EUROPEAN DIVISION
TRAVENOL INTERNATIONAL SERVICES INC.

Chaussée de La Hulpe 130
1050 Brussels - Belgium.

TELECOPY

to: CH. CHARD - Thetford (Telecopy)
A. CAMERON - Thetford

date: May 31, 83

from: J. VAN CALSTER

copies: F. BONANNI
G. ROLLAND
G. DE CARITAT
E. PLATTEAU
R. SRIGLEY - GLO (Telecopy)

subject: HEMOFIL - T in relation to AIDS

Hereunder, you will find my response to the questions raised by your Health Dept.

1. Which precautions are we instigating to prevent AIDS cases from donating blood ?

The HYLAND DIVISION OF TRAVENOL LABORATORIES Inc. has instituted donor screening procedures designed to eliminate high risk donor groups from its donor population. This was done well before the March 24, 83 recommendations to decrease the risk of transmitting Acquired Immune Deficiency Syndrome (AIDS) from Plasma Donors issued by the National Center for Drugs and Biologics of the FDA (Att. 1)

These procedures include :

- Educational programs to inform persons of increased risk of AIDS and to ask them to voluntarily exclude themselves from routine plasma programs.

- Donor screening programs to identify early signs and symptoms of AIDS in donors

- Coding system to identification of plasma from donors and of donors belonging to one of the high risk donor groups

Additional to that, TRAVENOL does not collect plasma from Centers in New-York, Miami, Hollywood and San Francisco from where the vast majority of AIDS cases have been reported.

2. Do we have any reports of recipients of HYLAND products developing AIDS after administration ?

No reports are known of recipients of HYLAND products developing signs or symptoms of AIDS.

RECEIVED
JUN 02 1983 ./.

MDL BAX004018
CONFIDENTIAL

AZ1 BAX 005998

Plaintiff's Exh. #0589

PLTF005601

CGRA0000293_0001

3. Have we used plasma from donors subsequently found to be AIDS positive ?

In spite of the above mentioned precautions, TRAVENOL became recently 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, we subsequently develop some of the clinical findings associated with AIDS, including an inverted T4/T8 ratio and generalized lymphadenopathy. This final diagnosis is still in question.

This donors plasmawas included in pools that were fractionated into several therapeutic products for hemophiliac, including Anti-Hemophilic 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 States, TRAVENOL has recalled the only coagulation product fractionated from plasma containing that donor's plasma that had been distributed to the customers.

The recall involved one lot of Anti-Inhibitors Coagulant Complex and has been taken at TRAVENOL's initiative and NOT at the request of the National Center 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 U.S. or Europe.

4. What are we doing with suspect AIDS positive products / plasma pools ?

Plasma collected from suspect AIDS donors is coded and quarantined.

Suspect AIDS positive products are properly identified and quarantined.

In addition of the screening procedures to eliminate high risk donor groups and placing in quarantine all products made from plasma pools affected by this one donor, TRAVENOL has taken a third major action it believes could contribute to the safety of the hemophiliacs. Travenol has converted both its European and U.S. facilities to manufacture only Heat-Treated Factor VIII product.

This new Heat-Treated product (HEMOFIL-T) is already registered by the FDA in the U.S. and by the BGA in Germany.

The Heat-Treated product has equal potency and effectiveness as normal HEMOFIL (Anti-Hemophilic Factor - Human), but has been subjected during manufacture to an additional heat-treated step designed to reduce active viral content.

At a recent press conference at the D.H.S.S., Dr Edward N. BRANDT, Jr - Assistant Secretary for Health (Public Health Service) announced that the FDA has approved a new heat treatment to reduce infection agents in the blood factor required by hemophilia patients (see Att. II)

Since the causative agent for AIDS has not been identified and since the effects of the heat heating process on all viruses have not been determined, TRAVENOL cannot, at present, give assurance that the heat treated product eliminates the risk of transmission of AIDS.

However, TRAVENOL believes that administration of the heat-treated product, designed to reduce active viral content, may increase patient and center personnel safety.

Recently, a group of researchers from the National Cancer Institute, the Harvard School of Public Health and the Institute Pasteur has published their observations about the isolation of Human T-Cell Leukemia Virus in patients with AIDS (Science, Vol. 220, 20 May 83).

Their preliminary observations were also published in the "Morbidity and Mortality Weekly Report" from the CDC (see Att. III)

A variation to the current HEMOFIL license in order to include the heat treatment as part of the manufacturing process has been submitted to the DHSS on May 13, 83.

TRAVENOL 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 Hemophilic population.

Regards,

GRO-C

JVC/ad

MDL BAX004020
CONFIDENTIAL

AZ1 BAX 006000