

## HR 6543

Drug Safety Enhancement Act of 2011

**Congress:** 111 (2009–2011, Ended)

**Chamber:** House

**Policy Area:** Health

**Introduced:** Dec 17, 2010

**Current Status:** Referred to the House Committee on Energy and Commerce.

**Latest Action:** Referred to the House Committee on Energy and Commerce. (Dec 17, 2010)

**Official Text:** <https://www.congress.gov/bill/111th-congress/house-bill/6543>

### Sponsor

**Name:** Rep. Dingell, John D. [D-MI-15]

**Party:** Democratic • **State:** MI • **Chamber:** House

### Cosponsors (3 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Pallone, Frank, Jr. [D-NJ-6]	D · NJ		Dec 17, 2010
Rep. Stupak, Bart [D-MI-1]	D · MI		Dec 17, 2010
Rep. Waxman, Henry A. [D-CA-30]	D · CA		Dec 17, 2010

### Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred To	Dec 17, 2010

### Subjects & Policy Tags

**Policy Area:**

Health

### Related Bills

No related bills are listed.

Drug Safety Enhancement Act of 2011 - Amends the Federal Food, Drug, and Cosmetic Act to expand safety and inspection requirements for the manufacture and importation of drugs by: (1) expanding registration requirements for foreign and domestic drug producers; (2) requiring drug manufacturers to have in effect and implement an effective quality system; (3) expanding and equalizing inspection requirements for foreign and domestic drug producers; (4) imposing additional requirements relating to the notification, nondistribution, and recall of adulterated or misbranded drugs; (5) permitting the detention of drugs found to be in violation of drug safety requirements; (6) allowing for the destruction of drugs that pose a significant adverse health effect; (7) providing enhanced civil and criminal penalties and forfeiture for violations of drug safety requirements and enhanced subpoena authority for investigating violations; (8) prohibiting the importation of drugs into the United States lacking documentation of safety; (9) requiring unique identification numbers for drug establishments and importers; and (10) expanding protections for whistleblowers who refuse to violate, or who disclose violations of, this Act.

#### **Actions Timeline**

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- **Dec 17, 2010:** Introduced in House
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