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America's Blood Centers Supports FDA's Change Toward Individual Risk-Based Blood Donor Screening

Draft guidance treats all donors with respect, upholds the safety of our nation's blood supply, and would allow more people to donate at a critical time

Washington, DC – America's Blood Centers (ABC), the national organization of community-based, independent blood centers that supply 60 percent of the nation's blood supply, today applauds the Food and Drug Administration's (FDA) [draft guidance that](#) would establish blood donor screening based on individual risk behaviors, not sexual or gender identity. A final guidance will follow and must be issued before any changes are made that would allow blood centers to welcome previously deferred donors. ABC supports the use of rational, science-based deferral periods that are applied fairly and consistently among all blood donors. All U.S. blood centers are regulated by the FDA and must adhere to their donor eligibility policies.

“This is a milestone day in the history of blood donation in America. The FDA's proposal to a move to an individual risk-based deferral policy maintains the safety of our nation's blood supply while treating all donors with the fairness, equality, and respect they deserve. The swift action by FDA to propose this change reflects the strength of the data collected as a part of the Assessing Donor Variability And New Concepts in Eligibility (ADVANCE) Study, which demonstrated the ability to make this change without impacting the safety of the blood supply. We look forward to working with our member blood centers, the FDA, and key stakeholders to welcome impacted donors once this new change is finalized and implemented,” said Kate Fry, Chief Executive Officer at America's Blood Centers.

This change, which will expand donor eligibility nationwide, is happening at a critical time for the blood supply.

The COVID pandemic continues to disrupt many traditional school and work-based blood drives – the backbones of blood donation - resulting in critically low levels of available blood in many areas of the country. As a result, donations from individuals 19 and under have dropped nearly 50 percent over the last two years.

ABC recently released [a first of its kind guide](#) showing that although a blood transfusion is needed every two seconds in the United States, just three percent of the U.S. population donates blood each year.

The FDA initially instituted a lifetime deferral on blood donations for gay and bisexual in 1983 to reduce the chance of HIV in the blood supply at a time when testing was limited or non-existent. In 2015, the FDA revised this policy and moved to a 12-month deferral in response to comprehensive testing capabilities and data demonstrating safety in shortened deferral. This policy was revised again in 2020 to the current 3-month deferral during the COVID-19 public health emergency. ABC strongly supported these changes while continuing to advocate for the establishment of donor-screening based on individual risk behaviors, not sexual or gender identity.

The “Assessing Donor Variability And New Concepts in Eligibility” (ADVANCE) Study began in 2020. It was a pilot study funded by the FDA that focused on the blood donor deferral policy for gay and bisexual men. Three blood collection organizations, including ABC-members OneBlood and Vitalant, collaborated with LGBTQ community centers and organizations in eight U.S. locations to enroll participants.

The study, which concluded in December, sought to determine if different eligibility criteria could be used at blood centers nationwide that focuses on each donor’s individual risk behavior rather than their sexual orientation. Today’s updated guidance reflects the scientific data gathered as part of the ADVANCE Study.

Of note, the proposed draft guidance is only the first step in a lengthy process of welcoming previously deferred individuals as blood donors. The entire process, including the public comment period, final guidance, and blood center implementation, will take time. Individuals impacted by the proposed eligibility changes are encouraged to contact their local blood center to learn more.

Founded in 1962, America’s Blood Centers is the national organization bringing together community-based, independent blood centers. Its member organizations operate more than 600 blood collection sites providing close to 60 percent 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. All ABC U.S. members are licensed and regulated by the U.S. Food and Drug Administration. For more information, visit www.AmericasBlood.org.

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