THE ROYAL INFIRMARY OF EDINBURGH

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Your Ref.:
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21st April, 1988

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

Dear Dr. Forrester,

Haemophilia/SNBTS Directors Meeting, 5th May

I write to bring to your attention some issues that should perhaps be considered at our meeting on 5th May.

1. I understand that the Department may be prepared to accept liability for factor VIII concentrates under ABPI Guideline cover until a product licence is obtained. In the event of a mishap, and in appropriate circumstances, three assessors may be appointed. I believe it has been suggested that these should be.

   1. the legal adviser CSA
   2. Regional Transfusion Director
   3. A CAMO (or nominee)

   Whilst I welcome this development, I am concerned that two of the assessors are employees of the manufacturer. I would like to suggest that other individuals should be considered. If the panel is to consist of individuals with specialist experience, it might seem appropriate to have a Haemophilia Director as a member.

2. As you know there have been discussions about the legal basis under which products are being issued for the treatment of patients with congenital disorders. I should be grateful if you could clarify the position for products issued since 1983 (particularly as these now form the basis of a legal action)

3. I am concerned about future arrangements for the testing of coagulation factor concentrates produced by PFC. The potential difficulties are exemplified by Z8 and testing it for viral safety. It is likely that the present trial of 8Y which is just starting will be completed within a year. Our difficulty in Scotland will be to find sufficient previously untreated patients in which to assess this product. I should welcome a discussion as to how this could be overcome.

I thought it would be useful to you and your colleagues if you had an opportunity to consider these matters prior to our next meeting.

Yours sincerely,

GRO-C

C.A.Ludlam, Director, Haemophilia Centre