

March 31, 2023

Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Submitted to: [www.regulations.gov](http://www.regulations.gov)

Re: Docket No. FDA-2015-D-1211 for “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Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Draft Guidance for Industry.”

Dear colleagues,

The Fenway Institute at Fenway Health submits this comment in response to the RFI on blood donation practices, Docket No. FDA-2015-D-1211. The Fenway Institute is the research, training, and health policy division of Fenway Health, a federally qualified health center and Ryan White Part C HIV clinic in Boston, Massachusetts, and one of the world’s largest health centers focused on LGBTQIA+ communities.

Of our 35,000 patients, some 2,200 patients are people living with HIV, and about 3,000 are on PrEP for HIV prevention. Roughly half of our patients are LGBTQIA+, and over 5,000 are transgender and nonbinary. A major focus of our work is HIV and STI prevention and research.

We write to express strong support for the FDA’s proposed updated recommendations for evaluating blood donor eligibility. We commend FDA leaders for working hard to protect the safety of the nation’s blood supply while proposing to end a categorical deferral that contributes to stigma against gay and bisexual men and other men who have sex with men (MSM). This important proposed move will allow many thousands of gay and bisexual men and other MSM at low risk of HIV infection to donate blood. This will thereby increase the blood supply and better ensuring the ability to meet emergency needs as well as the needs of patients with leukemia and kidney disease and those undergoing surgery. The proposed new policy is strongly grounded in science and blood safety.

As you know, blood donation deferrals were first introduced in the early 1980s, when our understanding of HIV and AIDS was more limited, and technological advances such as nucleic acid testing were not yet developed. We are aware of the tragedy that happened in the 1980s, when many thousands of people with hemophilia were infected with HIV through blood products. We realize that the FDA has worked hard to prevent such an incident from occurring again. It’s also important to point out that it is likely that most of those blood products were not made from blood donated by gay and bisexual men and other MSM.

While advancements in HIV testing, treatment, and prevention progressed over the subsequent decades, blood donation deferral guidelines failed to keep pace. Donation guidelines were updated in 2015, when a lifetime ban for MSM was changed to a one year deferral, and again at the beginning of the COVID-19 pandemic in 2020, when the deferral was reduced to three months. These two policy updates were significant and positive steps towards greater eligibility and less stigma for gay and bisexual men and other MSM.

The FDA's proposed new guidelines would introduce major changes that would make donation safer. First, the new update would rely on individual risk assessments to determine a donor's eligibility. HIV-negative men in monogamous same-sex relationships and other MSM at low risk of HIV transmission should be allowed to donate their blood, and this proposed change would permit them to do so. These recommendations further take into account that risk of HIV transmission is highest through anal sex without a condom and lubricant and/or PrEP. Other forms of sexual activity that carry low risk of transmission should no longer be cause to restrict eligibility. The proposed updates are also gender-neutral in their risk stratification, which appropriately recognizes that individuals who are not MSM and have multiple, new anal sexual partners also are at risk of sexually transmitted infection transmission, including HIV transmission.

Importantly, the new guidelines would remove the stigmatizing nature of previous restrictions by no longer singling out MSM for exclusion. We welcome the fact that the current proposal eliminates reference to MSM altogether and uses gender neutral language that focuses on risk behavior and relative risk. Linking HIV risk to MSM propagates the false notion that only MSM are at risk of becoming infected with HIV and transmitting HIV. The current guidelines which single out MSM can push this group away from the healthcare system, further disconnecting an already marginalized and vulnerable group. They also cause many young people to choose not to donate blood. Removing the MSM-specific exclusion should help increase blood drive participation not only among gay and bisexual men and other members of the LGBTQIA+ community, but also among youth in general. This is critical given that people often become lifelong donors after starting as high school or college students, and that blood drives often occur on college and university campuses.

It is important for the FDA and blood products community to understand that many gay and bisexual men and other MSM—and many transgender and gender diverse people who are unclear on how the current policy affects them—may experience a significant degree of frustration with the current deferral policy, even though it is an improvement over the lifetime ban in place until eight years ago. It's important that federal government agencies and the blood industry support community education efforts with gay and bisexual men to rebuild trust.

