HYLAND THERAPEUTICS DIVISION
TRAVENOL LABORATORIES, INC.

Interoffice correspondence

To: D. L. Castaldi

From: W. R. Srigley

Subject: AIDS

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cc: H. Kingdon
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On Thursday, June 9, a meeting was held with O.B. officials at PMA Headquarters in Washington to discuss product recall issues related to AIDS. This meeting was held at the request of interested PMA member firms in anticipation of an open meeting on the same topic which the FDA expects will be scheduled for July.

Those attending from the Office of Biologics were: Dr. Petricciani-Director of the Office of Biologics, Dr. Donohue-Director of the Division of Blood and Blood Products, Madge Crouch-Acting Deputy Director of the Office of Biologics, Sammie Young-Director of Compliance and Tom Bozzo-Chief of the Case Guidance Branch of the Division of Compliance.

Attending from Industry were: Bob Bennett-Merck Sharp & Dohme, Penny Carr-Alpha Therapeutic, Steve Ojalla-Cutter Laboratories, Mike Rodell and Bill Weathersby-Revlon Health Care and Rick Srigley.

PMA representatives in attendance were: John Jennings-President, Paul Kaufman-PMA Biological Section Representative and Geoffrey Smith-PMA Legal Department.

This meeting was an opportunity to discuss with the O.B. the concerns which manufacturers have in attempting to live with the potential that a donor whose plasma has been used in one or more pools over a period of time may later be found to have AIDS. The O.B. feels that there is a need to develop a policy to handle that eventuality and that the policy should be developed in a public forum involving the CDC, National Hemophilia Foundation and other interested parties. For their part, however, the policy must be one which does not interrupt the supply of coagulation products to hemophiliacs or cause a panic condition in the mind of users. Given the degree to which a relatively small number of donations can affect a large number of product lots and the uncertain - but long - gestation period for the disease, developing a policy which is acceptable to the major interest groups is seen as a real challenge.

The PMA, at this point, sees itself as a facilitator between the manufacturers and the O.B. and doesn't appear anxious to take a position.

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After considerable discussions, two alternative points of view began to emerge.

1) When a donor is found to have AIDS, his plasma is excluded from pools. If the manufacturer has followed donor screening guidelines, product need not be recalled. If donor records show signs of prior illness and the manufacturer had continued to plasmapherese the donor the manufacturer may be required to recall product. Left unanswered are questions related to the status of processed, but undistributed product. One corollary to this plan which was discussed was the feasibility and legality of discontinuing the distribution of product under the company's control but not recalling product which had already been sold. While this appeared to be workable from the point of view of the Compliance people, it has obvious shortcomings.

2) Pick a time period prior to diagnosis which the donor's plasma would be considered to be "at risk" and withhold from distribution (or recall) product manufactured from pools containing "at risk" plasma. The difficulty pointed out with this plan was that unless a very short (perhaps indefensibly short) time period were chosen, the amount of product affected could be very large.

A major point of disagreement was raised by the manufacturers with regard to the double standard imposed by the March 24 recommendations. It was pointed out that on the 20/20 news program the AHF product which had been shown in conjunction with one of the AIDS victims was ARC product processed by Cutter. Dr. Petricciani stated that the March 24 recommendations were interim and that the O.B. would welcome comments from industry regarding the donor screening and examination provisions - including the double standard. Dr. Donohue (reluctantly it seemed) agreed. Dr. Petricciani also pointed out that nothing prevents the manufacturers from imposing their own standards on top of those recommended by the O.B. Penny Carr said that Alpha had done just that, and had lost several vendors of recovered plasma as a result.

After some time it became apparent that no additional new issues remained to be discussed. The meeting adjourned with the following actions to be taken.

1) The O.B. will be scheduling an open meeting in July to discuss blood product issues related to AIDS; including the need for product recall.

2) The manufacturers will meet prior to that to assemble information pertinent to the subject which would be of benefit to the O.B. in formulating a policy. i.e.:

a) What effect has donor screening had on donor rejection for AIDS related reasons.

b) What's the feasibility and effect on product supply of a policy which required recall of product based on a presumption that the plasma of an AIDS victim is infectious for a period of time prior to the appearance of symptoms. What is the effect if that time period is short (approximately 1 month) vs. if it is long (12 months).

c) What action is recommended by the manufacturers to deal with this problem, given that the O.B. feels that it will be forced to take some sort of position on the matter which is scientifically defendable and, at the same time, politically responsive.

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