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March 27, 2023

Division of Dockets Management (HFA-305)
Docket No. FDA-2015-D-1211
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Submitted via regulations.gov

Re: Docket No. FDA-2015-D-1211, "Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products," Draft Guidance for Industry

Dear Dockets Manager:

The undersigned organizations of the Alliance for a Strong Blood Supply applaud the Food and Drug Administration (FDA) for issuing draft guidance recommending that blood donor eligibility be determined based on individual assessment, regardless of gender or sexual orientation. We support FDA's evidence-based decision to eliminate the current time-based blood donor deferral for men who have sex with men while preserving the safety of blood as an essential medicine.

We commend FDA for advancing a new approach to blood donor eligibility that considers the evidence developed over many years from multiple sources, including surveillance information from the Transfusion-Transmissible Infections Monitoring System, data regarding the performance characteristics of nucleic acid testing, and the experiences of other countries, including the United Kingdom and Canada. Additionally, we appreciate that FDA's draft guidance was informed by the results from the ADVANCE (Assessing Donor Variability and New Concepts in Eligibility) study, which evaluated individual assessment strategies, and we look forward to reviewing the data when it is published. As the science continues to evolve, we encourage FDA to continue evaluating its policies in a timely manner to ensure that blood donation is as inclusive as possible without compromising safety.

Additionally, we urge FDA and the Department of Health and Human Services (HHS) to develop public-facing messaging related to this significant policy change that raises awareness related to the importance of blood donation and provides education about the new policy. We encourage FDA and HHS to co-develop this messaging with LGBTQ+ collaborators to ensure that it supports cultivating relationships and repair work with the communities that were previously ineligible to donate blood. Blood collection establishments, hospitals and providers that furnish blood transfusions will need to educate prospective donors and blood transfusion recipients about blood safety and the science supporting the evolving blood donor

eligibility criteria. FDA has a unique role in protecting the safety and availability of the blood supply and robust messaging that targets donors and patients, developed in collaboration with LGBTQ+ communities, is critical to supporting this effort.

Our organizations are committed to advancing the safety and availability of the blood supply. We are dedicated to championing the importance of blood donation and being good stewards of the blood supply to ensure that patients have access to life-saving blood transfusions. FDA's draft guidance is a significant step towards ensuring that blood donor deferral policies do not unnecessarily exclude individuals who are able to donate blood safely. We look forward to supporting the implementation of this new policy.

Sincerely,

AABB
AdventHealth Orlando
American Red Cross
American Society of Anesthesiologists
American Society for Clinical Pathology
American Society of Hematology
American Society for Transplantation and Cellular Therapy
America's Blood Centers
Blood Centers of America
Blood Centers of California
City of Hope
Community Blood Center, Inc.
LifeSouth Community Blood Centers
Medi-Ops
National Marrow Donor Program/ Be The Match
Northern California Community Blood Bank
Pride & Plasma
San Diego Blood Bank
Society for the Advancement of Patient Blood Management (SABM)
Stanford Blood Center
The University Blood Initiative (UBI)
UF Health Shands
University of Rochester Medical Center