S 185

PATH Act

Congress: 114 (2015–2017, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Jan 16, 2015
Current Status: Placed on Senate Legislative Calendar under General Orders. Calendar No. 425.
Latest Action: Placed on Senate Legislative Calendar under General Orders. Calendar No. 425. (Apr 18, 2016)
Official Text: https://www.congress.gov/bill/114th-congress/senate-bill/185

Sponsor

Name: Sen. Hatch, Orrin G. [R-UT]
Party: Republican • **State:** UT • **Chamber:** Senate

Cosponsors (6 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Bennet, Michael F. [D-CO]	D · CO		Jan 16, 2015
Sen. Ayotte, Kelly [R-NH]	R · NH		Feb 3, 2015
Sen. Isakson, Johnny [R-GA]	R · GA		Feb 25, 2015
Sen. Kirk, Mark Steven [R-IL]	R · IL		Apr 29, 2015
Sen. Carper, Thomas R. [D-DE]	D · DE		Jul 21, 2015
Sen. Blumenthal, Richard [D-CT]	D · CT		Apr 7, 2016

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Apr 18, 2016

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Apr 18, 2016)

Promise for Antibiotics and Therapeutics for Health Act or the PATH Act

(Sec. 2) This bill amends the Public Health Service Act to require the Department of Health and Human Services (HHS) to encourage the health care facilities of the Department of Defense, the Department of Veterans Affairs, and the Indian Health Service to report on antibacterial drug use, bacterial resistance to antibacterial drugs, and antibiotic stewardship programs.

HHS must: (1) annually publish information on antibacterial resistance and antibiotic stewardship; (2) disseminate guidance and materials regarding antibiotic stewardship; (3) continue working with state and local public health departments on antibacterial resistance programs; and (4) collect, evaluate, and publish data from the antibiotic stewardship activities of health care facilities.

(Sec. 3) This bill amends the Federal Food, Drug, and Cosmetic Act to permit the Food and Drug Administration (FDA), at the request of the drug sponsor, to approve an antibiotic drug for use in a limited population if the drug is intended to treat a serious infection in a limited population of patients with unmet medical needs. The FDA must issue guidance on demonstrating the safety and effectiveness of such drugs. The FDA's determination of the safety and effectiveness of such a drug must reflect the drug's use in the intended limited population.

The label and prescribing information of such a drug must indicate that the drug has been approved for use only in a limited population. The sponsor of such a drug must submit promotional materials for the drug to the FDA prior to dissemination. The FDA may remove these requirements for such a drug that is approved for broader use.
The FDA must report the number of requests for approval and the number of approvals of such drugs. The Government Accountability Office must report on activities to combat antimicrobial resistance and the limited population drug approval process established by this bill.

Actions Timeline

- **Apr 18, 2016:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Alexander with an amendment in the nature of a substitute. Without written report.
- **Apr 18, 2016:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 425.
- **Apr 6, 2016:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Jan 16, 2015:** Introduced in Senate
- **Jan 16, 2015:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.