Report to: **Campaign Group**

From: GRO-D

Re: **Pharmaceutical Companies & response to DOH announcement**

Date: **6 March, 1998**

The three suppliers of rFVIII are: Bayer, Centeon and Baxter. I have spoken to all three companies with regard to the response they have had from haemophilia centres, and their stock levels of recombinant. They have been trying to obtain extra stock from the US and Germany where their other offices are based.

The companies have been speaking to centre directors such as Dr Ludlam about how to approach the issue of supply. It would seem that at present there is not enough product available to give to all children under 16. It could take a couple of months to get all children on recombinant (this is not definite as there are no absolute figures on total no. of children already on recombinant and total no. of units in UK). It is in the companies interest to make it available a.s.a.p. However they are very wary of providing recombinant now, and finding they have not got enough supply in a couple of month's time thus forcing the individual to go back onto plasma derived.

They recognise that there will have to be an action plan produced by clinicians and suppliers. This will take the form of how much recombinant can be available in April, May, June and so on, whilst the clinicians will need to establish priority patients to be given rFVIII in the first phase.

One suggestion was to follow the approach of Denmark which put children on recombinant in 1996. It prioritised patients, but allowed some flexibility e.g. giving recombinant to siblings, and not just to one child.

BPL have written to the Society (see attached) outlining their plans to start using US blood products.

The UKHCDO are planning to meet shortly when they will discuss how to implement the new policy.

Other issues:

- possible stockpiling of rFVIII?
- where Health Authorities have decided to provide recombinant for all, should products be first diverted to children in other HA's?

BPL

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- 3 MAR 1998

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2 March, 1998

Joan Doyle
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Dear Joan

Maintaining our supply of fractionated plasma products whilst the nvCJD issue is being assessed.

Over the past few months there has been a good deal of attention focused on the subject of nvCJD. The uncertainty surrounding this disease has been a major cause of concern for haemophilia centres who are facing a dilemma regarding the use of UK fractionated blood products. Bio Products Laboratory (BPL) fully appreciates these concerns and knows that the welfare of patients is paramount, even though there is currently very little firm data on the risk posed by nvCJD.

BPL is therefore pleased to tell you that a decision has been taken by the Department of Health to allow us to commence the production of our fractionated products from imported US plasma. This measure is intended to ensure continued confidence amongst the medical community and the public whilst the theoretical risk of transmission of nvCJD through fractionated blood products is further investigated.

All of our current products will continue to be available for their licensed indications.

The production of US plasma-derived coagulation factors at the earliest possible date is an absolute priority for us and we will let clinicians and yourselves know when the new US-derived products will be available.

In the meantime, we will continue to be closely involved in the research into nvCJD and we will be monitoring new data closely. Equally, we will remain in regular contact with all medical and patient organisations that are affected by the nvCJD issue.

Yours sincerely,

GRO-C

Richard Walker
Chief Executive