APPENDIX 6
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THE ROYAL INFIRMARY OF EDINBURGH

HAEMATOLOGY DEPARTMENT

DR. A. C. PARKER (Ext. 2079)
DR. C. A. LUDLAM (Ext. 2099)

Senior Chief M.L.S.O.
MR. P. F. J. NEWMAN (Ext. 2768)

LAURISTON PLACE
EDINBURGH EH3 9YW

Telephone: 031-229 2477

Your Ref.:
Our Ref.: CAL/PmS

6th July, 1987

Dr. B. Leonard,
Chairman,
Clinical Oncology,
MRC Building,
WGH

Dear Dr. Leonard,

Clinical Assessment of Heat Treated Factor VIII

I enclose an application for a Phase II study.

The factor VIII concentrate is produced by the Protein Fractionation Centre, Edinburgh and as such does not need a Product Licence. The material has recently been issued for the routine therapeutic use in patients in what I believe is a Phase II trial. As far as I know a Clinical Trial Certificate has not been obtained. Additionally the SHHD is not prepared to offer ABPI Guideline cover in the event of a patient experiencing a severe reaction.

I would be happy to discuss the application with you personally or attend a meeting of the Committee to give further information and clarification.

Yours sincerely,

C.A.Ludlam
Director, Haemophilia Centre

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CLINICAL ASSESSMENT OF HEAT TREATED FACTOR VIII

Introduction

Bleeding in patients with haemophilia A can be stopped by infusion of factor VIII concentrates prepared from blood donor plasma. One of the potential side effects of this therapy is that the product may transmit viral infections eg hepatitis and HIV (AIDS virus). Some viruses can be inactivated by heating eg HIV, and all factor VIII concentrates are so treated. The SNBTS has recently produced a new factor VIII concentrate which has been heated to greater than 75°C for 72 hours. This new material has been given to a small number of patients to measure its half life.

AIM

To assess the clinical efficacy to stop bleeding of factor VIII produced by SNBTS which has been heated to greater than 75°C for 72 hours. All side effects will be documented.

PROTOCOL

1. If possible written informed consent will be obtained.

2. The appropriate calculated dose of factor VIII, sufficient to stop bleeding, will be infused intravenously. The dose will be repeated as often as clinically indicated. Factor VIII levels will be measured when clinically necessary.

3. The clinical response and adverse reactions to the infusion will be recorded.

SUBJECTS

Haemophilia A patients who require therapeutic factor VIII infusions. No. of subjects - up to 100.

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LOTHIAN HEALTH BOARD
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Please direct all correspondence to:
DEPARTMENT OF CLINICAL ONCOLOGY
WESTERN GENERAL HOSPITAL
EDINBURGH EH4 2XU
Telephone: 031 332 2525 Ext. 4080

RCFL/PR

8th July 1987

Dr C A Ludlam
Director, Haemophilia Centre
Haematology Department
Royal Infirmary
EDINBURGH

Dear Christopher

Thank you for your letter and following our phone call I can confirm that the Committee will find it rather difficult to give an approval for a substance which is given to patients which has not yet had ABPI guideline cover in the event of patients experiencing a severe reaction. The treatment of the product seems to be perfectly reasonable, the aims of treating it with heat of course are very important in minimising the risk from hepatitis and HIV infection. I do not see why this particular product should produce any extra risks to the patients, the only problem of course if lack of efficacy in protecting against haemophilia related bleeds but of course I presume these can be treated with more conventionally processed factor VIII in the event of the tests product being relatively ineffective. Please convey to the SHHD my misgivings about approving the use of such a compound when it has not received the appropriate ABPI cover.

The Committee of course will discuss this in more detail in August but I have circulated by letter to you so that individual members of the Committee can make their comments direct to you in the next few weeks if they feel moved so to do.

Best wishes.

Yours sincerely

R C F Leonard
Chairman, Medical Research Sub-committee
for Medicine & Clinical Oncology

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Northern
General
Hospital

FERRY ROAD, EDINBURGH EH5 2DQ

Telephone: 031 332 2525

Ref: GN/GS/MCO/78/87

12th August, 1987

Doctor C.A. Ludlam,
Dept. of Haematology,
Royal Infirmary,
Edinburgh.

Dear Dr. Ludlam,

re: Ethics of Medical Research Sub-Committee
for Medicine and Clinical Oncology

I write to acknowledge receipt of your application form and protocols for consideration by the sub-committee.

I will write to inform you of the sub-committee decision at a later date.

Please quote reference no. MCO/78/87 in any future correspondence.

Yours sincerely,

pp C. Scott

Martin Farrar,
Administrator.

Protocol: Clinical Assessment of heat treated factor VIII.

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Northern
General
Hospital

FERRY ROAD, EDINBURGH EH5 2DQ

Telephone: 031 332 2525

Ref: GH/GN/MCO/78/87

20th August, 1987.

Doctor C.A. Ludlam,
Department of Haematology,
Royal Infirmary of Edinburgh,
Lauriston Place,
Edinburgh.

Dear Doctor Ludlam,

I write with reference to your recent application to the Ethics of Medical Research Sub-Committee for Medicine and Clinical Oncology entitled "Clinical assessment of heat treated factorV111".

I write to inform you that this application was given ethical approval at the last meeting of the Sub-Committee.

Yours sincerely,

G. Naismith,
Acting Secretary.