

SNBTS DOCUMENT REQUEST No

2011-00092

The Penrose Inquiry

SUPPLEMENTARY STATEMENT IN RELATION TO FACTOR VIII BATCH 023110090 from DR R J PERRY

The Inquiry has requested the SNBTS to provide a written statement explaining step by step how the SNBTS came to identify the "implicated batch" and the evidence relied on in doing so. The Inquiry has also sought clarification as to what evidence was considered by which individuals before the document entitled "Actions surrounding FVIII Batch 023110090" was prepared.

1. Who carried out the original investigations concerning the 'Implicated Batch' in 1984?

RESPONSE:

The original investigation which led to the identification of batch 023110090 (NY3-009) as possibly implicated in the transmission of HTLVIII to a number of haemophilia patients in Edinburgh was carried out by Dr B McClelland of SNBTS and Dr C A Ludlam.

Following notification of their findings to the Protein Fractionation Centre on 1st November 1984 follow up actions and investigations were carried out by Dr B Cuthbertson (PFC QA Manager), and subsequently by myself, following my return to PFC on the 5th November.

2. How the SNBTS came to identify the "implicated batch" and the evidence relied on in doing so?

RESPONSE:

This information will be provided in a separate statement by Dr McClelland.

3. Clarification of what evidence was considered by which individuals before the document entitled "Actions surrounding FVIII Batch 023110090" was prepared?

RESPONSE:

Following the announcement of the Public Inquiry, the SNBTS recognised early on in its preparations that the circumstances surrounding the identification of batch NY3-009 as a likely source of HTLVIII infection of the 'Edinburgh Cohort', and the actions taken by the SNBTS, would be an important topic for consideration by the Inquiry. Accordingly work began to identify and gather relevant evidence and information on this topic in 2008, including the discovery of a single and hitherto unknown vial from batch NY3-009 in a research laboratory at the University of Edinburgh.

The evidence and information gathered included:

- Records of the initial notification to the SNBTS (Dr McClelland) by Dr Ludlam on 26th October 1984.
- Original records of SNBTS actions following this notification including details of the recall procedures initiated by SNBTS/PFC.
- Records of follow up discussions and actions by the SNBTS.

- PFC reports (1991) of the event including analysis of subsequent information concerning seroconversions in patients from Glasgow Royal Infirmary.
- Relevant scientific publications concerning the Edinburgh cohort.
- Expert independent analysis by NIBSC of the recovered vial from batch NY3-009.

Unfortunately neither the SNBTS nor, it is understood, Professor Ludlam have been able to locate the original data, analysis and rationale which led to the conclusion that NY3-009 was implicated in the transmission of HTLVIII. Some of the data was included in the report prepared by Dr Cuthbertson and this is attached as an appendix to the paper submitted to the Inquiry in 2010.

Whilst it has never been proven beyond doubt that FVIII batch NY3-009 was the cause of infection in the Edinburgh cohort, this was and continues to be accepted as the most likely explanation.

A number of individuals closely involved at the time with the events and actions surrounding NY3-009 participated in discussions and preparation of the paper entitled "Actions surrounding FVIII Batch 023110090" between 2008 and 2010. These included Dr B McClelland, Dr B Cuthbertson, Dr P Foster and Dr R Perry. Their personal recollection of events supported by the above evidence has enabled the SNBTS to construct what it believes to be an accurate and detailed narrative.

Relevant documentation :

The key evidence is provided in the references to the SNBTS paper "Actions surrounding FVIII Batch 023110090" and also in Table 1 of this paper (Narrative of events surrounding PFC Factor VIII Batch NY3-009). A revised copy of this table listing the relevant references is attached to this statement, along with an updated reference list.

Copies of references cited in the SNBTS paper and documents referred to in Table 1 of this paper are attached to this statement.

Individuals involved in preparation of the document were:-

Dr B Cuthbertson (SNBTS Quality Director and lead author)
Dr B McClelland (former Director SEBTS)
Dr P Foster (former PFC R+D Manager)
Dr R Perry (former PFC Director)
Dr A Welch (SNBTS PI Team)
Dr C Bienek (former SNBTS PI Team)
Prof Ian Franklin (former SNBTS Medical and Scientific Director until December 2010)
Mr N Billing (SNBTS PI Team)

Dr Robert J Perry
14 June 2011