



The Royal Victoria Infirmery & Associated Hospitals NHS Trust

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27 November 1997

DR RAL BREWIS
MEDICAL DIRECTOR
RVI

Dear Alistair,

re. **CJD and Blood Products**

I enclose facsimile transmissions from BPL about precautionary product recall.

I also include product recall from one of the commercial products Alphanine.

The front page tells you that as far as the BPL haemophilia product recalls are concerned the situation has not been discussed with patients who have received the batches and used them up.

The Alpha Therapeutic Product Recall was rather easy and we have in fact discussed the situation with all the patients affected.

There is a particular problem in haemophilia in that there is a choice between using Replenate, the British product which has been subject to recalls and Alphenate, a commercial product. Before Peter went away he was persuaded that because Alphenate undergoes two viral inactivation steps, solvent detergent and heat treatment, it probably was biologically plausible to think it was the safer product. It was also cheaper than the BPL product. For this reason he has suggested to the local haemophiliacs that it is perfectly reasonable that anyone who has been on Replenate before, changed to Alphenate. There are some patients who wish to remain on Replenate because that is the product they have always used, they are familiar with, and some patients believe that as it is a British product as opposed to a foreign product, it must be safer.

The UK Haemophilia Centre Directors have recently met. Unfortunately, I was unable to be at their meeting although invited last Thursday as I had a prior engagement. They have however produced a letter which I believe will be written to the Lancet or BMJ which I enclose.

On the second page, I have outlined a paragraph which suggests that products made in the United States are less likely than UK products to transmit new variant CJD.

As a result of that statement, Sister Fearn who has to deal with patients who are coming up and discussing the different products all the time, now finds herself in a dilemma. Should she be telling patients who wish to remain on Replenate that really it would be better if they changed to Alphenate? I can sympathise with her predicament. I have advised her to talk it over with the Royal College of Nursing.

There are many issues in all this. They need quite a lot of untangling and the need for logical thinking. It must be said however that patients are beginning to ask whether they are at risk of CJD from ordinary blood transfusions and I think it is very difficult for us as haematologists to advise them. Both Dr Reid and I have discussed this and we feel that the important situation is that we have to weigh up the importance of having a blood transfusion against the minimal risk of having CJD and that the patient themselves is at liberty after hearing this to make an informed choice and refuse blood transfusion if they so wish.

Unfortunately, in many cases the benefits of having a blood transfusion are not quite so black and white as many would have us believe.

I do not believe that these are questions that can be thrashed out by anyone other than patients and doctors and although one can be led by ethical committees and government committees, I find that the advice from the Lothian Ethical Committee enclosed in the Precautionary Product Recall of 30.10.97 issued by BPL is probably unacceptable.

Yours sincerely,

Dr Peter J Hamilton
Consultant Haematologist

cc Sister M Fearn