THE HAEMOPHILIA SOCIETY

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Mr John Horam MP
Department of Health
Parliamentary Under Secretary
Richmond House
79 Whitehall
London
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Dear Mr. Horam,

Re: UKHCDO Guidelines and the use of Recombinant Factor VIII

The Society has become increasingly concerned that the Department of Health has perhaps unwittingly played a role in undermining the UK Haemophilia Centre Directors' Organisation's (UKHCDO) Guidelines on therapeutic products to treat haemophilia and other hereditary coagulation disorders. It would appear that a number of Health Authorities have been influenced by the Department of Health in making a decision not to fund the use of recombinant factor VIII for children with haemophilia A.

In your letter dated 12 November 1996 you state that on the basis of the two early drafts of the UKHCDO Guidelines the Department does not consider that the case for recommending the general use of recombinant factor VIII has been made. Your letter goes on to state that you understand that recombinant products are not themselves without side effects. I understand that the Department has in its correspondence to Health Authorities also claimed that there is an increased risk of inhibitors. Could you please provide the evidence to support these claims as these issues are of great importance to our members.

The UKHCDO is the expert professional body in the field of haemophilia care; their guidelines were well researched by a small working party and after widespread consultation, unanimously endorsed at their AGM. We understand that they have also been endorsed by the Royal College of Physicians, the Royal college of Pathologists and the British Society for Haematology. The Society is therefore surprised to see the Department challenging these Guidelines. We would very much like to see the Department's evidence for doing this and would like the UKHCDO to have the opportunity of responding to any new evidence the Department may have.

The Society is concerned that the letter sent by Dr Graham Winyard to Directors of Public Health on 11 October gave the impression that the Department actively opposed the guidelines rather than, as we assume, that it merely wished to make clear that it had not formerly approved the guidelines as an early draft appeared to suggest.

Dr Winyard's letter also contained the following statement which we believe to be misleading:-
"bearing in mind the good safety record of products derived from human plasma".

While there may have been no recorded cases of HIV or HCV infection since 1986 in the UK, the haemophilia community has twice been devastated by infections from plasma derived products prior to this date. As long as plasma derived products are used the risk of blood borne viral infections remains. The risk of infection from as yet unknown viruses is a major worry; history has surely shown us that it would be wrong to assume that there

will be no more blood borne viruses. This is why the haemophilia community is so strongly in favour of recombinant products.

The Society believes the letter from Dr Winyard is misleading because it gives a false sense of safety. Unfortunately some Health Authorities have used this statement as a justification for not funding recombinant factor VIII. The Society would like to see Dr Winyard's letter withdrawn and the guidelines of the UKHCDO promoted as good practice.

I look forward to hearing from you.

Yours sincerely,

GRO-C

The Rev. Prebendary A.J. Tanner
Chairman of the Haemophilia Society