Another area where community engagement is needed is in relation to pre-exposure prophylaxis for HIV prevention, or PrEP. The Fenway Institute has been involved in PrEP research since the iPrEx study, which showed efficacy for HIV prevention with MSM and transgender women in 2010. Fenway Health has helped more than 5,000 patients in Boston access PrEP, and many thousands more around the U.S. through the National LGBTQIA+ Health Education Center's PrEP technical assistance partnership with the Bureau of Primary Health Care and the Ryan White HIV/AIDS Program.

We understand the reasons why people on PrEP are excluded from donating blood under the proposed new policy. PrEP may decrease the ability of current diagnostic tests to detect HIV in donated blood. It increases the chance that a unit will falsely test negative for HIV, because PrEP suppresses viral RNA expression and may delay antibody seroconversion.<sup>1</sup> Some individuals on PrEP may be low-risk, but as a group people on PrEP are by definition likely to engage in condomless sex. People take PrEP because they are worried about being exposed to HIV in order to minimize their chances of infection. We recognize that individuals who are not adherent to PrEP or who become infected with a drug resistant strain of HIV could test seronegative and yet could transmit HIV via their transfused blood, but these situations will be exceedingly rare, so clear messaging to affected communities will be important.

We understand that the ADVANCE Study provided preliminary data that supports allowing gay and bisexual men who are at low risk of HIV infection and not on PrEP to donate blood. We understand that more than half the ADVANCE participants were on PrEP. We encourage the FDA to look more closely at those data and consider possible future changes to donation policy that are warranted by the data.

In the January 2023 community partner call one prominent HIV activist expressed a concern that the proposed policy stigmatizes people on PrEP for HIV prevention. We don't want this to be the case. We encourage individuals to take PrEP to reduce their risk of HIV infection. Perhaps at a different point in their lives they will discontinue PrEP use and be eligible to donate blood. It's important that the FDA and HHS agencies focused on promoting LGBTQI+ health equity engage with gay and bisexual male communities on the issue of PrEP use and blood donation.

We understand that the FDA is trying to let as many people as possible to donate, end a stigmatizing policy, and protect the nation's blood supply. We realize that this is a balancing act where safety is paramount. We think that you have done a good job getting it right. We appreciate the thoughtfulness with which the FDA has considered changes to this policy over the past two decades. We also encourage you to review and end the exclusionary policy for gay and bisexual men who wish to donate sperm. This policy causes significant hardship for families trying to have children.

Thank you for this opportunity to provide comment. If you have any questions, please feel free to contact Sean Cahill, Director of Health Policy Research at [scahill@fenwayhealth.org](mailto:scahill@fenwayhealth.org).

Sincerely,

Ellen LaPointe  
Chief Executive Officer, Fenway Health

Kenneth Mayer, MD, FACP  
Co-chair and Medical Research Director, The Fenway Institute

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<sup>1</sup> Seed, C. R., Styles, C. E., Hoad, V. C., Yang, H., Thomas, M. J., & Gosbell, I. B. (2021). Effect of HIV pre-exposure prophylaxis (PrEP) on detection of early infection and its impact on the appropriate post-PrEP deferral period. *Vox sanguinis*, 116(4), 379–387. <https://doi.org/10.1111/vox.13011>

Director of HIV Prevention Research, Beth Israel Deaconess Medical Center  
Professor of Medicine, Harvard Medical School

Jennifer Potter, MD

Co-Chair and LGBT Population Health Program Director, The Fenway Institute  
Professor of Medicine, Harvard Medical School  
Advisory Dean, William Bosworth Castle Society

Juan Jaime de Zengotita, MD

Medical Director, Fenway Health

Alex Keuroghlian, MD, MPH

Director of Education and Training  
The Fenway Institute

Sean Cahill, PhD

Director of Health Policy Research, The Fenway Institute

Carrie Richgels

Manager of Policy and Advocacy, Fenway Health

Amitai S. Miller, BA

Medical student, Harvard Medical School  
Research Fellow, The Fenway Institute