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

You wouldn't regulate haircuts as surgical procedures. Unfortunately, the FDA is currently doing something similar by regulating islets as drugs rather than organs.[1] This regulatory framework has squashed potentially life-saving innovation by subjecting islet transplantation[2] to costly and unnecessary regulations.

Islets are micro-organs found in the pancreas that secrete[3] hormones, including insulin, which is critical for our survival. Individuals with Type 1 Diabetes aren't able to produce insulin normally because they lack functioning islets. Islet transplantation is the process by which islets are taken from deceased donors and given to patients with Type 1 Diabetes.[4] The transplanted islets can then produce insulin without the additional cost of injecting insulin and Continuous Glucose Monitoring (CGM). Clinical trials have found that some individuals who receive an islet transplant can go for years without needing to inject insulin.[5]

In 1993, the FDA chose to regulate islets as drugs. This decision, unfortunately, has stymied innovation because drugs are subject to regulations that do not make sense 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 mismatch, islet transplantation is only considered investigational and limited to a single center in the U.S., while in other advanced countries,[6] islets are recognized as organs and their transplantation has become the standard of care.

It is time for Congress to act and move islets to a less onerous regulatory framework. Doing so would expand treatment options for people with diabetes, and likely improve outcomes and quality of life for patients with Type 1 Diabetes.

This Bill:

- Updates the current definition of organ in the Public Health Service Act 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) or as biological products or HCT/Ps under the Public Health Service Act (PHSA) and its regulations.
- 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] 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
[2] In this one-pager, islet transplantation refers to allogeneic transplantation (from donors), not autologous transplantation (from one's own body post- pancreatectomy).
[3] "islet of Langerhans cell," National Cancer Institute, Accessed April 26, 2023.
[4] Currently, islet transplantation is reserved for patients with brittle diabetes. As of 2018, there were approximately 70,000 such patients in the U.S.
[5] Emily Ayshford, "Patients with diabetes insulin-free for years after islet transplantation," November 28, 2022, UChicago Medicine.
[6] Canada, the UK, France, Italy, Australia, and Japan

For more information concerning this bill or to be added as a cosponsor, please contact Chris Medrano (Chris_Medrano@Lee.Senate.Gov) in Senator Lee's office.