Howard Brown Health

March 31, 2023

Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

RE: Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products (FDA-2015-D-1211)

Howard Brown Health is the largest LGBTQ+ health center in the Midwest, serving more than 30,000 patients across eleven clinic locations in Chicago. Howard Brown serves adults and youth in its diverse health and social service delivery system focused around seven major programmatic divisions: primary medical care, behavioral health, research, HIV/STI prevention, youth services, elder services, and community initiatives. As a federally qualified health center, Howard Brown provides services regardless of a patient's ability to pay or insurance status. We provide affirming care to over 5,000 patients living with HIV, as well as comprehensive HIV screening and prevention services, including pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP).

The proposed Individual Risk Assessment for Blood Donations from the (FDA) is a long-needed update to blood donation eligibility that will continue to safeguard the U.S. blood supply while reducing decades-long stigma and discrimination against gay, bisexual and other men who have sex with men (MSM). The inclusion of sexually active gay and bisexual men for the first time since the lifetime ban in 1985 will expand the pool of eligible blood donors, which is critically necessary as the American Red Cross declared its first-ever national blood crisis due to severe blood shortages in 2022. These new blood donation guidelines also align with policies in other countries, such as the United Kingdom and Canada, that have also lifted outdated and stigmatizing blood donation bans on MSM. **As such, we support the FDA's proposed blood donation guidance and urge the FDA to finalize and implement the guidance as soon as possible. Below, we discuss the importance of these proposed changes, as well as areas where improvements can still be made.**

These proposed guidelines are much more reflective of current science around HIV prevention and care compared to the blanket deferrals currently in place for MSM. The ban on MSM was originally enacted when there was no effective treatment or prevention for HIV, and little was known about the disease other than the fact that it was primarily affecting MSM. This resulted in the creation of stigmatizing policies, including blood donation policies, that excluded and ignored MSM. In the decades since the blood donation ban was enacted, HIV medical science has advanced dramatically. In 1995, a new combination drug regimen called antiretroviral therapy (ART) revolutionized the

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treatment and prevention of HIV.[1] ART was much more effective and less toxic to the body than previous HIV treatment options, allowing for easier medication adherence and improved health outcomes and life expectancy for people living with HIV. Now, we know that patients who adhere to ART are able to live full and healthy lives. In addition to treatment advances, HIV prevention has also advanced dramatically with the advent of PrEP and PEP. Research shows that consistent use of PrEP reduces the risk of getting HIV from sex by 99%,[2] and PrEP knowledge and usage among MSM continues to increase and expand. However, even with rapid advancements in HIV treatment and prevention, the FDA retained identity-based bans and deferrals that have grown increasingly outdated with current medical science around HIV.

Our ability to detect HIV in its early stages has also improved massively. Decades ago, HIV tests had a window period of up to 10 weeks and could not detect a new HIV infection until several months after exposure. Current laboratory tests close this window period significantly, allowing for earlier detection of HIV in blood donations. For example, the current nucleic acid test (NAT) has a window period of just 3 days with virtually 100% accuracy. [3] The CDC requires that every donated unit of blood is rigorously tested with a 2-pronged approach including NAT testing and antibody testing.[4] With all of these testing advances, HIV transmission through donated blood has become incredibly rare in the U.S. Based on estimates by the CDC in 2010, the conservative estimated risk for HIV infection is one in 1.5 million, which is a much lower risk than other transfusion-related complications like acute lung injury.[5] Blanket blood donation bans based on sexual orientation ignore these technological advancements and do not meaningfully improve safety of the blood supply.

The new proposed guidance will also help to reduce discrimination and stigma against gay, bisexual, and other MSM. The use of identity-based eligibility requirements automatically

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[1] Tseng A, Seet J, Phillips E. The evolution of three decades of antiretroviral therapy: challenges, triumphs and the promise of the future. *Br J Clin Pharmacol.* 2015 Feb; 79(2): 182-194. Available online at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4309625/

[2] Centers for Disease Control and Prevention. Effectiveness of Prevention Strategies to Reduce the Risk of Acquiring or Transmitting HIV. Available online at: https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html#anchor_1562942347

