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# STATEMENT

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## **Behavior-Based Blood Donor Deferrals in the Era of Nucleic Acid Testing (NAT)**

*Statement before the Blood Products Advisory Committee*

*Steven Kleinman, MD, Senior Medical Advisor*

**March 9, 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. AABB, ABC, and ARC commend FDA for holding a workshop to review the issues associated with the deferral of prospective blood donors on the basis of an elicited history of behavioral risk. In the context of that workshop, we would like to comment on the deferral criteria for men who have previously had sex with men.

On September 14th, 2000, AABB spoke before the Blood Products Advisory Committee, making the following recommendation:

"Since 1997 AABB has advocated that the deferral period for male to male sex be changed to 12 months. Modifying the deferral time period for male to male sexual contact to 12 months will make that deferral period consistent with the deferral period for other potentially high risk sexual exposures and will improve the clarity and consistency of the donor screening questions. The potential donor will be directed to focus on recent, rather than remote risk behaviors and should have better recall for answers to the screening questions."

The recommendation was not accepted, largely on the grounds that any relaxation in the criteria would increase the number of Human Immunodeficiency virus (HIV) seropositive individuals presenting to give blood and thereby increase risk to recipients because of false negative laboratory screening or inadvertent release of infectious units. We now have evidence to show that the vast majority of donors

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with prevalent infections will be positive by both antibody tests and nucleic acid amplification testing (NAT), thus assuring redundancy in laboratory testing.

AABB, ABC and ARC believe that the current lifetime deferral for men who have had sex with other men is medically and scientifically unwarranted and recommend that deferral criteria be modified and made comparable with criteria for other groups at increased risk for sexual transmission of transfusion-transmitted infections. Presenting blood donors judged to be at risk of exposure via heterosexual routes are deferred for one year while men who have had sex with another man even once since 1977 are permanently deferred.

Current duplicate testing using NAT and serologic methods allow detection of HIV- infected donors between 10 and 21 days after exposure. Beyond this window period, there is no valid scientific reason to differentiate between individuals infected a few months or many years previously. The FDA-sanctioned Uniform Donor History Questionnaire was developed recognizing the importance of stimulating recall of recent events to maximize the identification of donors at risk for incident, that is, recent, infections. From the perspective of eliciting an appropriate risk history for exposure to HIV and other sexually transmitted infections, the critical period is the three weeks immediately preceding donation since false negative NAT and serology reflect these window-period infections, and the length of these window periods provide the scientific basis for the deferral periods imposed for at risk sexual behaviors.

It does not appear rational to broadly differentiate sexual transmission via male-to-male sexual activity from that via heterosexual activity on scientific grounds. Neither does it seem reasonable to extend this reasoning to other infectious agents. To many, this differentiation is unfair and discriminatory, resulting in negative attitudes to blood donor eligibility criteria, blood collection facilities and, in some cases, to cancellation of blood drives. We think FDA should consider that the continued requirement for a deferral standard seen as scientifically marginal and unfair or discriminatory by individuals with the identified characteristic may motivate them to actively ignore the prohibition and provide blood collection facilities with less accurate information.

AABB, ABC and ARC acknowledge the concern that relaxation of deferral criteria may increase the number of presenting donors who are marker positive. However, this impact has not been measured directly; it has only been modeled using what may be incomplete assumptions. The blood collectors are willing to assist in collecting data regarding the actual impact of changes in the deferral, in order to allow for informed decision-making, and/or for the development of additional, appropriate interventions to ameliorate the impact.

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In summary, AABB, ABC and ARC believe that the deferral period for men who have had sex with other men should be modified to be consistent with deferrals for those judged to be at risk of infection via heterosexual routes. We believe that this consideration should also be extended to donors of human cells, tissues and cellular and tissue-based products.

#### **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. Seventy-seven blood centers operate more than 600 collection sites in 45 U.S. states and Canada, providing half of the United States, and all of Canada's volunteer donor blood supply. These blood centers serve more than 180 million people and provide blood products and services to more than 4,200 hospitals and health care facilities across North America. ABC's U.S. members are licensed and regulated by the U.S. Food & 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 6 million units of whole blood were collected from more than 4 million Red Cross volunteer donors, separated into 12 million components, and supplied to 3000 hospitals to meet the transfusion needs of patients last year.

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