



March 23, 2023

Robert M. Califf, MD
Commissioner
Food and Drug Administration
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Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Draft Guidance for Industry [FDA-2015-D-1211]

Dear Commissioner Califf,

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Food and Drug Administrations' (FDA) draft guidance on Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products. ACP believes this proposed policy change begins to mitigate the discriminatory impact of federal blood donation policy in a way that both increases the blood donor pool while also protecting the integrity of the national blood supply. The College applauds the Agency for undertaking such action and urges final adoption of this guidance.

ACP is the largest medical specialty organization and the second largest physician membership society in the United States. ACP members include 160,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge, clinical expertise, and compassion to the preventive, diagnostic, and therapeutic care of adults across the spectrum from health to complex illness. Internal medicine specialists treat many of the patients at greatest risk from COVID-19, including the elderly and patients with pre-existing conditions such as diabetes, heart disease and asthma.

FDA has historically issued guidance recommending that blood establishments implement screening questions to identify at-risk donors out of fears of higher risk of human immunodeficiency virus (HIV) and hepatitis transmission by such individuals through donated blood. In 1985, FDA initially imposed a lifetime ban on the donation of blood by men who had ever had sex with another man. In the years that followed, FDA continued to evaluate risk factors for HIV as well as its donor history questions and deferral recommendations. By 2015,

new research as well as epidemiological data from other countries that had shortened the deferral period for MSM had spurred FDA to update its guidance to reduce the lifetime ban to a 12-month deferral period. Further studies and experiences of other countries who had shortened their time-based deferral period for MSM, as well as the public health emergency created by the COVID-19 pandemic, prompted FDA to again revise their guidance to recommend a 3-month deferral period for MSM. The Agency also committed to explore the implementation of an individual risk assessment as an alternative to the time-based deferral approach, funding and facilitating the ADVANCE (Assessing Donor Variability And New Concepts in Eligibility) study, a pilot study that investigated HIV risk factors such as anal sex and rates of HIC among MSM study participants. **ACP contends that while protecting the safety and integrity of the nation's blood supply should be the paramount focus of FDA regulatory policy, it should do so in a way that is nondiscriminatory.**

During the COVID-19 pandemic, the U.S. experienced historical blood shortages throughout the country. On January 11, 2022, the [American Red Cross announced its first-ever blood crisis](#), calling it “the worst blood shortage in over a decade,” with donations down by roughly 10%. This decrease in blood supply has arisen from an unfortunate combination of factors, including virtual classes for high school and college students, resulting in a 62 percent decrease in campus blood drives; blood drive cancellations due to recent bouts of extreme winter weather; staffing limitations; and recent surges in COVID-19 and influenza cases. As a result, there had been less than a one-day supply of critical blood types at times, limiting the distribution of blood products to hospitals and causing some trauma centers to temporarily close. In light of these historic shortages, [ACP sent a letter to FDA](#) in February 2022 urging FDA to expedite its study and implementation of alternative policies that would safely increase the blood donor pool in a manner that does not discriminate against donors on the basis of sexual orientation and gender identity. While the worst of the crisis has subsided, [blood shortages still persist](#): roughly a year later, 22% of community blood centers have less than a 1 day supply, while another 32% have only a 1-2 day supply. Urgent action is needed to increase the blood supply and alleviate these shortages.

Draft Guidance

In the draft guidance, FDA proposes to direct blood establishments to update their donor history questionnaire (DHQ) to ask potential donors whether they have engaged in sex with a new partner or more than one partner in the past three months. Those answering affirmatively to either question should be further assessed for a history of anal sex in the previous three months. The Agency further recommends that potential donors who have had more than one sexual partner and/or have had a new sexual partner in the previous three months and have had anal sex in the previous three months defer blood donation.

ACP supports FDA's proposed guidance as a reasonable approach that shifts away from profiling entire groups and towards an individual risk-based assessment. The College believes this approach better aligns with the existing evidence around HIV transmission risks and reflects the evidence-based approaches [other countries have taken](#). ACP's longstanding [policy on](#)

[LGBTQ+ health](#) calls for the continued review of blood donation deferral policies for men who have sex with men and the establishment of evidence-based deferral policies that take into account a comprehensive assessment of the risk level of all individuals seeking to donate, which may result in varying deferral periods or a lengthened or permanent deferral on blood donation. Further, [ACP strongly opposes](#) all legislation and regulation with discriminatory intent upon individuals based on their gender, gender orientation, and/or sexual orientation. The College applauds the Agency for answering the numerous calls for expediting its study of the issue and updating its guidance as appropriate. These actions are a small step towards eliminating policies discriminatory towards the LGBTQ+ community and will have a meaningful impact on bolstering the nation's blood supply.

Conclusion

As the U.S. grapples with a dire blood shortage, ACP urges the FDA to take immediate action to reassess its current blood donation policies to allow for the safe donation of blood by all of those who wish to do so. ACP welcomes your agency's leadership on this issue and looks forward to working with you, the rest of the medical community, and other policy stakeholders on this issue. Please contact Josh Serchen, Associate, Health Policy at jserchen@acponline.org if you have any questions or need any additional information.

Sincerely,

A handwritten signature in black ink, appearing to read 'RDM', enclosed within a large, loopy oval shape.

Ryan D. Mire, MD, FACP
President