MEMORANDUM

To: Richard Walker

cc: Clive Ronaldson
Duncan Thomas
Incident file (93/235-257)
Dr H H Gunson (NBA, Manchester)
Alan Slopecki (NBA, Watford)

From: Terry Snape

November 15, 1993

REVIEW OF VIRAL SAFETY OF A PLASMA DONATION

SOUTH EAST THAMES (TOOTING): P93/235-257

The attached letter (2 pages) sets out the detail of a recent incident report which, depending on interpretation, might be seen as compromising a number of plasma pools.

The incident involves 17 plasma donations, most fractionated by BPL, potentially implicated in the transmission of Hepatitis C by cellular components. There would appear to be reasonable concern that cellular products from one of the donations were responsible for transmission of hepatitis C, but review of the test information on the original donations confirms that tests performed at that time were valid.

The procedure defined in the current plasma specification is unambiguous: under such circumstances, no further action is required. In the proposed draft P&P on "Review of Viral Infectivity Status", once again no further action would be required. My understanding of FDA guidelines is that a similar line is adopted.

I have discussed the incident in some detail with Duncan Thomas, and we are agreed that the incident should be closed. I have three reasons for raising the current incident with you:

i. the decision not to progress intermediates from the recent Trent incident (D93/192) is inconsistent with such an approach - I would wish to review that incident with you also;
ii. we still do not have an agreed procedure for review of viral infectivity status - this is unacceptable;
iii. the current incident illustrates just how far-reaching a single "jaundice enquiry" can be - of the 17 donations, 14 have been pooled and processed (the remaining three will be returned to Tooting for reconciliation and testing).

The 14 donations found their way into 9 plasma pools, potentially compromising three batches of Replenate, two batches of 8SM and two batches of 8Y, as well a range of albumin, immunoglobulin and clotting factor intermediates as yet unfinished. Subsequent donations from the same donors implicate a further seven pools, potentially compromising one more batch of 8SM, one more batch of 8Y, and seven batches of cryoprecipitate (one sold to the Dutch Red Cross, one with Kabi for 8SM production).

Even if the incident is finally resolved, and traced to a single donation, the potential delay to products from 16 plasma pools is unthinkable. This consideration I'm sure conditioned FDA/industry thinking on review of "late reports". I don't believe that BPL/NBA can afford to take a more cautious line.

GRO-C

Terry Snape,
Technical Director (BPL).

WTD/ 521

File Reference: nbts/plasma93.036

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Your Ref :

9 November 1993

Dr Terry Snape
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WD6 3BX

BPL Quality Control
DATE 10 NOV 1993
ACTION
FILING

Dear Terry

Re: 029/TMW/93

I am writing to confirm the details of yesterday's conversation. On 3 November, we received written notification that a 59 year old female, who had received transfusions between September 1992 and March 1993 became jaundiced in August 1993 and seroconverted for hepatitis C in October 1993.

Although the case has certain unusual features, following discussion with PHLS and the Virology Department at UCMSM, we are investigating this as a potential case of post-transfusion hepatitis C.

17 donors are involved, several of which have subsequently donated. The O.D's of all anti-HCV tests (Ortho EIA-2) from these donors have been reviewed and fall within the manufacturer's criteria for negative results.

The donation numbers of the plasma you have received from these donors are listed overleaf. In the notification from the hospital, we believe that there is a transcription error in that unit number 644 759 P7 was mistyped as 644 757 P7. We are seeking confirmation of this error.

cont/d...2

WTD/ 522

Re: 029/TNW/93 cont/d...

Archive samples from the implicated donations are being sent to UCMSM and I shall update you of these results as soon as possible.

Best wishes

Yours sincerely,

GRO-C

Dr Sue Knowles
Clinical Director

c.c. Penny Tanebourne
File: Trans.Assoc.Inf.

WTD/ 523