U.S. Donor Conceived Council
a voice for donor conceived people

February 1, 2025

VIA REGULATIONS.GOV

U.S. Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Support of Draft Guidance on Donor Eligibility for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Docket Nos. FDA-2022-D-0465, FDA-2022-D-0466, and FDA-2022-D-0467

Dear FDA/CBER:

The U.S. Donor Conceived Council ("USDCC") submits this comment in support of the FDA's draft guidance on donor eligibility for human cells, tissues, and cellular and tissue-based products (HCT/Ps) (which includes donor gametes). USDCC strives to increase awareness of the needs, interests, and challenges of donor-conceived people and to advance change that promotes and protects their health, welfare, and human dignity. Given our commitment to policies in gamete donation that advance the needs and interests of donor conceived persons and their families, we strongly support the FDA's proposed revisions to modernize donor eligibility standards and eliminate outdated exclusions that have limited the supply of gamete donors.

The FDA's Proposed Guidance is a Critical Step Forward for Gamete Donation

For decades potential gamete donors have faced a five-year deferral period under outdated policies. While blood and organ donation policies evolved to reflect advancements in HIV screening, tissue donation policies remained unchanged—unnecessarily excluding many potential gamete donors and failing to incorporate modern risk-based approaches. The FDA's proposed guidance takes a scientifically sound and equitable approach by:

1. Implementing an individual risk-based approach applicable to all potential gamete donors, which will enhance screening accuracy.

2. Aligning tissue donor eligibility standards with the May 2023 blood donation policy updates and international best practices (e.g., Canada, United Kingdom).

These changes are backed by decades of medical advancements, including nucleic acid testing, which has significantly reduced the risk of undetected HIV infections. By replacing outdated categorical deferrals with targeted behavioral risk assessments, the FDA will ensure fairness and recipient safety.

Expanding the Pool of Eligible Gamete Donors Benefits Donor Conceived People

In addition to improving safety, these proposed updates will expand the pool of eligible gamete donors to help meet high demand for donor sperm in the U.S. The previous exclusions of many potential gamete donors unnecessarily restricted access to otherwise healthy, qualified individuals who meet all medical and ethical standards for donation. By modernizing donor eligibility criteria to focus on scientifically valid risk factors, the FDA's updated policy will ensure that more individuals who meet safety requirements can contribute to gamete donation, benefiting both donors, intended parents, and donor conceived people.

Conclusion

USDCC strongly urges the FDA to (1) finalize and implement the revised donor eligibility criteria without delay, and (2) continue evaluating the effectiveness of individual risk-based screening to ensure continued safety in gamete donation. We commend the FDA for taking this important step toward modern, evidence-based gamete donation policies and appreciate its commitment to scientific integrity and public health. Thank you for considering our comments.

Sincerely,

/s/ Tyler Levy-Sniff

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