NATIONAL LGBTQ TASK FORCE

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Food and Drug Administration
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**Public Comment Re: Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; FDA-2015-D-1211**

Dear Ms. Butler:

The National LGBTQ Task Force and the undersigned organizations are grateful for this opportunity to comment on the Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products (Proposals). These Proposals are the most recent revisions by the Food and Drug Administration (FDA) since its last revision in 1992. In the past 33 years, the U.S. has made significant improvements and advancements in research, detection, and treatment of human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS). However, despite these scientific achievements affecting HIV/AIDS, the FDA's Proposals maintain discriminatory practices in their deferral policies for men who have sex with men (MSM), people who have injected drugs (PWID), and people who have engaged in sex work (PSW). These procedures, manifested as screening questions, are particularly harmful to the LGBTQ community. We recommend several changes to the FDA's donor deferral policy that would reduce harmful stigma towards marginalized groups of people and more accurately reflect the nation's scientific knowledge about HIV/AIDS.

**Men who have sex with men**

In 1985, situated in the historical context of HIV/AIDS in the U.S., the FDA issued recommendations that barred groups of people from donating blood based on certain behaviors and sexual orientation. HIV/AIDS was originally thought of as a disease contracted exclusively by gay men, but we now know that is far from true. Prior to these Proposals, there was an indefinite deferral for all MSM, regardless of transmission risk. We applaud the FDA for recognizing that the indefinite deferral was a discriminatory practice that perpetuated stigma surrounding HIV/AIDS and the LGBTQ community. However, we believe the FDA's proposed 12-month deferral period has similar stigmatizing effects as did the indefinite deferral.

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To defend this practice, the FDA points to countries with 12-month deferrals for MSM, but fails to acknowledge that other countries, such as Italy, Spain, and Mexico, have implemented procedures that ask each potential donor about risk behaviors, regardless of sexual orientation.[1] When the FDA briefly considered using individualized assessments, the FDA deemed them as "logistically challenging" and worried that they "would likely also be viewed as discriminatory by some individuals."[2] The FDA neglects to explain how these individualized assessments would be logistically challenging. It provides no follow-up statements or information indicating the FDA's current allocation of funds or why individualized assessments would be a financial burden. The FDA already subjects every pint of donated blood to a series of tests. Yet, it effectively rebuffs the concept of individualized assessments as too much of an inconvenience. Furthermore, the FDA is concerned that the new practice would be viewed as discriminatory by some individuals, but the Proposals still maintain discriminatory practices. In contrast, an individualized assessment would help eradicate discrimination because it subjects every potential donor to the same procedures, rather than deferring individuals based assumptions related to their sexual orientation.

**Recommendation**

Not all MSM pose equal risks to the blood supply. The proposed 12-month deferral for MSM ignores each of the potential donors' diverse histories and current sexual behaviors. Since the risk of acquiring HIV and other sexually transmitted diseases varies depending on the frequency and type of sexual behaviors in which an individual engages, regardless of sexual orientation, the FDA should individually assess each potential donor. Under the current Proposals, and previous procedures, heterosexuals are permitted to donate without any specific questions about high risk activities, while MSM are subject to a 12-month deferral regardless of transmission risk. We recommend an individualized assessment based on risk behaviors, rather than on sexual orientation. We believe this will not pose any additional "resource constraints" since every blood donation is already subjected to tests for diseases.

At the very least, we recommend the adoption of the recommendations made by AIDS United and other partner organizations, which explain that a deferral period of more than three months is unjustifiable. A deferral of no more than three months is consistent with

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[1] The Washington Post. (2014). *Why the FDA's expected decision to end a ban on blood donations from gay men may fall short*. Accessed from http://www.washingtonpost.com/blogs/wonkblog/wp/2014/12/02/why-the-fdas-expected-decision-to-end-a-ban-on-blood-donations-from-gay-men-may-fall-short/.

[2] U.S. Department of Health and Human Services. (2015). *Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products*. Accessed from http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM446580.pdf.

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the current Nucleic Acid Testing used by the FDA, which can detect HIV, HCV, and HBV within 25 days of exposure.[3] Considering this data, a deferral of three months is a more than adequate amount of time given the speed of these tests. Therefore, if the FDA cannot perform individualized risk assessments, it should at least recommend a policy that conforms more closely to statistics and data.

