THE ROYAL INFIRMARY OF EDINBURGH

604 56
16.3.87

HAEMATOLOGY DEPARTMENT

DR. A. C. PARKER (Ext. [redacted]
DR. C. A. LUDLAM (Ext. [redacted]

Senior Chief M.L.S.O.
MR. P. F. J. NEWMAN (Ext. [redacted]

LAURISTON PLACE
EDINBURGH EH3 9YW

Telephone: [redacted]

Your Ref.:
Our Ref.: CAL/PMS

12th March, 1987

Dr. J.M. Forrester,
Scottish Home and Health Dept.,
St. Andrews House,
EDINBURGH.

Dear John,

SNBTS/Haemophilia Directors Meeting Monday, 9th February, 1987

Thank you for the draft Minutes of the above meeting.

Under item 3 sub section (d), it was my clear understanding that the ABPI guidelines arrangement would apply to all clinical trial infusions. The initial infusions given of any product are to ensure that there are no major side effects and the factor VIII response is reasonable. The second part of the clinical trial involves giving the new product to many patients therapeutically to ensure that it is effective. As you know it is not possible to get a product licence without such clinical data.

These two phases of the clinical trial must be covered by the Department's commitment and several members of the Committee were of this view at the meeting. Mr. Murray gave this undertaking. I should be grateful if you could clarify this matter as it will be difficult to use the material therapeutically without this undertaking.

I am pleased to report that we have started the trial infusions of the new heat treated (80°C) material.

With best wishes,
Yours sincerely,

C.A.Ludlam
Consultant Haematologist