

February 1, 2023

United States Senate
Washington, DC 20512

United States House of Representatives
Washington, DC 20515

Dear Members of Congress:

On behalf of the American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST), we are pleased to have the opportunity to outline the importance of islet transplantation and request your assistance in having islets regulated as organs in the United States. ASTS is a medical specialty society representing approximately 2,000 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. AST is a medical specialty society representing over 4,200 members engaged in advancing the field of organ transplantation.

Islet transplantation is a recognized and approved medical procedure in Canada, the UK, France, Italy, Australia, Japan, and a host of other countries.¹ Islet recipients generally enjoy a much better quality of life with improved glucose levels, requiring little or no insulin to manage diabetes. Islet infusion is a less invasive procedure than a traditional organ transplant. For this procedure, the pancreas is recovered from a deceased donor. Rather than transplanting the whole organ, islets are extracted from the pancreas, purified, and counted in a lab to ensure that there are enough present before infusion into the recipient.

Since 2000, the FDA has regulated allogenic islets for transplantation/infusion. Islets are recognized as drugs and, as a result, must follow a new drug development process.² The outcome of this is that islets are not considered standard of care. They are not broadly available to Americans with Type 1 Diabetes and are not reimbursed due to this unapproved drug status. Academic transplant centers where islet

¹ Islet Transplantation at a Crossroads - Need for Urgent Regulatory Update in the United States: Perspective Presented During the Scientific Sessions 2021 at the American Diabetes Association Congress" *Frontiers in Endocrinology*, 2022. Jan 6;12:789526. doi: 10.3389/fendo.2021.789526

² On behalf of Islets for US" Collaborative and Cellular Transplantation Committee of the American Society of Transplant Surgeons. Pancreatic Islets Quality and Potency Cannot be Verified as Required for Drugs: Reflection on the FDA Review of a Biological License Application for Human Islets. *Transplantation* 2021. Jul 1. doi: 10.1097/TP.0000000000003880. PMID: 34231527

transplants are performed are not structured to act as drug manufacturers and submit the required Biologics License Applications (BLA) necessary to meet the FDA's requirements.

We strongly oppose FDA regulation for this procedure as a drug.

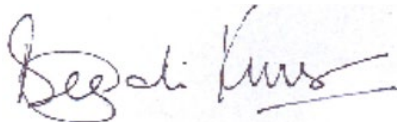
- Islets exist in the human body, with their own morphology and structure.
- Islets cannot be frozen and can only be preserved for short periods of time- like solid organs.
- Biologics or drugs are artificially created in a lab and do not exist in the human body.

Drug manufacturing regulations are not able to assure islet quality and safety and are not practical for application to islets. This FDA requirement is leading to the rapid demise of islet transplantation, removing a potential treatment for Americans that is available in many other countries.

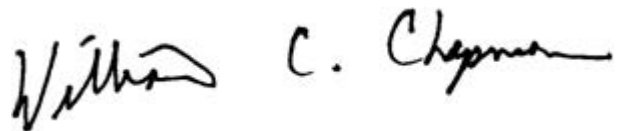
We firmly believe that the Organ Procurement and Transplantation Network (OPTN) should be responsible for islet transplant program oversight. This is the case for solid organ transplantation, including pancreata. Islets are a subset of the pancreas, a solid organ as outlined in the National Organ Transplantation Act (NOTA). While FDA regulation was appropriate in 2000, the scientific knowledge has grown regarding islet transplantation significantly since that time. Such a reclassification will remove the false reassurance of islet quality implied with the current BLA requirement and stimulate positive competition among islet transplant programs- improving access to this procedure for diabetic patients and promoting cost effectiveness for the procedure itself.

We seek your assistance as Congressional champions to help us advance this request for change in regulatory oversight. This will benefit Americans with diabetes in having the option for islet transplantation that is available in many other parts of the world. We would be glad to provide additional insight or respond to any questions you might have regarding this request.

Respectfully,



Deepali Kumar, MD, MSc, FRCPC, FAST
President
American Society of Transplantation



William Chapman, MD
President
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