

HR 4304

ISLET Act

Congress: 118 (2023–2025, Ended)

Chamber: House

Policy Area: Health

Introduced: Jun 22, 2023

Current Status: Referred to the Subcommittee on Health.

Latest Action: Referred to the Subcommittee on Health. (Jun 23, 2023)

Official Text: <https://www.congress.gov/bill/118th-congress/house-bill/4304>

Sponsor

Name: Rep. Rosendale Sr., Matthew M. [R-MT-2]

Party: Republican • **State:** MT • **Chamber:** House

Cosponsors (4 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Bacon, Don [R-NE-2]	R · NE		Jun 22, 2023
Rep. Greene, Marjorie Taylor [R-GA-14]	R · GA		Jun 22, 2023
Rep. Bice, Stephanie I. [R-OK-5]	R · OK		Jun 30, 2023
Rep. Smith, Christopher H. [R-NJ-4]	R · NJ		Sep 5, 2023

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Jun 23, 2023

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
118 S 2205	Identical bill	Jun 22, 2023: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

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 23, 2023:** Referred to the Subcommittee on Health.
- **Jun 22, 2023:** Introduced in House
- **Jun 22, 2023:** Referred to the House Committee on Energy and Commerce.

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