

S 2818

Timely Review and Increased Access to Affordable Drugs Act

Congress: 107 (2001–2003, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Jul 29, 2002

Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Jul 29, 2002)

Official Text: <https://www.congress.gov/bill/107th-congress/senate-bill/2818>

Sponsor

Name: Sen. Gregg, Judd [R-NH]

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

Cosponsors

No cosponsors are listed for this bill.

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Jul 29, 2002

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Timely Review and Increased Access to Affordable Drugs Act - Amends the Federal Food, Drug, and Cosmetic Act to revise provisions concerning the timing of generic drug availability.

Prohibits (for subsequently issued patents) an extension of the 30 month stay of Food and Drug Administration (FDA) approval for any new drug where an abbreviated new drug application (ANDA) 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.

Requires the first generic applicant (ANDA) 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 delay or prevent the marketing of the generic drug, including failure to market and agreements with the patent holder which violate the antitrust laws.

Continues current regulations concerning bioequivalence.

States that drugs which no longer require a prescription (over-the-counter) but that are sold as if they did are deemed misbranded (mislabeled and subject to seizure).

Actions Timeline

- **Jul 29, 2002:** Introduced in Senate
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