T1D Women, Inc.

Public Comment – Docket No. FDA-2026-N-10738

To: U.S. Department of Health and Human Services

T1D Women, Inc. is a 501(c)(3) nonprofit organization dedicated to supporting women and girls living with Type 1 diabetes through community, resources, and events.

We strongly support the proposed reclassification of unmodified deceased donor pancreatic islet cells as organs for transplantation and the transition to an organ transplantation regulatory framework.

Type 1 diabetes is a lifelong autoimmune condition in which the body's immune system destroys the insulin-producing beta cells in the pancreas. People with Type 1 diabetes are insulin-dependent and require lifelong insulin therapy to survive. No changes in diet or lifestyle can prevent, reverse, or eliminate the need for insulin in people with Type 1 diabetes. Managing the condition also requires ongoing blood glucose monitoring and careful consideration of food intake, physical activity, stress, illness, and other factors that affect blood glucose levels. People living with Type 1 diabetes face the risks of severe hypoglycemia and hyperglycemia, as well as serious long-term complications, including diabetic retinopathy, a leading cause of blindness, kidney disease, nerve damage, and cardiovascular disease.

Advances in diabetes technology, including continuous glucose monitors and automated insulin delivery systems, do not cure Type 1 diabetes or restore the body's natural insulin production. These devices also do not eliminate the daily demands of managing Type 1 diabetes or prevent all dangerous hypoglycemia, hyperglycemia, and long-term complications.

Islet transplantation offers the potential to restore insulin production and reduce or eliminate the need for insulin therapy in eligible individuals living with Type 1 diabetes.

We support this proposed regulatory change because unmodified deceased donor pancreatic islet cells are intended for transplantation and should be regulated within an organ transplantation framework.

As an organization focused on women and girls with Type 1 diabetes, we recognize the importance of continued research and treatment advances that may improve the health and quality of life of people living with this condition.

T1D Women, Inc. encourages HHS to move forward with the proposed change and establish an appropriate transplantation framework for unmodified deceased donor pancreatic islet cells.

Thank you for considering our comments.

Renee Rayles
Founder & President
T1D Women, Inc.
501(c)(3) Nonprofit Organization