



Association of
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March 31, 2023

Peter Marks, M.D., Ph.D.
Director
Center for Biologics Evaluation and Research
Food and Drug Administration
Attention: FDA-2015-D-1211
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Submitted electronically via *www.regulations.gov*

RE: Revised Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products (FDA-2015-D-1211)

Dear Dr. Marks:

The Association of American Medical Colleges (AAMC) appreciates the opportunity to comment on the draft revision to the recommendations from the Food and Drug Administration (FDA) on reducing the risk of human immunodeficiency virus transmission through evaluation of blood donor eligibility. The revision of the existing standards, which included a 3 month donation deferral for men who have sex with men (MSM) regardless of any other risk factors, is welcome. This discriminatory prohibition based on gender and sexual orientation alone has been stigmatizing to the LGBTQ+ community and has negatively impacted the size of the blood donor pool.

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 157 U.S. medical schools accredited by the [Liaison Committee on Medical Education](#); 13 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened the AAMC's U.S. membership and expanded its reach to international academic health centers.

In general, the movement away from a time-based deferral for MSM and women who have sex with MSM to a more gender-inclusive and individual risk-focused set of criteria for donation eligibility has been widely recommended and anticipated. The AAMC is supportive of the removal of many of the existing restrictions on blood donation and urges the FDA to continue to revisit its recommendations to reassess whether remaining restrictions are still warranted, with additional research into transmission risk in connection with HIV viral suppression and advances in blood supply screening.

AAMC appreciates the FDA's goals of reducing unnecessary restrictions on blood donation while upholding its obligation to protect the safety of the nation's blood supply. The public and the medical community rely on the FDA to base its recommendations on the best available scientific knowledge and

to clearly identify where further areas of research are needed. We urge the FDA to continue active research into the risk of transmission of HIV through blood donation, especially for blood from individuals with an undetectable HIV viral load and those taking pre-exposure prophylaxis (PrEP).

Maintaining the public's trust in science is paramount and that communications about these changes must be thoughtfully developed. A key component of maintaining that trust is ensuring that messages from the nation's federal science agencies are clear, credible, and consistent. Decades of advances in biomedical research have resulted in effective viral suppression therapeutics and a growing confidence in PrEP to prevent HIV infection. We note that if the FDA's blood donation guidance appears to be at odds with parallel messages about the effectiveness and importance of these products, public health efforts to protect people living with HIV and their partners could be undermined.

The Centers for Disease Control and Prevention (CDC) website assures people living with HIV that to protect their partners they should "get and keep an undetectable viral load."¹ The first bullet under this heading affirms that "If you take HIV medicine and get and keep an undetectable viral load, you will not transmit HIV to your sex partner." The "undetectable equals untransmissible" or "U=U" campaigns have reinforced this viewpoint, with the NIH website declaring "an overwhelming body of clinical evidence has firmly established the HIV Undetectable=Untransmittable, or U=U, concept as scientifically sound."² The FDA recommendations to defer all donors who are taking medications to treat or prevent HIV infection, assert that untransmissible for sexual transmission "does not apply" to transfusion transmission. Similarly, the CDC website assures viewers that "if taken as prescribed, PrEP is highly effective for preventing HIV from sex and injection drug use." Without careful, cross-agency coordination of the message and a commitment to continuing research in these areas, the FDA risks sowing mistrust in the effectiveness of HIV treatment and prevention medications, the safety of the blood supply, or both.

The AAMC appreciates FDA's commitment to apply scientific evidence to its recommendations for keeping the nation's blood supply safe without needlessly excluding individuals who wish to donate blood. These revisions are a substantial step in that direction. Should you have any questions regarding this response, please contact me (rmckinney@aamc.org) or Heather Pierce, JD, MPH, Senior Director for Science Policy and Regulatory Counsel (hpierce@aamc.org).

Sincerely,

A handwritten signature in blue ink that reads "Ross McKinney, MD". The signature is stylized and includes a circled "MD" at the end.

Ross McKinney, MD
Chief Scientific Officer

cc: David J. Skorton, MD, President and Chief Executive Officer

¹ HIV Basics: Protecting Others, available at <https://www.cdc.gov/hiv/basics/livingwithhiv/protecting-others.html>.

² HIV Undetectable=Untransmittable (U=U), or Treatment as Prevention, available at <https://www.niaid.nih.gov/diseases-conditions/treatment-prevention>.