

S 2205

ISLET Act

Congress: 118 (2023–2025, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Jun 22, 2023

Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Jun 22, 2023)

Official Text: <https://www.congress.gov/bill/118th-congress/senate-bill/2205>

Sponsor

Name: Sen. Lee, Mike [R-UT]

Party: Republican • State: UT • Chamber: Senate

Cosponsors (3 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Blackburn, Marsha [R-TN]	R · TN		Jun 22, 2023
Sen. Budd, Ted [R-NC]	R · NC		Jun 22, 2023
Sen. Paul, Rand [R-KY]	R · KY		Jul 11, 2023

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Jun 22, 2023

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
118 HR 4304	Identical bill	Jun 23, 2023: Referred to the Subcommittee on Health.

Increase Support for Life-saving Endocrine Transplantation Act or the ISLET Act

This bill removes pancreatic islets that are donated from human cadavers from regulation as a drug or biological product by the Food and Drug Administration (FDA). (Islets are groups of cells, including those that make insulin, in the pancreas, and islet transplantation is an experimental treatment for certain conditions, such as type 1 diabetes.)

Current FDA guidance treats pancreatic islets as a biological product, which makes them subject to the biological license application process and related standards for manufacturing practices, safety, identity, purity, and potency.

The bill, instead, treats human cadaveric islets as organs, which makes them subject to the regulatory framework that governs the allocation, safety, and efficacy of organ donation and transplantation. That framework, developed by the Health Resources and Services Administration, is carried out by contract through the Organ Procurement and Transplantation Network. (The network is a public-private partnership that links the professionals involved in the U.S. donation and transplantation system.)

Specifically, the bill defines human cadaveric islets as organs and excludes them from definitions related to the regulation of drugs and biological products.

Actions Timeline

- **Jun 22, 2023:** Introduced in Senate
- **Jun 22, 2023:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.