

**W3063002**

THIS IS THE EXHIBIT marked W3063002 referred to in the Statement of Dr Nicola Curry dated 11 October 2019.

3<sup>rd</sup> December 1997

Mr. Robert Hodgkins

GRO-C

Dear Mr. Hodgkins

**NEW VARIANT CREUTZFELD-JAKOB DISEASE AND BLOOD PRODUCTS**

We are writing to you about recent developments relating to the brain disease, Creutzfeld-Jakob disease (CJD), and blood products used for the treatment of haemophilia. It may be necessary to change your treatment and we would like you to understand the reasons for such changes.

Creutzfeld-Jakob disease (CJD) is a rare, fatal, neuro-degenerative condition of middle aged or old people of low infectivity which affects about 50 people a year in the UK. In the past people have been infected with classical CJD by exposure to brain and growth hormone prepared from the pituitary gland at the base of the brain. The infective agent is thought to be a prion protein found in the central nervous system in patients with CJD. There is no evidence so far that CJD can be transmitted by blood or blood products. There have been no reports of classical CJD in patients requiring regular blood transfusion or in patients with haemophilia.

CJD is one of a number of similar conditions known as transmissible encephalopathies found in other animals. Sheep scrapie and bovine spongiform encephalopathy (BSE) are the best known. Each of these conditions are generally only found in their own species and tend not to cross the "species barrier" infecting other animals. Even experimentally, it has been difficult to infect an animal with a transmissible spongiform encephalopathy from a different species.

The recently described new variant CJD (nvCJD) is different from classical CJD and appears to be caused by the BSE agent, and is presumably acquired through eating infected beef and related products. Over the past three years, 22 young adults have been reported with this condition in the United Kingdom and one in France. No cases of BSE or of nvCJD have been reported in the USA but there is a low incidence of BSE throughout Europe.

The Oxford Radcliffe Hospital  
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Recently prion protein has been shown in the tonsils and lymph nodes of patients with nvCJD. Since cells from lymph nodes also circulate in the blood, there is a very small possibility that nvCJD might be transmitted by blood transfusion. In the light of this, the government has been advised to consider the possibility of filtering out all the white cells from whole blood, and is currently commissioning an independent risk-assessment which will take six months to report.

At present, there is no screening test available which manufacturers of concentrates could use to screen donors for prion agents. Three weeks ago, the British manufacturer BPL withdrew a batch of 8Y and a batch of Replenate because two of the donors had subsequently developed nvCJD. According to our records, you did not receive either of these batches.

The Executive Committee of the UK Haemophilia Centre Directors' Organisation met recently with experts in CJD and plasma fractionation to consider the problem. Blood products like factor VIII are already made from plasma with white cells removed and do not transmit infections associated with white cells like glandular fever or cytomegalovirus and may not therefore transmit nvCJD.

The Haemophilia Centre Directors concluded that there was most likely to be little or no risk of infection with nvCJD from blood products but there can be no absolute certainty about this. They advised that "the risk would be reduced by using concentrates prepared from donor plasma collected in other countries, e.g. the United States of America, where there are no recorded cases of nvCJD or BSE." This recommendation was subsequently endorsed by the Haemophilia Society, which has written separately to all its members. In line with these recommendations, we would like to offer alternative American products to those patients currently receiving the British products 8Y, Replenate and Replenine. For patients currently using the BPL products Replenate and Replenine, we should be able to offer supplies of the American products Alphanate and Alphanine as stocks become available. However, if you wish to continue to receive your BPL product we will endeavour to supply it. For those on 8Y, additional funding will need to be secured and discussions with the purchasing authorities are continuing.

We would have preferred to have been able to have spoken to you personally about this issue. However, we hope you appreciate that the requirement to inform so many people in a short period of time does not permit this. Should you wish to discuss this further do not hesitate to call the Centre to speak to us at the numbers above. In order to ensure that patients have the fullest possible information on all the issues, and reasons that we have taken this step, we have arranged for a meeting in lecture theatre 1 at the John Radcliffe Hospital on Monday, 15<sup>th</sup> December 1997 at 7.30pm to present the evidence and discuss the matter, to which you are invited.

Yours sincerely

**GRO-C**

Dr. P.L.F. Giangrande  
Consultant Haematologist

**GRO-C**

David Keeling  
Consultant Haematologist