[3] Park C, Gellman C, O'Brien M, et al. Blood Donation and COVID-19: Reconsidering the 3-Month Deferral Policy for Gay, Bisexual, Transgender, and Other Men Who Have ex With Men. *Am J Public Health.* 2021 Feb; 111(2): 247-252. Available online at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7811078/

[4] Centers for Disease Control and Prevention. Blood safety basics. Available online at: https://www.cdc.gov/bloodsafety/basics.html

[5] Park C, Gellman C, O'Brien M, et al. Blood Donation and COVID-19: Reconsidering the 3-Month Deferral Policy for Gay, Bisexual, Transgender, and Other Men Who Have ex With Men. *Am J Public Health.* 2021 Feb; 111(2): 247-252. Available online at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7811078/

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assigns HIV risk factors to gay, bisexual, and other MSM, regardless of if they are actually engaging in those risk behaviors or not. This perpetuates harmful stereotypes that gay, bisexual, and other MSM are more promiscuous and engage in riskier sex behaviors compared to heterosexual people, but we know that heterosexual people can also engage in risk behaviors for HIV. In 2019, 22% of new HIV cases in the U.S. were among people reporting heterosexual contact.[6] And yet, heterosexual people are assessed for blood donation eligibility more based on individual risk, while MSM are subject to a blanket ban or deferral without consideration of risk factors. While identity-based restrictions were eased somewhat over the years, requiring abstinence still infers that the only way to ensure a safe blood donation from MSM was for them not to engage in sex at all—continuing the cycle of stigma and discrimination. The new FDA guidance will finally determine blood donation eligibility based on an individual risk assessment for all potential donors, regardless of sexual orientation. Under this proposal, anyone without a recent history of anal sex with new or multiple partners is eligible to donate if other criteria are met, regardless of sexual orientation.

We also support the elimination of gender-centric pronouns and language in the FDA's proposed guidance. This helps to eliminate gender-based discrimination and it provides much needed clarity for trans and nonbinary (TNB) donors. The FDA's current policy on blood donation includes gendered language that defers donation from men who have sex with men. This language is confusing for potential donors who identify as TNB or who have had sexual partners who are TNB because it is unclear whether or not TNB individuals are included under the "MSM" umbrella for the donor assessment. The lack of clarity also creates confusion for blood donation centers, leading many to essentially ban low-risk TNB people from donating.[7] The proposed updates remove this gendered language from the assessment, instead focusing on specific behaviors that are asked in the same way to every donor, regardless of gender. This makes it much more clear for TNB people whether or not they are eligible to donate blood.

Given all the barriers to blood donation for LGBTQ+ people, these new proposed guidelines are a very welcome update that will reduce stigma and increase the nation's blood supply without risking safety. As the FDA continues to refine the blood donation guidelines, we wanted to elaborate on areas for improvement in the proposed guidelines.

PrEP Usage

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[6] Centers for Disease Control and Prevention. HIV Incidence. Available online at: https://www.cdc.gov/hiv/statistics/overview/in-us/incidence.html

[7] Lopez G. The absurd reason the FDA bans many transgender women from donating blood. *Vox.* https://www.vox.com/2015/7/23/9025903/fda-blood-ban-transgender

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The proposed guidelines include a 3-month deferral for anyone taking oral PrEP, and a 2-year deferral for anyone taking injectable PrEP. We request clarification on whether or not taking PrEP without other risk factors should result in a deferral, and if so, what the evidence base is for that decision. For instance, should someone on PrEP but abstinent for the last 3 months still receive the 3-month deferral? We understand that there is some research suggesting that PrEP may reduce efficacy of tests used to screen blood donations for HIV. We request prioritizing completion of studies that investigate what potential risk PrEP poses to the blood supply, including the FDA ADVANCE Study. We urge for the dissemination of results around PrEP and blood donation safety, and altering guidelines to reflect evidence, as soon as that information is available. Gaining clarity on PrEP usage as it relates to blood donation may help to further expand the pool of eligible donors within LGBTQ+ communities especially.

