



COLLEGE of AMERICAN PATHOLOGISTS

March 27, 2023

Robert Califf, M.D
Commissioner
US Food and Drug Administration (FDA)
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: 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Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products DRAFT GUIDANCE [Docket No. FDA-2015-D-1211]

Submitted via Electronic Submission to www.regulations.gov

Dear Dr. Califf:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Food and Drug Administration draft guidance entitled, *Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products*. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. As physicians specializing in the diagnosis of disease through laboratory methods, pathologists have a long track record of delivering high quality diagnostic services to patients and other physicians.

The draft guidance is recommending the elimination of the time-based deferrals for individuals with increased risk for transmitting human immunodeficiency virus (HIV) and instead assessing donor eligibility using gender-inclusive, individual risk-based questions relevant to HIV risk. The CAP supports the use of individual risk-based questions instead of gender-based criteria to evaluate donors for risk of HIV. We supported the 2020 shortening of the donor deferral period for men who have sex with men (MSM). We also supported the Assessing Donor Variability and New Concepts in Eligibility (ADVANCE) study, in which the FDA sponsored evaluation of new questions to screen donors on an individualized basis. We look forward to peer-reviewed publication of the study findings.

Based on the proposed FDA recommendations for blood donor deferral and requalification related to reducing the risk of HIV transmission by blood and blood products and the successful experience of numerous countries with individualized risk assessment, the CAP supports these recommendations in the draft guidance. **The**

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proposed recommendations are inclusive and more objective blood donor screening criteria, which expand opportunities for many prospective donors who have been excluded and potentially increases the blood supply while maintaining the high level of safety for life-saving blood transfusions that the medical community and the public expects.

In addition, the CAP encourages the FDA to continue monitoring blood donor and donation safety, as is necessary for all changes in donor suitability criteria via the Transfusion Transmissible Infections Monitoring system (TTIMS); and to perform an on-going evaluation of donor regulations for opportunities to be as inclusive as possible while maintaining transfusion safety. This includes support of further studies of the deferral period for HIV risk exposure. We also urge the development of public information and education to promote blood donations from everyone who is eligible including partnering with the LGBTQ+ community for messaging to ensure that the new policy becomes widely communicated. As part of an optimal communication strategy one suggestion may be to change the wording from “individual risk assessment” to “individual donor assessment” to focus on a less stigmatizing message and to be more welcoming to newly eligible donors. This change was recently recommended by the AABB.

In conclusion, the CAP supports the use of individual risk-based assessment (individual donor assessment) for blood donor screening and the prompt adoption of this guidance.

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Thank you for the opportunity to submit these comments. The CAP looks forward to working with the FDA. Please direct questions on these comments to Helena Duncan at (202) 354-7131 or hduncan@cap.org.