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(Original Signature of Member)

118TH 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 2023'' or the ''BENEFIT Act of 2023''.

SEC. 2. STRENGTHENING THE USE OF PATIENT-EXPERIENCE DATA WITHIN RISK-BENEFIT 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 patient experience data submitted by the medical product sponsor 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 at the end.