OXFORDSHIRE HEALTH AUTHORITY

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Our ref
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DEPARTMENT OF CLINICAL IMMUNOLOGY

John Radcliffe Hospital
Headington
Oxford
OX3 9DU

11th October, 1988

Mr. J.S. Adey,
Baxter Healthcare Ltd.,
Thorpe Lea Manor,
Thorpe Lea Road,
Egham.
Surrey.
TW20 8HY

URGENT : BY FAX
FOR THE ATTENTION OF
Mr. Ron Seakes.

RECEIVED
12 OCT 1988

Dear Mr. Adey,

I am concerned that Baxter Healthcare can no longer supply Gammagard for immunodeficiency patients outside approved clinical trials.

I have been using Gammagard since January 1985 and found it to be extremely satisfactory in the forty-five patients that I have treated with it. Liver function tests have been monitored regularly and we have had no concern about Non-A, Non-B Hepatitis; I would gladly supply the details of these liver function tests if they are needed. I am anxious to avoid patients receiving more than one type of immunoglobulin preparation since this would obviously complicate any retrospective analysis [if it were needed] in connection with any immunoglobulin preparation. It is for this reason that it is considered better immunological practice to maintain patients on a single preparation.

There is a particular group of patients who should avoid a change of preparation; these are patients who give their own infusions at home. The success of the Home Therapy Programme over the last two and a half years has been dependent on the very low rate of adverse reactions seen with Gammagard. Whilst other preparations can be used in the home setting, we would have to re-hospitalise patients for a period whilst changing their preparation which would be costly. In my view this cost would be unjustified as well as extremely inconvenient for the patients and hospital staff.

There is a third category of patients in whom there is no alternative for Gammagard. There are patients who are totally deficient in IgA and [illegible] developed, or [illegible] the risk of developing, antibodies to IgA. Such anti-IgA antibodies are associated with severe reactions to immunoglobulin therapy and it is therefore mandatory to give an immunoglobulin [IgG] preparation which has miminal contamination with IgA. Gammagard is the only preparation currently available in the UK which is safe for these patients. Presently five such patients attend the Oxford immunodeficienty clinic, two of whom are on the Home Therapy Programme. All patients are monitored carefully for anti IgA antibodies, so this number may increase.

and who either developed or ran the risk of developing antibodies to

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WTA486X

Mr. J.S. Adey,
Baxter Healthcare Ltd.,

11th October, 1988

A further patient suffers from diabetes mellitus in addition to hypogammaglobulinaemia. Since the alternative to Gammagard is based in 10% Maltose, the infusions with this alternative preparation would make management of his diabetes more difficult and it [illegible] Gammagard if at all possible. I can supply confidential clinical details about these six patients if this is necessary
about these 6 patients if this is necessary

I hope that this letter makes it clear that the management of Immunodeficient patients will be difficult, in some cases impossible, if Gammagard is no longer available on a prescription basis. Having used Gammagard for three and a half years and followed forty-five patients extremely carefully during this time, I am amazed that you are unable to continue to supply Gammagard on a prescription basis. Please let me know if you would like me to forward the liver function test data on these forty-five British patients.

Yours sincerely,

GRO-C

Dr. H.M. Chapel,
Consultant Immunologist.

management of his diabetes more difficult and he should remain