



**America's Blood Centers®**  
It's About *Life.*

1717 K Street NW, Suite 900, Washington, DC 20006  
Tel: 202-393-5725 | Fax: 202-899-2621

[www.AmericasBlood.org](http://www.AmericasBlood.org)

June 23, 2020

Center for Biologics Evaluation and Research  
Food and Drug Administration  
10903 New Hampshire Ave.  
Bldg. 71, Rm. 7301,  
Silver Spring, MD 20993-0002

Re: Docket Number FDA-2015-D-1211, "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products" April 2020.

Dear Docket Manager:

America's Blood Centers (ABC) submitted joint comments to the docket on June 5, 2020 with AABB, American Red Cross (ARC), and the Plasma Protein Therapeutics Association (PPTA) on "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products", April 2020. Again, we appreciate the FDA's efforts to support the blood industry during the COVID-19 public health emergency by revising the guidance to allow additional blood donors during the inventory shortage.

ABC wants to supplement these comments and bring to your attention the need for an immediate technical correction to this guidance.

### **Section III B, Recommendation 4 for deferral for sexual contacts (page 8)**

*"Defer for 3 months from the most recent sexual contact, any individual who has a history of sex with a person who: has ever had a positive test for HIV, **ever** exchanged sex for money or drugs, or **ever** engaged in nonprescription injection drug use."*(emphasis added)

As written, an ongoing sexual partner of a person who has **ever** exchanged money or sex for drugs or has a history **ever** of non-prescription drug injection would not be able to donate unless they did not have sex with this partner for 3 months. The high-risk partner can donate after 3 months but their ongoing sexual partner cannot donate unless they refrain from sex with their partner for 3 months. The use of the word **ever** results in the on-going sexual partner being continuously deferred, but the high-risk donor being able to donate 3 months after the behavior.

The inconsistent application of the HIV risk criteria for sexual contact results in the deferral of certain donors based on sexual contact with individuals who are themselves eligible to donate. It also, of course, directly affects the accuracy of two questions (Questions 16 and 17) in the Guidance “Implementation of Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Blood and Blood Components Guidance for Industry”, May 2020.

**Q16** In the past three months, have you had sexual contact with a prostitute or anyone else who has **ever** taken money or drugs or other payment for sex? Deferral 12 weeks from sexual contact.

**Q 17** In the past three months, have you had sexual contact with anyone who has **ever** used needles to take drugs or steroids or anything not prescribed by their doctor? Deferral 12 weeks from sexual contact.

Because of the inconsistency, some blood centers are waiting for FDA clarification before they implement the guidance, thereby losing a valuable opportunity to expand the donor pool and reenter otherwise eligible donors during this public health emergency. **ABC requests an immediate technical correction** of the guidance to rectify this situation by removing “**ever**” from the behavior criteria in **Section III B, Recommendation 4 for deferral for sexual contacts so it now reads as two separate statements to ensure clarity. We also suggest adding “in the past three months” to the behavior criteria (refer to Section III A Recommendation 3.d.)**

*“Defer for 3 months from the most recent sexual contact, any individual who has a history of sex with a person who: has ever had a positive test for HIV”*

*“Defer for 3 months from the most recent sexual contact, any individual who has a history of sex with a person who: in the past three months, exchanged sex for money or drugs or engaged in nonprescription injection drug use.”*

Founded in 1962, America's Blood Centers is North America's largest network of community-based, independent blood programs. Recognized by the U.S. Congress for its critical work in patient care and disaster preparedness and response, the federation operates more than 600 blood collection sites providing close to 60 percent of the U.S., and a quarter of the Canadian blood supply.



Katherine Fry, MBA, CAE  
Chief Executive Officer  
America's Blood Centers