HR 4429

Food and Drug Administration Safety Act of 2005

Congress: 109 (2005–2007, Ended)
Chamber: House
Policy Area: Health
Introduced: Nov 18, 2005
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Dec 2, 2005)
Official Text: https://www.congress.gov/bill/109th-congress/house-bill/4429

Sponsor

Name: Rep. Tierney, John F. [D-MA-6]
Party: Democratic • **State:** MA • **Chamber:** House

Cosponsors (3 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Ramstad, Jim [R-MN-3]	R · MN		Nov 18, 2005
Rep. McDermott, Jim [D-WA-7]	D · WA		May 9, 2006
Rep. Kucinich, Dennis J. [D-OH-10]	D · OH		Sep 7, 2006

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Dec 2, 2005

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
109 S 930	Identical bill	**Apr 27, 2005:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of Nov 18, 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

- **Dec 2, 2005:** Referred to the Subcommittee on Health.
- **Nov 18, 2005:** Introduced in House
- **Nov 18, 2005:** Introduced in House
- **Nov 18, 2005:** Referred to the House Committee on Energy and Commerce.

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