SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE
EDINBURGH & S.E. SCOTLAND
BLOOD TRANSFUSION SERVICE

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MLT/LP

12 May 1997

Mr Sullivan
Neurosurgeon
Western General Hospital
Crewe Road
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Dear Mr Sullivan

SNBTS FIBRIN SEALANT KIT

Sarah Reading from our Product Services Department has informed me that you wish to use the SNBTS fibrin sealant as a replacement for Tisseel fibrin sealant for the repair of CSF leakage in neurosurgery. You will be aware that, like Tisseel this is currently an unlicensed product and that we have no ongoing clinical studies in neurosurgery. As a manufacturer our responsibility under the Consumer Protection Act, 1987 is to provide a product of suitable quality and to inform you of any potential adverse events or risks associated with its use. Responsibility for adverse events arising out of this application and for obtaining patient consent will lie with you as attending clinician.

In view of this I felt it appropriate that I should share with you some of my concerns with the use of fibrin sealant in neurosurgical applications. You will be aware, of course, of the history of transmission of CJD by dura mater, corneal implants and neurosurgical instruments. There has been no clinical evidence of transmission of CJD by blood or blood products in general usage. There is experimental evidence which demonstrates that in *in vivo* murine experiments, intracerebral inoculation of CJD infected blood does transmit infection. Until a few weeks ago transmission was thought to be linked to the leukocyte fraction, however Paul Brown from the National Institute of Health in the United States presented data to the WHO last month demonstrating that plasma from CJD infected individuals can also give rise to infection

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following intracerebral murine inoculation. You may be aware that blood and plasma products cannot be decontaminated of prion infection without destroying the product. Also the potential transmission of nvCJD, has not been studied.

I think it is fair to say therefore, that we are in a position of profound uncertainty as to whether blood products are capable of transmitting CJD or nvCJD, but our view is that if they are, transmission is most likely to occur if products are used adjacent to the brian. In view of these considerations we would not recommend using fibrin sealant in the context of neurosurgery. Ultimately, of course, the decision must be yours to balance the relative risks of the procedure without fibrin sealant, or the possibility of using alternative methods, against the current theoretical risk of transmitting CJD.

I am sorry to pass this problem along the line to you, but I feel that I do have a responsibility to keep you informed of these issues so that you can make your own decisions as to the appropriateness of usage. I would be interested to hear your thoughts.

Best wishes

Yours sincerely

GRO-C

Dr M Turner
Senior Lecturer & Honorary Consultant