

NORTHERN REGIONAL HAEMOPHILIA SERVICE

NEWCASTLE HAEMOPHILIA CENTRE

THE ROYAL VICTORIA INFIRMARY

QUEEN VICTORIA ROAD, NEWCASTLE UPON TYNE, NE1 4LP

TELEPHONE

NEWCASTLE 325131, Ext. GRO-

STD. GRO-C

Ref: PJ/MB

18 February 1986

The Medical Assessor
The Committee on Safety of Medicines
Market Towers
1 Nine Elms Lane
LONDON
SW8 5NQ

Dear Sir

AIDS, heat treatment of clotting factor concentrates and haemophilia

I enclose information I have that suggests HTLV III seroconversion in previously seronegative haemophiliacs being infused with some types of factor VIII concentrate, especially that heat treated in the dry state for less than three days. I do realise that the evidence is only suggestive, but I thought it sufficiently worrying to mention the possibility that we were not out of the woods yet in my paper to the AIDS Conference. A copy of this is enclosed, together with a covering letter written to Haemophilia Centre Directors.

In this Centre, in addition to available NHS concentrate which is at least heated for 72 hours, we have changed our patients to the Alpha material because of a report to me by Dr Koerper that it was free of virus, after testing by Dr Levy in San Francisco. It is my personal opinion that, unless there is irrefutable evidence to the contrary, the Armour material should be withheld until its safety can be endorsed by the C.S.M.

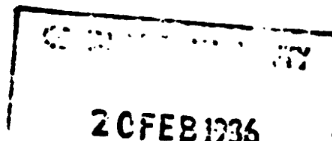
Yours faithfully

GRO-C

PETER JONES MD FRCP DCH
Director

cc Dr J Smith
Director, P.H.L.S.

Dr A Smithies
DHSS



Evidence about seropositivity following heat treated factor concentrates

Product

Source of information

Adult haemophiliac followed for almost a year on HT material, heterosexual, no other risk factors, repeatedly tested after being seronegative

Armour

Dr. Breederveld, University of Amsterdam. Permission to quote given February 1986

3 haemophiliacs all reported to CDC who appear to "probably" fulfil criteria for seroconversion in one case and "possibly" fulfil criteria in 2 cases.

Not Known

Dr. Levine. Permission to quote given February 1986

Virus detected in material subjected to heating for less than 34 hours. One product said to cause seroconversion.

Armour

Dr. Koerper, University of California, San Francisco, also quoting work of Dr. Levy, December 1985

haemophiliac without other risk factors treated at Chapel Hill and reported as seroconversion after HT material.

Hyland

Reported to Professor Manucci, February, 1986

Seroconversions in the FDR were also reported to a meeting of the Haemophilia Society in November 1985.

David Watters, co-ordinator Haemophilia Society, London February 1986