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Dr. L. K. Fowler

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products (in particular Factor VIII) not be reduced to levels where patients can not be treated. The statement by Professor Bloom in the attached communication from The Haemophilia Society is particularly pertinent.

All participants in the procurement and supply of Factor VIII (either cryoprecipitate or concentrate) face the same dilemma. There is no test for AIDS. What we (and presumably other countries, including the U.K.) are doing is to attempt an unproven and probably inadequate screening of donors by certain gross definitions of high risk groups and general physical examinations. Only time will tell if these checks on donors are accurate.

More specifically addressing your questions:

1. By common agreement and with the regulatory pressure of the U.S. DHHS, all plasma donors are screened to an extent consistent with present medical-scientific knowledge. This program is spelled out in the attached Cutter documents and FDA directives which may be the same as already supplied to you by Mrs. Tatt. Cutter and the other manufacturers are complying in every detail.
2. The cases of AIDS in hemophiliacs are of course complicated to follow up but our investigations indicate that none received Koate.
3. So far, we have not had to make a decision concerning disposition of a lot of Koate from a donor who has become an AIDS victim. It is our plan that if this circumstance should occur, the decision concerning the lot would depend on many factors including, most importantly, receipt of advice from government health authorities based on the latest knowledge concerning AIDS.

Cutter intends to keep aware of progress in the world in the identification of the mechanism of the syndrome itself, of possible tests which may be applicable and of methods of treatment of product designed to prevent transmission of AIDS.

bcc: J. Hjorth
V. Shalson
W. Ewald

cc: M. W. Tatt
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JNA/jwk

encl.

Sincerely yours,

GRO-C

J. N. Ashworth, Ph.D.
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