

JDC/EP/MM

1st July 1986

Dr F E Boulton
Deputy Director
Edinburgh & South East Scotland
Blood Transfusion Service
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Dear Frank

Re: "Trials" of Factor VIII Products

Many thanks for your letter of the 27th June 1986.

Some points arise:

1. You may remember we (you and I) produced a detailed protocol for studying NANB in virgin haemophiliacs. Please feel free to discuss this with Eric Preston. I'd welcome any further thoughts with regard to "what is a virgin". If practicable I would favour Eric's puritanical approach.
2. You may be under some misunderstanding with regard to the type of studies we require. I can best emphasise the point by stating that we have already agreed that until such times as we have a product which is to be the definitive product for at least 5 years we won't consider further the awesome task of a NANB study on virgin haemophiliacs. In the meantime we will require to consider $\frac{1}{2}$ life and in vivo recovery studies (on small numbers of non-virgin patients) in order to get us nearer to producing a definitive product. This latter feature is all we require to do at the present time.

I hope this clarifies the position.

Kindest regards.

Yours sincerely

John D Cash

no copy to Eric