Joint Statement before the Advisory Committee on Blood Safety and Availability

Donor Deferral for Men Who Have Had Sex with Another Man (MSM)
June 11, 2010

AABB, America's Blood Centers (ABC) and American Red Cross (ARC) appreciate the opportunity to address the Advisory Committee on Blood Safety and Availability (ACBSA) regarding the deferral criteria for prospective male blood donors who have had sexual contact with another male (MSM).

In 2006, AABB, ARC and ABC presented a joint position to the Food and Drug Administration's (FDA) Blood Products Advisory Committee (BPAC) stating our belief "that the current lifetime deferral for men who have had sex with other men is medically and scientifically unwarranted" and recommending that the deferral criteria "be modified and made comparable with criteria for other groups at increased risk for sexual transmission of transfusion-transmitted infections."

After reviewing the data and publications available since the above mentioned 2006 BPAC meeting, our organizations, which represent the blood banking and transfusion medicine community, maintain our recommendation that FDA amend the indefinite deferral currently in place for a male who has had sex with another male since 1977 to a 12-month deferral. This change in policy would conform the deferral period for MSM with the deferrals for other similar high-risk sexual behavior. For example, the current deferral period for individuals who have had sexual contact with an individual with HIV or viral hepatitis is 12 months. There is no sound scientific justification for these different deferral periods. In each of these cases, the vast majority of donors with prevalent infections will be positive by both antibody tests and nucleic acid amplification testing (NAT). This remains true even with increased numbers of HIV-infected MSM, as recently reported by the Centers for Disease Control and Prevention. The current "window period" from the time an individual is infected and the time screening tests would detect infection – approximately nine days for HIV, 7.4 days for HCV, and 30-38 days for HBV (without NAT) – falls well within a one-year deferral period.

In addition, our organizations do not believe the data regarding quarantine release errors (QREs) justify a different deferral period for MSM than that for individuals with similar high-risk sexual behavior. Blood centers and the vast majority of hospitals collecting allogeneic units now have systems allowing for computerized control of blood product release. We believe it remains critical for the transfusion medicine community to take steps to reduce the number of such errors

whenever possible. However, there is no sound rationale for focusing on QRE numbers as a justification for a near lifetime deferral for MSM and not for other high-risk behaviors.

AABB, ABC and ARC believe that the time is overdue for a change in the MSM deferral policy and urge the FDA to adapt a 12-month deferral period. As with other blood policies, it will be important to track the impact of this policy change. Our organizations remain willing to assist in collecting data regarding the actual impact of changes in MSM deferral periods on blood safety. Maintaining a safe and available blood supply continues to be our highest priority.

AABB is an international, not-for-profit association representing individuals and institutions involved in the field of transfusion medicine and cellular therapies. The association is committed to improving health by developing and delivering standards, accreditation and educational programs that focus on optimizing patient and donor care and safety. AABB membership consists of nearly 2,000 institutions and 8,000 individuals, including physicians, nurses, scientists, researchers, administrators, medical technologists and other health care providers. Members are located in more than 80 countries.

Founded in 1962, America's Blood Centers is North America's largest network of community-based, independent blood programs. Recognized by the U.S. Congress for its critical work in patient care and disaster preparedness and response, the federation operates more than 600 blood donor centers providing nearly half of the U.S., and a quarter of the Canadian blood supply. These blood centers serve more than 150 million people and provide blood products and services to more than 3,500 hospitals and healthcare facilities across North America. America's Blood Centers' U.S. members are licensed and regulated by the U.S. Food and Drug Administration. Canadian members are regulated by Health Canada.

The American Red Cross, through its 36 Blood Services Regions and five National Testing Laboratories, supplies more than 40% of the nation's blood supply. Over six million units of whole blood were collected from nearly four million Red Cross volunteer donors, separated into 9.5 million components, and supplied to approximately 3,000 hospitals and transfusion centers to meet the needs of patients last year.