

S 468

Food and Drug Administration Safety Act of 2007

Congress: 110 (2007–2009, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Jan 31, 2007

Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (text of measure

Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (text of measure as introduced: CR S1455-1457) (Jan 31, 2007)

Official Text: https://www.congress.gov/bill/110th-congress/senate-bill/468

Sponsor

Name: Sen. Grassley, Chuck [R-IA]

Party: Republican • State: IA • Chamber: Senate

Cosponsors (4 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Bingaman, Jeff [D-NM]	D · NM		Jan 31, 2007
Sen. Dodd, Christopher J. [D-CT]	D · CT		Jan 31, 2007
Sen. Mikulski, Barbara A. [D-MD]	D · MD		Jan 31, 2007
Sen. Johnson, Tim [D-SD]	D · SD		Jun 14, 2007

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Jan 31, 2007

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
110 HR 788	Identical bill	Feb 2, 2007: Referred to the Subcommittee on Health.

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**

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- **Jan 31, 2007:** Introduced in Senate
- **Jan 31, 2007:** Sponsor introductory remarks on measure. (CR S1454-1455)
- **Jan 31, 2007:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (text of measure as introduced: CR S1455-1457)