

**STATEMENT OF THE AMERICAN ASSOCIATION OF BLOOD BANKS
BEFORE THE BLOOD PRODUCTS ADVISORY COMMITTEE**

HBV NAT vs. HBsAg

March 15, 2001

**Presented by Louis Katz, MD
Chair, AABB Transfusion Transmitted Disease Committee**

The American Association of Blood Banks (AABB) is the professional society for over 8,000 individuals involved in blood banking and transfusion medicine and represents roughly 2,000 institutional members, including community and Red Cross blood collection centers, hospital based blood banks, and transfusion services as they collect, process, distribute, and transfuse blood and blood components and hematopoietic stem cells. Our members are responsible for virtually all of the blood collected and more than 80 percent of the blood transfused in this country. For over 50 years, the AABB's highest priority has been to maintain and enhance the safety and availability of the nation's blood supply.

AABB is happy to provide its perspective on the specific issues related to HBV transmission by blood products, and the broader issue of test selection for improvement of blood safety.

We have heard well derived comparative data that should allow rational consideration of the utility of NAT screening of volunteer whole blood donors for window period infection with HBV. AABB will cooperate eagerly and in a timely manner with the orderly implementation of this technology when appropriate assays are available.

More generally, we support the application of sensitivity standards across the various donor screening platforms being considered for implementation now and in the future. Test selection should be based on equivalent, or greater sensitivity and not on the specific technology being used. Assuming that an assay for HBsAg can be shown to provide equivalent detection of potentially infectious donors to a nucleic acid based test, there is no *a priori* reason to mandate exclusive use of the latter. Of course, if greater sensitivity and specificity are demonstrated, these considerations should drive the decision. Considerations of specificity, logistics, and resolution, among others, should drive the choices among equivalently sensitive assays. We believe that the FDA can play an important facilitating role in adoption of this approach in the international blood community.