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Public Comment on the FDA's Proposed *Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products*, published May 15, 2015

Dear colleagues,

The Fenway Institute is pleased to see the proposed removal of the lifetime ban on blood donation for gay and bisexual men, and other men who have sex with men (MSM). We believe that this represents a significant step in the right direction. The lifetime ban policy was implemented in 1983. Since then, vast improvements have been made in scientific knowledge about HIV and in technology that can test blood for communicable diseases, rendering the lifetime MSM blood ban scientifically obsolete and unnecessary. In addition, the lifetime ban stigmatized gay and bisexual men, especially because the majority of blood donations occur at blood drives in workplaces or schools, where gay and bisexual men face dilemmas regarding disclosure of their sexual orientation and the social ramifications of not donating blood with their peers and coworkers. We believe that the removal of the lifetime ban represents an important incremental step towards a science-based policy which maintains the safety of the blood supply without stigmatizing gay and bisexual men.

While we are pleased with the removal of the lifetime ban, we believe there remain some problems with the proposed policy for a 12 month deferral from most recent contact for any man who has had sex with another man within the last year. First, we believe that this deferral period is too long and unfairly prohibits sexually active MSM engaging in low-risk sexual behaviors from donating blood. The nucleic acid test (NAT) that is used to screen blood after it has been donated can typically detect the presence of HIV in just 9 – 11 days

after infection.[1] Because the window period for the NAT test is so short, it greatly decreases the risk of HIV-infected blood escaping detection. Deferral periods that are substantially in excess of known window periods, as is the case with the newly proposed FDA recommendations, provide little additional value to ensuring disease detection, but increase the potential for unfair limitations against the groups subject to those deferrals.[2]

In addition, new pathogen inactivation technologies provide an additional layer of protection for ensuring the safety of the blood supply. The FDA recently approved the use of a pathogen inactivation technology system called the Intercept Blood System to reduce the risk of transfusion transmissible infections in platelets and plasma in December 2014.[3] Studies have shown Intercept to have robust efficacy in the inactivation of a large array of bacteria and viruses, including HIV, in platelet and plasma blood components used for transfusions.[4] The FDA did not account for this new technological advancement in its underlying risk assessment for the new recommendations for change to the blood donation policy for MSM. Considering the sensitivity of the NAT test and the efficacy of new pathogen inactivation technologies like the Intercept Blood System in ensuring that the blood supply remains safe from HIV, we believe that the 12 month deferral period may be longer than necessary.

Furthermore, the new FDA recommendations still do not adequately distinguish between low-risk and high-risk sexual behaviors by MSM donors or others. Both MSM and non-MSM donors can engage in low-risk sexual behaviors—such as using protection (e.g., condoms and/or pre-exposure prophylaxis) or having monogamous sex with an HIV-negative partner, or high-risk sexual behaviors—such as having sex with multiple partners of unknown HIV status. Individuals who consistently practice low-risk sexual behaviors will pose little threat to the blood supply; conversely, individuals who consistently

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[1] FDA. 2010. *Guidance for Industry: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry.*
http://www.fda.gov/downloads/biologicsblood%20vaccines/guidancecomplianceregulatoryinformation/guidances/blood/ucm210270.pdf

[2] Gay Men's Health Crisis. 2010. *A Drive for Change: Reforming U.S. Blood Donation Policies*.
http://www.gmhc.org/files/editor/file/a_blood_ban_report2010.pdf

[3] FDA. 2014. News Release. *FDA approves pathogen reduction system to treat platelets.*
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm427500.htm

[4] Irsch, Johannes and Lin, Lily. 2011. "Pathogen Inactivation of Platelet and Plasma Blood Components for Transfusion Using the INTERCEPT Blood System." *Transfusion Medicine and Hemotherapy*. 38:19 – 31. DOI: 10.1159/000323937.

engage in high-risk sexual behaviors will pose a significant threat to the blood supply regardless of the individual's sexual orientation. However, instead of basing the deferral policy on individual risk behavior, the FDA's new recommendations still treat all MSM as a single high-risk group. This is unfair and illogical, because it would block a sexually active MSM who consistently practices low-risk behaviors from donating blood, but it would allow a sexually active heterosexual man who engages in high-risk behaviors, such as having multiple partners or having unprotected sex, to donate blood without a deferral.

We believe that a better alternative policy would be to screen all donors for high-risk behavior. The Donor History Questionnaire should be modified to ask all potential donors for both low- and high-risk sexual behaviors that they engage in. After screening, only donors who are determined to be at high risk should be deferred, and the deferral time should be carefully tailored to known window periods consistent with current technology. This would allow low-risk MSM donors to donate blood while deferring high-risk MSM until a time when they are adequately beyond the window period for HIV screening tests. The highest-risk members of the MSM population—such as those who report IV drug use, sex with commercial sex workers, or sex with HIV-positive partners—may justifiably be subject to lengthy or permanent deferrals.

In summary, we are pleased with the proposed removal of the lifetime ban on blood donation for gay and bisexual men and other MSM. We believe that this is an important and essential step forward towards an optimal policy which would ensure the safety of the blood supply without stigmatizing gay and bisexual men. However, we do believe that the 12 month deferral period for any man who has had sex with a man in the past year is problematic. The lengthy deferral period is unnecessary for low-risk MSM given the capabilities of current technology. Additionally, the new recommendations still do not adequately distinguish donors based on low- and high-risk sexual behaviors. We believe a better, science-based policy would be one that is based on screening for individual risk behavior, and deferring potential donors based on high-risk behavior rather than sexual orientation.

Thank you for the opportunity to comment on the proposed recommendations. Should you have any questions or require more information on any of the suggestions made here, please contact Sean Cahill at scahill@fenwayhealth.org or 617-927-6016.

Sincerely,

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