DIABETES LEADERSHIP COUNCIL

DIABETES PATIENT ADVOCACY COALITION

November 9, 2026

Kyle A. Diamantas, J.D.
Acting Commissioner
U.S. Food and Drug Administration
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Improving Patient Access to Deceased Donor Islet Cells and Cell Products; Request for Information [FDA-2026-N-10738]

Dear Acting Commissioner Diamantas:

On behalf of the Diabetes Leadership Council (DLC) and the Diabetes Patient Advocacy Coalition (DPAC), we appreciate the opportunity to respond to this Request for Information. Groundbreaking treatments, some even curative, are in development for people with type 1 diabetes who are eligible and amenable to islet cell transplantation. As research and innovation continue to advance, we urge HHS to take every appropriate step to ensure these promising treatments are accessible to patients who need them. We thank HHS and the FDA for soliciting feedback from the community and considering reclassification as an important step toward improving access to these treatments.

DLC unites former leaders of national diabetes organizations, dedicated to securing effective, affordable health care for every person with diabetes. DPAC is an alliance of people with diabetes, caregivers, patient advocates, health professionals, and others working together to support public policy initiatives to improve the lives of all 38 million Americans with diabetes. As an organization run by and for people with diabetes, DPAC seeks to ensure quality of and access to care, medications, and devices for people living with diabetes.

The Need for Regulatory Reclassification

Outdated regulatory classifications are limiting access to this safe, effective, and potentially curative therapy for those who are eligible. We ask for consideration of targeted regulatory reclassification that would expand access for eligible patients while maintaining rigorous safety oversight.

NIH-funded clinical trials, and decades of research, have shown deceased donor islet cell transplantation to be a safe and effective treatment for people with type 1 diabetes (T1D) who qualify for this procedure. Donated islet cells come from an organ donor and may be transplanted into an eligible person with T1D to help restore the body's ability to produce insulin. However, patient access remains extremely limited, in part because of the currently required biologics regulatory pathway which, in this case, unnecessarily imposes significant costs and administrative burdens.

Classifying these donated cells as biological products creates an unnecessary regulatory barrier that makes this transplant option harder for eligible patients to access. These cells are derived from deceased organ donors, are not further modified, and function as micro-organs. They are biologically analogous to transplanted whole organs and should be regulated accordingly, rather than as manufactured biologic products. Applying pharmaceutical manufacturing standards to unmodified donor islet cells also imposes expectations of product uniformity that do not account for the inherent biological variability of donated human tissue. We urge the Department of Health and Human Services to reclassify unmodified deceased donor islet cells as organs for purposes of transplantation, rather than their current classification as biological products requiring approval of a Biologics License Application (BLA). All manufactured islet cells, as well as deceased donor islet cells that involve further modification, should remain subject to FDA's BLA oversight. With appropriate quality and safety controls, reclassification could improve access for eligible patients to access this treatment.

Recommended Framework for Quality and Safety

We support the framework outlined by T1D stakeholders, which draws on approaches successfully adopted in other countries and includes the following measures:

- **Accredited Centers of Excellence**: Islet isolation and/or transplantation will be permitted only in UNOS/OPTN accredited centers that ensure safety by meeting well defined standards of qualification, infrastructure and appropriately trained and experienced personnel.
- **Stringent Quality Controls**: Implementation of rigorous measures for deceased donor islet cell purification and potency.
- **Distribution Framework:** A formalized plan for deceased donor islet cell distribution to the point of care.
- **Scalability**: A strategic roadmap for expanding transplantation capabilities to additional centers.

Thank you for your consideration of these comments. DLC and DPAC welcome the opportunity to work with HHS and FDA to advance these recommendations and others to improve access to care, support continued innovation, and strengthen health outcomes for people with and at risk for diabetes.

Sincerely,



Erin M. Callahan
Chief Operating Officer
Diabetes Leadership Council, Diabetes Patient Advocacy Coalition