VIA ELECTRONIC SUBMISSION

Attention: U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research November 2016
FDA-2016-N-1502

Group Comments Regarding the "Blood Donor Deferral Policy for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products"

The undersigned organizations submit these comments in response to the FDA's request for comments on the "Blood Donor Deferral Policy for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products" (hereinafter "Blood Donor Deferral Policy"). We are very pleased that the Food and Drug Administration (FDA) is considering potential options to the current blood donor deferral policy to reduce the risk of HIV transmission. As we have stated in previous submissions on this topic, we believe the current scientific evidence supports implementation of an individual risk assessment and deferral period based on the actual time needed for detection of HIV and other transfusion transmissible infections (TTIs) in the bloodstream. The one subject that requires further research and study is the development of an instrument to accurately assess an individual's level of risk. Below, we describe in greater detail the parameters of a policy based on the current scientific understanding of HIV and other bloodborne pathogens.

Given current testing technologies, a deferral period of, at most, three months is appropriate. The FDA has established Nucleic Acid Testing (NAT) as the industry standard for

the testing of blood donations in the United States.[1] Using NAT has reduced the "window period" for pooled donation testing to 6.3 days for HIV, to 3.1 days for HCV and to 24.4 days for HBV.[2] Since NAT allows for detection of all three of these bloodborne pathogens within 25 days of exposure,[3] a deferral period of three months—possibly significantly less—for those who have engaged in activities that have placed them at some pre-determined, unacceptable level risk would remove from the donor pool all donors whose infections might not be caught by the universal testing that currently takes place.[4]

An accurate assessment of an individual's risk behaviors will allow for deferral of any potential donor presenting anything more than a de minimus risk to the blood supply. Once a reasonable deferral period that is firmly rooted in the science is established, the FDA need only

[1] *See* U.S. Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, *Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components (including Source Plasma and Source Leukocytes) to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV*, (October 2004) (hereinafter "HIV/HCV Guidance for Industry").; *see also* U.S. Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, *Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components, including Source Plasma, to Reduce the Risk of Transmission of Hepatitis B*, (October 2012) (hereinafter "HBV Guidance for Industry").

[2] Jos Weusten, Marion Vermeulen, Harry van Drimmelen & Nico Lelie, *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*, 51 Transfusion (1), 203-15 (Jan 2011); *see also HBV Guidance for Industry*, at 4 (stating that HBV can be detected 14-35 days after infection, depending on the relative sensitivity of the tests used).

[3] We note that the "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood or Blood Products; Guidance for Industry" ostensibly are designed to address only the risk of HIV transmission. If that were indeed the case, the window period at issue would be only 6.3 days, justifying a deferral period of only 2-3 weeks. The policy we are suggesting is designed to reduce the risk of transmission of HIV, HCV, and HBV, thereby justifying a deferral period based on a 24.4 day window period associated with HBV.

[4] A lifetime deferral for those who have engaged in commercial sex worker (CSW) and injection drug use (IDU) is unwarranted and unjustifiable. The amount of time after exposure before a TTI will be detected by current testing technologies does not change based on the activity that led to infection or whether money was exchanged for the sexual activity that may have led to infection. A person who has discontinued injection drug use or engaging in sexual activity involving a significant degree of risk for the shorter deferral period (at most 3 months), regardless of whether that activity involved the exchange of money, is at no higher risk of having becoming infected during the window period than anyone else. Along with adjustments the necessary changes for men who have sex with men (MSM), we recommend that the FDA substantially reduce the deferral period for commercial sex workers and injection drug users, in keeping with the sensitivity of the current testing technologies.

determine which activities present an unacceptable level of risk if engaged in during that substantially 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 undoubtedly present an unacceptable level of risk, while other activities, such as oral sex, likely would not present an unacceptable level of risk.[5]

Similarly, we would expect that the FDA would decline donations from people who have participated in receptive anal sex during the substantially reduced deferral period, but it would perhaps be a closer call as to whether insertive anal sex and receptive vaginal sex—which present very similar degrees of risk—present a risk that is unacceptable.[6] 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. In any event, the undersigned strongly believe that deferral should 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.

