S 930

Food and Drug Administration Safety Act of 2005

Congress: 109 (2005–2007, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Apr 27, 2005
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 27, 2005)
Official Text: https://www.congress.gov/bill/109th-congress/senate-bill/930

Sponsor

Name: Sen. Grassley, Chuck [R-IA]
Party: Republican • **State:** IA • **Chamber:** Senate

Cosponsors (7 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Dodd, Christopher J. [D-CT]	D · CT		Apr 27, 2005
Sen. Cochran, Thad [R-MS]	R · MS		Apr 28, 2005
Sen. Chafee, Lincoln [R-RI]	R · RI		May 25, 2005
Sen. Bingaman, Jeff [D-NM]	D · NM		Jul 19, 2005
Sen. Mikulski, Barbara A. [D-MD]	D · MD		May 4, 2006
Sen. Rockefeller, John D., IV [D-WV]	D · WV		Jun 16, 2006
Sen. Johnson, Tim [D-SD]	D · SD		Sep 20, 2006

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Apr 27, 2005

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
109 HR 4429	Identical bill	**Dec 2, 2005:** Referred to the Subcommittee on Health.

Summary (as of Apr 27, 2005)

Food and Drug Administration Safety Act of 2005 - Amends the Federal Food, Drug, and Cosmetic Act to establish the Center for Postmarket Drug Evaluation and Research within the Food and Drug Administration (FDA).

Requires the Director of the Center to conduct activities to ensure the safety and effectiveness of FDA-approved drugs and licensed biological products, including by: (1) conducting postmarket risk assessment and surveillance of such drugs and products; (2) determining whether a postmarket study is required; (3) contracting, or requiring the sponsor of such a drug or product to contract, with the holders of domestic and international surveillance databases to conduct epidemiologic and other observational studies; (4) determining whether a drug or product may present an unreasonable risk to the health of patients or the general public; (5) taking corrective action if such an unreasonable risk may exist; and (6) making information about the safety and effectiveness of such drugs and biological products available to the public and health care providers in a timely manner.

Requires the Drug Safety and Risk Management Drug Advisory Committee to make recommendations to the Director on postmarket studies, drugs and biological products that may present an unreasonable risk, and appropriate corrective actions.

Allows the Secretary of Health and Human Services to assess civil penalties for violations of this Act.

Allows the Director to withdraw or suspend approval of a drug or license for a biological product using expedited procedures under certain circumstances.

Transfers to the Center the functions and duties of the Office of Drug Safety.

Actions Timeline

- **Apr 27, 2005:** Introduced in Senate
- **Apr 27, 2005:** Sponsor introductory remarks on measure. (CR S4426-4427)
- **Apr 27, 2005:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.