

## S 54

### Greater Access to Affordable Pharmaceuticals 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 Health, Education, Labor, and Pensions. (text of measure

**Latest Action:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (text of measure as introduced: CR S55-58) (Jan 7, 2003)

**Official Text:** <https://www.congress.gov/bill/108th-congress/senate-bill/54>

### Sponsor

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

**Party:** Democratic • **State:** NY • **Chamber:** Senate

### Cosponsors (21 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Clinton, Hillary Rodham [D-NY]	D · NY		Jan 7, 2003
Sen. Collins, Susan M. [R-ME]	R · ME		Jan 7, 2003
Sen. Daschle, Thomas A. [D-SD]	D · SD		Jan 7, 2003
Sen. Dorgan, Byron L. [D-ND]	D · ND		Jan 7, 2003
Sen. Durbin, Richard J. [D-IL]	D · IL		Jan 7, 2003
Sen. Edwards, John [D-NC]	D · NC		Jan 7, 2003
Sen. Feingold, Russell D. [D-WI]	D · WI		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. Kohl, Herb [D-WI]	D · WI		Jan 7, 2003
Sen. Leahy, Patrick J. [D-VT]	D · VT		Jan 7, 2003
Sen. McCain, John [R-AZ]	R · AZ		Jan 7, 2003
Sen. Miller, Zell [D-GA]	D · GA		Jan 7, 2003
Sen. Nelson, Bill [D-FL]	D · FL		Jan 7, 2003
Sen. Pryor, Mark L. [D-AR]	D · AR		Jan 7, 2003
Sen. Reed, Jack [D-RI]	D · RI		Jan 7, 2003
Sen. Rockefeller, John D., IV [D-WV]	D · WV		Jan 7, 2003
Sen. Stabenow, Debbie [D-MI]	D · MI		Jan 7, 2003
Sen. Landrieu, Mary L. [D-LA]	D · LA		Jan 21, 2003
Sen. Bingaman, Jeff [D-NM]	D · NM		Feb 25, 2003
Sen. Dayton, Mark [D-MN]	D · MN		Mar 12, 2003

## Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions 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)

Greater Access to Affordable Pharmaceuticals Act of 2003 - 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.

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.

## Actions Timeline

- **Jan 7, 2003:** Introduced in Senate
- **Jan 7, 2003:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (text of measure as introduced: CR S55-58)