Headquarters :
Blood Products Laboratory
Dagger Lane, Elstree
Borehamwood, Herts. WD6 3BX

Plasma Fractionation Laboratory
Churchill Hospital
Oxford OX3 7LJ

Telephone : Direct Line 0865-62002
~~via Hospital 0865-64841~~

21st April, 1988.

Dr. A.E. Robinson,
Consultant Haematologist,
Regional Transfusion Centre,
Bridle Path,
Leeds,
LS15 7TW.

Dear Angela,

Thank you for passing on Peter Jones' protocol for clinical trial of NYBC's (or Octapharma's) SD factor VIII. I do not know when it was written, but several points are positively misleading or untrue today. Peter attended Dr. Savidge's International Workshop on Haemophilia Care in London on 18th and 19th April, and has no excuse to maintain these errors in future.

P1, para 3. 8Y is available to Newcastle Haemophilia Centre and, unlike other products heated at 60° for 30h, has not been shown to transmit NANBH and emphatically not HIV - approximately 800 patients are solely on 8Y or 9A and there have been no seroconversions, even though some of the batches used were made before HIV screening was standard.

P2. Clinical trial of the efficiency of 80° heating in inactivating NANBH and HIV has now been reported at three international meetings, and all HCDs updated approximately annually. None out of 32 eligible patients on 8Y and 9A appeared to be infected by NANBH in a prospective trial. A manuscript has been prepared for publication now that the study is complete. A Clinical Trial Exemption Certificate (CTX) has been issued for the continuation of NANBH surveillance to stricter ISTH "rules" (although I will continue to defend the criteria for the original trial).

Behringwerke Hemate, pasteurised in solution with agents which protect both F.VIII:C and viruses, is now reported to have transmitted HB twice and NANBH at least once (Mannucci and Scharrer at the London meeting).

P3 et seq. NYBC SD VIII has been subjected to NANBH trial in the US, France and Brazil. The data are of uneven quality and fewer than 15 patients have been accrued in the US study at the last report. The in vitro and chimp work is beyond reproach, but Peter Jones should feel embarrassed by his flimsy grounds for concluding that he has no safe alternative.

His proposed trial does not meet all ISTH recommendations, and he will be participating in this trial, knowing that a rather safe national product is the subject of a well-publicised and impeccably designed clinical trial, in the hands of two of the most experienced HCDs in the UK.

Your Scarborough haematologist might like to know what he is lending his patients and support to. I am perfectly happy if you copy my views to him.

Yours sincerely,

GRO-C

J.K. Smith
Chief Project Scientist.

cc. Dr. R.S. Lane.