Submit Comments to the FDA on Update Tissue Donation

Comment (*Highlight & Copy This*)
For three decades federal policy has denied the dying wishes of thousands of queer men who hoped to give the gift of life through tissue donation. The blanket 5-year deferment criteria for MSM donors was discriminatory, unnecessary, and grounded in the stigma of the HIV/AIDS crisis. With the advances in understanding of HIV as well as scientific progress in detection of infectious diseases, this update should have been drafted years ago.

At the same time that tissue banks and facilities have been forced to turn away healthy donors due to their sexuality, those same tissue banks have accepted donations from increased risk donors to meet the demands of their communities. In recent years, donors at risk of tuberculosis have resulted in outbreaks from bone grafts, while septic donors of ocular tissue have transmitted other infections. These recipients could have received safer transplants if the FDA had acted and revised this policy within a reasonable time frame.

Blood donor eligibility criteria was revised in 2015, 2020, and 2023. Organ donor eligibility was revised in 2013 and 2020. The United Kingdom updated their tissue donor screening to an individual risk assessment in September of 2023. Despite progress on these reciprocal policies, tissue donor criteria remained stagnant for three decades.

Within this update, the ability of living donors to be screened differently, and to utilize quarantine capabilities within reproductive tissues is a significant step forward. The transition to an individual risk assessment will promote uniformity within blood and tissue donor screening.

I hope the FDA will conduct research on the effect of prophylaxis medications related to testing for HIV in order to allow these donors to give as long as it is safe to do so. I urge the FDA to promote transparency related to the impact of this policy, and continue to advance eligibility criteria to ensure that all safe donors are permitted to give. Additionally a time frame for implementation of a finalized guidance should be included in the final policy.

Link
We are only requesting your comments on the HIV document, but welcome submission to the Hepatitis B and C dockets if you choose.

- HIV: https://www.regulations.gov/document/FDA-2022-D-0467-0002

- Hepatitis B: https://www.regulations.gov/document/FDA-2022-D-0465-0002
- Hepatitis C: https://www.regulations.gov/document/FDA-2022-D-0466-0002

Background

In 1994 with the height of the HIV/AIDS crisis, the United States government implemented a ban on tissue donation from queer men (defined as ‘men who have sex with men’, or MSM in the document) if they had been sexually active even once in the previous five years. This policy was routinely applied to transgender women, nonbinary donors, and other gender-diverse individuals. In 2005 the FDA absorbed the policy, keeping eligibility criteria the same, last updating the document in 2007.

The ban was justified by the FDA due to a perceived risk of HIV and Hepatitis B, but the advances in testing and understanding of these infections over the past three decades no longer require deferral criteria. Updates to organ donor eligibility as well as blood donor eligibility reflect these scientific advances.

Tissue donation includes parts of the eyes, heart valves, skin, ligaments, cartilage, sperm, eggs, and more.

In January of 2023, Pride and Plasma began researching and advocating for a revision to the policy, submitting research briefs on the issue to the FDA’s Cellular, Tissue, and Gene Therapies Advisory Committee in September of 2023, October of 2023, and November of 2024. The United Kingdom updated tissue donor eligibility to an individual risk assessment in September of 2023.

Update 1/6/25

On Monday, January 6, 2025, the FDA released updated draft guidances for tissue donation. The new policies break up the previous document into 6 new policies, one for general donation and five for infectious disease screening and prevention. The five new policies provide recommendations for HIV, Hepatitis B, Hepatitis C, Tuberculosis, and donors at risk of sepsis.

The new policies for HIV, Hepatitis B, and Hepatitis C have replaced the blanket 5-year ban on donations from queer men with the individual risk assessment, the same policy implemented by the FDA for blood donation in May of 2023. Now all donors will be asked about their sexual history and will be determined to be eligible based upon the number of partners and new partners if the donor is participating in anal sex.

There is also a new provision in HIV risk for donors taking prevention medications (called PrEP and PEP). These medications, while clinically effective at preventing infection, work by preventing replication of the HIV virus. This interferes with the accurate testing of potential donors, as there may be an undetectable but non-zero viral load within an individual, that will not progress to an infection with the assistance of these medications. However, that very low viral load may be transmissible to a recipient of the donation if the individual were permitted to donate. Donors will be ineligible to donate if they have taken oral medications within 3 months or injectible medications within 2 years. This rationale is identical for the deferral criteria for individuals who have been treated for STIs within the previous 3 months- where the medications interfere with accurate testing.