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March 15, 1984

Dr. Duncan Thomas
Head, Division of Blood Products
National Institute for Biological
Standards and Control
Holly Hill, Hampstead
London, NW3 6RB England

Dear Dr. Thomas:

As a result of the December, 1983 meeting of the FDA's Blood Products Advisory Committee, a study Group was formed to consider the appropriateness of testing potential blood and/or plasma donors for core antibody to hepatitis B (Anti-HBc) as an additional means of identifying members of high risk groups associated with AIDS.

The Study Group met on March 6, 1984, at which time each member presented views, information, and data relative to the issue. We felt it appropriate to issue a summary statement regarding our findings and conclusions in advance of a full report to be prepared in the near future.

I am enclosing a copy of the Study Group's Interim Summary Statement, and hope that it will be helpful to you.

Sincerely,

GRO-C

Michael B. Rodell, Ph.D.
Vice President, Regulatory
and Technical Affairs

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Enc.

Interim Summary Statement

of

Hepatitis B Core Antibody Testing Study Group

by

Michael B. Rodell, Ph.D., Chairman

On March 6, 1984 the Study Group, formed subsequent to the December, 1983 meeting of the FDA Blood Products Advisory Committee, met to discuss the issue of testing potential blood and/or plasma donors for core antibody to hepatitis B (Anti-HBc). Membership of the Study Group consisted of representatives of the commercial and noncommercial fractionation industry, the plasmapheresis community, nonprofit blood collection and processing organizations, and the Food and Drug Administration.

The purpose of the meeting was to review all aspects and ramifications of the use of testing for Anti-HBc as an additional means of determining whether potential donors were members of high risk groups associated with Acquired Immuno Deficiency Syndrome (AIDS). Although a full report of the Study Group's deliberations and conclusions will be furnished to the Food and Drug Administration in the near future, it was felt that an interim statement should be made available at this time.

The Study Group was divided in its position on testing for Anti-HBc as a means of identifying AIDS high risk group members, with the majority believing that such testing was not appropriate for that purpose. However, members of the majority group indicated that they would likely be compelled to follow suit if any of the organizations represented initiated Anti-HBc testing programs. The report to be prepared will contain position papers summarizing the majority and minority opinions on this issue.

It was clearly recognized by the Study Group that a positive finding of Anti-HBc in an individual was not necessarily indicative of AIDS or the future development of the disease state; rather, it was viewed as a possible mechanism of identifying high risk group members, a number of whom are positive for this serologic marker. It was the prevailing opinion of the Study Group that if testing programs for Anti-HBc are employed they should not be confined to the plasma donor population, but should extend to whole blood donors as well.

There was unanimity on two additional issues that the Study Group addressed. First, the Study Group recommended the initiation of a pilot study in at least two metropolitan areas to ascertain the effectiveness of allowing plasma donors to privately provide a written indication as to whether their plasma should be used in the manufacture of products used in hemophilia treatment, analogous to the system currently utilized by the New York Blood Center in whole blood collections. Secondly, the Study Group recommended that pilot studies involving testing for β-2-microglobulin levels be designed, since the presence of this analyte appears to offer a higher degree of correlation with prodromal or active AIDS.