

## S 1597

### Patient-Focused Impact Assessment Act of 2016

**Congress:** 114 (2015–2017, Ended)

**Chamber:** Senate

**Policy Area:** Health

**Introduced:** Jun 17, 2015

**Current Status:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 413.

**Latest Action:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 413. (Apr 5, 2016)

**Official Text:** <https://www.congress.gov/bill/114th-congress/senate-bill/1597>

## Sponsor

**Name:** Sen. Wicker, Roger F. [R-MS]

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

## Cosponsors (8 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Bennet, Michael F. [D-CO]	D · CO		Jun 17, 2015
Sen. Collins, Susan M. [R-ME]	R · ME		Jun 17, 2015
Sen. Franken, Al [D-MN]	D · MN		Jun 17, 2015
Sen. Isakson, Johnny [R-GA]	R · GA		Jun 17, 2015
Sen. Klobuchar, Amy [D-MN]	D · MN		Jun 17, 2015
Sen. Donnelly, Joe [D-IN]	D · IN		Oct 26, 2015
Sen. Cotton, Tom [R-AR]	R · AR		Feb 29, 2016
Sen. Murkowski, Lisa [R-AK]	R · AK		Mar 9, 2016

## Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Apr 5, 2016

## Subjects & Policy Tags

### Policy Area:

Health

## Related Bills

No related bills are listed.

## Patient-Focused Impact Assessment Act of 2016

(Sec. 2) This bill amends the Federal Food, Drug, and Cosmetic Act to require the Food and Drug Administration (FDA), after approving an application for a new medication, to publish a brief statement on any patient experience data or related information that was part of the application. Patient experience data is information about the impact of a medical condition or a related therapy on a patient's life and the patient's preferences for treatment.

(Sec. 3) The FDA must issue guidance on the collection of patient experience data and the use of that data in drug development.

(Sec. 4) The Paperwork Reduction Act does not apply to voluntary collection of patient experience data.

(Sec. 5) The FDA must report on its review of patient experience data as part of approving applications for new medications.

## Actions Timeline

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- **Apr 5, 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 5, 2016:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 413.
- **Mar 9, 2016:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Jun 17, 2015:** Introduced in Senate
- **Jun 17, 2015:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.