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FDA Considers Easing Blood Donation Restrictions for Gay Men

On January 27, the U.S. Food & Drug Administration (FDA) released draft guidance that would ease the restrictions on eligibility to donate blood. Current FDA guidance places donor restrictions through mandated deferral periods on men who have sex with men (MSM). While these newly released draft guidelines do not yet reflect changes in the law, they indicate the agency's current viewpoint, which may lead to changes in regulations concerning blood donation based on clinically available data. The FDA is requesting comments on its proposed guidance by March 27. Following the comment period, the FDA will issue a final rule, likely later this year.

The FDA draft guidance is likely in response to the critical blood shortages many communities are experiencing. Specifically, supply levels of Type O blood, the universal donor, are critically low. The FDA guidance is intended and expected to increase the donor pool and allow donations from those populations previously restricted from donating. Historically, donations by MSM have been deferred for a period of months out of a concern about infection with the human immunodeficiency virus (HIV). This deferral period was reduced to three months in 2020.

The draft guidance would shift the policy to a gender-inclusive individual risk assessment, where individuals, regardless of gender or sexual orientation, would be asked questions regarding their sexual history and risk for infection. While each unit of donated blood receives rigorous testing, including for HIV, protecting the blood supply remains a top concern for FDA regulators. The FDA has reviewed available data, and these proposed guidelines indicate that it believes a gender-neutral approach will continue to maintain a high level of safety in blood transfusions while widening the donor pool. Specifically, the draft guidance eliminates the deferral period of three months for all individuals based on a gender-neutral, temporal limitation on sexual partners.

These changes signal a probable shift in FDA policy and will likely lead to more inclusive practices in blood donation. The changes also could have an impact throughout the healthcare sector and lead to increased supply in the nation's blood stores.

Full text of the draft guidance is available here.

Day Pitney's healthcare attorneys are available to assist in answering questions or drafting comments in response to these proposed guidelines.

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