

Chicago, March 11th, 2026

The Honorable Secretary Robert F. Kennedy Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Kennedy:

On behalf of the Islets for US Collaborative (www.isletsforus.org), we are writing to express our deep and urgent concern that patients with type 1 diabetes are being denied access to potentially life-saving therapy because of the FDA's existing regulatory framework—despite the ever-growing body of scientific evidence supporting islets' safety and efficacy. We support the proposal submitted by Breakthrough T1D that urges reclassification of deceased donor islets for transplantation.

In keeping with the National Organ Transplant Act (NOTA), we respectfully call on you to reclassify deceased donor islets by adding them to the list of human organs regulated under the OPTN Final Rule. We believe that regulatory oversight of these islets for transplantation should reside with the Health Resources and Services Administration (HRSA), as it does for all other organs, rather than with the FDA under its classification as a biological drug. This simple clarification will ensure that eligible American adults with type 1 diabetes are not deprived of islet transplantation, which is already standard of care therapy in numerous countries including Canada, Australia, Japan, and many in the European Union.

We represent a coalition of over fifty experts in islet transplantation, drawn from leading academic institutions and professional organizations in the U.S. As the Islets for US Collaborative, we write to express our deep concern regarding the safety and access to this therapy for patients suffering from life-threatening severe hypoglycemic episodes due to type 1 diabetes with hypoglycemia unawareness.

Deceased donor islet transplantation is a safe, effective, and well-accepted therapy, as demonstrated in U.S. clinical trials and through routine clinical practice internationally over the past two decades. However, this lifesaving therapy remains largely unavailable in the United States due to the current regulatory approach in which these islets are classified as biologic drugs and require a Biologics License Application (BLA) approval for clinical use. In contrast, other nations that classify islet transplantation as an organ or tissue-based therapy perform routinely those transplants.

Proposed Remedy

1. **Recognize deceased donor islets as small human organs** with distinct anatomical and physiological properties and regulate them under the National Organ Transplantation Act (NOTA).

2. **Transfer regulatory oversight of deceased donor islets to HRSA/OPTN**, aligning them with other organ transplants to ensure safety and efficacy.
3. **Implement this regulatory shift by including islets on the list of organs regulated under HRSA/OPTN** and developing protocols to ensure safety and quality.

This proposal has been endorsed by the following organizations and many experts listed at the end of this letter:

- The Council of the American Society of Transplant Surgeons
- The Board of Directors of the American Society of Transplantation
- Leaders of UNOS, including the President and members of the Pancreas and Islet Transplantation Committee

In summary, **deceased donor islets are not drugs; they are naturally occurring, highly specialized micro-organs that cannot be standardized, stored, or evaluated like pharmaceutical products.** Ensuring their quality requires expert oversight by transplant physicians, who manage donor selection, organ retrieval, preservation, transplantation, and patient care. The existing organ transplant framework—developed by UNOS and OPTN—provides the necessary oversight to ensure patient safety and treatment success. Islet transplantation should be incorporated within this system.

We now urgently request your intervention to reclassify deceased donor islets for transplantation under HRSA/OPTN oversight. This regulatory change would enable safe and effective islet transplantation in the U.S., aligning our policies with international standards and ensuring that American patients receive the care they need.

We appreciate your attention to this urgent matter and look forward to your leadership in addressing this critical issue.

Sincerely,

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