HR 1165

SAFE Drug Act

Congress: 110 (2007–2009, Ended)
Chamber: House
Policy Area: Health
Introduced: Feb 16, 2007
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Feb 27, 2007)
Official Text: https://www.congress.gov/bill/110th-congress/house-bill/1165

Sponsor

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

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Eshoo, Anna G. [D-CA-14]	D · CA		May 9, 2007

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Feb 27, 2007

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Feb 16, 2007)

Swift Approval, Full Evaluation Drug Act or the SAFE Drug Act - Amends the Federal Food, Drug, and Cosmetic Act to authorize the Secretary of Health and Human Services to: (1) order postmarket studies of approved drugs upon receiving evidence of a significant issue regarding the safety or lack of effectiveness of such a drug; and (2) establish restrictions on the distribution or use of the drug during the period in which the study is conducted.

Directs the Secretary to amend regulations to require postmarket studies of drugs approved under an accelerated approval process for new drugs for serious or life-threatening illnesses.

Deems a drug or device to be misbranded if there is a failure to comply with requirements under this Act.

Prohibits discrimination against individuals who provide information in an investigation or proceeding regarding a violation of any law, rule, or regulation, censorship, distortion, or suppression of scientific information, research, or analysis, or the willful disclosure of false, misleading, or incomplete scientific information.

Authorizes Food and Drug Administration (FDA) officers, employees, and sponsored individuals to publish in peer-reviewed journals and other scientific publications and make oral presentations at professional society meetings and other meetings of their peers, with certain exceptions.

Prohibits an FDA officer or employee from directing any other FDA officer or employee to: (1) censor, distort, or suppress any scientific research, analysis, opinion, or recommendation; or (2) willfully disclose scientific information that is false, misleading, or incomplete.

Requires the Secretary to publish a summary statement of the scientific basis for approval of any new drug and how the final decision balanced the risk and benefits within 48 hours after approval of an application.

Actions Timeline

- **Feb 27, 2007:** Referred to the Subcommittee on Health.
- **Feb 17, 2007:** Sponsor introductory remarks on measure. (CR E390-391)
- **Feb 16, 2007:** Introduced in House
- **Feb 16, 2007:** Referred to the House Committee on Energy and Commerce.