Transplant International

POINT OF VIEW

US food and drug administration (FDA) panel endorses islet cell treatment for type 1 diabetes: A pyrrhic victory?

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SUMMARY

Allogeneic islet transplantation is a standard of care treatment for patients with labile type 1 diabetes in many countries around the world, including Japan, the United Kingdom, Australia, much of continental Europe, and parts of Canada. The United States is now endorsing islet cell treatment for type 1 diabetes, but the FDA has chosen to consider islets as a biologic that requires licensure, making the universal implementation of the procedure in the clinic very challenging and opening the manufacture of islet grafts to private companies. The commercialization of human tissues raises significant legal and ethical issues and ironically leads to a situation where treatments developed as a result of the scientific and economic efforts of academia over several decades become exploited exclusively by for-profit entities.

Transplant International 2021; 34: 1182–1186