Witness Name: William Wright
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INFECTED BLOOD INQUIRY

EXHIBIT WITN2287021

Final Version
NOTES OF A MEETING BETWEEN THE HAEMOPHILIA SOCIETY AND THE SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE

Date: 25 November 1999

Venue: Scottish Health Services Centre, Western General Hospital, Edinburgh

Present	Haemophilia Society:	K Pappenheim (KP)	L McGrath (LM)
		P Dolan (PD)	GRO-D
		GRO-D	B Wright (BW)
		GRO-D	GRO-D
		GRO-A	GRO-A
	SNBTS:	A MacMillan Douglas (AMD)	R J Perry (RJP)
		B McClelland (BMcC)	I Franklin (IF)
		P Foster (PF)	R McIntosh (RMcI)
		B Cuthbertson (Notes Only)	
	Scottish Office Observers:	A Keel (AK)	T Teale (TT)
	CSA Observer:	R Wallace	

1. INTRODUCTION

AMD welcomed the Haemophilia Society and made introductory remarks which emphasised the following points:

- SNBTS is an integrated part of the Health Service in Scotland.
- SNBTS's services are clinically driven and respond to the needs of patients in Scotland.
- SNBTS is part of the Common Services Agency in Scotland.
- The Protein Fractionation Centre (PFC) is an integral part of the SNBTS.
- The purpose of the meeting was established by the Minister and "is to present the factual chain of events behind the development of heat treated blood products in Scotland in the 1980s and take any questions on the subject from the Haemophilia Society."

AMD emphasised that the SNBTS wishes to be as open and helpful as possible.

In her introductory remarks, KP emphasised that there were still many unanswered questions and that the Society wished to use the meeting to help gain an understanding of events during the 1980s.

2. PRESENTATION

PF made a detailed presentation of the SNBTS's Factor VIII (FVIII) developments up until 1987 when Z8 (an advanced dry heated product) was introduced. He placed these developments in a national and international context. The overheads used in this presentation were made available to the Haemophilia Society. For this reason, the detailed content is not included in this note.

However, the summary was as follows:

- All SNBTS FVIII made HIV-safe from December 1984.
- Scotland first in the world to have HIV-safe FVIII available for all of its Haemophiliacs.
- Some UK patients were the first in the world to receive 80°C treated FVIII following breakthrough at BPL (PFL).
- SNBTS first manufacturer of FVIII to reproduce this technology.
- Scotland first in the world to have HCV-safe FVIII available for all its Haemophiliacs.

3. DISCUSSION

Following the presentation by PF, the meeting was opened to questions from the Haemophilia Society. The following notes are not a direct transcript of the comments raised, nor are they in the sequence raised during the meeting. Instead they attempt to bring together the main themes raised and the detail of the SNBTS responses.

3.1 *Operating Policies*

PD first raised the question of who determined the operating policies for haemophilia provision.

- AMD advised that SNBTS provides products following consultation with clinicians and with the Scottish Executive.

- AK advised that, at the time concerned, there was an advisory committee in operation (Coagulation Factor Working Party) which consisted of personnel from the SNBTS, Haemophilia Directors and the Scottish Office. This group met quarterly and discussed relevant matters relating to the provision of coagulation factors in Scotland.

- AK also advised that national policy in matters relating to donor testing were the responsibility of UK ministers. They took advice from a UK advisory committee the Advisory Committee for the Virological Safety of Blood (ACVSB).

- The membership of the ACVSB was discussed. It was noted that the Scottish Office sent observers. Personnel from the SNBTS attended as experts in their own right, rather than as representatives of the SNBTS.

- The ACVSB was reconstituted in 1995 and is now known as the MSBT (Advisory Committee On The Microbiological Safety Of Blood And Tissues for Transplantation). However, this Committee retains the role of advising the Government on the safety of the UK blood supply.

3.2 ***Links With Other BTS Organisations***

- AMD noted that SNBTS co-operates with other UK BTS organisations via many professional links whereby best practice is exchanged. He also emphasised that this exchange does not stop at the UK and that SNBTS regularly exchange information with European and World-wide Organisations. This interchange of information helps to ensure that good practice was promulgated.

- BMcC confirmed that there was a long history of professional collaboration with other UK organisations.

- RJP advised that collaboration between SNBTS and BPL had been of key importance in the development of advanced dry heat treatment of FVIII products by both organisations.

- PF advised that this collaboration extended to FIX also, where a joint project to develop a heat treated FIX concentrate was initiated by the SNBTS.

3.3 ***Donor Selection Policies***

KP raised the issue of donor selection policies and what was done to exclude donors at risk of transmitting hepatitis.

- BMcC advised that the policies for exclusion of donors at high risk of transmitting HIV, introduced late 1983 (e.g. drug misusers), would also exclude donors with a high risk of transmitting HCV.

- Donor testing and exclusion policies were formulated on a UK basis following discussions within ACVSB. (Such policies are now reviewed by the MSBT).

Several questions were asked on why ALT testing was not introduced in the UK.

- BMcC advised that the link between high ALT and hepatitis was known in the 1970s. However, he did not know of any organisation which introduced ALT testing of donors at that time. The USA introduced ALT testing in 1986, following consensus agreements by the American Association of Blood Banks.

- AK advised that the ACVSB had considered this issue over a number of years. On each occasion, they agreed that ALT testing should not be introduced because of the poor specificity of this test.

