HYLAND THERAPEUTICS DIVISION
TRAVENOL LABORATORIES, INC.

Interoffice correspondence

To: D. L. Castaldi

From: W. R. Srigley

Date: December 30, 1983

Subject: Observations Regarding the Advisory Committee Hearing Meeting on December 15 & 16, 1983

My conclusions following the Advisory Committee Meeting on December 15 and 16 regarding surrogate testing of plasma are as follows:

1. The Office of Biologics is under great pressure to do something more regarding the AIDS problem. In view of the fact that there is no test which can detect the agent of AIDS or carriers of the agent, the only thing more that the office can do is to strengthen donor screening procedures. One of the biggest loopholes that has been cited in donor screening is the possibility that members of high risk groups would not admit to it. Since the anti-core test is so effective at distinguishing donors in increased risk groups, it's really the only straw that the office has to grasp at.

2. Dennis' position that the core test be implemented for source plasma collected from commercial centers caught most people, including his own staff and other members of the Office of Biologics, by surprise. Many did not support one or more aspects of his proposal. This can only increase the dissent within the Office of Biologics with regards to this issue.

3. I believe that the review of Dennis' proposal by the Task Force needs to be done in an open forum. Many people feel that a distinction between blood and plasma or between paid and volunteer plasma is untenable. An open Task Force will assure that these points of view are considered.

4. I believe that in the end anti-core testing will be mandated by the Office of Biologics either through the Administrative Procedure Act or by guideline in a manner similar to that used to institute donor screening procedures last March. We should consider the practicality of instituting such screening unilaterally prior to the enactment of such a requirement. This would have several advantages.

   A. It would reemphasize Hyland's position as a leader in the implementation of procedures designed to render products safer.

   B. If Dennis' point of view is supported by the agency, i.e., that the combination of anti-core testing and

201015

PLAINTIFF'S EXHIBIT

HDL BAX020126
CONFIDENTIAL

Plaintiff's Exh. #0596

PLTF003958

CGRA0000284_0001

heat treatment obviates the need for market withdrawals of product associated with an AIDS problem, it may be of significant financial value to us in the future.

C. Because of what was stated in item B., we may be able to utilize such a position as a means of encouraging prompt approval of our PROPLEX-SX T license amendment.

D. By establishing our own procedures and practices we may be able to influence the Task Force to recommend procedures similar to those which we would already have implemented.

5. I believe we should promptly require that all plasma processed in our facility be tested for anti-core as well as $HbsAg$ preferably by our own screening laboratory. This includes plasma purchased on the spot market and Red Cross plasma.

6. I believe we should investigate the possibility of using anti-core positive plasma for Albumin, PPF, and ISG. This would require that the Office of Biologics agree that inadvertant contamination of an AHF pool with a small quantity of core positive plasma would not constitute reason for withdrawing product from the market. The early implementation of screening may increase our chances of selling this concept to the Office of Biologics.

7. Implementation before the rest of the industry may allow us to establish a position with Abbott which may be to our advantage.

dc GRO-C

701016

MDL BAX020127
CONFIDENTIAL