

115TH CONGRESS  
1ST SESSION

# S. 1052

To strengthen the use of patient-experience data within the benefit-risk framework for approval of new drugs.

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IN THE SENATE OF THE UNITED STATES

MAY 4, 2017

Mr. WICKER (for himself and Ms. KLOBUCHAR) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To strengthen the use of patient-experience data within the benefit-risk framework for approval of new drugs.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Better Empowerment  
5 Now to Enhance Framework and Improve Treatments Act  
6 of 2017” or the “BENEFIT Act of 2017”.

7 **SEC. 2. STRENGTHENING THE USE PATIENT-EXPERIENCE**  
8 **DATA WITHIN BENEFIT-RISK FRAMEWORK.**

9 Section 569C of the Federal Food, Drug, and Cos-  
10 metic Act (21 U.S.C. 360bbb–8c) is amended—

1 (1) in subsection (a)(1)—

2 (A) in subparagraph (A), by striking “;  
3 and” and inserting a semicolon;

4 (B) in subparagraph (B), by striking the  
5 period and inserting “; and”; and

6 (C) by adding at the end the following:

7 “(C) as part of the risk-benefit assessment  
8 framework in the new drug approval process de-  
9 scribed in section 505(d), considering relevant  
10 patient-focused drug development data, such as  
11 data from patient preference studies (benefit-  
12 risk), patient reported outcome data, or patient  
13 experience data, developed by the sponsor of an  
14 application or another party.”; and

15 (2) in subsection (b)(1). by inserting “, includ-  
16 ing a description of how such data and information  
17 were considered in the risk benefit assessment de-  
18 scribed in section 505(d)” before the period.

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