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[5] *See* Centers for Disease Control and Prevention, *HIV Transmission: Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act*, http://www.cdc.gov/hiv/policies/law/risk.html (last updated July 1, 2014) (identifying the per-act risk associated with needle-sharing during injection drug use as approximately 38 in 10,000 while the per-act risk associated with receptive or insertive oral intercourse is less than 1 in 10,000 and characterized simply as "low.").

[6] *See id*. (stating the per-act risk for receptive anal sex is approximately 138 in 10,000 (1.38%), the per-act risk from insertive anal sex is approximately 11 in 10,000 (.11%), and the per-act risk from receptive vaginal sex is approximately 8 in 10,000 (.08%)).

Regardless of where the line for an acceptable degree of risk is drawn—and the line must be drawn somewhere, because a "zero-risk" standard is not realistic or achievable—the line should be drawn without regard to the sexual orientation or gender identity of the prospective donor. 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 based on donor activity, rather than identity, will not only be safer but will also be truly nondiscriminatory.[7]

A donor questionnaire that produces candid and accurate answers is extremely important. As the move is made to an individualized risk assessment, a donor questionnaire that produces honest and accurate answers will be one of the most critical components in ensuring the safety of the blood supply. For this reason, we recommend the FDA spend the time and money necessary to develop an instrument that will accurately assess individual donor risk and provide that improved risk assessment questionnaire as part of its guidance to industry. We are hopeful that the new questionnaire will be more streamlined than the current questionnaire, but we also believe that the risk assessment instrument must not be afraid to

[7] Furthermore, people are more likely to comply with a policy that is evaluating risk activities within the window period for detecting TTIs. As the current Guidance notes, there are currently men who are noncompliant with the lifetime ban on blood donations from men who have sex with men. The Guidance further notes that at least some of these men would reluctantly agree to a one-year deferral if it was part of a process working toward a shorter deferral period. What this signals is that the more reasonable and science-based the policy is, the more likely people will be to comply with the policy. Close to full compliance with a policy based on a questionnaire that evaluates individual risk would make the blood supply much safer than insistence upon a policy that continues to discriminate and is not adhered to by a substantial number of people who feel it is unjust and poorly tailored to identifying potential donors at actual risk of infection with a TTI.

ask the necessary questions related to specific sexual activities in which the potential donor has engaged within the shortened deferral period. A safe blood supply is too important to let outdated notions regarding moral norms or the delicacies of propriety interfere with collection of the information necessary to ensure its continuing safety.

The current one year deferral for men who have sex with men (MSM)—which for most represents a de facto lifetime ban—excludes over 2 million potential donors and an estimated nearly 300,000 pints of blood annually.[8] While deferral is necessary for some donors, we maintain that anything more than at most a 3-month deferral period is excessive. We further assert that risk during the substantially reduced deferral period should be evaluated based on the individual risk behaviors of every donor, rather than on community-wide prevalence for those of a particular sexual orientation or a particular occupation, such as sex worker, or who have a history of injection drug use. We ask the FDA to consider why it is willing to accept donations from heterosexual donors who have engaged in sexual activities with a relatively high level of risk, while excluding <u>all</u> gay and bisexual men who have had any kind of sex with another man in the past 12 months, regardless of the degree of risk involved in those sexual activities. With that in mind, we encourage the FDA to move toward a policy based on the science, with a significantly shortened deferral period and an individualized, activity-based risk assessment that does not hinge on one's sexual orientation or other aspect of identity.

Should the FDA decide to adopt a truly nondiscriminatory policy employing an individualized risk-based assessment, the undersigned organizations stand ready to assist in

[8] *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.

educating the communities we serve about the contours of and ensuring the greatest level of compliance possible with such a policy. Recognizing that it will take time to increase understanding and move opinion within the community, we encourage the FDA to make clear as soon as possible its intention to adopt an individualized risk assessment and to develop the donor history questionnaire necessary to implement that policy. Definitive indication that the FDA is taking steps in the right direction will allow the undersigned organizations to be of maximum assistance in preparing the ground for this important change in policy.

Thank you for your consideration.

Sincerely,

AIDS Foundation of Chicago
AIDS United
Gay Men's Health Crisis (GMHC)
Human Rights Campaign
Lambda Legal
National Center for Lesbian Rights
National Center for Transgender Equality
PFLAG National