Appendix 24

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Department of Haematology,
Central Pathology Laboratory,
St. James's Hospital.

14th June 1988.

Mr. T. Keyes,
Chief Executive Officer,
Blood Transfusion Service Board,
Pelican House,
40 Mespil Road,
Dublin 4.

Dear Mr. Keyes,

I regret I will be unable to attend the Board meeting on 15th June 1988. I trust however that the contents of this letter will assist in arriving at a satisfactory decision regarding factor VIII production in 1989. The included suggestions are made following discussions with representatives of the Board including Dr. T. Walsh, UK Directors of the Haemophilia Reference Centre, Directors and other experts in the worldwide Haemophilia community.

All products mentioned are considered to have a neglible risk of HIV infection. Factor VIII concentrates, following the AIDS disaster may be regarded as belonging to first, second and third generation products. The present product using Irish plasma fractionated by Armour is heat treated for 72 hours at 68 C and belongs to the first generation group. This group is being rapidly removed from the world market partially because of previous HIV disasters and also because dry heat treatment seems inadequate to destroy the non A, non B hepatitis (NANBH) virus. There are likely to be commercial considerations also.

Only one first generation product has retained its reputation in relation to HIV infection and remains on the market - Cutter Koat HT, a product which until recently was used intensively by the National Haemophilia Treatment Centre. The heat treatment conditions of this product are those insisted upon by the Board and the centre, when the recent contract to fractionate Irish plasma was granted to Armour.

The Board is aware that Armour is only producing this first generation product for the Irish market as it has withdrawn first generation products from the world market. The Board is also aware that Cutter only fractionate in the US and Irish plasma is not permitted to enter the US. Thus the Board is dependent upon a unique concession from Armour to produce a first generation product for Irish haemophiliacs.

Second generation products are either 'wet' heat treated, or are dry heated to 80 C, rather than 68 C, as for the first generation products, or are solvent/detergent treated. These products decrease the risk of NANBH infection. Of those Haemate P (Bohringer) a pasteurized product and NHS 87 (heated to 80 C) have been given adequate trials. The former is available commerically and will be used by the National Haemophilia Centre for infants and young children who have not come in contact with blood products.

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The problem with commerically available second generation products is the price. Pasteurised products are at least twice the price of dry heat treated products.

Third generation products are monoclonal purified (Armour and Baxter). They are as yet unlicensed and still involved in clinical trials. They would appear to be associated with minimal risk of NANBH transmission. There is no definite idea of costs but they are likely to be at least twice the cost of dry heat treated products.

The Board should understand that in the present period of financial stringency the hospitals could not be expected to meet a doubling of the cost of concentrates in 1989. Some balance will have to be struck between cost and the infection dangers associated with blood products. Using Cutter Koat HT and the Irish Plasma/Armour products no new HIV seroconversion has occured for at least 12 months. Virtually all of our treated haemophiliacs have had NANBH. There is no definite evidence that crude products such as Irish Plasma/Armour FVIII produces immune deficiency despite their large content of protein.

In my view therefore the logical conclusion for the Board is to make every effort to obtain Armours agreement to take on production of FVIII concentrates using Irish Plasma for 1989 in the same manner as for 1988. This would have my support as the Director of the National Haemophilia Centre. For 'virgin patients' (i.e. usually infants) Haemate P will be used protecting them from NANBH.

Yours sincerely,

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Professor I. Temperley,
DEAN.

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