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December 6, 1984

Prof. Ian Temperley National Hemophilia Treatment Center St. James' Hospital P.O. Box 580 Dublin 8, Eire

Dear Professor Temperley:

We have received a report of development of AIDS with Pneumocystis pneumonia in a hemophilia A patient at your center. We also understand that this patient has received only Koate³⁰ Antihemophilic Factor (Human) from Lot NC8502A since 31 January, 1984 (a period of 10 months), and that prior to that time, he had received various combinations of other products.

A recent publication from the Centers for Disease Control in Atlanta entitled "Update: Acquired Immunodeficiency Syndrome (AIDS) in Persons with Hemophilia" MMWR 33 (42): 589-591, 26 October, 1984, indicated the incidence of AIDS in hemophilia patients who had received cenly Factor VIII concentrates during the incubation period of AIDS. These patients also were in no other high risk group. Of the total number of AIDS in hemophilia patients in the U.S., 52, only nine qualified for inclusion in this category. The incubation period is considered to be up to five years. Since AIDS runs a general incubation period of 14 months to two years, and the CDC considers 5 years the maximum, it is entirely possible that the products your patient received prior to 31 January, 1984, could have transmitted the AIDS virus.

We also respectfully point out, of these 52 hemophilia patients with AIDS, 3 (5.8%) were also members of other high risk categories. Even though this individual is from the deep country, this alone does not guarantee exclusion from another high risk group.

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To date, we know of no case of AIDS which has been specifically traced to use of KoateB or Konyne® Factor IX Complex Human, nor have we been notified of such by the CDC or F.D.A., and no specific Lot, including NC 8502A, has been suspect.

Since this patient had received Koate[®] from this Lot for only 10 months, he could well have come into contact with and have become infected by the AIDS agent in various therapy modalities in the four year period prior to institution of Koate^R infusion from Lot NC 8502A on 31 January, 1984.

Cordially yours

G.M. Akin, M.D., F.R.S.H. Director, Medical Services

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GMA/dmc

CC: E. Greene R. Rousell R. Schwartz V. Shalson K. Fernandez B. Elliott-U.K. B. Dyos-U.K.

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