

Reference

cc Mr Hale
Mr Hagger
Mr Grimsman

Dr Jones
1628 MT

AIDS AND HEAT TREATED FACTOR VIII

You will wish to see this letter we have just received from Peter Jones in which he is suggesting that we take action against the Armour material. The current situation in relation to possible transmission of HT LV-III virus by heat treated Factor VIII products is under further investigation by Dr Rotblat. She will be in communication with individual physicians as well as the American and Dutch regulatory authorities to determine the details of individual cases and in addition we have a meeting with Armour at their request, scheduled for Monday, March 3. Following this meeting, and in the light of all the information available at that point, Dr Rotblat will prepare a tabled paper for Biologicals Sub-committee so that CSM can be considered to have had an early look at the situation. This paper, together with associated papers, documenting the position in regard to the safety of immunoglobulins and heat treated Factor VIII generally can also be submitted to the next meeting of the Expert Advisory Group on AIDS.

GRO-C

26 February 1986

DR A J ISAACS

1602 MT

GRO-C

cc Dr Harris D803 AFH (with enclosures)
Dr Rotblat 1511 MT (minute only)

ENCs

GRO-C

Mr Emberson

Mr Fowler

To see if for a file
on Factor VIII

GRO-C

Also p5 paper* a MF file

NORTHERN REGIONAL HAEMOPHILIA SERVICE

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THE ROYAL VICTORIA INFIRMARY

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STD

GRO-C

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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

20 FEB 1986

Evidence about seropositivity
following heat treated factor
concentrates

Product

Source of
Information

Adult haemophilic 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. This
product said to cause seroconversion.

Armour

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

Haemophilic 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