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July 20, 2026

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services (HHS)
200 Independence Ave. SW
Washington, D.C. 20201

Dear Secretary Kennedy,

Re: Please Act to Reclassify Deceased Donor Islet Cells as Organs to Improve Diabetes Treatment Availability

I write to urge HHS to take administrative action to improve access to deceased donor islet cell transplantation for individuals living with type 1 diabetes (T1D). Scientific progress has brought the 1.6 million Americans living with T1D closer to transformative and potentially curative therapies than ever before, but outdated regulatory classifications continue to limit patient access to this safe and effective treatment option. This must be fixed.

Recognizing the need to expand access to deceased donor islet cell transplantation for individuals living with T1D, I introduced the ISLET Act. This legislation would reclassify unmodified deceased donor islet cells as organs for purposes of transplantation—rather than continuing to regulate them solely as biological products requiring approval through a Biologics License Application (BLA)—so more centers across the United States can offer this therapy option. However, it is also possible for this reclassification to be made under existing HHS authority. Such administrative action, consistent with the policy goals of the ISLET Act, could simplify the transplant process, help align oversight with the biological nature of these cells, and ensure patients are not denied access to a potentially transformative therapy.

Deceased donor islet cell transplantation has been studied for decades, and clinical research shows meaningful benefits for individuals with T1D who experience severe hypoglycemia and hypoglycemia unawareness. Yet, despite FDA approval of a deceased donor islet cell product in 2023, patient access remains extremely limited. This suggests that the current US regulatory pathway is not functioning in a way that supports broad, practical availability of this therapy for the patients most likely to benefit from it. Reclassifying unmodified deceased donor islet cells under the Organ Procurement and Transplantation Network (OPTN), while maintaining FDA oversight for manufactured cell therapies and any deceased donor islet products that undergo further modification, is a sensible and targeted solution.

Importantly, this approach would not require compromising patient safety. Rather, it could be implemented through a carefully designed framework that includes qualified transplant centers, appropriate quality controls, clear distribution protocols, and a pathway for responsible expansion to additional accredited sites. Such an approach would also better align the United States with the regulatory treatment of deceased donor islet cell transplantation in other developed nations and help strengthen American leadership in diabetes innovation and cure-focused research.

I urge HHS to act now, within its existing authority, so eligible patients are not forced to wait for access to a therapy that could significantly improve their lives, and I welcome the opportunity to work with you and your team on a swift path forward.

Sincerely,

Michael S. Lee
United States Senator

363 RUSSELL SENATE OFFICE BUILDING PHONE: (202) 224–5444