Letters

Reproductive tissue donors

June 2022—The CAP issued a statement on April 5 in support of the ADVANCE study, which hopes to end discriminatory practices based on sexual identity and/or sexual orientation in donor risk assessments and deferral periods for blood donation. Originally, the FDA instituted such discriminatory criteria on the assumption that potential donors who are gay and bisexual men who have sex with men are at an increased risk of transmission of communicable diseases, such as human immunodeficiency virus. If the results of the ADVANCE study prove this antiquated idea false, the FDA will hopefully amend the official guidance on donor eligibility for blood donation.

The FDA should be applauded for decreasing donor deferral periods for gay and bisexual men from 12 months without having sex with a man to three months in an effort to address blood shortages during the COVID-19 pandemic. However, eliminating discriminatory practices against potential donors from the LGBTQ+ community should not be limited only to blood donation. Currently, gay and bisexual men who have sex with men are automatically excluded and are ineligible to be anonymous donors of reproductive tissues (sperm, oocytes, and embryos). While directed (known) donors who are gay and bisexual men can still be used, they remain FDA ineligible and the recipient must sign waivers concerning the risk of exposure to communicable disease.

While eliminating HIV transmission risk in reproductive tissue donors demands accurate and evidence-based screening strategies, there is little to no scientific basis for the automatic exclusion of men who have sex with other men from FDA eligibility. These guidelines were put into place when HIV testing was in its infancy and the scientific rationale was to mitigate the likelihood of false-negative testing events. Fortunately, we now have third- and fourth-generation HIV assays that are highly reliable, with reported sensitivities of 99.7 to 100 percent. As such, current practices to reduce the risk of infectious disease transmission are robust and effective without any need for the discriminatory exclusion criteria.

For anonymous sperm donors, as an example, blood from the potential donor is tested within seven days of sample collection for all FDA-required infectious agents (HIV 1/2, HTLV 1/2, hepatitis B, hepatitis C, West Nile virus, cytomegalovirus, syphilis, gonorrhea, chlamydia). If test results are negative, samples can be cryopreserved and quarantined for 180 days. After 180 days, blood is once again drawn from the donor and tested. If results are negative again, then samples can be released from quarantine and distributed. This method effectively "bookends" samples between two sets of negative blood tests six months apart. While a theoretical risk of transmission remains, and can never be fully eliminated, that theoretical risk does not likely increase for donors who are men who have sex with men.

As the leading authority for the accreditation of reproductive laboratories in the United States, the CAP should advocate also for the elimination of discriminatory eligibility criteria for donors of reproductive tissues. CAP-accredited reproductive laboratories could be recruited to participate in and design a pilot study, much like the ADVANCE study, which could validate these proposed changes to FDA eligibility criteria. Members of the LGBTQ+ community should have the ability to safely donate reproductive tissues if they so choose, just the same as any cis-gendered heterosexual individual. The CAP should lead this effort to advance diversity and inclusivity, not only for the LGTBQ+ community but also for all reproductive donor tissue recipients.

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