November 14th, 2024

Food and Drug Administration

Center for Biologics Evaluation and Research (CBER)

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

Dear U.S. Food and Drug Administration; Cellular, Tissue, and Gene Therapies Advisory Committee,

We are writing to express our concern regarding the Food and Drug Administration's 2007 guidance for industry, "Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products"[1]. The policy, updating the 1994 Public Health Service guidelines, "Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs"[2] maintained a five-year deferral for ocular, cardiovascular, musculoskeletal, and other body tissues from men who have sex with men (MSM) donors. We bring attention to the support for revised screening criteria to facilitate the donation of these tissues from MSM individuals.

The current literature and scientific research do not support these policies. Other countries such as the United Kingdom have transitioned to an individual risk assessment for all tissue donors[3]. Blood donation eligibility has transitioned to an individual risk assessment within the United States, and organ donation eligibility for MSM individuals has been reduced to a 30-day time frame. The advances in the past 17 years have promoted the safety and effectiveness of testing for Human Immunodeficiency Virus and Hepatitis B Virus. A five-year deferral is not only unnecessary, but discriminatory.

This policy continues to have a widespread impact not only upon marginalized groups, but the population at large by reducing the supply of safe, healthy donors. Blood donor eligibility for MSM individuals was revised by the FDA in 2015, 2020, and 2023[4]. Organ donor eligibility was reduced from the 5-year deferral in 2013 to a 12-month policy[5], and to a 30-day policy in 2020[6]. There are various ways to move forward with revised screening criteria, a 30-day policy would remain in line with organ donation, an individual risk assessment would remain in line with both global consensus and current blood donor eligibility. However, the FDA should take serious consideration into adapting current screening criteria into separate policies for living and deceased donors, as the capabilities of quarantining and screening reproductive tissues from living donors are hindered by grouping all donors together.

There are various ways to move forward with revised screening criteria. A 30-day policy would remain in line with organ donation; an individual risk assessment would remain in line with both global consensus and current blood donor eligibility.

The American Medical Association[7], GLMA: Health Professionals Advancing LGBTQ+ Equality[8], members of the 117th Congress[9], and countless health care professionals have voiced their concerns with the longevity of this policy. We urge the FDA to act upon this topic, and act quickly, to prevent an additional three decades of MSM individuals from facing differential treatment.

Sincerely,

Pride and Plasma
www.prideandplasma.org

CellRight Technologies
Adam A. James MBA, CPHQ, CTBS
Associate Vice President, Donor Services
www.cellrighttechnologies.com

Eye Bank Association of America
www.restoresight.org

The Fenway Institute
www.thefenwayinstitute.org

Gift of Hope Organ & Tissue Donor Network
Harry Wilkins, MD
President/CEO
www.giftofhope.org

We are Sharing Hope- SC
Michael Palmisano
Director of Tissue Recovery Services
sharinghopesc.org

Whitman-Walker Institute
www.whitman-walker.org

Sources

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3. https://www.gov.wales/changes-cell-and-tissue-donation-be-introduced-wales
4. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-evaluating-donor-eligibility-using-individual-risk-based-questions-reduce-risk-human
5. https://journals.sagepub.com/doi/10.1177/003335491312800403
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