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

IN THE HOUSE OF REPRESENTATIVES

Ms. Matsui introduced the following bill; which was 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”.
SEC. 2. STRENGTHENING THE USE PATIENT-EXPERIENCE DATA WITHIN BENEFIT-RISK FRAMEWORK.

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

(1) in subsection (a)(1)—

(A) in subparagraph (A), by striking ‘‘; and’’ and inserting a semicolon;

(B) in subparagraph (B), by striking the period and inserting ‘‘; and’’; and

(C) by adding at the end the following:

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

(2) in subsection (b)(1), by inserting ‘‘, including a description of how such data and information were considered in the risk-benefit assessment described in section 505(d)” before the period.