THE ROYAL INFIRMARY OF EDINBURGH

HAEMATOLOGY DEPARTMENT

DR. A. C. PARKER (Ext. GRO-C)
DR. C. A. LUDLAM (Ext. GRO-C)

Senior Chief M.L.S.O.
MR. P. F. J. NEWMAN (Ext. GRO-C)

LAURISTON PLACE
EDINBURGH EH3 9YW

Telephone: 031-229 2477

Your Ref.:
Our Ref. CAL/PMS

6th July, 1987

Dr. A.D. MacIntyre,
Scottish Home and Health Dept.,
St. Andrews House,
Edinburgh.

Dear Dr. MacIntyre,

I have received your letter of 30th June.

The document that was sent to you was a draft that I let Dr. F.E. Boulton see on an informal basis. Prior to Dr. Cash's letter and yours, I made a number of modifications and in particular deleted the commitment to provide commercial factor VIII. Although this is an option that I must retain I have not made this explicit. You will know that I am and always have been, deeply commited to the use of NHS products.

I enclose a revised copy of my document which I propose to give to patients. I cannot agree with your view that it will cause alarm. Disquiet and suspicion arise when patients feel they are not being fully informed. As I am sure you will be aware haemophiliacs are very well informed about the disorder and the complications of therapy.

I am being asked to assess the clinical efficacy of the new PFC factor VIII concentrate. As none of these therapeutic materials have Product Licences I ask you to acquire an appropriate Clinical Trial Certificate for the present factor VIII concentrate. I am led to believe that for me to be administering such a concentrate may well be illegal under the Medicines Act(1968)

I must ask the Department to reconsider its decision not to offer ABPI Guideline cover for patients participating in what I believe is a Phase II clinical trial. I fail to see why my patients should receive less cover than that offered by the commercial pharmaceutical industry.

Please will you confirm that the Department will be accepting product liability as defined in the Bill currently before Parliament, for all therapeutic materials manufactured by PFC.

Yours sincerely,

GRO-C

C.A.Ludlam
Director, Haemophilia Centre

c.c. Medical Defence Union, London