

S 3546

Dietary Supplement and Nonprescription Drug Consumer Protection Act

Congress: 109 (2005–2007, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Jun 21, 2006

Current Status: Became Public Law No: 109-462.

Latest Action: Became Public Law No: 109-462. (Dec 22, 2006)

Law: 109-462 (Enacted Dec 22, 2006)

Official Text: <https://www.congress.gov/bill/109th-congress/senate-bill/3546>

Sponsor

Name: Sen. Hatch, Orrin G. [R-UT]

Party: Republican • **State:** UT • **Chamber:** Senate

Cosponsors (5 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Durbin, Richard J. [D-IL]	D · IL		Jun 21, 2006
Sen. Enzi, Michael B. [R-WY]	R · WY		Jun 21, 2006
Sen. Harkin, Tom [D-IA]	D · IA		Jun 21, 2006
Sen. Kennedy, Edward M. [D-MA]	D · MA		Jun 21, 2006
Sen. Cornyn, John [R-TX]	R · TX		Jul 10, 2006

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Sep 5, 2006

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
109 HR 6168	Related bill	Oct 2, 2006: Referred to the Subcommittee on Health.

(This measure has not been amended since it was reported to the Senate on September 5, 2006. The summary of that version is repeated here.)

Dietary Supplement and Nonprescription Drug Consumer Protection Act - (Sec. 2) Amends the Federal Food, Drug, and Cosmetic Act to require a manufacturer, packer, or distributor whose name appears on the label of a nonprescription drug or dietary supplement marketed in the United States to: (1) submit to the Secretary of Health and Human Services within 15 business days any report of a serious adverse event associated with use of such drug or supplement in the United States; (2) submit within 15 business days any related medical information that is received within one year of the initial report; (3) maintain records related to each report for six years; and (4) permit inspection of such records. Allows a retailer whose name appears on the label as a distributor to authorize the manufacturer or packer to submit the required reports so long as the retailer directs all reported adverse events to such manufacturer or packer.

Requires the Secretary to develop systems to ensure that duplicate reports of a serious adverse event are consolidated.

Allows the Secretary to establish an exemption from such reporting that would have no adverse effect on public health.

Considers a serious adverse event report to be: (1) a safety report that may be accompanied by a statement, which shall be included in any public disclosure of the report, that denies that the report or the records constitute an admission that the product involved caused or contributed to the adverse event; and (2) a record about an individual and a medical or similar file the disclosure of which violates the Freedom of Information Act unless all personally identifiable information is redacted.

Provides that the submission of any adverse event report shall not be construed as an admission that the drug or supplement involved caused or contributed to the adverse event.

Prohibits any state or local government from establishing or continuing any requirements related to a mandatory system for adverse event reports for nonprescription drugs or dietary supplements that are not identical to the requirements of this Act.

Prohibits the responsible person from: (1) refusing to permit access to any required record; or (2) failing to establish or maintain any record, or make any report, required under this Act.

Deems a nonprescription drug or dietary supplement that is marketed in the United States to be misbranded unless its label includes a domestic address or phone number for the reporting of a serious adverse event.

(Sec. 4) Prohibits the falsification of a serious adverse event report.

(Sec. 5) Prohibits the importation of a drug or supplement subject to this Act if the Secretary has credible information indicating that the responsible person has not complied with the requirements of this Act or has not allowed access to its records.

Actions Timeline

- **Dec 22, 2006:** Signed by President.
- **Dec 22, 2006:** Signed by President.
- **Dec 22, 2006:** Became Public Law No: 109-462.
- **Dec 22, 2006:** Became Public Law No: 109-462.
- **Dec 20, 2006:** Presented to President.
- **Dec 20, 2006:** Presented to President.
- **Dec 9, 2006:** Mr. Barton (TX) moved to suspend the rules and pass the bill.
- **Dec 9, 2006:** Considered under suspension of the rules. (consideration: CR 12/8/2006 H9243-9246)
- **Dec 9, 2006:** DEBATE - The House proceeded with forty minutes of debate on S. 3546.
- **Dec 9, 2006:** At the conclusion of debate, the Yeas and Nays were demanded and ordered. Pursuant to the provisions of clause 8, rule XX, the Chair announced that further proceedings on the motion would be postponed.
- **Dec 9, 2006:** Considered as unfinished business. (consideration: CR 12/8/2006 H9303-9304)
- **Dec 9, 2006:** Passed/agreed to in House: On motion to suspend the rules and pass the bill Agreed to by the Yeas and Nays: (2/3 required): 203 - 98 (Roll no. 543).(text: CR 12/8/2006 H9243-9245)
- **Dec 9, 2006:** On motion to suspend the rules and pass the bill Agreed to by the Yeas and Nays: (2/3 required): 203 - 98 (Roll no. 543). (text: CR 12/8/2006 H9243-9245)
- **Dec 9, 2006:** Motion to reconsider laid on the table Agreed to without objection.
- **Dec 7, 2006:** Message on Senate action sent to the House.
- **Dec 7, 2006:** Received in the House.
- **Dec 7, 2006:** Held at the desk.
- **Dec 6, 2006:** Passed/agreed to in Senate: Passed Senate with an amendment by Unanimous Consent.(consideration: CR S11376-11381; text as passed Senate: CR S11377-11378)
- **Dec 6, 2006:** Passed Senate with an amendment by Unanimous Consent. (consideration: CR S11376-11381; text as passed Senate: CR S11377-11378)
- **Sep 5, 2006:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Enzi with an amendment in the nature of a substitute. With written report No. 109-324.
- **Sep 5, 2006:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Enzi with an amendment in the nature of a substitute. With written report No. 109-324.
- **Sep 5, 2006:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 586.
- **Jun 28, 2006:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Jun 21, 2006:** Introduced in Senate
- **Jun 21, 2006:** Sponsor introductory remarks on measure. (CR S6285-6287)
- **Jun 21, 2006:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.