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THE ROYAL INFIRMARY OF EDINBURGH

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CONFIDENTIAL

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Action
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Dr. F.E. Boulton,
B.T.S.
RIE

Dear Frank,

I am led to believe that the issue of Z8 to patients has begun. I was aware that the standard product was running short and that we had agreed to discuss the further evaluation of the new material but I was under the impression that there were several weeks' supply left. I do not recall that I agreed that patients should be treated with this material. So far as I am aware it does not have a Product Licence from the CSM nor a Clinical Trials Exemption Certificate. I am unclear on what legal basis it is being issued and who is responsible for any adverse side effects. As you will be aware much greater responsibility in these circumstances lies with the clinician who uses the product. Whilst it might be difficult, but not impossible, for a patient to prove negligence, I am very keen that if individuals suffer as a result of treatment they receive appropriate "compensation" I believe you support this view. You will recall at the meeting at St. Andrews House on 9th Feburary we discussed the issue of compensation. Mr. Macniven gave an undertaking that ABPI Guidelines would apply not only to the half-life infusions, but to all test infusions to assess the clinical efficacy, sufficient to gain a Product Licence. The draft Minutes of the Meeting are not a true record of the discussion.

As you know one patient who received Z8 developed central chest tightness (as described in the BBTS abstract) and I am naturally very worried that this material has been issued without any agreed monitoring arrangements.

I am now faced with a fait accomplis over Z8. This has comprised my position and reduced the clinical options open to me; ie either to accept the situation and hope for the best or to go over to the purchase of commercial factor VIII.

Yours sincerely,

CAL

C.A.Ludlam
Consultant Haematologist

c.c. Dr. D.B.L. McClelland