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INSIGHT

FDA Regulation of Blood and Blood Products: Recent Draft Guidance on Donor Eligibility

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The nation's blood supply is largely managed by a network of independent blood centers and the American Red Cross, with oversight from the Food and Drug Administration (FDA). FDA's role includes making policy to determine who may donate blood to minimize the risk for transfusion-transmitted illness, such as Human Immunodeficiency Virus (HIV). FDA guidance has changed throughout the years due to advances in science and social trends. Most recently, FDA published draft guidance for a 60-day comment period on January 30, 2023, that would eliminate recommendations for time-based deferrals for specific subpopulations and implement recommendations for individual risk assessments. This Insight briefly explains FDA's role in regulation of blood and the evolution of FDA's deferral policy, and discusses the potential risk of HIV transmission through blood under the recommendations in the January 2023 draft guidance.

FDA Blood Regulation and Guidances

FDA oversees the collection of blood and its components (e.g., plasma, red blood cells, and platelets) intended for transfusion or for the manufacture of pharmaceutical products. FDA regulates blood and blood products under two statutes: the Federal Food, Drug and Cosmetic Act (FFDCA) and the Public Health Service Act (PHSA). Blood establishments must comply with FDA regulations governing blood collection, storage, testing, and processing, among other things. FDA regulations also describe eligibility criteria to donate blood that both protect the health of the donor and ensure the safety, purity, and potency of the blood product. Current FDA guidances recognize an industry-prepared standardized donor history questionnaire as an acceptable mechanism for determining eligibility. The donor history questionnaire incorporates all FDA guidance and regulations pertaining to donor eligibility.

FDA guidances represent the agency's "current thinking" on a particular topic and are framed as recommendations; they are not legally binding. However, blood establishments treat FDA guidances as requirements and use them to create standard operating procedures.

Reducing the Risk of HIV Transmission from Blood or Blood Products

Long-standing FDA guidance, first established in 1985, deferred men who have sex with men (MSM)—including men who had sex with men even once—from donating blood for life. The intent of the deferral

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was to reduce the risk of HIV transmission by blood and blood products. At the time, the capability to test donated blood for HIV did not exist, so life-time deferrals were the only mechanism available to protect the blood supply.

In 1992, FDA issued a memo that reiterated the lifetime deferral for MSM and consolidated recommendations regarding the deferral of donors at risk of HIV. FDA revised its recommendations in 2015 to narrow the application of the deferral to MSM from lifetime to 12 months; FDA also extended the application of the 12-month deferral period to women who had sex with MSM. Additionally, individuals who were tattooed or pierced, had sex in exchange for money or drugs, had engaged in nonprescription injection drug use, had received a blood transfusion, had come into contact with another individual's blood, and/or had a history of syphilis or gonorrhea were required to defer blood donation for a period of 12 months from the last time that the activity took place.

Guidance issued in response to the COVID-19 pandemic revised the recommended deferral period temporarily from 12 months to 3 months for each of these groups. Mitigation strategies to prevent the spread of COVID-19, such as closures of schools and workplaces, led to blood drive cancellations, resulting in a critical blood supply shortage at the time. The revised deferral period was intended to increase supply by allowing individuals to donate who were previously unable. This revised guidance, issued April 2, 2020, is still in effect for the duration of the public health emergency.

On January 30, 2023, FDA published draft guidance that would remove recommendations for time-based blood donation deferrals and instead implement recommendations for individual risk assessments to assess suitability for blood donation. Rather than a blanket 12-month or 3-month deferral for MSM or other groups, the draft guidance recommends that all individuals regardless of gender be assessed for whether they have had a new sex partner in the past three months and, if so, whether they had anal sex. An individual answering yes to both of those questions would be deferred from donation for three months from the sexual encounter. The draft guidance also would apply an individual risk assessment to anyone in the other categories of at-risk activities listed above.

The draft guidance recommends that individuals defer permanently if they have ever taken medications to treat an HIV infection (e.g. antiretroviral therapy). The draft guidance also recommends deferrals for individuals taking pre-exposure prophylaxis (PrEP). There are currently two types of medications approved by the FDA for PrEP: oral taken daily and an injection every two months. The recommended deferral periods are three months for the oral medications and two years for the injectable medication. Industry has already implemented these medication deferrals in advance of the final guidance.

Risk of HIV Transmission in the Blood Supply

Assessing donor suitability via an individual risk assessment appears unlikely to pose any additional risk to the blood supply because (1) FDA already requires blood and blood components destined for transfusion or for use in manufacturing blood products to be tested for HIV and other transfusion-transmitted infections, and (2) other countries (notably the United Kingdom and Canada) have already implemented individual risk assessments and have not reported any safety concerns following implementation.

The draft guidance would continue to recommend requiring individuals determined to be at risk for HIV infection to defer for a specified period of time. This would reduce the likelihood of donations from individuals with a recent HIV infection who may be in the window period—a period of time where infections are still undetectable using current testing methods.

FDA funded the Assessing Donor Variability and New Concepts in Eligibility (ADVANCE) study, which was carried out by multiple leading blood centers to determine whether a donor deferral policy different from the one currently in effect under the April 2020 guidance could be used at blood centers nationwide

while still maintaining the safety of the blood supply. The ADVANCE study was carried out in 2022, with enrollment ending in September 2022. The study asked MSM additional questions to assess individual risk of HIV infection as an alternative to the April 2020 guidance in effect for a three-month time deferral. Blood donations were then screened for HIV to evaluate the safety of individual risk assessments. As of publication, the results of the study are not publicly available. However, study results were considered among the available data used for creation of the January 2023 draft guidance.

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