



Joint Statement on FDA MSM Deferral Policy

December 2016

AABB, America's Blood Centers and the American Red Cross issued the following joint statement regarding the U.S. Food and Drug Administration's guidance "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products" which outlines the deferral criteria for men who have had sex with men (MSM):

"All blood collectors in the U.S. are required to follow the rules and regulations issued by the U.S. Food and Drug Administration, including blood donation eligibility. AABB, America's Blood Centers and the American Red Cross support the FDA's revised MSM blood donation policy of a 12-month deferral. Our top priority is the safety of our volunteer blood donors and the patients in need of lifesaving blood products.

Based on several years of research, the FDA's decision to change the MSM blood donation policy from a lifetime deferral to a 12-month deferral is consistent with selection criteria for other activities that are used to safeguard the blood supply from equivalent risks of transfusiontransmissible infections. At present, there are insufficient scientific data available to determine whether it is safe to rely only on individual behavioral risk factors when determining donation eligibility.

While testing has greatly improved, it is not 100 percent effective at detecting infectious diseases in donors with very early infection. The FDA selected the 12-month deferral to provide adequate time for the detection of infected individuals.

Donors who were previously deferred under the prior MSM policy may be evaluated by the blood collection organization for reinstatement. It is important to understand that the donor

reinstatement process involves potentially thousands of donors, and it will take time. We advise previously deferred donors to review information about the reinstatement process at their blood collection organization before presenting to donate:

- America's Blood Centers: americasblood.org
- American Red Cross: redcrossblood.org/donating-blood/lgbtq-donors

AABB, America's Blood Centers and the American Red Cross continue to work with the FDA to gather additional scientific risk data to assist the FDA in determining whether further changes are warranted in the future.

Individuals can also visit the FDA website for <u>detailed information</u> about its decision and the scientific data that it relied upon to make it."