

## S 2307

Reliable Entry for Medicines at Everyday Discounts through Importation with Effective Safeguards Act of 2004

**Congress:** 108 (2003–2005, Ended)

**Chamber:** Senate

**Policy Area:** Health

**Introduced:** Apr 8, 2004

**Current Status:** Read twice and referred to the Committee on Finance.

**Latest Action:** Read twice and referred to the Committee on Finance. (Apr 8, 2004)

**Official Text:** <https://www.congress.gov/bill/108th-congress/senate-bill/2307>

### Sponsor

**Name:** Sen. Grassley, Chuck [R-IA]

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

### Cosponsors

*No cosponsors are listed for this bill.*

### Committee Activity

| Committee         | Chamber | Activity    | Date        |
|-------------------|---------|-------------|-------------|
| Finance Committee | Senate  | Referred To | Apr 8, 2004 |

### Subjects & Policy Tags

**Policy Area:**

Health

### Related Bills

*No related bills are listed.*

Reliable Entry for Medicines at Everyday Discounts through Importation with Effective Safeguards Act of 2004 - Amends the Federal Food, Drug, and Cosmetic Act to revise provisions governing the importation of prescription drugs. Requires the Secretary of Health and Human Services to promulgate regulations allowing the importation of qualifying prescription drugs from permitted countries (defined as Canada, other countries that may be designated by the Secretary as meeting qualifying requirements, and, after a specified report due within 18 months is published, Australia, European Union countries, Japan and New Zealand). Allows such importation only from registered exporters by importers or by individuals for personal use.

Sets conditions on registered exporters, including that they must: (1) submit to the jurisdiction of U.S. courts; (2) export only qualifying drugs manufactured in and obtained from registered establishments; (3) permit facility and record inspections and place of business monitoring; (4) pay user fees to cover the costs of administering this Act; and (5) be authorized under foreign law to dispense drugs that are only safe for use under supervision of a licensed practitioner.

Requires the Secretary to regulate such importation, including by verifying the chain of custody of drugs from the manufacturer to the exporter, conducting random sampling of exports for personal use to determine whether all conditions are being met, and listing registered exporters on the Food and Drug Administration (FDA) web site.

Allows non-FDA approved drugs to be imported if the drugs have the same manufacturer and the same active ingredients, route of administration, dosage form, and strength as FDA approved drugs, with specific limitations.

Bars importation of qualifying drugs supplied for free or for a nominal cost by a manufacturer to a charitable or humanitarian organization or a foreign government.

Allows for the immediate importation for personal use under certain conditions.

Provides for penalties for violations of this Act, including the destruction without notice of drug shipments.

Amends the Controlled Substances Import and Export Act to repeal the exemption that permitted individuals to import controlled substances for personal medical use.

Amends the Internal Revenue Code to: (1) disallow any deduction for advertising expenditures of a drug manufacturer that does not certify that it has not taken any action to prevent authorized importation; and (2) provide a 20 percent increase in the tax credit for research activities for a drug manufacturer that makes such certification.

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## **Actions Timeline**

- **Apr 8, 2004:** Introduced in Senate
- **Apr 8, 2004:** Sponsor introductory remarks on measure. (CR S4042-4046)
- **Apr 8, 2004:** Read twice and referred to the Committee on Finance.