

NACCHO

National Association of County & City Health Officials

The National Connection for Local Public Health

November 25, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Blood Donor Deferral Policy for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Establishment of Public Docket; Request for Comments (Docket No. FDA-2016-N-1502)

To whom it may concern:

On behalf of the National Association for City and County Health Officials (NACCHO), I am writing to provide comment on potential blood donor deferral policy options following the release of “Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry” in December 2015. NACCHO is the voice of the nearly 3,000 local health departments across the country. These city, county, metropolitan, district, and tribal departments work every day to protect and promote health and well-being for all people in their communities. In response to FDA’s invitation for additional information regarding potential blood donor deferral policy options, NACCHO offers the following comments on reducing stigma and discrimination against men who have sex with men (MSM) and the critical role of local health departments in enhancing the safety of the blood supply.

NACCHO supports FDA’s transition from an indefinite deferral period for MSM. The implementation of a time-based deferral policy provides an opportunity for a limited number of MSM and their male or female sexual partners interested in reducing the critical, nationwide deficit of lifesaving blood products to do so should they meet established donor eligibility requirements.

While the existing time-based deferral policy is a substantive shift from an indefinite deferral period, the existing policy in practice is functionally indefinite as it bans individuals based on a generalized, identifying trait rather than specific, measurable risk attributes. NACCHO supports FDA in continuing to explore individual risk assessments and other deferral options that better capture these specific, measurable risk attributes and reduce potential stigmatization and discrimination of individuals due to a behavioral trait. In other words, entire groups of people being ineligible to donate based on who they are, rather than what they do deviates from the intention of FDA to effectively reduce the risk of disease transmission by blood and blood products.

Additionally, focusing on risk attributes is more consistent with current knowledge regarding transmission and test characteristics for bloodborne infections. There have been significant advances in human immunodeficiency virus (HIV) testing that have shortened the window period – or the amount of time between a person becoming infected with a virus to when it is detectable by a test – and improved sensitivity, or the ability of the test to correctly indicate disease. As stated in the New England Journal of



Medicine, “The risk of HIV in the blood supply comes mainly from the risk of donation during the first few weeks after infection. Any policy designed to protect the blood supply from HIV would focus on excluding potential donors — of any sexual orientation — at risk for having acquired HIV in the several weeks before donation.”¹

The current time-based deferral policy thus continues to carry with it the potential to stigmatize MSM. Stigma and discrimination must be addressed in the public health realm as they are often cited as barriers to the testing, access to care, and treatment of communicable diseases such as HIV. Several federal agencies, including the Centers for Disease Control and Prevention and the Department of Health and Human Services, have recognized the need to reduce stigma in order to promote and increase screening, testing, treatment, and prevention efforts, which ultimately advances both individual health and disease prevention and control more broadly among the communities we serve.

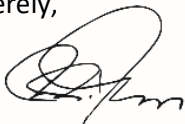
Local health departments play an important role in enhancing the safety of the population and the blood supply. They proactively coordinate, communicate, and exchange data with blood collection centers; investigate reports of potential infectious disease transmission; investigate and track potential transfusion-associated cases of infection; and activate blood safety interventions when appropriate. Emerging infectious diseases like Zika highlight the importance of this partnership as health departments and blood centers have worked together to identify, investigate, and follow-up on suspected and confirmed local vector-borne cases. This benefits the public’s health by helping to combat and prevent outbreaks.

NACCHO recognizes FDA leadership for their commitment to continuing to reevaluate and update blood donor deferral policies as new scientific information becomes available. To ensure a high level of safety for the blood supply, NACCHO encourages the FDA to:

- Continue to demonstrate political will and leadership in recognizing and addressing stigmatization in its policies;
- Continue to expand the use of evidence-based practices in its programs;
- Support research and collaboration to identify effective and affirming assessment methods and deferral approaches; and
- Explore screening tools and consider advances in HIV testing technology.

Thank you for the opportunity to provide comments on this policy and input on this important matter. If you have any questions or would like to further discuss our comments, please contact Gretchen Weiss, Director, HIV, STI, and Viral Hepatitis, at 202-507-4326 or gweiss@naccho.org.

Sincerely,



LaMar Hasbrouck, MD, MPH
Executive Director

References

¹ Sacks, C.A., Goldstein, R.H., & Walensky, R.P. (2016, November 16). Rethinking the Ban — The U.S. Blood Supply and Men Who Have Sex with Men. *The New England Journal of Medicine*.