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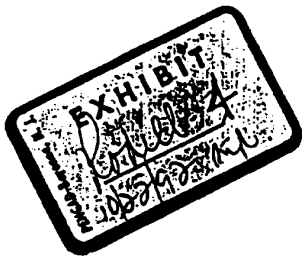

HYLAND THERAPEUTICS DIVISION
TRAVENOL LABORATORIES, INC

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Glendale, California 91202, U. S. A.
213-956-3200

JOHN BACICH
DEC 14 1982
DIRECTOR
BIOPRODUCTS

December 9, 1982

Mr. Charles J. Carman,
Chairman of the Board
Dr. Louis M. Aledort,
Medical Co-Director
The National Hemophilia Foundation
19 West 34th Street
Suite 1204
New York, New York 10001

Dear Mr. Carman and Dr. Aledort:

In your letters of November 2, 1982 to Mr. David Castaldi and myself, you advised us of the resolution passed by the Foundation's Medical and Scientific Advisory Council recommending the exclusion from plasma donations of certain groups of individuals considered to be in a high risk category relative to AIDS.

As a responsible manufacturer of Antihemophilic Factor (Human), our organization certainly shares your concern over the reported incidence of AIDS among hemophiliacs. In its recommendation, the Council identified homosexuals, intravenous drug abusers, and recent residents of Haiti as those groups for which participation in plasma donation should be restricted. I believe that it is appropriate for us to delinate procedures that are in effect in our plasma collection centers, and to comment on what further steps are being contemplated.

It has consistently been our practice to eliminate from our donor population those individuals known or suspected to be illicit users of intravenously administered drugs. Our standard operating procedures require that the forearms of donors be checked every time they present themselves, for evidence of drug injection. Unless recent needle marks can be ascertained to result from plasma donation, donors showing such marks are rejected. Donors with recent scar tissue indicative of drug abuse are likewise rejected from participation. Thus, we believe that we are taking good precautionary measures to eliminate this population from plasma programs.

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Within the past several months, we have made a commitment to withhold from AHF manufacture any plasma obtained as a result of specific recruiting activities aimed at the gay community. You are no doubt aware of a significantly greater incidence of high titered anti-HBs plasma among homosexuals, likely due to close personal contacts with members of that community having clinical hepatitis B infections. Such plasma is of great need in the production of HBIG; however, we no longer allow this plasma to enter those pools leading to AHF manufacture.

We have not yet made any efforts to determine sexual preferences among our general donor population, and question whether any organization has the ability to obtain totally reliable information of this nature. It might be possible to identify some homosexuals directly, using conduct, appearance and mannerisms as a guide; however, it is likely that the great majority of homosexuals cannot be readily differentiated from the general population by these parameters. Questioning individuals as to their sexual preference would be extremely difficult and may not lead to identification of homosexuals in any appreciable numbers. We will be evaluating ways and means of communicating the AIDS situation to donors and will urge any of them who are homosexuals to so indicate during qualification procedures. These individuals will be withheld from normal programs.

We will also instruct the plasmapheresis centers to question all potential donors to determine if they have been residents of or visitors to Haiti within the past 36 months. Those replying affirmatively will be excluded from participation.

I must point out that we, and other manufacturers, produce AHF derived from source material other than plasma donations. A significant amount of AHF is derived from Recovered Plasma, resulting from whole blood programs. Since manufacturers do not control the recruiting activities of collectors of whole blood, I cannot comment on the characteristics of their donors, other than that they represent the general population. Consequently, plasma obtained from these organizations is likely to include material from one or more of those groups the Foundation has identified as high risk. To the best of my knowledge, those hemophiliacs who have contracted AIDS have received AHF concentrate from a number of manufacturers and sources, and that no product in particular can be excluded from consideration as being involved.

I have been in frequent contact with Dr. Bruce Evatt at CDC, and have provided him with quantities of material for his laboratory programs. These contacts will be continued as we attempt to gain a better insight on any relationships between AHF concentrate and AIDS.

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I hope that this response will be helpful to you.

Sincerely,

GRO-C

Michael B. Rodell, Ph.D.
Vice President,
Regulatory Affairs and Quality Control

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