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CAL/MJ

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Dr J S Metters
Deputy Chief Medical Officer
Department of Health
Richmond House
79 Whitehall
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Dear Dr Metters

I am replying to your letter of 15th December 1994, which was a reply to my original letter of 18th November 1994. I enclose copies of both of those letters, as I am aware that this is some time ago. The reason I have taken some time to respond to you, was that I was awaiting the publication in the Lancet, which no doubt you have seen, about a case of life-threatening human parvovirus B19 infection in an immunocompetent adult patient with haemophilia. Clearly the significance of this publication is that plasma derived products continue to transmit viruses and we can never be certain that there may be as yet, undiscovered viruses in addition. I think this publication is also very important in that the people who are most at risk from parvovirus infection will of course, be children.

In your letter, you state that you had received advice that suggests that "there is no evidence that recombinant factor VIII is any safer than plasma derived factor VIII at the present time". I would dispute this, even with the fact that the presently licensed recombinant factor VIII contains albumin as a stabiliser - the amount of albumin that has been used globally is sufficient for us to know that this does not transmit viruses. However with plasma derived concentrates, we are continuing to have evidence of firstly hepatitis A transmission and more recently, a number of reports about parvovirus transmission. Parvovirus is resistant to not only solvent detergent sterilisation but also heating. For patients who have never received plasma derived products in the past, which will inevitably be the majority of newly diagnosed children, there are now compelling reasons to treat these individuals with recombinant factor VIII and soon, recombinant factor IX.

Again in your letter of 15th December you say that " I also understand the recombinant products themselves are not without side-effects". You do not expand on this statement but I suspect you are referring to the fact that inhibitor production has occurred with these products. There are now a number of studies published in the literature discussing both retrospective and prospective incidence and prevalence of inhibitors in haemophilia. The present published data shows that this is a problem both with plasma derived products and recombinant products.

You then go on to discuss the importance of purchasers buying healthcare which is "value for money". At the present time, patients with haemophilia are litigating for previous hepatitis C infection which was transmitted by concentrates. In this case, that treatment was given before 1986 and it was the best care available at that time. In 1995, in my view, the best care available to treat patients for the first time with concentrate is recombinant factor VIII (or factor IX, when that is available).

Since the major argument from your letter is one of the economics of using recombinant factor VIII versus plasma derived concentrate, perhaps the cost of potential litigation by patients should enter the equation. For clinical and scientific reasons, there is no doubt in my own mind and that of many of my fellow treaters that we should at lest be offering recombinant factor VIII to children under the age of 10 and previously untreated adult patients with haemophilia.

Yours sincerely

GRO-C

Christine A Lee

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