

S 470

FACT Act

Congress: 109 (2005–2007, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Feb 28, 2005

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 S1798-1803) (Feb 28, 2005)

Official Text: https://www.congress.gov/bill/109th-congress/senate-bill/470

Sponsor

Name: Sen. Dodd, Christopher J. [D-CT]

Party: Democratic • State: CT • Chamber: Senate

Cosponsors (7 total)

| Cosponsor | Party / State | Role | Date Joined |
|--------------------------------|---------------|------|--------------|
| Sen. Grassley, Chuck [R-IA] | R · IA | | Feb 28, 2005 |
| Sen. Johnson, Tim [D-SD] | D · SD | | Feb 28, 2005 |
| Sen. Wyden, Ron [D-OR] | D · OR | | Feb 28, 2005 |
| Sen. Chafee, Lincoln [R-RI] | R · RI | | May 24, 2005 |
| Sen. Durbin, Richard J. [D-IL] | D · IL | | Jul 25, 2005 |
| Sen. Harkin, Tom [D-IA] | D · IA | | Jul 25, 2005 |
| Sen. DeWine, Mike [R-OH] | R · OH | | Jun 29, 2006 |

Committee Activity

| Committee | Chamber | Activity | Date |
|--|---------|-------------|--------------|
| Health, Education, Labor, and Pensions Committee | Senate | Referred To | Feb 28, 2005 |

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Fair Access to Clinical Trials Act of 2005 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 trials 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; and (2) copies of written consultations on a drug's safety conducted by the Office of Drug Safety.

Requires the Secretary to assess civil monetary penalties for failure to comply with the reporting requirements of this Act.

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

- **Feb 28, 2005:** Introduced in Senate
- **Feb 28, 2005:** Sponsor introductory remarks on measure. (CR S1797-1798)
- **Feb 28, 2005:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (text of measure as introduced: CR S1798-1803)
- **Jan 26, 2005:** Sponsor introductory remarks on measure. (CR S538-539)