

THE ROYAL INFIRMARY OF EDINBURGH

HAEMATOLOGY DEPARTMENT

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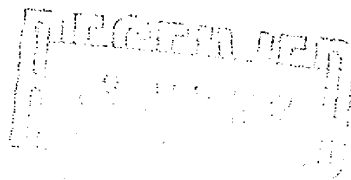
Telephone: 031-229 2477

Your Ref.:

Our Ref.: CAL/PMS

9th January, 1987

Dr. J.D. Cash,
 Scottish National Blood Transfusion
 Service,
 Headquarters,
 Ellen's Glen Road,
 EDINBURGH.



Dear John,

Assessment of new NHS Blood Products

Thank you for your letter 7th January.

Given written SHHD assurance that appropriate compensation will be available to patients/relatives in the context of clinical assessment of Z8, then I would respond to your questions as follows.

- (a) I would be happy to organise immediately the appropriate infusion studies. Dr. Forrester telephoned me a couple of days ago about this point and I said that if he could give me a date when he might expect an appropriate letter from the Department, I would be happy to organise appropriate volunteers in anticipation. We could thus ensure that not a day is lost. I am prepared to act very quickly particularly as my decision has embarrassed PFC plans.
- (b) I assume that once you are satisfied with the results of the infusion data Z8 would then be available on a "named patient basis" until a product licence were available. Under these circumstances I believe that I might be liable if any patient were to experience an adverse reaction. This raises the same question of product liability as giving the test doses to assess survival etc. In this event I would ask that the Department extends its indemnity until a product licence is obtained.
- (c) I would be very reluctant to purchase commercial factor VIII and would prefer old intermediate (NY) factor VIII. I do not underestimate the difficulty of PFC undertaking this particularly as to have stocks ready for February it will be necessary to start production presumably now.

SHHD

I gather from Dr. Forrester that the Department hopes to be able to issue appropriate reassurance in the near future. I am most grateful to you for

2.

9th January, 1987

your general support of my concern but I do apologise for the extra worry and time it is causing both you and PFC.

With best wishes,
Yours sincerely,



C.A.Ludlam
Consultant Haematologist