

115TH CONGRESS
1ST SESSION

S. 1052

AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

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

5 **SEC. 2. STRENGTHENING THE USE PATIENT-EXPERIENCE**
6 **DATA WITHIN BENEFIT-RISK FRAMEWORK.**

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

9 (1) in subsection (a)(1)—

10 (A) in subparagraph (A), by striking “;
11 and” and inserting a semicolon;

12 (B) in subparagraph (B), by striking the
13 period and inserting “; and”; and

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

15 “(C) as part of the risk-benefit assessment
16 framework in the new drug approval process de-
17 scribed in section 505(d), considering relevant
18 patient-focused drug development data, such as
19 data from patient preference studies (benefit-
20 risk), patient reported outcome data, or patient
21 experience data, developed by the sponsor of an
22 application or another party.”; and

23 (2) in subsection (b)(1). by inserting “, includ-
24 ing a description of how such data and information

- 1 were considered in the risk benefit assessment de-
- 2 scribed in section 505(d)” before the period.

Passed the Senate August 3, 2017.

Attest:

Secretary.

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