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*File BUK/2
 BLK/1*

Your reference:
 Our reference:

2658

Dr H H Gunson
 Regional Transfusion Centre
 Roby Street
 MANCHESTER
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1 July 1983

Dear Harold

Thank you for your letter of 29 June, enclosing the letter from Mr O'Sullivan of Trevenol.

I, too, have been told that three chimpanzees which received the Hyland heat-treated Factor VIII had developed hepatitis. This is the sort of information that the Licensing Authority will obviously need when considering applications for product licenses for heat-treated concentrates.

I am not expecting to be at the CSM meeting on 13 July. Obviously, the possible cost implications of the introduction of heat-treated Factor VIII into this country will not be material to the Committee's deliberations, which one would expect to be confined to matters relating to the quality, safety and efficacy of heat-treated Factor VIII and other coagulation concentrates. However, your comments about the potentially major financial consequences for health authorities, in the event of unjustified demands for this material being made, could be used to support the argument for the need for properly controlled clinical trials before such material is introduced into this country.

I shall copy your letter to Dr Keith Fowler, for his information.

With best wishes.

Yours sincerely

Diana

DIANA WALFORD

cc Mr Winstanley