Multiple Partners

While the risk assessment is a great step forward in eliminating stigmatizing bans based on sexual orientation, we urge the FDA to be thoughtful about stigmatizing other groups as well—including people who have multiple partners. The proposed guidance requires a 3-month deferral if a potential donor has multiple partners and reports recent anal sex. This may be unnecessary and stigmatizing for those who are in committed polyamorous relationships. For example, if a donor is only having anal sex in a committed polyamorous relationship with two HIV-negative partners, that donor would be deferred. However, if a donor is having anal sex in a committed monogamous relationship with one HIV-negative partner, they would be allowed to donate. Even though the risk factors for both situations are essentially the same, those engaged in a polyamorous relationship are considered to have higher risk factors. There needs to be more clarity around how this risk assessment can improve identifying low-risk factors when it comes to a deferral for potential donors with multiple long-term partners.

Serodiscordant Couples

The proposed guidance recommends deferring an individual who has had sex with a person who has ever had a positive test for HIV for 3 months from the most recent sexual contact. This guidance does not take into account risk-reduction strategies individuals to prevent HIV transmission. This may be especially problematic for potential donors in long-term relationships with HIV-positive partners as they would essentially be barred from donating no matter what risk reduction strategies are in use. Given what is known about U=U, that people living with HIV who maintain an undetectable viral load have effectively

no risk of sexually transmitting HIV to their HIV-negative partner,[8] there may be some additional adjustments necessary to the risk assessment so that low-risk individuals in serodiscordant relationships are not turned away unnecessarily.

Injection Drug Users and Sex Workers

The blanket deferrals attached to sex work and injection drug use continue to proliferate stigma against these individuals. The guidance defers for 3 months from the most recent event, an individual who has engaged in non-prescription injection drug use and defer for 3 months from the most recent event, an individual who has exchanged sex for money or drugs. We would urge the FDA to take steps to ensure that we are moving more towards individualized risk assessments rather than blanket deferrals for these groups of people as well. Ideally, these individualized risk assessments would take into account emerging strategies that are proven effective in reducing the risk of HIV transmission during injection drug use and/or sex work. For example, the use of needle exchanges and safe injection sites that provide sterile supplies is a growing harm reduction strategy that can help to dramatically reduce HIV transmission risk. When drug users used a sterile needle at every injection, HIV transmission can be reduced by almost 60%.[9] Similarly for sex work, individualized risk assessments that identify specific sexual risk behaviors that sex workers may or may not engage in will help to ensure that sex workers who are not high risk for HIV are still able to donate rather than being deferred simply for their job. We need more large-scale studies on blood donation and risk factors among sex workers and injection drug users as there continues to be little research and data on these populations. This data can inform what kinds of risk factors and risk reduction behaviors among these populations are evaluated on the individual assessment.

Increasing Blood Donation Among BIPOC Communities

While these proposed guidelines will increase blood donation eligibility, the FDA should also work to address disparities in blood donation among diverse communities. In Black, Indigenous, and people of color (BIPOC) communities, the rate of blood donation lags behind their White counterparts. Blood donation rates among Black individuals are 25-50% of that of White individuals.[10] Creating a tailored approached to educate BIPOC

[8] National Institute of Allergy and Infectious Disease. HIV Undetectable = Untransmittable (U=U), or Treatment as Prevention. Available online at: https://www.niaid.nih.gov/diseases-conditions/treatment-prevention

[9] Broz D, Carnes N, Chapin-Bardales J, et al. Syringe Services Programs' Role in Ending the HIV Epidemic in the US: Why We Cannot Do It Without Them. *American Journal of Preventive Medicine.* Available online at: https://www.ajpmonline.org/article/S0749-3797(21)00389-5/fulltext

[10] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3082202/

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communities on the new guidelines, especially among gay and bisexual men, and trans individuals, can significantly increase rates of donation.[11]

Howard Brown Health supports the FDA's proposed Individual Risk Assessment for Blood Donations and we urge for its quick finalization. The proposed guidelines will help to end decades-long discrimination against gay, bisexual, MSM in blood donation eligibility, and it will bring our blood donation policies in line with current medical science. We thank the FDA for the opportunity to submit a comment. Thank you for your consideration. If you would like to discuss our recommendations further, please reach out to Tim Wang, the Director of Policy and Advocacy, at TimothyW@howardbrown.org.

Sincerely,

David Ernesto Munar
President and CEO

[11] Shaz B and Hillyer C.Minority Donation in the United States: Challenges and Needs. *Curr Opin Hematol.* 2010 Nov; 17(6): 544-549. Available online at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3082202/