

117TH CONGRESS
1ST SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

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

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 2021” or the “BENEFIT Act of 2021”.

1 **SEC. 2. STRENGTHENING THE USE OF PATIENT-EXPERI-**
2 **ENCE DATA WITHIN BENEFIT-RISK FRAME-**
3 **WORK.**

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

6 (1) in subsection (a)(1)—

7 (A) in subparagraph (A), by striking “;
8 and” and inserting a semicolon;

9 (B) in subparagraph (B), by striking the
10 period and inserting “; and”; and

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

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

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