

NOTE OF A TELEPHONE CONVERSATION WITH DR. DUNCAN P. THOMAS, NIBSC

6 JUNE 1988

RECALL OF KOATE HT, BATCH NO. 50S021

1. On Friday, 3 June 1988, Dr. Thomas telephoned to ask whether it was, in fact, hepatitis B that occurred in Plymouth and not non-A, non-B hepatitis.
2. JMB confirmed to Dr. Thomas on Monday, 6 June 1988 that it was hepatitis B.

Dr. Thomas's comment was that this eased the situation since it is a known hazard with this product, although one questioned why the patient had not been vaccinated. Owing to the sensitivity of the current assays, it is not possible to detect hepatitis B in the final product. However, he referred to the previous time a batch had to be recalled in 1986 after an outbreak of hepatitis B in Ireland. At that time the company apparently wrote to the DHSS saying that plasma pools would be tested in future and he asked if this was indeed still the case. This will be confirmed with Eli Greene when he visits Newbury on 20 June.

The question remains whether the NIBSC is prepared to release the current sample of Koate HT which it has, since this latest outbreak of hepatitis B questions whether heating the product at 68° for 72 hours is sufficient. Dr. Thomas is discussing the situation with the FDA which last Friday knew nothing about this current outbreak. The NIBSC notifies the FDA automatically whenever there is a situation such as this. It was agreed that the matter would be left in abeyance until 20 June when Eli Greene will telephone Dr. Thomas while he is in Newbury to discuss his perception as to why this has happened twice within the last eighteen months.

GRO-C

JMB/ER  
7 June 1988

cc: Dr. R. Wheywell  
Donald Lee