

THE ROYAL INFIRMARY OF EDINBURGH

HAEMATOLOGY DEPARTMENT

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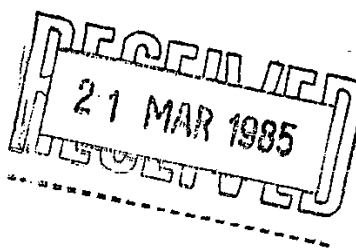
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Your Ref.:
 Our Ref.: CAL/PMS

19th March, 1985

Dr. F.E. Boulton,
 Blood Transfusion
 Service,
 Royal Infirmary,
 Edinburgh.



Dear Frank,

Thank you for your letter of 15th March letting me know that you have received two further batches of heat treated factor VIII for clinical evaluation.

As you will no doubt have heard we discussed at some length the testing of new blood products at the Haemophilia/BTS Directors Meeting at St. Andrews House recently. As you know one of my patients had a reaction to a previous batch we were invited to test and I am therefore a little more apprehensive about testing further batches. Clearly these require urgent clinical evaluation. Although I raised the question of compensation for individuals who suffer materially as a result of testing new products at St. Andrew's House some time ago, there has been little progress. The commitment of either the CSA or Scottish Home and Health to give reasonable compensation has not been demonstrated to my satisfaction. I am reasonably conversant with the principle reason why this is difficult to achieve.

Before infusing the present factor VIII that is available for trial I shall have to apply to the Area Ethical Committee. In order to do so, and for my own information, I should be grateful if you could send me a full description of the product. Although it is not obligatory by law to submit such protocols to the Ethical Committee, in the circumstances I must do this. If I could be assured that there was a reasonable system for compensating patients, then I might be prepared to not seek ethical approval. I am afraid the acquisition of this proposal is going to take some time.

Although I gave an undertaking at St. Andrews House to test this current batch of factor VIII I am becoming increasingly apprehensive about testing further batches without adequate arrangements for compensation.

Yours sincerely,

ml

C.A. Ludlam
 Consultant Haematologist

c.c. Dr. J.D. Cash, Dr. R. Perry