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Haem AIDS C'lee

CONFIDENTIAL

ALB/PR

21st December 1987

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Dear Christopher,

You will probably have heard rumours concerning seroconversions to HIV in 'niaive' haemophialiacs in North America who have been treated with heat-treated Factor VIII.

I have recently had a long telephone call from Dr Dale Lawrence of CDC which has added some further information. Dr. Lawrence gave me permission to share this information with my colleagues. Rather than telephone each of you separately and after calling Charles Rizza, I can summarise the information as follows:

1. There have been 6 initial seroconversions reported from follow up in Vancouver, Canada in Spring to Summer 1987. These were in niaive patients.

2. All had received material from screened and (?unscreened) donors. As far as I can establish the materials included dry heat Cutter (68, 72h) and Armour (60 30h) and possibly others.

3. The Canadian CDC equivalent set up a good case control study with 12 non-seroconverters treated during the same period with similar materials and came up with one lot of Armour screened donor (60,30) as $p<0.05$ chance of implication.

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4. Another case was reported in Edmonton Alberta. Records were checked and it was found that a second lot of Armour material had been used. This had been prepared from the same donor pool as the implicated lot (i.e. 2 lots from same pool).

5. Other recepients of this pool are being checked and so far another seroconverted niaive recepient has been found in Winnipeg. The current significance for this pool of Armour Screened (60-30) is < 0.001. All lots of other materials used have not reached significance.

6. Seroconversion seems to be real for 2 other niaive's

   a. Los Angeles, Profilate Dry.
   b. Bonn. Profilate Heptane wet. Both these patients received 500,000 units i.e. extraordinarily high doseage. Also treated with Haemate

7. Cutter (68 - 72) has not been definitely implicated in any seroconversions but significance of this is doubtful because of use of multiple products.

8. Armour have now withdrawn dry heat material in USA. Travenol have stopped manufacturing.

9. These firms are promoting monoclonal affinity prepared concentrate but safety data incomplete (Some people, including me, have reservations on final dry heat protocol of Armour. Travenol uses chemical method. Both firms rely heavily on separation process to remove viruses - my comments. Not Dale Lawrence)

10. Switch to wet heat (aqueous) as in Haemate P (Hoechst) or Koate HT (Cutter) awould lead to shortages and very expensive. Haemate P is marketted by Armour in UK and USA.

11. CDC etc are so concerned that they are promulgating an "emergency" meeting of manufacturers and USA haemophilia doctors in Atlanta on January, 11th. Only one European (P. Manucci) is known to have been invited to contribute (expenses paid) but the conference is open to others (I shall probably go if I can find the funds). Hepatitis etc as well as HIV will be considered.

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It is not yet clear if FDA will withdraw dry heat licences in USA but this is likely. This leaves our situation regarding BPL(80.72) in the air. Also USA situation regarding PCC is not clear.

Presumably we should discuss all this in our February Meetings and possibly inform HCD's

Best wishes for Christmas and the New Year.

Yours sincerely,

GRO-C

A L BLOOM