PENROSE INQUIRY – DR JOHN GILLON – STATEMENT IN RELATION TO HIV LOOKBACK

Q1 : **What steps were taken to identify potentially infectious batches of blood and the individuals who received blood or blood products from those batches.**

Answer : In preparation for the introduction of testing of blood donors for antibodies to HIV, the NBTS Regional Transfusion Directors' Committee (which included SNBTS representation) established a Working Party on which SNBTS was represented by Dr D B L McClelland. The Working Party presented it's recommendations in the form of a report entitled "Screening of Blood Donations for Anti-HTLV III in Regional Blood Transfusion Centres" on 11 July 1985 (Appendix 1). This policy was endorsed by EAGA at it's 5th meeting on 30th July 1985 (Appendix 2).

The following recommendations were made in relation to "Lookback":

"7. Follow-up of recipients of previous donations given by donors found to be HTLV-III positive.

7.1. Efforts will be made to determine the names of any patients who received blood and components from the donations taken during the past five years and the information regarding the known or possible seropositivity of the donation given to the Consultant in charge of the patient.

7.2. If plasma from any of the donations was sent for fractionation, full follow-up of all patients receiving coagulation factor concentrates may be difficult or impossible. Since patients suffering from haemophilia A and B are being investigated for

anti-HTLV III at present, it is recommended that no additional follow-up be carried out."

The SNBTS Directors accepted the recommendation in 7.1 fully. In addition, SNBTS Regional Transfusion Centres informed PFC of any confirmed cases of donors with anti-HTLV III (HIV) whose plasma had been shipped to PFC for blood product manufacture. Steps were taken by PFC to recall batches of plasma or finished product. Details of these procedures have been supplied to the Inquiry by relevant SNBTS witnesses, with references made to the 'Recall of Stocks' paper (Appendix 3).

Q2 : **What steps were taken to trace and arrange testing for any such individuals?**

Answer : On receipt of a confirmed positive test for antibodies to HIV in a donor who had given at any time in previous 5 years, the Consultant responsible for the care and selection of donors in that region would request full details of previous donations and the fate of all blood components issued. Where components were issued to SNBTS administered blood banks, the patient(s) would be identified from Blood Bank records, and the Consultant in charge of the patient informed, with a recommendation that the patient should be informed, counselled and offered testing. Where the component was issued to a non-SNBTS Blood Bank, the information was passed to the Consultant Haematologist in charge of the Blood Bank, who would normally communicate directly with the Consultant in charge of the patient. Often, SNBTS advice would be sought as part of the process of informing and counselling the patient.

Q3 : **Who was responsible for the lookback programme at a national level?**

Answer : To my knowledge no individual doctor was delegated to manage the lookback procedures nationally, nor was any prospective data collection put in place. I would assume that responsibility therefore remained with the National Medical Director, Dr. J D Cash. This is supported by subsequent attempts initiated by Dr Cash to collate information on the outcome of lookback, requested by EAGA in September 1990 (copy form attached as Appendix 4) and by the DOH in 1992 (copy letters attached as Appendix 5).

Q4 : **How was the lookback programme put into effect:?**

Answer : As far as I can remember no formal policy was issued in respect of lookback, but SNBTS RTDs, having agreed to adopt the recommendations of the UK RTD Working Party, informed the relevant medical staff in their Centres. In addition, a meeting for medical staff on "Counselling etc" was held at SNBTS HQ on 4 October 1985. This was to include a "clinical overview and discussion on counselling", and each Region was required to arrange for appropriate training of individual doctors at St Mary's Hospital, London, prior to the meeting. Though the training in counselling was primarily aimed at blood donor counselling, my recollection is that lookback was discussed at the HQ meeting.

Within SEBTS a Working Party on the "preparation for the introduction of HTLV-III Ab screening" was established to ensure that all procedures relating to testing were discussed and written procedures were in place.

In essence, it was the responsibility of the RTD and the Consultant in Donor Care and Selection in each region to

ensure that appropriate arrangements were made for lookback. At that time there was no national donor administration system, and donor record management and blood bank records were mostly manual, though some centres had local computer systems for at least some of these processes. The national donor database, "DOBBIN", was established in 1987, though the data were still segregated regionally. In the case of a donor who claimed to have donated in another region, or in another part of the UK, the information was given by letter from the Consultant in Donor Care to his or her counterpart in the region in which the donor claimed to have donated.

Q5: **Were any written protocols / procedures created?**

Answer : No national written protocols or procedures were created. As stated above, this was regarded as a local matter, with procedures developed in relation to existing local systems of communication and documentation.

Individual files were maintained for each lookback investigation, cross-referencing the patient data to the donor record. These records have been retained as individual case-notes in the region in which the "index" HIV-positive donation occurred.