Our Ref: DRW/GC 3rd September 1982

Mr. H. W. Russell,
Russell Scanlan Insurance,
Wellington House,
15 Wellington Circus,
Nottingham,
NG1 5AL.

Dear Bill,

As promised in our recent telephone conversation, herewith some information on our clinical trial programme.

Human Factor VIII:C (MONO VIII:C)

Two trials are planned for 1983 in the United Kingdom. The first, at the Lord Mayor Treloar Haemophilia Centre, which is the National School for Haemophiliacs, will involve a maximum of 30 patients. The time scale for the trial is two terms, starting January and concluding in July. The second is at the Royal Free Hospital, London, where we will be looking at the product in newly diagnosed haemophiliacs. A maximum number of 10 patients will be involved and the trial will again last about six months.

Overseas, we will be carrying out studies in France and Germany. The Centres have not yet been nominated but, no more than 20 patients will be involved in each country.

HYATE:C

Only country where we are in a formal trial situation is the U.S.A. We have approval from the Bureau of Biologics for use of the product in a maximum of 10 treatments (not patients) in the following six Centres.

Worcester, Massachusetts
The Memorial Hospital.

New York
Mount Sinai Medical Centre

&

Cornell Medical Centre

Detroit
Children's Hospital of Michigan

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Los Angeles
Orthopaedic Hospital

Chapel Hill, North Carolina
Memorial Hospital

The only hospital which has asked for a letter of indemnity is Mount Sinai. Apparantly this is normal practice for this Medical Centre and no clinical trials are carried out without such a document. It is not a special for Speywood.

We will probably have to do trials in Canada as well, but I have no details as yet.

MONO vWf

Small number of patients will be involved in trials for this product in a number of countries. The total will be no more than 30 and the countries, U.S.A., Canada, France, Germany, Italy and U.K.

In considering the risks involved with Hyate:C, one should remember that the product has already been used extensively. It was introduced for sale on a named patient basis in July 1980 and we have now had over 150 treatments in 10 countries. The only problems have been minor and certainly not of a type where there has been any question of an insurance claim.

The situation is even easier with the two human plasma proteins, Mono VIII:C and Mono vWf. These are obtained from naturally occuring material in current use, using our purification technology. The safety of this technology has been checked extensively both chemically and by in vivo animal studies. The results of this work have convinced the United Kingdom Department of Health that the process is completely safe and adds nothing to the product. Whilst one can never say that adverse reactions are unlikely, the chance of a serious problem is extremely remote.

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I hope this gives you information you require.

Yours sincerely,

David R. Williams

c.c. Mr. P. Lees