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Cutter MILES

TO: Those listed DATE: 12/19/83

FROM: S. J. Ojala COPIES TO:
SUBJECT: Trip Report. FDA/NIH Non-Specific Testing Meeting Dec. 15-16, 1983

W F Schaeffler	J Akers	N Ashworth	J Cherry
R Cole	T Cooper	W Ewald	K Fischer
J Hjorth	M Mozen	J Ryan	M Sternberg
C Turner	C Patrick	W Johnson	C Moore
R Schwartz	R Rousell	B Modersbach	R Carmen
J Hink			

A meeting on non-specific (surrogate) testing was jointly conducted by the National Heart, Lung & Blood Institute and the Office of Biologics on Dec. 15-16, 1983. Following a general overview of plasma and blood donor characteristics, and the logistics of testing and shipping of products, several potential screening tests were reviewed in depth. Much of the information had been presented at earlier meetings, but we were not aware that Stanford had been using a T cell ratio test to screen blood for transfusion for nearly 6 months (at $12 per test).

Following the presentation of data, the Advisory panel for Blood products concluded that no one test was sufficiently selective and specific for AIDS screening. Dr. Donohue proposed that plasma donations be considered separately from blood donations, because the plasma industry had 6 centralized testing laboratories and could handle additional tests more readily. He pointed out that additional testing by blood banks could be a logistics nightmare.

Donohue recommended that Anti-core Hepatitis B testing be incorporated for routine plasma screening (in addition to current requirements) since it would indentify 90% of all potentially infectious (or high risk) donors. The Anti-core testing would add a further measure of confidence in product safety at a relatively low cost for the products involved. He reviewed the AHF market withdrawals that had been conducted and indicated that core testing and heat treatment could eliminate this potential for the future.

The advisory committee agreed with this recommendation, with the dissension of the Acting Chairman, Bill Miller of the St. Louis Red Cross. Dr. Miller stated that he believed that any testing required for plasma should also be required for whole blood. The committee is aware of a scheduled January publication in the New England Journal by the CDC indicating AIDS transmission in more than 30 transfusions. Several members of the audience objected to the proposal for one reason or another, but Mike Rodell of Armour proposed a Task Force to deliberate the details of the recommendation and provide further information in 3 months.

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This proposal was one that had been agreed upon by all the fractionators the previous evening. The general thrust of the task force is to provide a delaying tactic for the implementation of further testing. It was generally agreed that core testing would eventually become a requirement.

The addition of core testing is expected to eliminate approximately 15% of plasma donors, and 6-7% of whole blood donors if used by blood banks. Some blood bankers mentioned that public pressure would certainly be a motivating factor for core testing at their facilities.

The fractionators met with Donohue following the meeting and, although Donohue was not completely satisfied with the task force approach, he agreed to it. He stated that we should also take on the responsibility for all testing of recovered plasma. Rodell was named chairman of the Task Force and a meeting will be scheduled in January.

John Hink, in a prescient move, has already begun core testing at Cutter centers. We recommend that the implementation of core testing be accelerated to the maximum degree possible to obtain a competitive advantage in the market place. The approval of our heat-treat submission, in conjunction with core-screened plasma could present us with a potent marketing advantage. We made no mention of our plans to the others.

In summary, the conclusion of this meeting was that the time had come for Hepatitis core anti-body testing for plasma. Implementation will probably be achieved during 1984 for the industry.

GRO-C: Steven Ojala