FVIII AND AIDS

We spoke. As you know, on 24 March 1983, the FDA introduced certain requirements in respect of the selection of donors to reduce the possibility of the transmission of AIDS. Products manufactured from plasma taken before the new regulations were introduced have to be labelled to indicate this. However, the UK product licenses do not contain this requirement and there are fears among haemophilia centre directors that the more "dangerous" material may be dumped in the UK. You may like to consider whether there is a need to make a similar labelling requirement for material imported into the UK?

In relation to the whole issue of the transmission of AIDS in blood products, several questions have been put to me:

1. Is it possible to obtain concentrates made from American plasma which does not come from donor centres in New York (particularly) but also from San Francisco and Los Angeles, which are the cities with the highest numbers of AIDS cases?

2. Is it possible to accept only concentrates made from plasma taken after the 24 March regulations were published? If so, would sufficient finished product be immediately available?

3. Can we find out, for each manufacturer, the date of plasma collection in relation to each batch of concentrate in current use in the UK?

4. Could Immuno - or other European manufacturers - produce sufficient material derived from European plasma to supply up to 30 million i.u. of FVIII concentrate should it prove necessary to withdraw some or all of the American products?

Both the chairman of the Haemophilia Centre Directors and the Director of the CDSC have urged that these questions should be investigated as a matter of the utmost priority.

GRO-C

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16 May 1983

PS I attach copies of a letter to me from Travenol and a letter to me from Harold Gunson relaying a conversation which he had with Mr Gantz, Vice-President of Travenol.

cc Dr Field
Dr Oliver

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