

April 20, 2020

Center for Biologics Evaluation and Research  
Food and Drug Administration  
5630 Fishers Lane  
Rm. 1061  
Rockville, MD 20852

Re: Docket No. FDA-2015-D-1211-0109

To Whom It May Concern:

On behalf of the National Alliance of State & Territorial AIDS Directors (NASTAD), a leading non-partisan non-profit association that represents governmental public health officials who administer HIV and hepatitis programs in the U.S., I am writing to provide comments regarding the draft document, "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products."

NASTAD was pleased the Food and Drug Administration (FDA) recently updated its deferral policy for men who have sex with men (MSM), sex workers, and people who inject drugs who are seeking to donate blood. While NASTAD is pleased FDA supports the reduction of the antiquated and stigmatizing blood-donation deferrals, the three-month deferral remains discriminatory and does not reflect actual risk to the nation's donated blood supply. The three-month deferral for MSM continues to insinuate that all MSM have the same level of risk for HIV infection, simply because they are attracted to the same gender. This proposal does not actually assess individual risk of MSM or non-MSM. A deferral policy should apply to all donors and focus on specific risk behaviors. This type of deferral policy will ensure the safety of the blood supply, increase the donor pool, and stop the discrimination against all MSM.

In the decades since the FDA implemented the MSM blood ban, vast improvements have been made in technology that can test for blood-borne diseases that could be transmitted by blood

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transfusion. Nucleic Acid Amplification Testing (NAT) can detect HIV in a unit of blood within seven days of the donor becoming infected. When combined with best practices that screen prospective donors for high-risk behavior, regardless of sexual orientation, NAT renders the three-month MSM blood deferral scientifically obsolete and unnecessary.

Thank you for the opportunity to provide comments regarding FDA's blood donor deferral policy. We appreciate your attention and consideration. Please do not hesitate to contact me at (202) 434-8090 or by email at [slee@NASTAD.org](mailto:slee@NASTAD.org) if you have questions related to these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Stephen Lee", with a long horizontal flourish extending to the right.

Stephen Lee, MD, MBA, DHSM  
Executive Director