Our Ref: DH/GC 26th November 1982

Mr. D. E. Seymour,

GRO-C

Dear Don,

At your suggestion I have at last spoken with Dr. Keith Fowler.

Being as diplomatic as possible, I gave him an outline of the repercussions resulting from his conversations with Paul Joachim and yourself. To put it mildly he was amazed. He said that he felt we were vastly over reacting. He gave me permission to quote his view that 'in no way has Speywood jeopardised its chances of getting a licence for Hyate:C or Mono VIII:C'. In fact since speaking to you he has received a report from the 'blood products' inspector, Mr. Haythornthwaite, which commented that 'Speywood have probably the best unit in the country'.

All in all I consider that most of his comments to you were out of place. He had no knowledge of our Q.A. standards, since they have not been inspected, either officially or unofficially, nor had he any reason to say our clinical trials were anecdotal - he has not yet seen them. In fact they were designed by the U.K. inhibitor working party.

He concluded our conversation by assuring me that the Mono VIII:C application, which was on his desk, would go on the 'fast track' as soon as the Alpha cryo application was received. However, he also added that we were doing entirely the right thing to go for a full Product Licence for Hyate:C.

On reflection I think it was entirely wrong of me to condone Paul's request to speak to the D.H.S.S.. I feel that the Medicines Inspectorate in particular are anxious to be truly independent of any outside pressures either governmental or businesswise. If anything Speywood will get a hard ride because the B.T.G. owns 25% equity.

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Mr. D. E. Seymour 26th November 1982

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Hopefully, at the next Board Meeting, we shall be able to demonstrate that management is taking the necessary steps to ensure that Speywood has the best possible regulatory team that can be afforded.

Yours sincerely,

David Heath