

S 2996

PATH Act

Congress: 113 (2013–2015, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Dec 10, 2014

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. (Dec 10, 2014)

Official Text: <https://www.congress.gov/bill/113th-congress/senate-bill/2996>

Sponsor

Name: Sen. Bennet, Michael F. [D-CO]

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

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Hatch, Orrin G. [R-UT]	R · UT		Dec 10, 2014

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Dec 10, 2014

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Promise for Antibiotics and Therapeutics for Health Act or the PATH Act - Amends the Federal Food, Drug, and Cosmetic Act to require the Department of Health and Human Services (HHS) to establish a program to approve an antibacterial drug intended to treat a serious medical condition and address an unmet medical need within an identifiable limited population as a limited population antibacterial drug.

Requires the sponsor of a drug eligible for approval as a limited population antibacterial drug to demonstrate the safety and effectiveness of the drug for its intended use.

Requires an HHS determination of the safety and effectiveness of a limited population antibacterial drug to reflect the drug's benefit-risk profile in the intended limited population. Prohibits a lack of evidence of a favorable benefit-risk profile in a broader population from resulting in a denial of approval.

Directs HHS to require: (1) the labeling of a limited population antibacterial drug to indicate that the drug has been approved for use only in a limited population, and (2) submission of promotional materials related to the drug prior to dissemination.

Directs HHS to describe considerations for demonstrating the safety and effectiveness of limited population antibacterial drugs and how the limited population pathway can be expanded to other therapeutic areas.

Requires HHS to conduct postapproval monitoring programs to study how antibacterial drugs approved through the limited population pathway are used and to monitor changes in bacterial drug resistance.

Allows HHS to remove the labeling, marketing, and postapproval monitoring requirements of a limited population antibacterial drug if the drug is approved for broader use.

Allows the limited population pathway to be expanded to other drugs intended to treat serious illness beginning October 1, 2016.

Actions Timeline

- **Dec 10, 2014:** Introduced in Senate
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