

Bill Fact Sheet – December 5, 2025 https://legilist.com

Bill page: https://legilist.com/bill/108/s/2328

S 2328

Pharmaceutical Market Access and Drug Safety Act of 2004

Congress: 108 (2003–2005, Ended)

Chamber: Senate
Policy Area: Health
Introduced: Apr 21, 2004

Current Status: Committee on the Judiciary. Hearings held.

Latest Action: Committee on the Judiciary. Hearings held. (Jul 14, 2004) **Official Text:** https://www.congress.gov/bill/108th-congress/senate-bill/2328

Sponsor

Name: Sen. Dorgan, Byron L. [D-ND]

Party: Democratic • State: ND • Chamber: Senate

Cosponsors (31 total)

| Cosponsors (or total) | | |
|-------------------------------------|--------------------|---------------|
| Cosponsor | Party / State Role | e Date Joined |
| Sen. Chafee, Lincoln [R-RI] | R · RI | Apr 21, 2004 |
| Sen. Daschle, Thomas A. [D-SD] | D·SD | Apr 21, 2004 |
| Sen. Feingold, Russell D. [D-WI] | D · WI | Apr 21, 2004 |
| Sen. Johnson, Tim [D-SD] | D·SD | Apr 21, 2004 |
| Sen. Kennedy, Edward M. [D-MA] | D · MA | Apr 21, 2004 |
| Sen. Lott, Trent [R-MS] | $R \cdot MS$ | Apr 21, 2004 |
| Sen. McCain, John [R-AZ] | $R \cdot AZ$ | Apr 21, 2004 |
| Sen. Pryor, Mark L. [D-AR] | D · AR | Apr 21, 2004 |
| Sen. Snowe, Olympia J. [R-ME] | $R \cdot ME$ | Apr 21, 2004 |
| Sen. Stabenow, Debbie [D-MI] | $D\cdotMI$ | Apr 21, 2004 |
| Sen. Dayton, Mark [D-MN] | $D \cdot MN$ | Apr 22, 2004 |
| Sen. Feinstein, Dianne [D-CA] | D · CA | Apr 22, 2004 |
| Sen. Nelson, Bill [D-FL] | $D\cdotFL$ | Apr 22, 2004 |
| Sen. Schumer, Charles E. [D-NY] | $D \cdot NY$ | Apr 22, 2004 |
| Sen. Kerry, John F. [D-MA] | $D\cdotMA$ | Apr 26, 2004 |
| Sen. Leahy, Patrick J. [D-VT] | $D \cdot VT$ | Apr 26, 2004 |
| Sen. Boxer, Barbara [D-CA] | D · CA | Apr 27, 2004 |
| Sen. Durbin, Richard J. [D-IL] | $D\cdotIL$ | Apr 27, 2004 |
| Sen. Mikulski, Barbara A. [D-MD] | $D\cdotMD$ | Apr 29, 2004 |
| Sen. Levin, Carl [D-MI] | $D\cdotMI$ | May 4, 2004 |
| Sen. Kohl, Herb [D-WI] | $D\cdotWI$ | May 6, 2004 |
| Sen. Inouye, Daniel K. [D-HI] | D · HI | Jun 9, 2004 |
| Sen. Clinton, Hillary Rodham [D-NY] | $D \cdot NY$ | Jun 14, 2004 |
| Sen. Lincoln, Blanche L. [D-AR] | D · AR | Jun 15, 2004 |
| Sen. Specter, Arlen [R-PA] | $R \cdot PA$ | Jun 18, 2004 |
| Sen. Jeffords, James M. [I-VT] | I · VT | Jun 22, 2004 |
| Sen. Edwards, John [D-NC] | $D \cdot NC$ | Jun 24, 2004 |
| Sen. Conrad, Kent [D-ND] | $D \cdot N D$ | Jul 6, 2004 |
| Sen. Reid, Harry [D-NV] | $D \cdot NV$ | Jul 6, 2004 |
| Sen. Sarbanes, Paul S. [D-MD] | $D \cdot MD$ | Jul 6, 2004 |
| Sen. Dodd, Christopher J. [D-CT] | D · CT | Sep 10, 2004 |

Committee Activity

| Committee | Chamber | Activity | Date |
|--|---------|------------------------------|--------------|
| Health, Education, Labor, and Pensions Committee | Senate | Hearings By (full committee) | May 20, 2004 |
| Judiciary Committee | Senate | Hearings By (full committee) | Jul 14, 2004 |

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Apr 21, 2004)

Pharmaceutical Market Access and Drug Safety 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 prescription drugs by registered exporters or registered importers from Canada within 90 days of passage of this Act and from Australia, European Union countries, Japan, New Zealand, or Switzerland within one year.

Provides for inspection, tracking of drugs, and registration and inspection fees for registered importers and exporters.

Requires manufacturers to: (1) submit a statement to the Secretary explaining each difference between a drug approved and distributed in the United States and a related drug distributed in a foreign country; and (2) submit an application to the Food and Drug Administration (FDA) for approval of a related drug that is distributed in a foreign country if there is no comparable drug already approved in at least half of the permitted countries that can be imported to the United States.

Allows for the immediate importation of prescription drugs for personal use from licensed Canadian pharmacies.

Amends the Clayton Act to prohibit drug manufacturers from preventing importation by engaging in behavior such as charging higher prices or limiting supplies to registered exporters and importers or changing the form of the drug for such purpose.

States that the resale in the United States of prescription drugs that were properly sold abroad is not patent infringement.

Requires the Secretary of Homeland Security to refuse admission of drugs that violate importation provisions. Allows the destruction of certain violative shipments.

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

Actions Timeline

- Jul 14, 2004: Committee on the Judiciary. Hearings held.
- May 20, 2004: Committee on Health, Education, Labor, and Pensions. Hearings held. Hearings printed: S.Hrg. 108-470.
- Apr 21, 2004: Introduced in Senate
- Apr 21, 2004: Sponsor introductory remarks on measure. (CR S4227-4228)
- Apr 21, 2004: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.