United States Senate

WASHINGTON, DC 20510

June 16, 2026

Kyle A. Diamantas J.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Acting Commissioner Diamantas:

As Co-chairs of the Senate Diabetes Caucus, we share your commitment to addressing chronic diseases, such as diabetes. With the goal of better addressing the health needs of people with diabetes, we write to request that the Food and Drug Administration (FDA) take administrative action to improve access to deceased donor islet cell transplantation for certain individuals living with Type 1 diabetes (T1D). Recent scientific and clinical efforts have brought the medical field closer to potentially curative therapies for certain eligible patients. Some existing regulatory classifications, however, continue to limit patient access to islet cell transplantation, which holds promise as a treatment option that is both safe and effective for some individuals.

We ask the FDA to reconsider the regulatory pathway for transplantation of deceased donor islet cells and regulate them as organs, rather than biologics. With appropriate quality and safety controls in place, a targeted regulatory modernization could better align oversight with the biological nature of these cells, expand access for eligible patients, and preserve rigorous standards for safety and accountability. This proposed policy change is supported by leading transplant surgeons and organizations, as well as Breakthrough T1D (formerly JDRF).

We recognize that deceased donor islet cell transplantation is not indicated for the majority of individuals with T1D, but transplantation can be life-changing for individuals with particularly severe and uncontrolled T1D. As you know, deceased donor islet cell transplantation has been studied for decades, and clinical research has demonstrated meaningful benefits for individuals with T1D who experience severe hypoglycemia and hypoglycemia unawareness.

Patient access to deceased donor islet cell transplantation has remained extremely limited, despite FDA approval of a deceased donor islet cell product in 2023. The lack of access suggests the current regulatory pathway is not functioning in a way that supports broad, practical availability of this therapy for the patients most likely to benefit. While it is critical to oversee manufactured cell therapies and any deceased donor islet products that undergo further

modification through the biological products pathway, targeted and sensible reforms to current regulations and practices could improve short-term access to deceased donor islet cells for the subset of individuals with T1D for whom transplantation is indicated.

Approximately 1.6 million Americans are living with T1D, and many could benefit from increased access to deceased donor islet cell transplantation. We appreciate your attention to this issue and your leadership in advancing policies that improve outcomes for people living with chronic diseases. We would welcome your partnership on developing a pathway as swiftly as possible that provides effective oversight, expands access for eligible patients, and supports continued innovation in the search for cures and better treatments for T1D.

Thank you for your consideration.

Sincerely,

Jeanne Shaheen
United States Senator

Susan M. Collins
United States Senator