The recommendations by AIDS United and other coalition partners can be found here: http://www.aidsunited.org/data/files/Site_18/06-18-15%20Blood%20Donation%20Recommendations.pdf

**People who have injected drugs (PWID)**

In 1992, the FDA recommended an indefinite blood donation deferral for all people who have injected drugs (PWID) at any time in their life. The FDA website indicates that "intravenous drug abusers are excluded from giving blood because they have prevalence rates of HIB, HBV, HCV, and HTLV that are much higher than the general population."[4] However, the FDA doesn't exclude other groups from donating because of high prevalence rates. According to the Southern AIDS Coalition, the South accounts for 50% of new HIV infections, but the FDA does not bar Southerners from donating blood.[5] The way the FDA selects which populations to defer indefinitely is discriminatory. Instead, it must be changed to a system based on scientific evidence. Current technology allows for the detection of HIV and other diseases in a matter of weeks. The FDA's belief that an indefinite deferral for people who have injected drugs at any time in their life is inappropriate because there is currently no data to indicate that PWID have higher HIV transmission risk once they cease use of injection drugs.

This is particularly relevant to members of the LGBTQ community, who disproportionately engage in substance use. The Center for American Progress (CAP) estimates that 20-30% of gay and transgender people abuse substances, compared to about

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[3] Weusten, J., Vermeulen, M., Drimmelen, H. & Lelie, H. (2011). *Refinement of a viral transmission risk model for blood donations in seroconversion window phase screened by nucleic acid testing in different pool sizes and repeat test algorithms*. Pgs. 203-15.

[4] U.S. Food and Drug Administration. (2015). *Blood Donations from Men Who Have Sex with Other Men Questions and Answers*. Accessed from http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/QuestionsaboutBlood/ucm108186.htm.

[5] Southern AIDS Coalition. (2012). *Southern States Manifesto: Update 2012 Policy Briefs and Recommendations*. Accessed from http://southernaidscoalition.org/wp-content/uploads/2013/11/Southern-States-Manifesto-Update-2012.pdf.

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9% of the general population.[6] MSM are 9.5 times more likely to use heroin than heterosexual men.[7] CAP also indicates that the principal driver of these high rates is the stress LGBTQ people face from discrimination. Members of the LGBTQ community may also be discouraged from seeking health care providers because of negative experiences with providers. These examples show how stigma surrounding the LGTBQ community manifests itself in health issues for members in the community. Refusing willing donors just because they have injected drugs, regardless of their actual risk transmission, adds to this harmful stigma.

**Recommendation**

When potential donors are told they can never donate because they have injected drugs at some point in their life, it adds to harmful stigma. This is especially problematic for members of the LGBTQ community who disproportionately use substances. We recommend abolishing the indefinite ban the FDA put in place over 30 years ago. With advancements in HIV testing, there is no reason to continue this discriminatory practice that leads to stigma and significant health issues for many, including LGBTQ populations. Under its current proposal, the FDA recommends maintaining the indefinite deferral of PWID. Instead, the FDA should recommend the use of individualized assessments. This would allow individuals who no longer inject drugs to donate and help address the nation's growing need for blood. At the very least, we recommend a deferral period of no more than three months as recommended by AIDS United for MSM to be applied to PWID who are not currently injecting drugs.

**People who have engaged in sex work**

Along with people who have injected drugs, the FDA in 1992 also recommended an indefinite deferral for people who have engaged in sex work (PSW). The current Proposal seeks to maintain this ban. For many of the same reasons discussed in the previous section, this indefinite deferral is discriminatory. If a person had sex with 100 different partners, that person would still be able to donate, but if a person had sex with one person, one time, in exchange for money, this person would never be allowed to donate. This practice is discriminatory and ineffective. The FDA recommends and fully supports these procedures because they assert that there is no "additional data" for it to do anything other than continue these harmful practices.

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[6] The Center for American Progress. (2012). *Why the Gay and Transgender Population Experiences Higher Rates of Substance Abuse*. Pg. 1. Accessed from https://cdn.americanprogress.org/wp-content/uploads/issues/2012/03/pdf/lgbt_substance_abuse.pdf.

[7] *Id.* at 2.

