

March 29, 2023

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

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”

Dear Dr. Califf:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Food and Drug Administration’s (FDA) draft guidance proposing that blood donor eligibility be determined based on individual risk assessment, regardless of gender or sexual orientation. **The AHA applauds and supports this life-saving and science-based decision by the FDA to eliminate the current time-based blood donor deferral for men who have sex with men (MSM) while preserving the safety of blood as an essential product for the care hospitals and health systems provide to their patients.**

Hospitals and health systems depend on a steady and robust supply of blood and blood products to treat and save the lives of our patients. The FDA’s current blood donor deferral rules have for many years prevented blood donations from MSM and women who have sex with MSM. Therefore, we are heartened that the FDA has taken into consideration our previous advocacy for changes in federal blood donation policy in this proposal. **For this reason, the AHA strongly encourages the new draft guidelines to be finalized, as they would increase the blood supply, including by bolstering the [health care field’s efforts](#) to urge everyone who can to donate blood. This change would also correct this historic inequity between different donor populations.**



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In addition, we urge the FDA and the Department of Health and Human Services to develop public-facing messaging related to this significant policy change, in coordination with health care provider and LGBTQ+ communities, to raise awareness of the importance of blood donation and provide education about the new policy. As you know, there will always be a need for blood in health care, and meeting that need will benefit from consistent and sustained messaging from all involved stakeholders.

The AHA is committed to advancing the safety and availability of the blood supply, and we look forward to working with the FDA to ensure that this guidance is appropriately implemented and to jointly advocate for the importance of blood donation.

We appreciate your consideration of these issues. Please contact me if you have questions or feel free to have a member of your team contact Roslyne Schulman, AHA's director for policy, at rschulman@aha.org.

Sincerely,

/s/

Stacey Hughes
Executive Vice President