can see no point in introducing Immuno as a fifth company.

Kindest regards,

Yours sincerely,

GRO-C

PETER JONES
Director

P.S. Travenol pricing for another Reference Centre buying 2.75 million units with discount for early payment is 10.4 pence per unit heat treated material.

cc- Mr. C. Spry
Professor M. Rawlins
Mr. A. Rich
Mr. B. Dowdeswell
Sister M. Fearn