

Snappe Terry

From: Snape Terry
To: Williamson Sue
Cc: Jenkins Stephen; Snape Terry
Subject: Nycomed Amersham recall of Amerscan Pulmonate II
Date: Wednesday, 19 November, 1997 21:12PM

Sue,

I would be grateful if you would let Angela have a copy of this when she next returns to the office:

I was called this evening by Dr Trevor Nisbet, New Zealand DoH. The NZ DoH had been contacted by Amersham and have followed up the recall with some fairly frantic phone calls to Amersham, MCA and BPL. I had been warned by Amersham that they were seriously considering going public and advising individual patients who had been treated with Amerscan Pulmonate II.

I gave Nisbet the following information:

- 1.confirmed that the recall was strictly precautionary;
- 2.confirmed that if the patient had died from classical CJD we would not have recalled;
- 3.confirmed that we recalled for nv-CJD simply because we could not have confidence that the history of non-transmission by classical CJD could be extended at this stage to nv-CJD;
- 4.confirmed that, adopting ethical committee opinion, we would not be informing recipients of affected blood products;
- 5.confirmed, in response to a direct question (which I suspect was the main reason for the call), that we would not be taking action to exclude the recipients of Amerscan Pulmonate II (or of the original batches of Zenalb) from donating blood.

He indicated that he, or a medical colleague, would probably be ringing me again for more information. I took the liberty Angela, of giving your NBA number and your mobile number (since they are 13 hours ahead of us, and find difficulty getting through in our working hours). I suspect that they may want to follow up on the logic of not debarring recipients of "at risk" product from donating blood. My logic, if challenged, would have been that such a position is perfectly consistent with the precautionary basis of the recall.

Information relayed to me second hand after the visit of CSL (Melbourne) staff to BPL recently was that CSL have in the past recalled plasma products manufactured from NZ plasma based on notification of a donor in a CJD risk category. I have been unable to pin down precisely what the donor's risk was (family, human pituitary extracts, clinical CJD) or to determine who took the recall decision. It perhaps explains the acute interest of the NZ DoH in the Amersham recall though.

Terry.