S 484

Enhancing Drug Safety and Innovation Act of 2007

Congress: 110 (2007–2009, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Feb 1, 2007
Current Status: Committee on Health, Education, Labor, and Pensions. Hearings held.
Latest Action: Committee on Health, Education, Labor, and Pensions. Hearings held. (Mar 14, 2007)
Official Text: https://www.congress.gov/bill/110th-congress/senate-bill/484

Sponsor

Name: Sen. Enzi, Michael B. [R-WY]
Party: Republican • **State:** WY • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Kennedy, Edward M. [D-MA]	D · MA		Feb 1, 2007

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Hearings By (full committee)	Mar 14, 2007

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
110 HR 1561	Related bill	**Mar 20, 2007:** Referred to the Subcommittee on Health.

Summary (as of Feb 1, 2007)

Enhancing Drug Safety and Innovation Act of 2007 - Amends the Federal Food, Drug, and Cosmetic Act to require an application for approval for a new drug or biological product to include a proposed risk evaluation and mitigation strategy, which must include: (1) labeling for the drug for use by health care providers; (2) submission of reports for the drug; and (3) a statement as to whether the analysis and surveillance are sufficient to assess the serious risks of the drug.

Establishes a Drug Safety Oversight Board.

Requires the Secretary of Health and Human Services to establish the Reagan-Udall Institute for Applied Biomedical Research as a nonprofit corporation to advance the Critical Path Initiative to modernize medical product development, accelerate innovation, and enhance product safety. Requires the Institute to have a Board of Directors. Allows the Board to coordinate and collaborate with other entities to conduct research, education, and outreach and to modernize the sciences of developing, manufacturing, and evaluating the safety and effectiveness of diagnostics, devices, biologics, and drugs.

Amends the Public Health Service Act to require the Secretary, acting through the Director of the National Institutes of Health (NIH), to establish and administer a clinical trial registry database and a clinical trial results database. Requires a responsible part for a clinical trial to submit clinical trial information to the Director for inclusion in the databases.

Requires each individual under consideration for a term on an advisory committee providing advice or recommendations to the Secretary regarding FDA activities to disclose industry financial interests.

Actions Timeline

- **Mar 14, 2007:** Committee on Health, Education, Labor, and Pensions. Hearings held.
- **Feb 1, 2007:** Introduced in Senate
- **Feb 1, 2007:** Sponsor introductory remarks on measure. (CR S1530-1532)
- **Feb 1, 2007:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.