Increase Support for Life-saving Endocrine Transplantation (ISLET) Act

For individuals with Type 1 Diabetes, the absence of functioning islets prevents normal insulin production, which can lead to life-threatening complications. Islet transplantation, a process in which islets from deceased donors are transplanted into patients, enables recipients to produce insulin naturally, reducing reliance on insulin injections and Continuous Glucose Monitoring (CGM). Clinical trials have shown that some patients can remain insulin-independent for years following a successful transplant.[1]

The Food and Drug Administration (FDA) currently classifies islets as drugs instead of organs, despite their role as micro-organs in the pancreas.[2] This misclassification has hindered life-saving innovation by imposing costly and overly stringent regulations on islet transplantation.[3]

In 1993, the FDA chose to regulate islets as drugs. This decision has stiffled innovation by subjecting islets to regulations that do not apply for organ transplants. For example, drug manufacturing regulations require that each "dose" be identical. But islets from deceased donors are by nature always different. As a result of this regulatory difference, islet transplantation is only considered investigational and limited to a single center in the U.S., while in other advanced countries,[4] islets are recognized as organs and their transplantation has become the standard of care.

Congress must act to reclassify islets under a less burdensome regulatory framework. This reform would expand treatment options, improve outcomes, and enhance the quality of life for individuals with Type 1 Diabetes.

This Bill:

- Updates the current definition of organ in the Public Health Service Act (PHSA) to include "human cadaveric islets." This would authorize HRSA and OPTN to regulate islets as organs.
- Prohibits HHS from regulating pancreatic islets as drugs under the Food Drug & Cosmetic Act (FDCA).
- Prohibits HHS from regulating pancreatic islets as biological products or Human Cells, Tissues, and Cellular/Tissue-Based Products (HCT/Ps) under the Public Health Service Act (PHSA).
- Requires the Secretary of HHS to update all regulations within a year of enactment to reflect the previously mentioned changes.
- Requires the Secretary of HHS to submit a report to Congress on its progress within 6 months of the date of enactment.

[1] Emily Ayshford, "Patients with diabetes insulin-free for years after islet transplantation," November 28, 2022, UChicago Medicine.
[2] American Journal of Transplantation, "The demise of islet allotransplantation in the United States: A call for an urgent regulatory update," April 2021, https://www.amjtransplant.org/article/S1600-6135(22)08486-6/fulltext
[3] Islet transplantation refers to allogeneic transplantation (from donors), not autologous transplantation (from one's own body post-pancreatectomy).
[4] Canada, United Kingdom, France, Italy, Australia, and Japan