

October 20, 2021

Janet Woodcock, MD
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Woodcock:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to urge the U.S. Food and Drug Administration (FDA) to re-evaluate policy requiring a five-year deferral period for men who have had sex with men (MSM) with regards to donating human cells, tissues, and cellular and tissue-based products (HCT/Ps). Included in HCT/Ps are tissues such as corneas, in which approximately 3000 corneal transplants are blocked each year due to this outdated policy, despite no recorded cases of HIV transmission from a corneal transplant.¹ AMA policy supports the use of “rational, scientifically-based blood and tissue donation deferral periods that are fairly and consistently applied to donors according to their individual risk.” The AMA strongly encourages HCT/Ps deferral policy to be in alignment with the current science as well as consistent with the ethical treatment of donors. The AMA applauds the FDA’s funding of research into individual risk assessments for blood donation, such as through the Assessing Donor Viability And New Concepts in Eligibility (ADVANCE) study, and encourages the FDA to expand this work to include HCT/Ps donation deferrals as well.

Current guidelines require MSM to defer HCT/Ps donation for five years since their last sexual contact with a man. These guidelines arose out of the HIV epidemic of the 1980s and 1990s in which MSM were at higher risk of HIV transmission, and HIV tests were lacking in accuracy and precision.² Modern HIV testing, including nucleic acid testing technology, can detect the presence of HIV as early as seven days post-infection.³

This deferral period is not consistent with the guidelines for other groups of comparable or higher risk. For example, only a one-year deferral period is advised for individuals who have had sex with someone known to be HIV-positive. A similar one-year deferral period is required for an individual who has had a needle-stick injury with a needle known to be infected with HIV. No known medical reason is given for the difference in deferral period for MSM, and only further promotes stigmatization and negative stereotypes of any lifestyle outside heteronormative culture.

Lessons on the importance of evidence-based deferral periods can be taken from blood donation policy, where MSM were banned entirely from donating blood between 1985 and 2015. In 2015, the ban was replaced with a one-year deferral period, which was then reduced to a three-month deferral period in 2020 in response to the increased need for blood donations during the COVID-19 pandemic.⁴ Public communications state that the FDA does not intend on returning to a 12-month deferral period for MSM blood donation after the COVID-19 pandemic has ended, a policy position that the AMA fully supports.⁵

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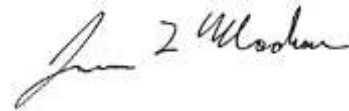
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As the COVID-19 pandemic has limited access to hospitals and reduced preventative and elective treatments, there is extra incentive to remove these artificial barriers causing HCT/Ps scarcity, a field that struggled to meet patient needs prior to the pandemic.^{6,7}

While these measures have been a step in the right direction, maintaining a blanket deferral period will still uphold the stigma around MSM.⁸ Even after the FDA updated its guidance for blood donation, many institutions were still turning away MSM donors during a national blood shortage.⁹ As such, the AMA encourages the FDA to expeditiously revise its HCT/Ps donor deferral policy to be in alignment with blood donation policy, and to use the ADVANCE Study or other similar research programs, as an opportunity to adopt individual risk assessment for HCT/Ps donors.

Thank you for considering our comments. If you have any questions, please contact Shannon Curtis, Assistant Director, Federal Affairs, at shannon.curtis@ama-assn.org or at (202) 789-8510.

Sincerely,



James L. Madara, MD

¹ Puente MA, Patnaik JL, Lynch AM, et al. Association of federal regulations in the United States and Canada with potential corneal donation by men who have sex with men. *JAMA ophthalmology*. 2020;138(11):1143-1149.

² Park C, Gellman C, O'Brien M, et al. Blood Donation and COVID-19: Reconsidering the 3-Month Deferral Policy for Gay, Bisexual, Transgender, and Other Men Who Have Sex With Men. *American Journal of Public Health*. 2021;111(2):247-252.

³ American Red Cross. Infectious disease testing. <https://www.redcrossblood.org/biomedical-services/blood-diagnostic-testing/blood-testing.html>. Published 2021. Accessed September 1, 2021.

⁴ U.S. Food and Drug Administration. Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products. <https://www.fda.gov/media/92490/download>. Published 2020. Accessed September 1, 2021.

⁵ U.S. Food and Drug Administration. Coronavirus (COVID-19) Update: FDA Provides Updated Guidance to Address the Urgent Need for Blood During the Pandemic. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-updated-guidance-address-urgent-need-blood-during-pandemic>. Published 2020. Accessed September 1, 2021.

⁶ Tanhehco YC, Schwartz J. How the COVID-19 pandemic changed cellular therapy at Columbia University Irving Medical Center/NewYork-Presbyterian Hospital. *Transfusion*. 2020;60(9):1905-1909.

⁷ Williams AM, Muir KW. Awareness and attitudes toward corneal donation: challenges and opportunities. *Clinical Ophthalmology (Auckland, NZ)*. 2018;12:1049.

⁸ Gobrial S, Lui PP. Attitudes toward Blood Donation and Deferral Policies Amid the COVID-19 Pandemic. 2021.

⁹ Ferguson C, Enright M. Gay men still unable to donate blood and plasma despite new FDA guidelines. Here's why. *NBC News*. April 15, 2020, 2020.