NORTHERN REGIONAL HAEMOPHILIA SERVICE
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Ref: PJ/LM

22nd November, 1984

Mr. B. Dowdeswell,
Administration Department,
RVI.

Dear Barry,

Heat Treated Factor VIII

I have received a copy of Peter Hopley's letter to you of 21st November. A number of points:

1. I have no option but to prescribe heat treated factor VIII and the Haemophilia Society Executive for our region have been told that.

2. The suggestion from one supplier that they would not be prepared to give us credit for existing stock of non heat treated material is totally unacceptable. If they persist in this attitude I have no doubt at all that I can persuade them by fair means or foul to change their minds very rapidly.

3. I quite understand the difficulty that you have in equating finances between District and Region. I have already spoken to Dr. Sackwood and will do so again today. As you know I have been working closely with Mrs. Saunders and our estimate for changeover of existing stocks of around £20,000 is based on the average price that she was quoted last Friday by the three firms who we are presently trading with, against the present cost of 9p a unit for non heat treated material. Mrs. Saunders has done a great job already because the week before we were being quoted 20p a unit for the heat treated material.

   One very important point. I have made the decision to change to heat treated material not because of the announcement of the death of our patient on 2nd November in Scotland, but because of the following recommendations by our American colleagues within the last month. In the light of these recommendations the death of our patient from AIDS has simply accelerated the necessity to reassure other patients and their families as positively as we can.

   Statement from Centers for Disease Control contained in the Morbidity and Mortality Weekly Report 26th October 1984

   The sera of 22 (42%) of the 52 hemophilia associated AIDS patients have been tested for antibody to antigens of the AIDS virus using Western blot analysis. Eighteen (82%) of these specimens contained antibody to one or more antigens. In co-operation ith numerous hemophilia treatment centers and physicians, CDC has studies over 200 recipients of factor VIII and 36 recipients of factor IX concentrates containing materials from US donors. Rates of AIDS virus antibody prevalence were 74% for factor VIII

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recipients and 39% for factor IX recipients. Only prospective evaluation will determine what risk of AIDS exists for seripositive individuals. A recently published study evaluated the thermostability of murine retroviruses inocculated into factor concentrates, using a cell transformation assay. After 48 hours at 68°C (154.4°F) viral titers dropped from 10^8 to two infectious particles/ml. In studies done at CDC, in co operation with Cutter Laboratories, AIDS virus was added to factor VIII concentrate (virus titer 10^5) and the factor was lyophilised and heated to 68°C (154.4°F). The residual virus titer was determined by an infectivity assay. Virus was undetectable after 24 hours of heat treatment, the shortest time period examined.

The preliminary evidence concerning the effects of heat treatment on the viability of the AIDS virus is strongly supportive of the usefulness of heat treatment in reducing the potential for transmission of the AIDS virus in factor concentrate products and suggest that the use of non heat treated factor concentrates should be limited. CDC and NHF will continue to study the effects of heat treated factor on the immune status of patients with hemophilia.

Statement by the National Hemophilia Foundation Medical and Scientific Advisory Committee 13th October 1984 Bulletin

Because heat treated products appear to have no increase in untoward effects attributable to the heat treatment, we now recommend that treaters using coagulation factor concentrates should strongly consider changing to heat treated products with the understanding that the protection against AIDS is yet to be proven. We again urge a prospective national study of the use of these and other materials in patients not previously exposed to pooled blood products. In addition, further basic studies on the efficacy of viral attenuation procedures are urged. The Medical and Scientific Advisory Council will continue to review its position on heat treated products as more complete studies become available.

We will of course continue to do everything we can to keep costs down but in the absence of response from Elstree until they can get heat treated material on line in April of next year we have no alternative. Indeed, we might face pressure from some patients not to use the National Health Service product at all. Preliminary and obviously highly confidential work has shown sero conversion in haemophiliacs who have received non heat treated National Health Service factor VIII concentrate prepared from our volunteer donor pools.

Finally there are articles in Nature Today updating our knowledge of genetically engineered factor VIII. I have already indicated that this is likely to be at least four times as expensive as the presently available material but of course it should be much safer. The timing for its introduction is said to be around 5 years.

Thank you for your help.

Yours sincerely,

GRO-C

PETER JONES
Director

cc. Mr P Hopley
Dr. M. Sackwood
Mrs. A. Saunders
Sister M. Fearns