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Prescription Drug Benefit and Cost Containment Act of 2003

Congress: 108 (2003–2005, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Jan 7, 2003
Current Status: Read twice and referred to the Committee on Finance.
Latest Action: Read twice and referred to the Committee on Finance. (Jan 7, 2003)
Official Text: https://www.congress.gov/bill/108th-congress/senate-bill/7

Sponsor

Name: Sen. Daschle, Thomas A. [D-SD]
Party: Democratic • **State:** SD • **Chamber:** Senate

Cosponsors (21 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Akaka, Daniel K. [D-HI]	D · HI		Jan 7, 2003
Sen. Clinton, Hillary Rodham [D-NY]	D · NY		Jan 7, 2003
Sen. Corzine, Jon S. [D-NJ]	D · NJ		Jan 7, 2003
Sen. Dayton, Mark [D-MN]	D · MN		Jan 7, 2003
Sen. Durbin, Richard J. [D-IL]	D · IL		Jan 7, 2003
Sen. Johnson, Tim [D-SD]	D · SD		Jan 7, 2003
Sen. Kennedy, Edward M. [D-MA]	D · MA		Jan 7, 2003
Sen. Lautenberg, Frank R. [D-NJ]	D · NJ		Jan 7, 2003
Sen. Leahy, Patrick J. [D-VT]	D · VT		Jan 7, 2003
Sen. Levin, Carl [D-MI]	D · MI		Jan 7, 2003
Sen. Mikulski, Barbara A. [D-MD]	D · MD		Jan 7, 2003
Sen. Reed, Jack [D-RI]	D · RI		Jan 7, 2003
Sen. Reid, Harry [D-NV]	D · NV		Jan 7, 2003
Sen. Rockefeller, John D., IV [D-WV]	D · WV		Jan 7, 2003
Sen. Sarbanes, Paul S. [D-MD]	D · MD		Jan 7, 2003
Sen. Schumer, Charles E. [D-NY]	D · NY		Jan 7, 2003
Sen. Stabenow, Debbie [D-MI]	D · MI		Jan 7, 2003
Sen. Boxer, Barbara [D-CA]	D · CA		Jan 9, 2003
Sen. Dodd, Christopher J. [D-CT]	D · CT		Jan 9, 2003
Sen. Byrd, Robert C. [D-WV]	D · WV		Feb 26, 2003
Sen. Nelson, Bill [D-FL]	D · FL		Apr 2, 2003

Committee Activity

Committee	Chamber	Activity	Date
Finance Committee	Senate	Referred To	Jan 7, 2003

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Jan 7, 2003)

Prescription Drug Benefit and Cost Containment Act of 2003 - Amends title XVIII (Medicare) of the Social Security Act (SSA) to establish: (1) a Medicare Outpatient Prescription Drug Benefit Program under new part D; (2) a Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund; and (3) a Medicare Prescription Drug Advisory Committee.

Provides for: (1) part D benefits under Medicare+Choice plans under Medicare part C (Medicare+Choice); and (2) Medicare cost-sharing and other assistance for low-income individuals.

Revises requirements for Medicare supplemental insurance policy (Medigap) benefit packages to conform to changes made by this Act.

Provides for coverage of immunosuppressive drugs for all Medicare beneficiaries under Medicare part B (Supplementary Medical Insurance).

Directs the Secretary of Health and Human Services to study and report to Congress on the feasibility and advisability of establishing a uniform format for pharmacy benefit cards provided to beneficiaries.

Expands the membership and duties of the Medicare Payment Advisory Commission (MEDPAC).

Amends the Federal Food, Drug, and Cosmetic Act to revise provisions concerning the timing of generic drug availability.

Requires applicants (pharmaceutical companies) to register their patents with the Food and Drug Administration (FDA) within 30 days of approval (or issuance for subsequently issued patents). Makes failure to timely register a bar to civil actions for patent infringement.

Requires applications for new drugs (NDA) or abbreviated new drug applications (ANDA) which rely upon investigations not conducted by or for the applicant and which concern a patent that claims both the drug and a method of use or more than one method of use to include a certification on a claim-by-claim basis that the patent is invalid or will not be infringed (known as a Paragraph IV filing/certification) by the new drug's (generic) manufacture and a statement regarding the method(s) of use claim.

Prohibits (for subsequently issued patents) an extension of the 30-month stay of FDA approval for any new drug where an ANDA or NDA contains a Paragraph IV filing/certification and the patent holder indicates an intention to bring a patent infringement suit against the new (generic) drug's manufacturer. Makes failure to timely file a civil action for infringement a bar to later action.

Requires the first generic applicant with a Paragraph IV filing to forfeit the 180 day marketing exclusivity period to a subsequent generic applicant if the first generic applicant engages in certain behaviors (forfeiture events) which delay or prevent the marketing of the generic drug.

Adds provisions on importation of prescription drugs and pediatric labeling of drugs and biological products.

Actions Timeline

- **Jan 7, 2003:** Introduced in Senate
- **Jan 7, 2003:** Sponsor introductory remarks on measure. (CR 1/9/2003 S134)
- **Jan 7, 2003:** Read twice and referred to the Committee on Finance.