Reject

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c.c. Mr C. R. Bishop

RBC/SLS/10437

August 7, 1986

Dr. Latis Puri,
"El Shaffey" Surgery,
Elmsleigh Drive,
Leigh-on-Sea,
Essex.

Dear Dr. Puri,

I understand that you recently enquired from our Plasma Product Sales Department for information regarding the risks for Hepatitis and AIDS from treatment with Factor VIII Concentrate and Gamma Globulins.

Naturally my experience is largely confined to our own products, although some information has been published in the medical press that provides a general background on other commercial products and those produced by the NHS.

A brief summary of the current situation is as follows :-

(1) Hepatitis

The main risks are from Hepatitis B and Non-A Non-B Hepatitis. All donors are screened for absence of Hepatitis B surface antigen which excludes virtually all donations into the plasma pool for Factorate that would cause Hepatitis B infection. No screening system can be 100% perfect and all haemophilia patients are normally vaccinated against Hepatitis B before starting treatment with Factor VIII concentrate.

Non-A Non-B Hepatitis is a more difficult problem. Armour are now screening all donors for raised plasma ALT levels. This is expected to substantially reduce the risk of a contaminated donation. In addition most manufacturers have adopted a heat treatment method to further reduce virus contamination. None of these heat treatments have been convincingly proved to totally eliminate the Non-A Non-B virus, with the probable exception of that used by Behringwerke in Germany. The more intense heat treatments are liable to damage the Factor VIII molecule and cause changes in globulin present in the product.

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IVGG is prepared by an alcohol fractionation method which is virucidal. This, together with donor screening, reduces the hepatitis risks from this product to a very low level. Isolated cases of Non-A Non-B hepatitis have however been reported.

(2) AIDS

All Factor VIII products are now subjected to a heat treatment process, which, based on in-vitro challenge data, can be expected to inactivate the highest expected infection with HIV virus.

In addition Armour, and some other manufacturers, are using only plasma from HIV antibody screened donors. Only HIV antibody negative donations are used for the manufacture of our 'Factorate' or IVGG.

Armour also own their plasma collection centres and do not buy commercial plasma for the manufacture of Factorate and IVGG. These centres are in the U.S.A., but away from the area of high risks for AIDS. All donors complete a questionnaire and undergo regular health checks.

Finally as mentioned previously the IVGG manufacturing process with alcohol fractionation has proved to be virucidal to the HIV virus. No case of AIDS has been linked to our IVGG or Heat Treated Factorate.

I hope that you will find this summary useful. If you require any further specific information please do not hesitate to contact me.

Yours sincerely,

GRO-C

R. B. Christie
Director, Clinical Sciences