Advancing Transfusion and Cellular Therapies Worldwide

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American Red Cross

STATEMENT

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Possible Criteria for Approval of Donor Screening Tests for vCJD

Statement before the Transmissible Spongiform Encephalopathies Advisory Committee

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September 19, 2006 – AABB, America's Blood Centers (ABC) and American Red Cross (ARC) thank the Food and Drug Administration (FDA) for the opportunity to speak at today's meeting. We are pleased that the FDA is considering ways to deal with the potential threat of transmission of Transmissible Spongiform Encephalopathies (TSEs) by transfusion and agree that it is important to consider ways to manage candidate blood tests for these diseases. However, we urge caution in the face of the many unknowns and the ethical concerns associated with the use of such tests, and will share general concerns related to possible approval of donor screening tests for vCJD. Several of these comments are based on a presumption of the absence of a confirmatory test being available for approval at the same time as a screening test might be submitted. We ask FDA to carefully consider the following issues.

- What are the criteria FDA will use to evaluate the proposed tests? Is there an adequate source of characterized samples? How would clinical trials be conducted? Would there be requirements for follow-up of presumptively positive individuals?
- What is the prognostic significance of a reactive test for those donors with and without a risk factor? What about the inherent difficulties of specificity and positive predictive value in a very low risk population?
- What is the nature of information to be provided to a donor with a reactive test? Please keep in mind that the blood collecting facility may be the primary source of information regarding potential vCJD issues, as practitioners are not likely to be well-informed about prion diseases.
- Similar issues arise when considering product recovery or recall based on a reactive test result.
- Would Lookback be required? If so, what is the nature of the information to be provided to the recipient?

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The blood and cellular therapy community has current experience with the use of screening assays for antibodies in the absence of a licensed confirmatory test – anti-HTLV-I/II and anti-hepatitis B core antigen (anti-HBc). There are no clear messages to be provided to the donor and currently there are no testing algorithms that can be used to assess the donor for re-entry. We would not like to see this occur, yet again, with vCJD donor testing, particularly given the potential severity of a reactive or positive test result.

We encourage FDA to use tools available to them through critical path initiatives to bring confirmatory testing methodologies forward at the same time that screening tests are being considered.

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About AABB

AABB is an international association dedicated to advancing transfusion and cellular therapies worldwide. Our members include 1800 hospital and community blood centers, transfusion and transplantation services and 8000 individuals involved in activities related to transfusion and transplantation medicine. For over 50 years, AABB has established voluntary standards and inspected and accredited institutions. Our members are responsible for virtually all of the blood collected and more than 80 percent of the blood transfused in this country. AABB's highest priority is to maintain and enhance the safety and availability of the nation's blood supply.

About ABC

Founded in 1962, America's Blood Centers is North America's largest network of community-based blood programs. Recognized by the U.S. Congress for its critical work in patient care and disaster preparedness and response, the federation of 78 blood centers together operate more than 600 collection sites in 45 U.S. states and Canada, providing half of the U.S., and all of the Canadian volunteer donor blood supply. These blood centers serve an area with more than 180 million people and provide blood products and services to more than 4,200 hospitals and healthcare facilities across North America. ABC's U.S. members are licensed and regulated by the U.S. Food and Drug Administration. Canadian members are regulated by Health Canada.

About ARC

The American Red Cross, through its 35 Blood Services Regions and five National Testing Laboratories, supplies nearly half of the nation's blood supply. Over six million units of Whole Blood were collected from more than four million Red Cross volunteer donors, separated into 12 million components, and supplied to 3.000 hospitals to meet the transfusion needs of patients last year.