



October 19, 2026

Kyle Diamantas, J.D.
Acting Commissioner
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD. 20852

Submitted Electronically

RE: Docket No. FDA-2026-N-10738. Improving Patient Access to Deceased Donor Islet Cell Products; Request for Information (“the RFI”)

Dear Acting Commissioner Diamantas:

The American Society of Transplant Surgeons (ASTS) is pleased to submit these comments in response to the RFI. ASTS is a surgical specialty society representing approximately 2,200 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through patient care, research, education, and advocacy.

The RFI seeks information on whether sufficient publicly available information exists to establish standards for how to transplant deceased donor islet cells and/or develop deceased donor islet cell products, as well as whether other publicly available data exists to support their safe and effective use. Additionally, the RFI seeks input on the possibility of defining unmodified deceased donor islet cells as organs, which would allow the procurement, allocation, and transplantation of these cells to be performed in accordance with applicable, existing Organ Procurement and Transplantation Network (OPTN) policy and regulated by the Health Resources and Services Administration (HRSA). Doing so would require OPTN to implement standards for safety, effectiveness, quality and consistency of islet cell processing and isolation, as well as surveillance and policies regarding the training and experience of transplant surgeons and transplant physicians in designated pancreatic islet cell transplant programs. It is noteworthy that those existing standards and surveillance processes were developed by the OPTN prior to the Food and Drug Administration’s (FDA) assertion of jurisdiction over islet cells and were used successfully for many years in the oversight of deceased donor islet cell transplant programs nationwide. The RFI also mirrors concerns addressed in the [*Increase Support for Life-saving Endocrine Transplantation \(ISLET\) Act*](#) (H.R.8018/S.3105).

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In 2020, [ASTS adopted a position statement](#) addressing the questions posed in the RFI. In that statement, ASTS requested that the FDA:

- Confirm islet allografts are “minimally manipulated” HCT/Ps as that term is defined in FDA regulations, because they are subject to only short-term incubation prior to allograft infusion that does not alter their relevant biological characteristics.
- Allow allogeneic islets from unrelated donors to be eligible for regulation as HCT/Ps exclusively under Section 361/Part 1271, provided that donors and recipients are immunologically compatible as determined by current clinical standards for immunological matching in organ and tissue transplantation.

Additionally in this position statement, ASTS recommended that HRSA return OPTN authority to include islet cell transplantation.

By defining allogeneic islets as organs, HRSA would re-establish OPTN authority (under HRSA oversight) to implement necessary safety, effectiveness, and quality standards as well as appropriate surveillance and compliance mechanisms. We further recommend that the FDA place oversight of deceased donor pancreas allo-islets for transplantation back into section 361 (minimal manipulation tissue/organ) and reverse its 2001 and 2004 decisions to move deceased donor pancreas allo-islet cells from section 361 to section 351 (biologics/drugs). In moving deceased donor pancreatic islet cells to Section 351, the FDA essentially put a moratorium on islet cell transplantation in the United States and blocked access to this life saving therapy for patients nationwide.

To the extent that implementation of the necessary standards and surveillance processes are not included in the OPTN budget, we recommend that funds appropriated by Congress to the OPTN (rather than the patient registration fees already dedicated to sustaining current OPTN activities and implementing Secretarial mandates) be utilized to support these activities.

We hope that these comments are helpful in considering how to fulfill the promise of islet cell transplantation for patients with otherwise unmanageable type 1 diabetes in the United States.

Sincerely,



Henry B. Randall, MD, MBA