Comments on the UKHCDO Bleeding Disorder Statistics for the Penrose Inquiry (PEN0190927)

Page	Line	SNBTS Comment
i	Line 7	Virus inactivated FFP is now supplied by SNBTS as a result of further developments in the virus inactivation of blood products.
i	Line 10	If the period 1985/86 is meant to represent the financial year 1985/86, then virus inactivation of FVIII was introduced by SNBTS in the financial year 1984/85.
i	Lines 13-14	The heat treated version of the FVIII concentrate know as Hemofil (from Travenol/Hyland (Baxter) was licensed in the UK in 1985.
i	Lines 15-17	Porcine FVIII was free from transmission of human viruses, but was eventually discontinued because of a risk of transmission of porcine viruses.
i	Line 27	"1993" should be 1983.
ii	Lines 1-2	Monoclate was licensed for use in the UK in December 1989 (PEN.013.1125). The product has been associated with at least 3 cases of Hepatitis C transmission (Shopnick et al, *Haemophilia* 1996, **2**, 100-103; Lusher J, letter to Prowse CV, SNBTS, 1991).
ii	Lines 3-5	Pasteurised FVIII from Behring has been reported to transmit Hepatitis C (Gerritzen et al,*Thrombosis Haemostasis* 1992, **68**, 781; Schulman et al, *Lancet* 1992, **340**, 305-306) and Hepatitis B (Brackmann & Egli, *Lancet* 1988, 2, 967).
ii	Lines 11-12	FVIII from Octapharma was essentially the same as the high-purity FVIII from France (see French FVIII).

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ii	Lines 13-14	Humanate was Koate that had been manufactured by Cutter/Bayer, purchased in the USA by Speywood Laboratories (Wrexham) and then re-labelled and distributed in the UK by Porton International as Humanate.
ii	Lines 15-20	The close technical collaboration between PFC and the French state fractionation centre at Lille began in 1989/90. In the mid-late 1980s the coagulation factor concentrates from each centre were not always "very similar". For example, Lille produced FVIII & FIX concentrates dry heated at 68°C for a number of years after PFC had introduced dry heat treatment at 80°C, a degree of heat treatment that was never achieved at Lille
3	Table 1 Lines 3, 10 & 12.	From 1956-1973 PFC produced a FVIII concentrate known as Anti Haemophilic Globulin (AHG). The product was based on Cohn Fraction I (Cohn et al. J Am Chem Soc 1946, **68**, 455-474) as was prepared according to Cumming et al. *Vox Sanguinis* 1965, **10**, 687-699. A new FVIII concentrate was introduced by PFC in 1974 based on the method of Newman et al. *Br J Haematology* 1971, **21**, 1-20.
9	Table 1 Lines 2,6 & 10	The FIX concentrate known as Defix was introduced by PFC in 1972 (PEN.017.2468) and was produced according to the method of Middleton et al. *Vox Sanguinis* 1973, **24**, 441-456. In the period 1968-1971, PFC provided a FIX concentrate for the treatment of haemophilia B based on the method of Soulier (PR 1.53, footnote 40).
9	Table 1 Line 23	Interhem was an intermediate-purity FVIII concentrate produced by Hyland/Travenol (Baxter).
19	Table 1 Lines 20,25 & 30.	Prothromplex was a FIX concentrate produced by Immuno – see Immuno IX (page ii).

20	Table 1 Line 23	The figure of 5,288,770 units of PFC FVIII for 1988 seems high compared to other years for this centre.
33	Line 3	Of the 68 patients who were probably infected with HIV via treatment in Scotland, it would be helpful to confirm how many were treated only with NHS (SNBTS) products. It should be noted that one patient ('David' designated earlier as patient G10) who is believed to have only received NHS (PFC) products may also have received commercial FIX, as one of the batch numbers listed in the record of his treatment is not recognised as being manufactured at the PFC. (see WIT.004.0441 (page 0527) – this refers to patient "David's" medical records – treatment sheet showing infusion of batch '05228408T' on 8.06.85).