5/4 File Mr Winstanley

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MDRABAR/JM

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Dr. D. Walford,
Department of Health & Social Security,
Hannibal House,
1025A Elephant & Castle,
London SE1 6TE.

Dear Dr. Walford,

I want to advise you of important developments and actions being taken by Hyland Therapeutics and Travenol Laboratories in connection with the risks of Acquired Immune Deficiency Syndrome (AIDS). While the causative agent of this disease remains to be identified, some evidence suggests it is caused by a virus that can be transmitted by blood and certain blood products. Based on epidemiologic experience with AIDS, certain groups of potential plasma donors have been identified as representing a higher risk of transmitting the disease. Hyland Therapeutics instituted donor screening procedures designed to eliminate the high risk donor groups from its donor population well before the March 24, 1983 directive on screening procedures issued by the National Centre for Drugs and Biologics in the United States.

In spite of these precautions, Hyland Therapeutics recently became aware that one of its plasma donors, though not finally diagnosed, has been identified as a possible victim of AIDS. The donor in question is a member of the high risk groups, although on several occasions prior to donating, he denied being a member of such group. While healthy at the time of donation, he subsequently developed some of the clinical findings associated with AIDS, including an inverted T4/T8 ratio and generalised lymphadenopathy. His final diagnosis is still in question.

This donors plasma was included in pools that were fractionated into several therapeutic products for the haemophiliac, including Anti Haemophilic Factor VIII, Factor IX complex, and Anti Inhibitor Coagulant Complex. No therapeutic products fractionated from plasma pools that contained this donors plasma have been shipped to any customer in Europe.

In the United States, Hyland has recalled the only coagulation product fractionated from plasma containing that donor's plasma that had been distributed to customers. The recall involves one

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lot of Anti Inhibitors Coagulant Complex and is being taken at Hyland Therapeutics initiative, and not at the request of the National Centre of Drugs and Biologics. As a precaution, all lots of Factor VIII and Factor IX Complex that were manufactured from this donors plasma have been placed in quarantine pending future resolution of this donor's medical condition. None of these quarantined products have been distributed to customers in either the United States or Europe.

In addition to screening procedures to eliminate high risk donor groups, and placing in quarantine all products made from plasma pools affected by this donor, Hyland is taking a third major action it believes could contibute to the safety of the Haemophiliac. Hyland will, as expeditiously as possible, convert both its European and U.S. facilities to manufacture only heat treated Factor VIII product.

This new heat treated product, (Hemofil T) which Hyland Therapeutics has recently introduced, has equal potency and effectiveness as normal Hemofil (Anti Hemophiliac Factor (Human)), but has been subjected, during manufacture, to an additional heat treating step designed to reduce active viral content. This new product is being offered at only a small price premium over the regular non-heated product.

Since the causative agent for AIDS has not been identified, and since the effects of the heat treating process on all viruses have not been determined, Hyland Therapeutics cannot, at present, give assurance that the heat treated product eliminates the risk of transmission of AIDS. However, Hyland Therapeutics believes that administration of the heat treated product, designed to reduce active viral content, may increase patient and centre personnel safety.

Hyland Therapeutics will also as expeditiously as possible, file for US and European regulatory approval of heat treated Proplex, Factor IX Complex (Human) and Autoplex Anti Inhibitor Coagulant Complex and convert its facilities so as to manufacture only heat treated versions of these products.

Travenol Laboratories believes that the above steps represent the most responsible action that can be taken at this time to assure a continued safe supply of coagulation factor concentrate to the Haemophiliac population.

I would welcome your comments and suggestions.

Yours sincerely,

GRO-C

A.W. Barrell
Managing Director