



April 2, 2020

Dear Commissioner Hahn,

As President of the Human Rights Campaign (HRC), I write on behalf of our more than 3 million members and supporters to reiterate the need for the Federal Drug Administration (FDA) to change its blood donation policy for men who have sex with men (MSM). We have repeatedly requested that the federal government change this policy, but unfortunately it remains in effect; increasing already unacceptable collateral consequences for patients and donors as our nation grapples with the COVID-19 pandemic. Although we confront a dizzying number of unknowns with the COVID-19 virus, what we do know is that this pandemic is placing unprecedented pressures on the nation's healthcare systems, including the increased need for blood for patients, which will continue to be punishing and unrelenting for months—if not years.

At no time in our nation's history has it been more critical to prioritize science and facts over fear and bias. Further, we must be cognizant that our response will define us for generations. In this vein, we again urge the FDA to revise the guidelines for blood donation to reflect current blood testing science and move expeditiously to implement meaningful evidence-based risk assessment instruments.

The current one-year deferral for MSMs represents a de facto lifetime ban for gay and bisexual men and excludes over 2 million potential donors and an estimated nearly 300,000 pints of blood annually.¹ While deferral is necessary for some donors, the current 12 month deferral period is not in line with evidence-based science. To ensure the blood supply is the safest it can possibly be, risk should be evaluated based on the individual risk behaviors of every donor, rather than on community-wide prevalence.

Current testing technologies support the adoption of a shorter deferral period. The FDA has established Nucleic Acid Testing (NAT) as the industry standard for the testing of blood donations in the United States. Using NAT has reduced the “window period” for pooled donation

¹ See Ayako Miyashita & Gary J. Gates, *UPDATE: Effects of Lifting Blood Donation Ban on Men Who Have Sex with Men*, The Williams Institute, at 2, Table 2 (September 2014), available at <http://williamsinstitute.law.ucla.edu/wp-content/uploads/Blood-Ban-update-Jan-2015.pdf>.

testing to 6.3 days for HIV, 3.1 days for Hepatitis C, and 24.4 days for Hepatitis B. A shorter deferral period for those who have engaged in activities that have placed them at a predetermined, unacceptable level of risk would screen donors whose infections might not be caught by the universal testing that currently takes place.

Once a reasonable, science-based deferral period is established, the FDA can determine which activities present an unacceptable level of risk if engaged in during that reduced deferral period. Using the Center for Disease Control and Prevention's (CDC) table of relative HIV transmission risks from an infected source, it is clear that some activities, such as the sharing of syringes or other injection drug paraphernalia, would present an unacceptable level of risk, while other activities, such as oral sex, likely would not present an unacceptable level of risk. Furthermore, the FDA should determine whether the use of a condom that remains intact during the activity, vaccination for the pathogen in question, or consistent use of pre-exposure prophylaxis (PrEP) medication should affect whether deferral is warranted.

It is critical that deferral be based on information that is within the personal knowledge and control of the prospective donor—and not on the sexual orientation or gender identity of the donor, the sexual orientation, gender identity, or activities of one's sexual partners, or on perceived monogamy. By focusing on the activities that present an unacceptable degree of risk (e.g., receptive anal sex without a condom), the need to identify the gender of the donor or the gender of the donor's sexual partner is eliminated. A policy focused on the prospective donor's activity, rather than identity, will not only be safer but rational.

As the global pandemic wears on, the integrity and safety of the blood supply in this country must be preserved, strengthened, and maintained. Continuing to enforce the de facto prohibition on blood donation by sexually active gay and bisexual men does not reflect the best science available. Modernization of the policy is essential to ensure that the blood supply remains as safe as possible while maximizing the donor pool. This must be a time of science and measured, unbiased thinking. The time to revise the current policy is today.

Sincerely,

Alphonso B. David
President, Human Rights Campaign