HR 788

Food and Drug Administration Safety Act of 2007

Congress: 110 (2007–2009, Ended)
Chamber: House
Policy Area: Health
Introduced: Jan 31, 2007
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Feb 2, 2007)
Official Text: https://www.congress.gov/bill/110th-congress/house-bill/788

Sponsor

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

Cosponsors (5 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Ramstad, Jim [R-MN-3]	R · MN		Jan 31, 2007
Rep. Clay, Wm. Lacy [D-MO-1]	D · MO		Jun 12, 2007
Rep. McGovern, James P. [D-MA-3]	D · MA		Jun 12, 2007
Rep. Miller, George [D-CA-7]	D · CA		Jun 12, 2007
Rep. Davis, Danny K. [D-IL-7]	D · IL		Jul 25, 2007

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Feb 2, 2007

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
110 S 468	Identical bill	**Jan 31, 2007:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (text of measure as introduced: CR S1455-1457)

Summary (as of Jan 31, 2007)

Food and Drug Administration Safety Act of 2007 - Amends the Federal Food, Drug, and Cosmetic Act to establish the Center for Postmarket Evaluation and Research for Drugs and Biologics 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 patient 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 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 Surveillance and Epidemiology.

Actions Timeline

- **Feb 2, 2007:** Referred to the Subcommittee on Health.
- **Jan 31, 2007:** Introduced in House
- **Jan 31, 2007:** Referred to the House Committee on Energy and Commerce.