

11th January, 1982

To all Haemophilia Centre Directors

Dear Colleague,

You are no doubt aware that at least 4 commercial companies are about to introduce preparations of factor VIII and possibly factor IX that have been processed in an attempt to reduce the risk of transmitting hepatitis B and non-A non-B. As far as we know the products have been subjected to a heat treatment process such as pasteurisation after removal of the bulk of fibrinogen but other methods such as treatment with E-propiolactone and UV-light or differential adsorption-elution may be used. Although initial production batches may have been tested for infectivity by injecting them into chimpanzees it is unlikely that the manufacturers will be able to guarantee this form of quality control for all future batches. It is therefore very important to find out by studies in human beings to what extent the infectivity of the various concentrates has been reduced. The most clear cut way of doing this is by administering those concentrates to patients requiring treatment who have not been previously exposed to large pool concentrates. Those patients are few in number but a study along those lines is being carried out at Oxford to determine the infectivity of factor VIII concentrates produced by the Plasma Fractionation Laboratory, Oxford and Blood Products Laboratory, Elstree. This study shows that it is possible to demonstrate infectivity using quite small numbers of previously untreated patients. It is very important also to find out as soon as possible whether the manufacturing methods used to reduce the hepatitis risk has resulted in a product with undesirable characteristics such as high