



March 31, 2023

Robert M. Califf, MD  
Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

Re: FDA-2015-D-1211

Dear Commissioner Califf,

On behalf of the Federal AIDS Policy Partnership (FAPP) and the 19 undersigned organizations, we are writing to provide comments on the draft *Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products*. FAPP is a coalition of local, regional, and national organizations advocating for federal legislation and policy seeking to ultimately end the HIV epidemic in the United States.

The draft recommendations put forth in January 2023 by the U.S. Food and Drug Administration (FDA) represent a long-awaited necessary change to address stigmatizing policies based on identity and expand populations eligible to donate blood. The elimination of time-based referrals for gay, bisexual, and other men who have sex with men is a hallmark advancement by the FDA rooted in scientific evidence and community advocacy. It also represents a significant opportunity to positively impact the lives of older gay, bisexual, and other men who have sex with men who were previously impacted by discriminatory blood-ban policies and can now donate blood if they meet the eligibility criteria.

The data utilized to inform this decision, including the Assessing Donor Variability And New Concepts in Eligibility (ADVANCE) study and existing policies in the United Kingdom and Canada, demonstrates the soundness of this change. The decades of discrimination from previous blood-ban policies for gay, bisexual, and other men who have sex with men lagged behind the science and shamed individuals from these communities based on identity alone. By creating a uniform assessment of all prospective donors, the safety of our blood supply increases by capturing all at-risk behaviors and removing harmful associations of sexual and gender identity with the ability to donate blood.

While FAPP supports the FDA's removal of discriminatory time-deferral policies and implementation of a revised current donor history questionnaire, the proposed recommendations fail to completely nullify indirect discrimination against gay, bisexual, and other men who have sex with men. Under the

proposed recommendations, any individuals taking pre-exposure prophylaxis (PrEP) or post-exposure prophylaxis (PEP) would be deferred, three months for oral modalities and two years for injectable medication. Many individuals who utilize PrEP or PEP overlap with gay, bisexual, and other men who have sex with men populations, so the indirect deferral of gay, bisexual, and other men who have sex with men populations will be widespread because of coinciding PrEP or PEP usage. We acknowledge the evidence behind this deferral is based on the best available data, where detection delay of HIV transmission may occur from currently licensed screening tests for blood donations. However, FAPP recommends a strategic research plan by the FDA on PrEP/PEP and blood donation – this is critical to the sustainability of the blood supply and should provide sufficient evidence to support removal of the current indirect discrimination.

Advancements in technology for testing donated blood for communicable diseases ensure a safe blood supply and leverage future opportunities to reduce any deferral policies for those utilizing the benefits of PrEP/PEP. The FDA should also continue to research and support the use of pathogen reduction technology that inactivate viruses and other infectious agents from donated blood products – technology that will be vital to ensuring a safe blood supply.

Additionally, we urge FDA to remove the prescreening requirements imposed on blood centers in order for them to accept gay, bisexual, and other men who have sex with men plasma and platelet donors. Singling out one population among all potential donors for a qualifying pre-test requirement further perpetuates stigmatization and discrimination.

Thank you for the opportunity to provide comments regarding proposed blood donor policy changes. We appreciate your attention, consideration, and commitment to the matter. Please do not hesitate to contact Nick Armstrong (NArmstrong@taimail.org) or Mike Weir (mweir@NASTAD.org) if you have any questions related to these comments.

Sincerely,

AIDS United

American Academy of HIV Medicine

APLA Health

Association of State and Territorial Health

Officials

Community Education Group

Five Horizons Health Services

HIV Dental Alliance

HIV Medicine Association

NASTAD

National Coalition of STD Directors

National Working Positive Coalition

PCAF

PrEP4All

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SAGE

San Francisco AIDS Foundation

The AIDS Institute

Treatment Action Group

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