- BMcC quoted a study by Gillon et al, published in Vox Sanguinis which demonstrated very limited value of ALT in predicting donations with a risk of causing post transfusion hepatitis. In view of the limited effectiveness of ALT testing, there is no doubt that this test would not substantially reduce the HCV load in plasma pools used in fractionation.

PD quoted from a minute in 1992 where UK policy not to introduce ALT testing was confirmed.

- IF responded by pointing out that the introduction of HCV testing in 1992 meant that a specific test was available and that the introduction of a non-specific test (e.g. ALT) was considered to be of no value at that time.

3.4 ***Product Literature***

KP asked what information was available to patients at the time.

- RJP advised that each vial of FVIII was accompanied by a leaflet which advised of the risks of virus infection. The wording of these leaflets was presented in an overhead.

- RJP agreed to supply copies of the product leaflets to the Haemophilia Society.

- RJP advised that the text was written primarily for clinicians and not for patients. The leaflets issued with the products met the regulations in force at the time.

- GRO-A advised that she had not seen any product leaflets until her son had started on home therapy in 1990.

3.5 ***Products Other Than SNBTS FVIII***

CR asked about transition to Heat treated FIX.

- PF showed an overhead which demonstrated that SNBTS DEFIX heated at 80°C for 72 hours was first available in October 1985 after extensive safety study in animals. He was asked why this was introduced earlier than Z8 and replied that the composition of the FIX concentrate was very different from that of FVIII and that the technical problems to be overcome were substantially different. In particular, it is important to appreciate that severe heat treatment could be applied to a modified version of the existing FIX product, whereas it was necessary to develop and install a completely new FVIII manufacturing process.

KP enquired about other products (e.g. FEIBA).

- RJP advised that the prescribing of non SNBTS products was entirely at the discretion of the treating clinicians and was not the responsibility of the SNBTS.

3.6 ***Data On Patients With HCV Infection***

GRO-D asked SNBTS to confirm that it did not hold a register of patients infected with HCV.

- SNBTS confirmed that it did not hold this information.

KP asked about the mechanism of post-marketing surveillance.

- RJP advised that data on infection in haemophiliacs was obtained by the treating clinicians. In the period in question, any significant adverse events were reviewed on a regular basis with SNBTS. He noted that post marketing surveillance was less sophisticated in the 1980s than it is today.

LM asked if there were any current regulatory requirements to obtain look back data on patients receiving earlier generations of product.

- RJP advised that there was no such requirement. He noted that any data available would be held by the treating clinicians.

3.7 ***Transition To Hepatitis Safe Concentrates***

- RJP confirmed that the transition from NY to Z8 took place early in 1987, following completion of a safety study in a limited number of patients.

- Arrangements for this transition were the subject of discussion and agreement with Haemophilia Directors.

- There was no formal product recall of NY but procedures were put in place to ensure that patients transferred to Z8 as soon as the batch of NY they were using was exhausted. This practice was designed to ensure that no patient was exposed to a new batch of NY after Z8 became generally available in April 1987.

- In response to a question by BW, it was confirmed that Centres could have simultaneously held stocks of NY and Z8.

- PF and BMcC both confirmed the point demonstrated during the presentation that non-hepatitis safe concentrates were still available in England and Wales until at least 1988 since, despite best efforts, there was insufficient 8Y available to meet all of the requirements of haemophiliacs in England & Wales. In response to a follow up question by LM, PF advised that SNBTS did not know precisely when different non-UK manufacturers made hepatitis safe concentrates available for UK patients.

3.8 ***Prescribing Of FVIII***

GRO-D asked who was responsible for deciding on the course of treatment.

- IF confirmed that this was a clinical decision and that SNBTS could not answer details on clinical practice (e.g. the role of DDAVP).

- In response to a question by GRO-A PF noted that the trial on the safety of 8Y was carried out under the auspices of the UK Haemophilia Centre Directors.

- AMD noted that the SNBTS were part of the health care continuum but that its specific role within this continuum is to provide product.

3.9 ***Timescales For Development Of Z8***

KP asked why it took so long to develop Z8 when an 80°C treated product was already being made by BPL.

- PF advised that FVIII concentrates are complex pharmaceutical products. The Z8 development took only 12 months. This is exceedingly fast in comparison to the standard times required for developing a pharmaceutical product. He advised that an Australian company (CSL) had taken over 3 years to replicate the BPL 8Y method.

- PF advised that co-operation with BPL had been very important in progressing the Z8 development so rapidly. IF pointed out that SNBTS expertise had benefited BPL by helping them to improve the reliability of the 8Y process.

4. CONCLUDING REMARKS

Both KP and PD thanked the SNBTS for the information provided. SNBTS agreed to answer any supplementary written questions which fell within the Service's remit. AMD agreed that questions should be sent to him.

- PD also suggested that a follow-up meeting may be valuable. AMD confirmed that SNBTS are willing to assist the Haemophilia Society with information.

- AMD requested that any press release from the Haemophilia Society be considered carefully to ensure that there was no adverse impact on donors, particularly in the build up to the year end, when blood supplies may be difficult to achieve. KP agreed to consider this request and to inform the SNBTS press officer (Elsbeth Girvan) in advance of any press release.

PD concluded for the Society in underlining the impact which hepatitis C has had on the lives of Haemophilia patients.

Note Compiled By: Dr B Cuthbertson
26 November 1999