S 736

Laboratory Test Improvement Act

Congress: 110 (2007–2009, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Mar 1, 2007
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. (Mar 1, 2007)
Official Text: https://www.congress.gov/bill/110th-congress/senate-bill/736

Sponsor

Name: Sen. Kennedy, Edward M. [D-MA]
Party: Democratic • **State:** MA • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Smith, Gordon H. [R-OR]	R · OR		Mar 1, 2007

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Mar 1, 2007

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Mar 1, 2007)

Laboratory Test Improvement Act - Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to deem a laboratory-developed test that is a direct-to-consumer test to be a prescription test if it satisfies the requirements of this Act.

Deems any laboratory-developed test to be a medical device.

Sets forth labeling and registration requirements for laboratory-developed tests.

Requires the manufacturer of a laboratory-developed test that has not been cleared or approved for its intended use to submit the analytical and clinical validity of the test for its intended use to the Secretary of Health and Human Services. Requires the Secretary to include such information in a public database.

Requires the Secretary to provide guidance to: (1) facilitate the use of reviews of the peer-reviewed biomedical literature and other information and data about the clinical validity of laboratory-developed tests and in vitro diagnostic products when clearing or approving such tests and products under the FFDCA; and (2) clarify when modifications to a laboratory-developed test require updating of the submitted information.

Sets forth provisions regarding classification of laboratory-developed tests.

Requires the Secretary to issue a proposed rule to establish a specialty area for the certification of laboratories for laboratory-developed tests to acquire genetic information, which shall include standards for proficiency testing of such tests.

Actions Timeline

- **Mar 1, 2007:** Introduced in Senate
- **Mar 1, 2007:** Sponsor introductory remarks on measure. (CR S2502-2503)
- **Mar 1, 2007:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.