# S 3807

Enhancing Drug Safety and Innovation Act of 2006

**Congress:** 109 (2005–2007, Ended)
**Chamber:** Senate
**Policy Area:** Health
**Introduced:** Aug 3, 2006
**Current Status:** Committee on Health, Education, Labor, and Pensions. Hearings held. Hearings printed: S.Hrg. 109-850
**Latest Action:** Committee on Health, Education, Labor, and Pensions. Hearings held. Hearings printed: S.Hrg. 109-850. (Nov 16, 2006)
**Official Text:** https://www.congress.gov/bill/109th-congress/senate-bill/3807

## Sponsor

**Name:** Sen. Enzi, Michael B. [R-WY]
**Party:** Republican • **State:** WY • **Chamber:** Senate

## Cosponsors (3 total)

| Cosponsor | Party / State | Role | Date Joined |
|---|---|---|---|
| Sen. Kennedy, Edward M. [D-MA] | D · MA | | Aug 3, 2006 |
| Sen. DeWine, Mike [R-OH] | R · OH | | Sep 5, 2006 |
| Sen. Dayton, Mark [D-MN] | D · MN | | Sep 8, 2006 |

## Committee Activity

| Committee | Chamber | Activity | Date |
|---|---|---|---|
| Health, Education, Labor, and Pensions Committee | Senate | Hearings By (full committee) | Nov 16, 2006 |

## Subjects & Policy Tags

**Policy Area:**

Health

## Related Bills

*No related bills are listed.*

## Summary (as of Aug 3, 2006)

Enhancing Drug Safety and Innovation Act of 2006 - Amends the Federal Food, Drug, and Cosmetic Act to require an application for approval for a new drug or biological product to include a proposed risk evaluation and mitigation strategy, which must include: (1) labeling for the drug for use by health care providers; (2) submission of reports for the drug; and (3) a statement as to whether the analysis and surveillance are sufficient to assess the serious risks of the drug.

Establishes within the Food and Drug Administration (FDA) the Reagan-Udall Institute for Applied Biomedical Research to advance the Critical Path Initiative to modernize medical product development, accelerate innovation, and enhance product safety. Requires the Institute to have a Board of Directors. Allows the Board to establish one or more Critical Path Institutes to conduct research, education, and outreach and to modernize the sciences of developing, manufacturing, and evaluating the safety and effectiveness of diagnostics, devices, biologics, and drugs.

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 administer a clinical trial registry database and a clinical trial results database. Requires a responsible part for a clinical trial to submit clinical trial information to the Director for inclusion in the databases.

Requires a member of a panel advising or recommending to the Secretary regarding FDA activities to disclose any financial involvements that the member may have. Directs the Secretary to recuse members with a high magnitude of financial involvement.

## Actions Timeline

- **Nov 16, 2006:** Committee on Health, Education, Labor, and Pensions. Hearings held. Hearings printed: S.Hrg. 109-850.
- **Aug 3, 2006:** Introduced in Senate
- **Aug 3, 2006:** Sponsor introductory remarks on measure. (CR S8818-8819)
- **Aug 3, 2006:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
- **Feb 1, 2006:** Sponsor introductory remarks on measure. (CR S1531)