ARMOUR
PHARMACEUTICAL
COMPANY

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August 14, 1985

Peter Jones, M.D., F.R.C.P., D.C.H.
Consultant Paediatrician
Director, Newcastle Haemophilia
Reference Centre
Royal Victoria Infirmary
New Castle Upon Tyne
NE1 4LP England

Dear Dr. Jones:

I have been requested by Mr. Duane Miller to respond to your letter of July 19, 1985. In my capacity as designated Responsible Head of Armour Pharmaceutical Company to the U.S.A. FDA, I am directly involved in issues associated with plasma collection and processing, as well as manufacture of Antihemophilic Factor (Human).

We share your concern regarding the appearance of signs and symptoms suggestive of AIDS, or the disease itself, in hemophilic patients receiving clotting factor products. Recent data from the Center for Disease Control indicate that, in this country, over 80 hemophiliacs have been diagnosed as having contracted AIDS. Our current activities and programs are designed to minimize the potential for continued transmission of the disease.

In 1983, Armour Pharmaceutical Company submitted supportive data and a license amendment request to the Food and Drug Administration in order to incorporate a heat treatment step in the manufacturing process for our FACTORATE Antihemophilic Factor (Human) products. This heat treatment step, which was intended to reduce the risk of transmission of hepatitis viruses, was approved by the Agency. Subsequently, the causative agent of AIDS (LAV/HTLV-III) was identified, isolated and shown to be extremely sensitive to heat by scientists in several countries. All FACTORATE concentrates manufactured and distributed by Armour Pharmaceutical Company now undergo heat treatment.

27/9 Discussed with P Jones in B'mouth. Arranging Exhibits + considering guest speakers with [illegible] — [signature]

...cont'd...

cc [illegible]
[illegible]
D Miller
[illegible] did not respond.

Within the past several months, the Food and Drug Administration granted product licenses to three manufacturers for the production and distribution of reagents intended for use in determining the presence of antibody to HTLV-III in blood, plasma or serum. Although testing for Anti-HTLV-III is not mandatory in the U.S., our Plasma Alliance subsidiary implemented system-wide testing of each donation of plasma very shortly after the availability of the test. Units of plasma found to be positive for Anti-HTLV-III are not used in the manufacture of clotting factor concentrates, and donors of these units are permanently deferred from further participation in our plasma programs. In addition, the donor education programs that we implemented in 1982, designed to discourage members of high risk groups from participating in plasma donation programs, have been augmented and are still in place.

During the recent International Congress on Thrombosis and Haemostasis, Armour Pharmaceutical Company provided information to the medical community on our current research activities involving the preparation of purified Factor VIII-C via monoclonal antibody-affinity chromatography techniques. This information presented at the conclusion of an informal dinner, which you attended, is preliminary in nature; however, results to date are quite promising and indicate that such a product will be available in the foreseeable future.

In your letter to Mr. Miller, you requested specific information on the movement of plasma and plasma products internationally. Armour Pharmaceutical Company has never utilized plasma collected outside the continental United States in the production of clotting factor concentrates, nor do we intend to in the future.

Additionally, for the manufacture of clotting factor concentrates, Armour has not used plasma collected from cities in the United States designated by the CDC as "high risk AIDS areas". A listing of the center location of our subsidiary Plasma Alliance is attached.

If you believe that it would be helpful to your Newcastle conference scheduled for February 11-13, 1986, I would be pleased to present a complete overview on current practices designed to maintain the safety, purity, potency and efficacy of plasma products manufactured by us. Equally, Mr. C. Bishop from our United Kingdom operation would be pleased to help you with the organization of the Congress.

...cont'd...

I sincerely hope that the information in this letter will be of value to you, and indicative of our great concern and commitment for the care and treatment of hemophilic patients.

Sincerely,

GRO-C

Michael B. Rodell, Ph.D.
Vice President
Regulatory & Technical Affairs
Responsible Head

MBR:ag

bcc: J. O'Brien
H. McDade
D. Miller

PLASMA ALLIANCE CENTERS

Knoxville, TN	West Lafayette, IN
Chattanooga, TN	Cleveland, OH
Atlanta, GA	Columbus, OH
Nashville, TN	Dayton, OH
Louisville, KY	Indianapolis, IN
Akron, OH	Lexington, KY
Omaha, NE	Oklahoma City, OK
St. Paul, MN	Minneapolis, MN