# HR 5252

Fair Access to Clinical Trials Act

**Congress:** 108 (2003–2005, Ended)
**Chamber:** House
**Policy Area:** Health
**Introduced:** Oct 7, 2004
**Current Status:** Sponsor introductory remarks on measure. (CR E1882-1883)
**Latest Action:** Sponsor introductory remarks on measure. (CR E1882-1883) (Oct 11, 2004)
**Official Text:** https://www.congress.gov/bill/108th-congress/house-bill/5252

## Sponsor

**Name:** Rep. Markey, Edward J. [D-MA-7]
**Party:** Democratic • **State:** MA • **Chamber:** Senate

## Cosponsors (4 total)

| Cosponsor | Party / State | Role | Date Joined |
|---|---|---|---|
| Rep. Waxman, Henry A. [D-CA-30] | D · CA | | Oct 7, 2004 |
| Rep. Allen, Thomas H. [D-ME-1] | D · ME | | Nov 18, 2004 |
| Rep. Frank, Barney [D-MA-4] | D · MA | | Nov 18, 2004 |
| Rep. Schakowsky, Janice D. [D-IL-9] | D · IL | | Nov 18, 2004 |

## Committee Activity

| Committee | Chamber | Activity | Date |
|---|---|---|---|
| Energy and Commerce Committee | House | Referred to | Oct 8, 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 - Amends the Public Health Service Act to prohibit an entity from receiving an award of a grant, contract, or cooperative agreement to conduct a clinical trial to determine the safety or effectiveness of a use of a drug or device unless the entity agrees to: (1) register the trial; (2) provide the results of such trial to the Secretary of Health and Human Services; (3) disclose specified information regarding the trial to the public; and (4) be subject to audits.

Requires the Secretary, acting through the Director of the National Institutes of Health (NIH), to establish and operate a databank of such clinical trial information provided to the Secretary. Requires the Director to assign to the National Library of Medicine the primary responsibility for operating such databank.

Requires the Secretary to: (1) identify false or misleading information in the databank, correct such information, and make appropriate public notifications; and (2) amend regulations to require institutional review boards to determine the safety or effectiveness of products registered under this Act and deny approval for trials that are not registered.

Specifies information required for registration of clinical trials, including information important to clinicians or researchers.

Sets forth provisions regarding periodic updates of databank information, submission of results of clinical trials, public disclosure of databank information, and violations of this Act.

Amends the Federal Food, Drug and Cosmetic Act to allow exemptions for clinical investigational use of drugs or devices only if such drugs are registered in accordance with this Act.

## Actions Timeline

- **Oct 11, 2004:** Sponsor introductory remarks on measure. (CR E1882-1883)
- **Oct 8, 2004:** Referred to the Subcommittee on Health.
- **Oct 7, 2004:** Introduced in House
- **Oct 7, 2004:** Introduced in House
- **Oct 7, 2004:** Referred to the House Committee on Energy and Commerce.

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