

S 812

Greater Access to Affordable Pharmaceuticals Act of 2002

Congress: 107 (2001–2003, Ended)

Chamber: Senate

Policy Area: Health

Introduced: May 1, 2001

Current Status: Held at the desk.

Latest Action: Held at the desk. (Sep 4, 2002)

Official Text: https://www.congress.gov/bill/107th-congress/senate-bill/812

Sponsor

Name: Sen. Schumer, Charles E. [D-NY]

Party: Democratic • State: NY • Chamber: Senate

Cosponsors (12 total)

Cosponsor	Party / State	Role	Date Joined
Sen. McCain, John [R-AZ]	R · AZ		May 1, 2001
Sen. Johnson, Tim [D-SD]	D · SD		Jun 8, 2001
Sen. Clinton, Hillary Rodham [D-NY]	D · NY		Apr 10, 2002
Sen. Carnahan, Jean [D-MO]	D · MO		Apr 23, 2002
Sen. Kohl, Herb [D-WI]	D · WI		Apr 23, 2002
Sen. Stabenow, Debbie [D-MI]	D · MI		Apr 23, 2002
Sen. Daschle, Thomas A. [D-SD]	D · SD		May 1, 2002
Sen. Durbin, Richard J. [D-IL]	D · IL		May 1, 2002
Sen. Wellstone, Paul D. [D-MN]	D · MN		May 22, 2002
Sen. Edwards, John [D-NC]	D · NC		Jun 4, 2002
Sen. Miller, Zell [D-GA]	D · GA		Jun 19, 2002
Sen. Feingold, Russell D. [D-WI]	D · WI		Jul 23, 2002

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Jul 11, 2002

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
107 HR 1862	Identical bill	May 7, 2002: Sponsor introductory remarks on measure. (CR H2110)

**Title I: Greater Access to Affordable Pharmaceuticals** - Greater Access to Affordable Pharmaceuticals Act of 2002 - Amends the Federal Food, Drug, and Cosmetic Act to revise provisions concerning the timing of generic drug availability.

(Sec. 103) 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.

(Sec. 104) 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 (within 45 days of notice of a Paragraph IV filing) a civil action for infringement a bar to later action.

(Sec. 105) 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 which cause the generic drug not to be brought timely to market.

(Sec. 106) Revises notice requirements for Paragraph IV filings to include and protect certain proposed formulation, composition, or method of use information.

Excludes an applicants's ability to pay damages from a court's consideration of whether or not to provide injunctive relief before the expiration of the 30 month stay of approval period.

(Sec. 107) Continues existing regulations and authorities regarding the bioequivalence of drugs and biological products.

(Sec. 108) Requires the Federal Trade Commission to report to Congress on how this Act has brought generic drugs to market faster.

(Sec. 109) Makes technical and conforming amendments.

**Title II: Importation of Prescription Drugs** - Amends the Federal Food, Drug, and Cosmetic Act to permit pharmacists and wholesalers to import (reimport) U.S. made prescription drugs into the United States from Canada.

Requires an importer to keep detailed records, including a drug's formulation, lot or control number, chain of distribution, and laboratory records.

Requires Canadian sellers to register with the Secretary. Directs the Secretary to suspend the importation of a drug or importations by a particular importer if a pattern emerges which suggests a risk to public health through counterfeit or other violations.

Prohibits drug manufacturers from offering pharmacists and wholesalers terms less favorable than those offered to a foreign purchaser. Prohibits a manufacturer from restricting access to a prescription drug that is permitted to be imported into the United States.

Declares that enforcement efforts concerning importation of prescription drugs by individuals should focus on significant threats to public health rather than importation that is clearly for personal use, particularly importation from Canada.

Provides for studies and reports to Congress by the National Academy of Sciences' Institute of Medicine and the Comptroller General concerning the effects of this Act, addressing compliance issues as well as its effect on trade, patent rights, and pricing.

Authorizes appropriations.

(Sec. 202) Amends title IX of the Social Security Act (Medicaid ) to permit States to enter into Medicaid-like drug rebate agreements with drug manufacturers on behalf of non-Medicaid residents.

(Sec. 203) Provides additional, temporary funding to States through the Medicaid FMAP (Federal medical assistance percentage) if a State plan's eligibility requirements are no more restrictive than those in effect on January 1, 2002. Increases the cap on Medicaid payments to the territories.

Amends title XX (Block Grants to States for Social Services) to provide State fiscal relief allotments, available through FY 2004.

## Actions Timeline

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- **Sep 4, 2002:** Message on Senate action sent to the House.
- **Sep 4, 2002:** Received in the House.
- **Sep 4, 2002:** Held at the desk.
- **Jul 31, 2002:** Considered by Senate. (consideration: CR S7618-7651)
- **Jul 31, 2002:** Cloture invoked in Senate by Yea-Nay Vote. 66 - 33. Record Vote Number: 200.
- **Jul 31, 2002:** Passed/agreed to in Senate: Passed Senate with an amendment by Yea-Nay Vote. 78 - 21. Record Vote Number: 201.
- **Jul 31, 2002:** Passed Senate with an amendment by Yea-Nay Vote. 78 - 21. Record Vote Number: 201.
- **Jul 30, 2002:** Considered by Senate. (consideration: CR S7516-7551)
- **Jul 29, 2002:** Considered by Senate. (consideration: CR S7462)
- **Jul 29, 2002:** Cloture motion on the measure presented in Senate. (consideration: CR S7462)
- **Jul 26, 2002:** Considered by Senate. (consideration: CR S7398-7413)
- **Jul 25, 2002:** Considered by Senate. (consideration: CR S7327-7336, S7342-7350)
- **Jul 24, 2002:** Considered by Senate. (consideration: CR S7249-7263, S7282-7291, S7292-7299)
- **Jul 23, 2002:** Considered by Senate. (consideration: CR S7194-7218)
- **Jul 22, 2002:** Considered by Senate. (consideration: CR S7127, S7134-7158)
- **Jul 18, 2002:** Considered by Senate. (consideration: CR S6977-7016, S7019-7028)
- **Jul 17, 2002:** Motion to proceed to measure considered in Senate. (consideration: CR S6878-6931; text of measure as reported in Senate: CR S6884-6887)
- **Jul 17, 2002:** Cloture on the motion to proceed invoked in Senate by Yea-Nay Vote. 99 - 0. Record Vote Number: 178.
- **Jul 17, 2002:** Motion to proceed to consideration of measure agreed to in Senate by Unanimous Consent.
- **Jul 17, 2002:** Measure laid before Senate by motion.
- **Jul 16, 2002:** Motion to proceed to measure considered in Senate. (consideration: CR S6818-6829, S6831-6853)
- **Jul 15, 2002:** Motion to proceed to consideration of measure made in Senate. (consideration: CR S6797-6801)
- **Jul 15, 2002:** Cloture motion on the motion to proceed to the measure presented in Senate.
- **Jul 11, 2002:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment favorably.
- **Jul 11, 2002:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Kennedy with an amendment. Without written report.
- **Jul 11, 2002:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Kennedy with an amendment. Without written report.
- **Jul 11, 2002:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 491.
- **May 1, 2001:** Introduced in Senate
- **May 1, 2001:** Sponsor introductory remarks on measure. (CR S3590-3591)
- **May 1, 2001:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.