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Health Care Limited

To: Mr. L. S. Lucas
From: C. R. Bishop
Subject: N.H.F. MEDICAL COUNCIL -
"SERO-CONVERSION REVIEW"

Date: 19th June 1986

Ref: CRB/PH

Copies to:

(Data also dictated to M. Samuelsson for discussion with Prof. I. Neilson 20.6.86 omitting Case 3 details).

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In preparation for the above I detail below a resume of the data which was the subject of our discussion with Dr. Margaret Hilgartner and Lou Aledort in Milan.

Introduction

The suggested implication of Armour heat-treated FACTORATE in HTLVIII Ab. sero-conversion is based on 3 cases all of whom received prior treatment with non-heat-treated products.

Case 1 - Lancet: April 5, 1986 p803 - W. Van Den Berg et al.
(see Technical Bulletin - R. B. Christie - 7.4.86)
Amsterdam

- No records since before January 1984.
- Single male, age 27, with non-married heterosexual relationship living in Amsterdam.
- Received product from 'AIDS' donor.
- No viral growth from patient serum cultures.
- Possible other risk factor unidentified or immune response to inactive virus or viral fragments.

Case 2 - Lancet: March 15, 1986 p612 - G. C. White et al.
Chapel Hill

- Known i.v. drug abuser, last located in Mexico City.
- No follow up.
- No viral growth from patient's serum cultures.
- Possible conversion due to i.v. drug abuse.

Inter-office memorandum

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Case 3 - Unpublished and classified personal communications.
Lewisham

- 'Recluse' male - tests not confirmed by Western Blot.
- Received product from 'AIDS' donor.
- Possible other risk factor or product as yet unidentified or "immune response provoked by inactive virus or viral fragments" (G. White et al.).

The 'defence' against FACTORATE should take into consideration the following factors:

a) In Vitro

- Many investigators including J. S. McDougal et al., Jnl Clin. Invest., Vol. 76, Aug 85, p875-877, confirm 60°C at 30 hours in dry state results in undetectable levels of virus.
- This is in line with Meloy Labs - internal memo 3.12.85 - which shows Armour process to inactivate >5.5 logs of HTLVIII.
- and Poster no. 387 (p220 of Abstracts) A. Werner et al. - XVII W.F.H. Congress June 1986, which demonstrates undetectable levels at 60°C for 20 hours Dry.
- AIDS Donor batches re-checked and no viral growth achieved or Ab. detected in any batch.

b) In Vivo

- Felding P, Nilsson I.M., Hansson B.G. - Lancet 1985, ii:832
No sero-conversion in 46 sero-negatives in the short term follow up.
- Preston E. et al. - Lancet July 27th, 1985
No sero-conversion in 2 "clean virgin" treated with Armour FACTORATE HT exclusively > 12 months ago.
- Personal communication - Pettigrew A., Ryl Infirmery, Glasgow - 1986
No sero-conversion in 1 "clean virgin" treated exclusively with Armour HT > 12 months ago.
- Personal communication - Smit Sbinga C., Groningen (BSH Congress, England) 1985
Confirmed XVII W.F.H. Congress, Milan. No sero-conversion in 15 sero-negatives treated exclusively with Armour HT > 12 months ago.
- Maggs - University College London
No sero-conversion in 1 "clean virgin" treated with the same AIDS donor batch as in Case 3 above > 12 months ago.
- Kernoff P., Royal Free Hospital, London
No reported sero-conversion in 1 "clean virgin" treated with Alpha Profilate HT and switched to Armour HT > 12 months ago.
- Amsterdam
No other reported cases of sero-conversion in sero-negative patients treated with the same batches as Case 1 even AIDS donor HT batches.

- Bradford, Birmingham, Leeds, Hammersmith, Gt. Ormond Street, St. Georges, London, Liverpool, Royal Infirmary, etc.

No reports from the above almost exclusively on Armour or other U.K. centres of sero-negative conversions since U.K. introductions of HT product in November/December 1984. (Armour U.K. market share 40-50% 1984/85) incl HT batches from known AIDS donor.

Summary

a) The in vitro and in vivo evidence on both intensively infused and "clean virgin" patients (even on those known to have received 'AIDS donor' material) points to either:-

- i) an immune response to inactive virus or viral fragments
- or ii) other as yet confirmed 'risk factors' (one was an i.v. drug abuser) in the 2 cases quoted in the literature.

In addition no sero-conversion on any other "clean virgin" not otherwise at risk for AIDS has been reported and live virus has never been isolated from Armour's heat treated FACTORATE.

The above is subject to final ratification and update of personal communications.

GRO-C