APPENDIX 5

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THE ROYAL INFIRMARY OF EDINBURGH

HAEMATOLOGY DEPARTMENT

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Telephone: 031-229 2477

Your Ref.:
Our Ref.: CAL/PMS

6th July, 1987

The Secretary,
Medical Defence Union,
3 Devonshire Place,
LONDON
W1N 2EA

Dear Sir,

Factor VIII Concentrate manufactured by the NHS Protein Fractionation Centre Edinburgh

I write to let you know of a potential difficulty that is developing in relation to the development and assessment of new heat treated factor VIII concentrates by the NHS in Scotland.

I have always worked closely with the Scottish National Blood Transfusion Service in the development of new blood products for treating patients with haemophilia. This has been on a fairly informal basis.

About 4 years ago I raised the question of compensation with SHHD for patients who might materially suffer as a result of assessment of concentrates during clinical trials. My aim was to get agreement to abide by ABPI Guidelines in the event of a clinical disaster without the patient having to sue for negligence (which there might not have been). No progress was made until earlier this year I refused to undertake a Phase I study of a new heat treated preparation. The Department then offered ABPI Guideline cover at a meeting between Departmental Officials, SNBTS and Scottish Haemophilia Directors on 9th February 1987. Unfortuantely there is disagreement as to what was offered by Department at the meeting. My recollection and that of at least one other person present, was that ABPI Guidelines cover was offered for Phase I and II trials, but the "official" view is only Phase I studies are to be covered. I am naturally very unhappy about such an arrangement and in my view the Department has reneged on a verbal undertaking.

I undertook the Phase I studies of a new heat treated preparation as requested without misadventure. Although I knew that the tested product was to be introduced for the routine treatment of patients this actually started without my formal agreement and without detailed arrangements being made to monitor the patients whilst I was out of the country recently at the AIDS Conference in Washington.

I am unhappy about the present arrangements for the following reasons.

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1. I have been asked to use the new heat treated factor VIII in what I believe could be considered a clinical trial to assess its clinical efficacy without the patients having the benefit of ABPI Guideline cover.

2. As far as I know no Clinical Trial Certificate has been obtained for this unlicenced product.

3. As you will see from the enclosed letter from Dr. MacIntyre he does not want me to issue the explanatory leaflet to my patients (copy enclosed). I am sending you a copy of my reply to Dr. MacIntyre.

I am not sure that any action is required by the MDU at present but I should be grateful for any observations you might like to make. At present I would rather you did not contact either SHHD or SNBTS without consulting me.

Yours faithfully,

C.A.Ludlam
Director, Haemophilia Centre