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This indefinite deferral of all PSW is an important issue, particularly in the LGBTQ community. Many LGBTQ people are forced into prostitution or sex work because they are a vulnerable population. For example, 46% of LGBTQ youth without a place to live leave home because their families rejected their sexual orientation. LGBTQ youth without a place to live are three times more likely to engage in survival sex (the exchange of sexual favors for basic needs like food, shelter, or clothing) than are heterosexual youth.[8] Many trans women turn to sex work because they face severe job discrimination and because of the fetishization of trans bodies. Because transgender individuals are four times more likely than the general population to have a household income of less than $10,000/year and twice as likely to be unemployed, many transgender people turn to sex work as a means of survival.[9]

**Recommendation**

Many individuals are forced into sex work as a means of survival because of the discrimination they face daily. Instead of further stigmatizing this group, the FDA should implement individual assessment based on current behaviors. We recommend that the FDA lift the indefinite deferral of all PSW who no longer engage in sex work and assess the individual risk behaviors of all potential donors. At the very least, we urge the FDA to adopt the recommendations made by AIDS United with respect to MSM and implement a deferral period of no more than three months for all PSW who no longer engage in sex work.

**Conclusion**

When men who have sex with men, people who have injected drugs, and people who have engaged in sex work see that they can't even donate blood, it perpetuates a belief that they should be ashamed for who they are. It's no surprise that HIV/AIDS, especially in the LGBTQ community, is still rarely discussed. When this type of stigma exists in society, few people want to talk about the serious public health issues that surround HIV/AIDS. Thus, many people in our community lack information about how to practice safe sex, how HIV/AIDS is spread, or how to get help.

[8] Human Trafficking Search. (2013). *Sex Trafficking of LGBT Youth*. Accessed from http://humantraffickingsearch.net/wp/sex-trafficking-of-lgbt-youth/.
[9] National LGBTQ Task Force and National Center for Transgender Equality. (2011). *Injustice at Every Turn: A Report of the National Transgender Discrimination Survey*. Pg. 2. Accessed from http://www.thetaskforce.org/static_html/downloads/reports/reports/ntds_full.pdf.

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A 12-month deferral for MSM, and an indefinite deferral for PWID and PSW, perpetuate stigma surrounding already marginalized groups of people, which leads to a disturbing lack of public health education in many communities. If the FDA's goal is to promote public safety, it should not uphold these discriminatory deferrals. Instead, it should focus on public health education and dismantling the stigma surrounding people living with HIV/AIDS in order to reduce transmission risks. According to the Kaiser Family Foundation, levels of knowledge about HIV transmission in the U.S. have not improved since 1987, around the time the FDA imposed the indefinite ban on all MSM.[10] In 2009, 27% of Americans believed HIV could be transmitted by sharing a drinking glass, a 5% *increase* from 2006.[11] Another study found that amount of time since HIV-diagnosis was positively associated with having experienced stigmatization.[12] Researchers in Los Angeles County found that respondents experiencing high levels of stigma are four times more likely to report poor access to care than those who were not and that poor self-reported access to health care is strongly associated with experiencing HIV stigma.[13] Stigma propagated by the FDA results in a profound lack of public health knowledge about HIV/AIDS that is detrimental to our community and our nation.

The National LGBTQ Task Force and the undersigned organizations strongly urge the FDA to implement these recommendations. The integration of these changes would reduce negative stereotypes that lead to harmful public health safety concerns and would increase the number of eligible blood donors. If you have any questions about the content of these recommendations, please contact Meghan Maury at (202) 639-6322, or by email at mmaury@thetaskforce.org.

Sincerely,

Athlete Ally
Center for Constitutional Rights (CCR)
Center for HIV Law and Policy
CenterLink: The Community of LGBT Centers

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[10] Kaiser Family Foundation. (2009). *Kaiser Family Foundation 2009 Survey of Americans on HIV/AIDS: Summary of Findings on the Domestic Epidemic*. Pgs. 4-5. Accessed from https://kaiserfamilyfoundation.files.wordpress.com/2013/01/7889.pdf.

[11] *Id.* at 5.

[12] NIH Public Access. (2006). *Impact of HIV-Related Stigma on Health Behaviors and Psychological Adjustment among HIV-Positive Men and Women*. Pg. 7. Accessed from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2566551/pdf/nihms70227.pdf.

[13] Division of General Internal Medicine and Health Services Research, David Geffen School of Medicine at University of California. (2009). *The Association of Stigma with Self-Reported Access to Medical Care and Antiretroviral Therapy Adherence in Persons Living with HIV/AIDS*. Pgs. 1104-1105. Accessed from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2762503/pdf/11606_2009_Article_1068.pdf.

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Gay & Lesbian Advocates & Defenders (GLAD)
Marriage Equality USA
National Center for Transgender Equality
National Latina Institute for Reproductive Health
National LGBTQ Task Force
National Queer Asian Pacific Islander Alliance (NQAPIA)
Services and Advocacy for GLBT Elders (SAGE)