Union Calendar No.

116TH CONGRESS
2D SESSION

H. R. 2117

[Report No. 116–]

To improve the health and safety of Americans living with food allergies and related disorders, including potentially life-threatening anaphylaxis, food protein-induced enterocolitis syndrome, and eosinophilic gastrointestinal diseases, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 8, 2019

Ms. MATSUI introduced the following bill; which was referred to the Committee on Energy and Commerce

JULY --, 2020

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on April 8, 2019]

A BILL

To improve the health and safety of Americans living with food allergies and related disorders, including potentially life-threatening anaphylaxis, food protein-induced enterocolitis syndrome, and eosinophilic gastrointestinal diseases, and for other purposes.

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 "Food Allergy Safety, Treatment, Education, and Research Act of 2020" or the "FASTER Act of 2020".

SEC. 2. FOOD ALLERGY SAFETY RECOMMENDATIONS OF THE NATIONAL ACADEMY OF MEDICINE.

(a) COLLECTION OF FOOD ALLERGY DATA.—The Public Health Service Act is amended by inserting before section 318 of such Act (42 U.S.C. 247c) the following new section:

"SEC. 317W. COLLECTION OF FOOD ALLERGY DATA.

"(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

"(1) expand and intensify the collection of information on the prevalence of food allergies for specific allergens in the United States, such as through the National Health and Nutrition Examination Survey and the National Health Interview Survey;

"(2) include such information within annual or other periodic reporting to the Congress and the public on other surveillance activities; and

"(3) encourage research to improve the accuracy of food allergy prevalence data.

"(b) BIOMARKERS.—Any research conducted pursuant to subsection (a)(3) shall include—

"(1) the identification of biomarkers and tests to validate data generated from such research; and

"(2) the investigation of the use of identified biomarkers and tests in national surveys conducted as part of that research.".

(b) ALLERGEN LABELING.—

(1) MAJOR FOOD ALLERGEN DEFINITION.—

(A) IN GENERAL.—Section 201(qq)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(qq)(1)) is amended by striking "and soybeans" and inserting "soybeans, and sesame".

(B) EFFECTIVE DATE.—The amendment made by subparagraph (A) shall apply with respect to food introduced or delivered for introduction into interstate commerce on or after January 1, 2022.

(2) ADDITIONAL ALLERGENS.—Section 201(qq) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(qq)) is amended by adding at the end the following:

"(3) Any other food ingredient that the Secretary determines by regulation to be a major food allergen, based on the scientific criteria determined by the Secretary (including the prevalence and severity of allergic reactions to the food ingredient) that establish that such food ingredient is an allergen of public health concern.".

(3) TECHNICAL CORRECTIONS.—Section 201(qq)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(qq)(2)) is amended by striking "paragraph" each place it appears and inserting "subparagraph".

SEC. 3. REPORT ON USE BY FDA OF PATIENT EXPERIENCE DATA ON TREATMENTS FOR PATIENTS WITH FOOD ALLERGIES.

Section 3004 of the 21st Century Cures Act (21 U.S.C. 355 note) is amended—

(1) by striking "Not later than" and inserting the following:

"(a) IN GENERAL.—Not later than"; and

(2) by adding at the end the following:

"(b) TREATMENTS FOR PATIENTS WITH FOOD ALLERGIES.—Each report under subsection (a) shall include a synopsis of the use by the Food and Drug Administration in regulatory decisionmaking of patient experience data on

products with an indication for the treatment of a food allergy.".