



## THE AIDS INSTITUTE

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Division of Dockets Management (HFA-305)  
U.S. Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852  
Submitted via: [Regulations.gov](http://Regulations.gov)

**Subject:** "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products: Draft Guidance for Industry" [Docket ID: FDA-2015-D-1211-0001]

U.S. Food and Drug Administration:

The AIDS Institute, a national non-profit organization that promotes action for social change through public policy, research, advocacy, and education, is pleased that the U.S. Food and Drug Administration (FDA) has issued draft guidance proposing changes to its current blood donor deferral policy for men who have sex with men (MSM), even once since 1977. The previous policy was outdated and discriminatory against gay and bisexual men who want to donate blood. In the FDA's current draft guidance, it proposes changing the lifetime ban for MSM to a deferral for any man who has had sex with another man in the last 12 months. While an improvement from the previous policy, this still excludes many MSM who avoid high-risk behaviors, including those in committed, monogamous relationships. This continues to stigmatize gay and bisexual men.

The previous policy ban on MSM blood donations was implemented in 1985, when much less was known about HIV/AIDS, and when diagnostic and blood screening tools were not nearly as sophisticated as they are today. The FDA's complete ban of MSM blood was implemented to prevent HIV infected blood from getting into the American blood supply. However, due to recent advances in new technologies, there is no reason why a lifetime ban—or even a 12 month ban—should be necessary to protect the blood supply and the public's health. In the FDA's own draft guidance for the proposed 12 month change, it cites that the current risk of HIV transmission from a blood transfusion is about 1 in 1.47 million and that "no transmission of HIV, hepatitis B virus (HBV), or hepatitis C virus (HCV) has been documented through U.S.-licensed plasma derived products in the past two decades."<sup>i</sup> Additionally, the draft guidance does not take into account the most recent science, including the preventive qualities of HIV treatment and pre-exposure prophylaxis, which drastically reduce the chances of HIV transmission.

For many gay and bisexual men who regularly engage in safe sexual activity, the draft guidance is essentially a de-facto lifetime ban. The guidance continues to unfairly discriminate against gay and bisexual men, and perpetuates the stereotype that HIV is a gay disease. The FDA should make its recommendations not based on sexual orientation, but rather based on actual behavior. Thousands of gay men are involved in monogamous, safe relationships yet are unfairly denied the ability to donate blood simply because of their sexual orientation. The FDA claims that same-sex monogamy does not always lower the risk of HIV, yet the rate of monogamy in heterosexual couples and same-sex male couples is estimated to be about the same—25 percent.<sup>ii</sup> Given this information, FDA should limit the ability to donate blood based on engagement in high-risk behaviors, such as unsafe sex practices, regardless of sexual orientation.

According to the American Red Cross, more than 41,000 blood donations are needed every day,<sup>iii</sup> yet due to the FDA's current and proposed blood donation policies, we are preventing perfectly healthy gay and bisexual Americans from donating. While the draft proposal would allow more gay and bisexual men to donate blood, it still vastly limits the potential donations that could be collected in a given year. According to The Williams Institute, a 12 month deferral would only result in approximately 185,800 additional blood donations from men, which would provide 317,000 additional pints of blood. However, if the entire blood donation ban for MSM were lifted approximately 360,600 additional men could donate 615,300 pints of blood. Lifting the entire ban would likely increase the entire U.S. blood supply by 2-4 percent and help save the lives of more than a million people.<sup>iv</sup>

The AIDS Institute strongly urges the FDA to revise its recommendation of a 12 month deferral for MSM who wish to donate blood and instead base its policy on the level of individual behavior rather than sexual orientation. The draft proposal changes very little for the majority of gay and bisexual men who wish to donate blood, does not take into account recent scientific advances, continues to stigmatize the gay community, and hurts the American blood supply. The FDA plays such an important role in protecting the lives of millions of Americans, but it should do so not at the expense of certain groups.

Sincerely,



Michael Ruppel  
Executive Director

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<sup>i</sup> Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products. Food and Drug Administration. May 2015

<sup>ii</sup> Ibid

<sup>iii</sup> Page on Blood Facts and Statistics. American Red Cross website. Available at: <http://www.redcrossblood.org/learn-about-blood/blood-facts-and-statistics>.

<sup>iv</sup> Miyashita, A, Gates, GJ. UPDATE: Effects of Lifting the Blood Donation Ban on Men who have Sex with Men. Los Angeles: Williams Institute, UCLA School of Law; 2014. Available at: <http://williamsinstitute.law.ucla.edu/wpcontent/uploads/blood-ban-update-sep-2014.pdf>.