S 467

FACT Act

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 S1449-1454) (Jan 31, 2007)
Official Text: https://www.congress.gov/bill/110th-congress/senate-bill/467

Sponsor

Name: Sen. Dodd, Christopher J. [D-CT]
Party: Democratic • **State:** CT • **Chamber:** Senate

Cosponsors (7 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Bingaman, Jeff [D-NM]	D · NM		Jan 31, 2007
Sen. Durbin, Richard J. [D-IL]	D · IL		Jan 31, 2007
Sen. Grassley, Chuck [R-IA]	R · IA		Jan 31, 2007
Sen. Harkin, Tom [D-IA]	D · IA		Jan 31, 2007
Sen. Wyden, Ron [D-OR]	D · OR		Jan 31, 2007
Sen. Collins, Susan M. [R-ME]	R · ME		May 24, 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

No related bills are listed.

Summary (as of Jan 31, 2007)

Fair Access to Clinical Trials Act of 2007 or the FACT Act - Amends the Public Health Service Act to require the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health (NIH), to establish and operate a data bank of information on clinical trials, to include: (1) a clinical trials registry of health-related interventions conducted to test the safety or effectiveness of any drug, biological product, or device intended to treat serious or life-threatening diseases and conditions; and (2) a clinical trial results database of health-related interventions to test the safety or effectiveness of any drug, biological product, or device.

Requires the Commissioner of Food and Drugs to make available to the public: (1) the full reviews conducted by the Food and Drug Administration (FDA) of new or supplemental new drug applications, including documentation of significant differences of opinion and the resolution of those differences; and (2) copies of written consultations on a drug's safety conducted by the Office of Surveillance and Epidemiology.

Requires the Secretary to assess civil monetary penalties for knowingly submitting inaccurate information to the FDA.

Allows the Secretary to correct any information included in the registry or database that is factually and substantively inaccurate, false, or misleading.

Extends requirements of this Act to clinical trials conducted outside of the United States under certain circumstances.

Prohibits a responsible person or a manufacturer from performing any act that prohibits, limits, or imposes unreasonable delays on the ability of an individual to discuss or publish the results of a clinical trial.

Requires the Secretary to enter into a contract with the Institute of Medicine to study the extent to which data submitted to the registry has impacted the public health.

Actions Timeline

- **Jan 31, 2007:** Introduced in Senate
- **Jan 31, 2007:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (text of measure as introduced: CR S1449-1454)