American Diabetes Association®

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June 1, 2026

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

Dear Secretary Kennedy:

The American Diabetes Association® (ADA) respectfully requests a change in the way that the U.S. Department of Health and Human Services (HHS) currently classifies deceased donor islet cells that can be used for the treatment of certain individuals with type 1 diabetes. The current regulatory framework has restricted access to this novel treatment, which research indicates has a significant potential to help cure this disease for certain individuals. By modifying an outdated regulatory framework, HHS could help to eliminate an unnecessary administrative burden and improve access to this innovative treatment. Background information on this important issue along with our recommended regulatory change can be found below.

About ADA

The ADA is a nationwide, nonprofit, voluntary health organization founded in 1940 and made up of individuals with diabetes, healthcare professionals who treat people with diabetes, research scientists, and other concerned individuals. The ADA's mission is to prevent and cure diabetes and to improve the lives of all people affected by diabetes. The ADA, the largest non-governmental organization that deals with the treatment and impact of diabetes, represents the 136 million individuals living with diabetes and prediabetes. The ADA also reviews and authors the most authoritative and widely followed clinical practice recommendations, guidelines, and standards for the treatment of diabetes[1] and publishes the most influential professional journals concerning diabetes research and treatment.

Background on Deceased donor islet cell transplantation

Deceased donor islet cell transplantation has been a proven and effective treatment for certain individuals with type 1 diabetes, such as those who experience severe hypoglycemia and hypoglycemia unawareness.[2] A clinical trial sponsored by the National

[1] American Diabetes Association: Standards of Care in Diabetes 2026, Diabetes Care 49: Supp. 1 (January 2026) https://diabetesjournals.org/care/issue/49/Supplement_1

[2] National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Pancreatic islet transplantation. Bethesda (MD): National Institutes of Health; [updated n.d.; cited 2026 May 28]. Available from: https://www.niddk.nih.gov/health-information/diabetes/overview/insulin-medicines-treatments/pancreatic-islet-transplantation.

Institutes of Health (NIH) found that 1 year after islet transplantation, nearly 9 out of 10 transplant recipients had an A1C level below 7 percent and did not have episodes of severe hypoglycemia. The individualized A1C goal for many people with diabetes is below 7 percent. About half of the recipients did not need to take any insulin at 1 year. Two years after islet transplantation, about 7 out of 10 recipients had an A1C level of less than 7 percent and did not have episodes of severe hypoglycemia, and about 4 out of 10 did not need insulin.[3] However, despite the effectiveness of islet cell transplantation, only one product has received approval from the Food and Drug Administration (FDA). Over thirty years ago, in 1993, the FDA decided to regulate islet cells as a biologic under the regulatory authority of the federal Food, Drug and Cosmetic Act. The FDA has therefore required that islet cells receive an approved Biologics License Application (BLA) before they can be used clinically. Lantidra (donislecel-jujn) is the only pancreatic islet cell product that has received BLA approval-- and it received such approval in 2023.

Issues with Current Approach

There are numerous challenges with the current regulatory framework, which has led to only one product being approved in over thirty years. For health systems, filing a BLA or qualifying an additional facility under an approved BLA are often prohibitively burdensome and difficult. In contrast, within the last thirty years, other countries have incorporated a different approach. Deceased donor islet cells are more biologically analogous to whole organs rather than manufactured biologic products. Countries such as France, Canada, the United Kingdom, Australia, China, and Japan are performing hundreds of deceased donor islet cell transplants each year under an organ-based regulatory approach.

Recommendation

To help ensure the availability of safe deceased donor islet cells and expand availability of such products to eligible adults with type 1 diabetes in the United States, we are requesting that HHS reexamine the decision it initially made in 1993 and make the following modifications:

- Unmodified deceased donor islet cells would be regulated just like whole organs: by the Health Resources Administration (HRSA) through the Organ Procurement and Transplantation Network (OPTN).

- The FDA would continue to regulate and provide oversight of manufactured cell therapies and deceased donor islet cell therapies that undergo any further modification.

Since unmodified deceased donor islet cells would be regulated as whole organs, they would follow the same requirements around donation and transplantation that currently

[3] Hering BJ, Clarke WR, Bridges ND, et al. Phase 3 trial of transplantation of human islets in type 1 diabetes complicated by severe hypoglycemia. *Diabetes Care*. 2016;39(7):1230–1240.

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apply to all organ transplants. Such an approach would allow for greater availability of deceased donor islet cells as a safe and effective therapy for eligible adults living with type 1 diabetes. Tens of thousands of organ transplants are conducted in the United States each year, including 915 pancreas transplants in 2023 (islet cells are derived from a human pancreas).[4] Further, this change balances the need to maintain appropriate oversight from the FDA while also promoting innovation and development of treatments that can help individuals with type 1 diabetes live longer and healthier lives. It would also help strengthen American competitiveness on the global path to curing type 1 diabetes.

Conclusion

The ADA appreciates the opportunity to share this recommendation. Should you have any questions or seek additional information, please reach out to Abigail Smith, Sr. Director of Policy and Strategy at asmith@diabetes.org.

Sincerely,



Lisa Murdock
Chief Advocacy Officer

CC: Thomas J. Engels, HRSA Administrator
Kyle Diamantas, Acting FDA Commissioner
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Matt Buckham, HHS Chief of Staff
Margaret Bush, HRSA Deputy Administrator
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Ken Callahan, HHS Senior Counselor for Policy
Grace Graham, FDA Deputy Commissioner for Policy

[4] Kandaswamy R, Stock PG, Miller JM, Handarova D, Israni AK, Snyder JJ. OPTN/SRTR 2023 Annual Data Report: Pancreas. Am J Transplant. 2025 Feb;25(2S1):S138-S192. doi: 10.1016/j.ajt.2025.01.021. PMID: 39947803; PMCID: PMC12334190.