S 2933

FACT Act

Congress: 108 (2003–2005, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Oct 7, 2004
Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Oct 7, 2004)
Official Text: https://www.congress.gov/bill/108th-congress/senate-bill/2933

Sponsor

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

Cosponsors (3 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Johnson, Tim [D-SD]	D · SD		Oct 7, 2004
Sen. Kennedy, Edward M. [D-MA]	D · MA		Oct 7, 2004
Sen. Wyden, Ron [D-OR]	D · OR		Oct 7, 2004

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Oct 7, 2004

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Oct 7, 2004)

Fair Access to Clinical Trials Act of 2004 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 registry information on clinical trials for drugs, biological products, and devices.

Requires the principal investigator or a responsible person to submit clinical trial information to the Secretary. Requires the Secretary to: (1) seek a memorandum of understanding with the heads of other Federal agencies to include in the registry clinical trials sponsored by such agencies; and (2) establish procedures to allow voluntary submission of clinical trial information not involving drugs, biological products, or devices.

Allows the Secretary to: (1) require that information from such other clinical trials be submitted to the registry in cases in which it is in the interest of public health; and (2) correct any information included in the registry 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.

Requires the responsible person for proposals submitted to the Secretary requesting financial assistance to conduct research to submit registry information to the Secretary.

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

- **Oct 7, 2004:** Introduced in Senate
- **Oct 7, 2004:** Sponsor introductory remarks on measure. (CR S10728-10730)
- **Oct 7, 2004:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.