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Food and Drug Administration  
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October 21, 2013

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City Hall  
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OFFICE OF THE CITY CLERK  
CAMBRIDGE, MASSACHUSETTS

Dear Donna Lopez and the City Council Members:

Thank you for your recent letter to Secretary Sebelius describing your council's resolution regarding the Food and Drug Administration's (FDA) blood donor deferral policy for men who have had sex with other men. Your letter was forwarded to FDA's Center for Biologics Evaluation and Research for reply.

FDA's primary responsibility with regard to blood and blood products is to assure the safety of patients who receive these life-saving products. FDA uses multiple layers of safeguards in its approach to ensuring blood safety, which include donor screening and deferral based on risk factors, blood testing for markers of infection, and inventory controls. The use of these multiple layers helps to assure the safety of the products in the event that one layer fails. We applaud the critical contributions made by blood donors and we are sensitive to the concerns of potential donors and other individuals affected by current blood safety policies.

FDA's current blood donation deferral policy recommends that men who have had sex with other men (MSM) at any time since 1977, the beginning of the U.S.-acquired immune deficiency syndrome (AIDS) epidemic, are not eligible to donate blood. Deferral of MSM from donation of blood and tissues is based on well-documented observations of much higher rates of transmissible diseases among some MSM than in the non-MSM general population.

HIV tests currently in use are highly accurate, but still cannot detect HIV 100% of the time. It is estimated that the HIV risk from a unit of blood has been reduced to about 1 per 2 million in the USA, almost exclusively from so called "window period" donations. The "window period" exists very early after infection, where even current HIV testing methods cannot detect all infections. During this time, a person is infected with HIV, but may not have enough virus or have developed sufficient antibodies to be detected by available tests. For this reason, a person could test negative, even when they are actually HIV positive and infectious. Therefore, blood donors are not only tested but are also asked questions about behaviors that increase their risk of HIV infection.

FDA defers other donors when they present similarly high risks for exposure to transfusion transmissible infections, whether through behavior (e.g., intravenous drug abusers; commercial sex workers), medical conditions (e.g., history of hepatitis after age 11), or geographical exposures (e.g., people who have traveled to or resided in areas with high levels of malaria or risk for exposure to Mad Cow Disease.)

Although scientific evidence has not yet demonstrated that blood donated by MSM or a subgroup of these potential donors does not have a substantially increased rate of HIV infection compared to currently accepted blood donors, FDA remains willing to consider new approaches to donor screening and testing. If those approaches can assure that blood recipients are not placed at an increased risk of HIV or other transfusion transmitted diseases, FDA will consider a change to its current policy.

The Health and Human Service's (HHS) Advisory Committee on Blood Safety and Availability (ACBSA) met to discuss the FDA MSM deferral policy on June 10-11, 2010. During that meeting, the ACBSA heard presentations and engaged in deliberations on the current MSM deferral policy. The Committee was asked to determine if there were sufficient data to support a change in policy at this time, or, if needed, to identify areas of further study that would establish a sound scientific basis for a change in policy. The committee found the current donor deferral policies to be suboptimal in permitting some potentially high risk donations while preventing some potentially low risk donations, but voted in favor of retaining the existing policy, and identified areas requiring further research.

In response to the ACBSA recommendations, HHS is in the process of conducting additional studies that aim to address the following questions:

- a) How does the risk of blood transmissible diseases in the current donor population relate to risk factors in donors?
- b) What is the root cause of the Quarantine Release Errors, the accidental release of blood not cleared for use that occur at blood collection centers and potentially put the blood supply at risk, and what mitigations can be considered?
- c) Do potential blood donors correctly understand and properly interpret the current standard questionnaire used to obtain donor history? What motivates men with MSM behavioral history to donate blood and would MSM be likely to comply with modified deferral criteria?
- d) Would an alternative screening strategy for MSM (and potentially other high-risk donors) assure blood safety?

When the results and data from the studies are available and potential policy revisions are brought forward for consideration, HHS intends to provide opportunities for discussion in a public forum.

In summary, the FDA's MSM deferral policy is based upon identifying and minimizing risk to the blood supply. FDA's blood safety efforts focus on minimizing the risk of transmitting infectious diseases, while maintaining an adequate supply of blood for the nation. The Agency welcomes scientific and public input and will continue to re-evaluate donor deferral policies as new data become available to ensure the safety of blood and blood products for patients who need these products. We will also continue to evaluate new technologies with potential to further reduce risks.

Sincerely,

A handwritten signature in black ink, appearing to read "Patricia Harley". The signature is fluid and cursive, with a large initial "P" and "H".

Patricia Harley  
Consumer Safety Officer  
Division of Communication and Consumer Affairs  
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