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March 23, 2023

The Honorable Robert M. Califf, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

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

Dear Commissioner Califf:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to comment on the U.S. Food and Drug Administration's (FDA) recommendations for evaluating donor eligibility using individual risk-based questions to reduce the risk of Human Immunodeficiency Virus (HIV) transmission by blood and blood products.[1] The AMA commends the FDA for taking this important step to update this policy in a manner that protects the nation's blood supply while keeping in line with the best available scientific evidence and ethics practices. With this step in the right direction, we encourage the FDA to expand the scope of this work to include other human tissue donation.

The AMA believes that the draft recommendations for deferral treat blood donors at risk for transmitting blood-borne infections, including HIV, in a fairer and more consistent manner. Moreover, the draft guidelines better align with principles for ethically well-grounded policy by extending the opportunity to participate in the socially valued activity of voluntary blood donation to a wider population of donors. In doing so, the revised recommendations minimize the problematic effects of stigma and discrimination associated with a 12-month deferral of blood donation by men who have sex with men (MSM).

AMA policy supports the use of rational, scientifically based blood and tissue donation deferral periods that are fairly and consistently applied to donors according to their individual risk. "Today, every unit of donated blood is rigorously tested to detect any trace of HIV, syphilis, hepatitis, West Nile virus or other blood-borne diseases."[2] Moreover, modern HIV testing, including nucleic acid testing technology, can detect the presence of HIV as early as seven days

[1] https://www.fda.gov/media/164829/download.
[2] https://ashpublications.org/blood/article/136/11/1223/463631/ART-and-science-of-keeping-HIV-out-of-the-blood.

post-infection.[3] As such, the AMA supports the FDA in its decision to not return to a 12-month deferral period for MSM blood donation after the COVID-19 pandemic has ended[4] and instead to maintain a three month deferral period since it is a positive step to increasing blood supply and advancing equitable scientifically based policy.

Furthermore, the FDA's funding of research into individual risk assessments for blood donation, such as through the Assessing Donor Viability and New Concepts in Eligibility (ADVANCE) study, is important work that must be continued. This vital research will help to ensure that blood donation standards continue to align with scientific progress. Moreover, as research in this area persists, we encourage the FDA to continue evaluating and monitoring regulations on blood donation and to consider modifications to the current exclusion policies if sufficient scientific evidence supports such changes.

With the strides that the FDA and the medical community have made in this area, the AMA encourages expansion of these efforts to policies regarding the donation of human cells, tissues, and cellular and tissue-based products (HCT/Ps). Current guidelines require MSM to defer HCT/Ps donation for 5 years since their last sexual contact with a man. This deferral period is not consistent with the guidelines for other groups of comparable or higher risk, and would similarly benefit from an individual, evidence-based risk assessment similar to that of blood donation. As the COVID-19 pandemic has limited access to hospitals and reduced preventive and elective treatments, there is extra incentive to remove these artificial barriers causing HCT/Ps scarcity, a field that struggled to meet patient needs prior to the pandemic.[5,6]

Finally, as the FDA makes this positive transition away from policy that defers categories of people based on membership to a population, and toward policy that defers individual donors on grounds of evidence-based risk assessment, we encourage additional research to improve the effectiveness of donor history questionnaires. Improvements in this area could complement donor education materials and could be a tool to identify ineligible donors in a fair and respectful manner. Therefore, we urge the FDA to encourage the blood supply community to draw on educational resources available in the HIV and public health communities and to engage these communities actively in reviewing updated donor education materials. Enhanced materials will not only serve the interests of blood safety but can also have the added benefit of providing health education to individuals who may need it most. Ensuring that information about testing and health services is available to individuals who are ineligible to donate would likewise serve broader goals of public health and individual well-being. In addition to donor education, providing a safe, private environment for self-disclosure that reduces the likelihood of stigma or

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[3] American Red Cross. Infectious disease testing. https://www.redcrossblood.org/biomedical-services/blood-diagnostictesting/blood-testing.html. Published 2021. Accessed September 1, 2021.

[4] U.S. Food and Drug Administration. Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products. https://www.fda.gov/media/92490/download. Published 2020. Accessed September 1, 2021.

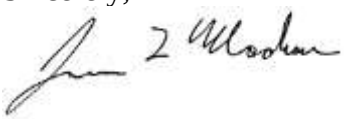
[5] Tanhehco YC, Schwartz J. How the COVID-19 pandemic changed cellular therapy at Columbia University Irving Medical Center/NewYork-Presbyterian Hospital. *Transfusion.* 2020;60(9):1905-1909.

[6] Williams AM, Muir KW. Awareness and attitudes toward corneal donation: challenges and opportunities. *Clinical Ophthalmology (Auckland, NZ).* 2018;12:1049.

embarrassment, e.g., by providing for computer-assisted donor history questionnaires, can help promote candor and self-deferral.

The AMA appreciates and supports the FDA in its recommendations to change its blood donation standards to focus on individually based risk assessments that are in line with current scientific evidence. Thank you for considering our comments. If you have any questions, please contact Shannon Curtis, Assistant Director, Federal Affairs, at shannon.curtis@ama-assn.org or at (202) 789-8510.

Sincerely,



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