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(Original Signature of Member)

117TH CONGRESS
1ST SESSION

H. R. _____

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Better Empowerment Now to Enhance Framework and Improve Treatments Act 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.