



## **Joint Statement from LGBTQ, HIV, and Plasma User Groups on Proposed Change from Identity-Based Deferrals to Individual Risk Assessment for All Potential Blood Donors**

(Washington, D.C., February 2, 2023) Last Friday, the Federal Drug Administration (FDA) announced proposed changes to guidance on blood donation that will eliminate the current 3-month deferral for sexually active gay and bisexual men and replace it with an individual risk assessment that applies to all potential donors regardless of sexual orientation or gender identity. The undersigned LGBTQ, HIV, and Plasma User Groups issue the following statement in support of these important proposed changes:

“The move from identity-based group deferrals to individual risk assessments based on a potential donor’s sexual activities is a transformative shift in U.S. blood supply management that we wholeheartedly support. The changes proposed by the FDA will substantially increase the number of eligible donors while maintaining the safety of the blood supply and eliminating the stigma engendered by the previous deferrals for gay and bisexual men. With further gathering and/or analyses of data from controlled studies, additional refinements to the individual risk assessment will be possible. We welcome future changes that are evidence based and increase the supply of blood while maintaining an extremely high level of safety.

“One additional change that we believe should be under consideration is a method to allow gay and bisexual men using pre-exposure prophylaxis (PrEP) to donate. Current guidance recommends that all HIV-negative individuals taking PrEP to prevent the acquisition of HIV be deferred; this deferral will not be eliminated by the proposed changes. PrEP is safe and

effective, but it suppresses the amount of virus associated with a recent HIV infection and may result in a false negative in the testing process used by blood collection centers. We hope the FDA will continue to evaluate the data and, if necessary, conduct additional studies to validate protocols to bring PrEP users into the pool of eligible donors.

“On the subject of antiretrovirals, we think it prudent to make clear that people who are taking antiretroviral medications as treatment because they are HIV-positive **cannot** donate blood, regardless of their viral load. **Please do not** try to donate blood if you are living with HIV.

“Though we are not quite there yet, the day may soon come when blood donations from people living with HIV and other bloodborne pathogens can be made safe for transfusion and these deferrals will no longer be necessary. ‘Pathogen inactivation,’ a process that eliminates a relatively comprehensive list of viruses and other infectious agents from donated blood components and whole blood, has been in testing and development for years. With the permission and oversight of the FDA, it is now being used to ensure the safety of some blood components in some locations within the U.S. We encourage the FDA to continue to support the development of this technology that likely will become the ultimate tool for ensuring the safety of the blood supply.

“In 2010, LGBTQ groups and plasma user groups came together to issue a statement like this one in support of evidence-based changes to the lifetime deferral for any man who had had sex with a man even once since 1977. These groups wanted to demonstrate that ‘both sides’ of the debate could work together and in fact shared the goals of an abundant and safe blood supply. Through each incremental step, these advocates kept pushing for a change to truly behavior-based deferrals from nominal ones (“men who have sex with men” or “MSM”) that were in fact identity-based (gay and bisexual men). We are very happy the FDA finally undertook the studies necessary to validate an individual risk assessment for all donors, regardless of sexual orientation or gender identity, and hope it will continue to conduct the research necessary to expand the donor pool and increase the supply of safe whole blood, blood components, and blood products.

AIDS United	Lambda Legal	PFLAG
HIV+HEP Policy Institute	NASTAD	The AIDS Institute
HIV Medicine Association	National Hemophilia Foundation	Whitman-Walker Health
Human Rights Campaign		