

Alpha THERAPEUTIC U.K. LTD.

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Dear Prof Bloom

ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)

Following the recent upsurge in interest and media publicity regarding this problem I have obtained from our parent company in the USA (Alpha Therapeutic Corporation of Los Angeles) more details of the precautionary steps that have been introduced to minimise the risk of this disease being transmitted via our pool of donors to the haemophilia population. They are as follows:-

- 1 Effective December 27 1982 all donors are screened to exclude those potential donors who are from or who have been in Haiti; have ever used illicit drugs intravenously; and male donors who have had sexual contact with a man. The plasmapheresis centre manager must accompany each shipment of plasma with a declaration to the effect that the exclusions above have been carried out.
- 2 Each potential donor is now issued with a leaflet on arrival at the centre giving the basic background information on AIDS and its possible transmission through plasma donations. The importance of them not donating if they belong to one of the exclusion groups is emphasised.

I also attach a transcript of a press release issued by the Corporation in January 1983.

I hope this adequately demonstrates the company's rapid response to the concern expressed by the medical community and that we appear to be 'leading the way' as far as major plasma fractionators are concerned to make our final products as safe as possible. If you have any other points you would like to raise on this issue please contact me asap.

Yours sincerely

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I D Marshall

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ALPHA THERAPEUTIC ACTS TO PROTECT HAEMOPHILIACS FROM AIDS EPIDEMIC

LOS ANGELES, CALIFORNIA 7 January 1983 in one of the first public health actions intended to protect hemophilia patients and other blood product users from AIDS - the deadly new epidemic that technically is called acquired immune deficiency syndrome - Alpha Therapeutic Corporation, a leading producer, has taken steps to exclude from its donor pool persons who may be at high risk of transmitting the disease to others.

Alpha Therapeutic Corporation of Los Angeles which is one of the world's principal suppliers of antihemophilic factor and other plasma products, has told its several hundred plasma suppliers that, as of 20 December 1982, they must "exclude donors" who may be part of three potentially high-risk groups: persons who have been in Haiti; drug abusers and male homosexuals. There is a "higher incidence of AIDS" in these groups than in the community at large, the company says.

The new Alpha policy was initiated in response to a request from the National Hemophilia Foundation (NHF), which recommended late last year that individuals belonging to these high-risk groups be excluded from donor pools. The Foundation issued its request after a half-dozen AIDS cases were discovered among hemophilia patients. None of these hemophiliac AIDS victims is homosexual.

The evidence suggests, although it does not absolutely prove, that a virus or other disease agent was transmitted to them in the Factor VIII concentrate, derived from pooled human plasma which they rely on for life - and for sustaining a relatively normal lifestyle.

Surveys now being conducted by NHF are producing other disquieting findings:

- * AIDS has jumped from the seventh to the second most common cause of death in hemophiliacs within a year.
- * The case rate appears to be rising.

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The Alpha move to bar the putative AIDS agent from Factor VIII donor pools was hailed by NHF medical advisor Louis Aledort, MD, a haematologist at the Mt Sinai School of Medicine in New York City. He said that he anticipated that other plasma and blood products suppliers quickly will follow Alpha's lead.

The new Alpha policy was announced by their medical director, Clyde McAuley, MD, at the US Centres for Disease Control (CDC) on 4 January 1983, at the second meeting of an ad hoc Workgroup to Identify Opportunities for Prevention of AIDS.

"I have a responsibility to hemophiliacs to produce a product that is not at increased risk of AIDS" Dr McAuley said. "We are excluding male homosexuals, Haitians, and drug users because frankly we don't have anything else to offer at this time".

These restrictions are not unique. Blood banks routinely exclude as donors recent travelers from Africa, who may be carrying malaria and persons who have suffered from hepatitis.

In the future, Dr McAuley and other plasma industry and government experts predict, other ways will be found to safeguard Factor VIII. At present, for example, Factor VIII concentrate - the most economical and convenient form of the clotting factor - is not heat-treated, because heat reduces its potency. In light of the apparent risk that it may carry an infectious agent for AIDS, however, drug companies are working with the US Food and Drug Administration (FDA) to develop and test effective heat-treated Factor VIII concentrate products.

Other safeguards were proposed at the CDC meeting, including tests - which now are being evaluated - which would detect donor blood and plasma that is at high risk of transmitting AIDS.

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Hemophiliacs are not the only potential beneficiaries of these actions. In recent months, three cases of AIDS appear to have occurred in persons who are not hemophiliacs, as the result of receiving blood transfusions - and blood bankers are fearful that there soon may be many more.

Pending firm identification of the AIDS causative agent, and the introduction of definitive measures to stop its transmission - which could take years - the introduction of measures to exclude high risk donors thus may be an important line of defence for the community at large.