PRIVATE & CONFIDENTIAL
Dr EM Armstrong
Chief Medical Officer
St Andrews House
Regent Road
Edinburgh
EH1 3DG

GDOL/RS

25th September 2002

Dear Dr Armstrong,

SNBTS FACTOR VIII AND FACTOR IX vICD NOTIFICATION STRATEGY

Further to our letter of 19th June 2002, and the relevant enclosures outlining the history of this incident (further copies enclosed), we thank you for agreeing to raise this issue at your last meeting of the UK Chief Medical Officers and to put questions to the Incidents Panel (draft Minutes of Annual Meeting of Scotland and Northern Ireland Haemophilia Directors, SNBTS Directors, and Scottish Executive Health Department, 14th June 2002). Could we ask for an update on progress, preferably before 10th October when we believe this issue may enter the public domain?

Can we also report our increasing concerns at the Incident Panel's delay in issuing advice in respect of this incident. As you know, we prepared a letter of information for patients with haemophilia in Scotland some months ago, which the Incident Panel requested us not to release, as well as a press statement on behalf of the three relevant NHS Scotland Trusts (for Haemophilia Centres at Aberdeen Royal Infirmary, Edinburgh Royal Infirmary and Glasgow Royal Infirmary). We understand that SNBTS have also prepared a press statement, however we have not yet seen this, and we now wish formally to request a review and the opportunity to comment. SNBTS have been sent a copy of our own press statement, and no comments have been received to date.

At the last meeting of the UK Haemophilia Doctors Organisation on 5th September 2002, UK Haemophilia Comprehensive Care Centre Directors discussed a UK-wide collaborative study on vCJD in patients with haemophilia (draft enclosed). We note that the study documentation lists specific BPL product batches but no SNBTS batches. We in Scotland feel it would be inappropriate not to participate in this study. During discussion, at the UKHCDO meeting, it was apparent that UK Haemophilia CCC Directors are well aware of the SNBTS incident, and asked us why patients had not yet been given information on this incident, in view of the information previously issued by UK Haemophilia Directors (including those in Scotland) following the similar BPL incident in 2001.

These matters were discussed at the Scotland and Northern Ireland Haemophilia Directors' Meeting on 23rd September 2002. We agreed the following:

1) That we write to you expressing our concerns, copying our letter to the Incidents Panel, the Medical Directors of the relevant Trusts, SNBTS and the UKHCDO Chairman.
2) We consider that the Incident Panel's request that we delay giving information on this incident to patients with haemophilia is not consistent with the approach adopted following the BPL incident; nor our professional responsibilities, the philosophy of a patient-involved NHS, or the interests of patients with Haemophilia.
3) In the event of any Haemophilia Director in Scotland being asked by a patient (or by the Haemophilia Society) as to whether SNBTS products including a donation from an individual subsequently diagnosed with vCJD had been given to patients with haemophilia, we should reply in the affirmative.
4) We have sought an early meeting with our respective Trust Medical Directors, to discuss developments and to request that we circulate our patient information letter. We look forward meantime to further advice from yourself and from the Incidents Panel. We would be interested to hear from the Panel their arguments for denying patients with haemophilia, who may have received the SNBTS incident products, information and counselling, which other patients with haemophilia, who may have received the BPL incident products, have already been given by the UK Haemophilia Directors.
5) Whatever the UK Incidents Panel's views, we understand that our line management in our actions is to the Medical Directors of our two Trusts, and through them to yourself. Because we may have to discuss this matter in public at the Annual Meeting of UKHCDO in Liverpool on 10th October 2002 (with members present from the UK and Scottish Haemophilia Society, UK and Scottish Haemophilia Nurses Association, and UK Haemophilia PAM's associations), we should be very grateful for your advice, particularly if our Trust Medical Directors cannot authorise us to circulate our patient information letter.

Best wishes.

Yours sincerely

CA LUDLAM GDO LOWE
Co-Chairmen

cc. Haemophilia Directors in Scotland and Northern Ireland
Professor M Banner, vCJD Incidents Panel
Ms Phillippa Edwards, vCJD Incidents Panel
Dr C Swainson, Medical Director, Lothian Acute Trust
Dr W Anderson, Medical Director, North Glasgow Trust
Dr , Medical Director, Aberdeen Royal Infirmary
Professor FGH Hill, Chairman, UKHCDO
Professor I M Franklin, Director, SNBTS
Dr A Keel, Deputy CMO