

S 2609

Safe Tissue Act

Congress: 109 (2005–2007, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Apr 7, 2006

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. (Apr 7, 2006)

Official Text: <https://www.congress.gov/bill/109th-congress/senate-bill/2609>

Sponsor

Name: Sen. Schumer, Charles E. [D-NY]

Party: Democratic • **State:** NY • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Leahy, Patrick J. [D-VT]	D · VT		Apr 7, 2006

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Apr 7, 2006

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
109 HR 5209	Identical bill	Apr 26, 2006: Referred to the House Committee on Energy and Commerce.

Safe Tissue Act - Requires the Food and Drug Administration (FDA) to inspect, at least once every two years, each establishment that engages in the manufacture of human cells, tissues, and cellular and tissue-based products. Allows the Secretary of Health and Human Services to establish a user fee to fund such inspections.

Requires the FDA to conduct periodic audits of all documentation submitted by each such establishment to determine compliance with all applicable requirements, including requirements related to ensuring: (1) that human cells, tissues, or cellular or tissue-based products are obtained legally; (2) that donor eligibility and donor medical history interviews are based on accurate information that was not provided or obtained in a fraudulent manner; and (3) current good tissue practice.

Requires the Secretary to publish a model form containing minimum requirements for establishments to use in obtaining consent from a potential donor of human cells, tissues, or cellular or tissue-based products. Sets forth penalties for failing to comply with model form requirements or for knowingly using fraudulent information.

Directs the Secretary to: (1) accredit establishments and the personnel of such establishments who participate in the recovery, processing, storage, labeling, packaging, or distribution of human cells, tissues, or cellular or tissue-based products; and (2) define "reasonable payments" that are associated with donation of human tissue and tissue-based products for purposes of the National Organ Transplant Act.

Actions Timeline

- **Apr 7, 2006:** Introduced in Senate
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