THE ROYAL INFIRMARY OF EDINBURGH

HAEMATOLOGY DEPARTMENT

DR. A. C. PARKER (Ext. 2079)
DR. C. A. LUDLAM (Ext. 2099)

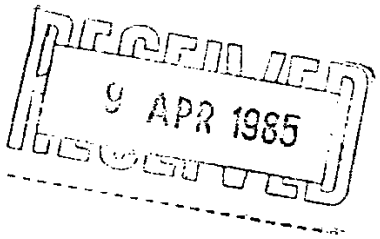
Senior Chief M.L.S.O.
MR. P. F. J. NEWMAN (Ext. 2768)

LAURISTON PLACE
EDINBURGH EH3 9YW

Telephone: 031-229 2477

Your Ref.:
Our Ref.: CAL/PMS

4th April, 1985



Dr. J.D. Cash,
SCottish National Blood
Transfusion Service,
Headquarters Unit,
Ellen's Glen Road,
Edinburgh.

Dear John,

Heat Treated Factor VIII

I write in reply to your letter of 22nd March. A number of issues have been raised both at our meeting at St. Andrew's House, in your letter, and in the letter you wrote on 11th March to Dr. Mutch. You imply that I have gone back on my undertaking at St. Andrew's House to test the next batch of heat treated factor VIII. This is not correct, and obviously there has been a misunderstanding.

In the past I have always received full details as to how the new factor VIII product was produced and the nature of the additives. I was asked by Dr. Boulton merely to test some vials of factor VIII that had been received from PFC without any details as to how the material had been produced. I think you would agree that the previous practice was reasonable and that I would be failing in my duty to the volunteers if I did not satisfy myself that the products were likely to be safe. You may not be aware, but ethical approval has been obtained for all previous infusions, and I am therefore merely continuing the previous practice. I hope you will agree therefore that there has been no change in my commitment to testing the latest factor VIII product.

As I indicated at St. Andrew's House, I am very unhappy about the lack of arrangements to compensate patients who materially suffer as a result of testing blood products. I was most interested in your letter to Mr. Mutch which raised a number of important issues. Firstly, I was unaware that arrangements had been made to compensate blood donors involved in the anti-D immunisation protocol and those undergoing aphersis. In the letter to Mr. Mutch you mentioned that you enclosed relevant SHHD documents about this; I wonder if it would be possible for

4th April, 1985

me to have a copy of these. As you yourself said at St. Andrew's House tribunals to decide upon levels of compensation are heavily weighted against the claimant and I should be interested to know how the amount of compensation is decided. I raised this issue of compensation a long time ago at the Department and they have therefore been aware of my concern. I have no doubt whatsoever of the commitment of the SNBTS but that of the Department has still to be demonstrated to me. I have not perceived any change in their position or enthusiasm to take up this issue since I first raised it.

The letter you have written to Mr. Mutch is in terms of the recipient of blood products and the SNBTS. There is no mentionof the clinician who is not only responsible for the long term management of the haemophiliacs but who would also be responsible for infusing the products under trial.

So far as the protocol for testing the factor VIII products is concerned, I did not wish to take up time at the meeting at St. Andrew's House. The proforma included in the most stimulating and useful document you produced for the meeting, was in fact devised by Frank Boulton without reference to me. As you will have gathered at the meeting I felt it was rather over elaborate.

I am very anxious to see the co-operation that, in my view, has been built up in the last few years between our department and the SNBTS continue to flourish. As you know I have been most appreciative of the support that I have received from your organisation since returning to Edinburgh. My commitment has inno way lessened. As soon as I receive details of the present factor VIII product that requires testing I shall be delighted to arrange this. So far as the future is concerned I shall be looking for a concrete guarantee from the Department for my patients.

Yours sincerely,

C.A.Ludlam
Consultant Haematologist