

Union Calendar No. 479

116TH CONGRESS
2^D SESSION

H. R. 2117

[Report No. 116–581]

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

NOVEMBER 16, 2020

Additional sponsors: Mr. ROSE of New York, Mrs. MURPHY of Florida, Mr. MCHENRY, Miss RICE of New York, Ms. KUSTER of New Hampshire, Mr. KHANNA, Mr. CONNOLLY, Mr. COOPER, Mr. GOTTHEIMER, Mr. BURCHETT, Ms. PINGREE, Mr. RASKIN, Mr. RYAN, Mr. FITZPATRICK, Ms. BARRAGÁN, Mr. LEVIN of California, Mr. KATKO, Mrs. LURIA, Ms. SHERRILL, Mr. SUOZZI, Mr. VAN DREW, Ms. WILD, Mr. STIVERS, Mr. LAMB, Mr. HARDER of California, Ms. SCHAKOWSKY, Mr. BRENDAN F. BOYLE of Pennsylvania, Mr. CLINE, Mr. BRINDISI, Ms. STEFANIK, Mr. HIMES, Ms. DEAN, Ms. BLUNT ROCHESTER, Mr. MCGOVERN, Mr. CUNNINGHAM, Mr. JOYCE of Ohio, Mr. UPTON, Mrs. DINGELL, Mr. POCAN, Mr. COX of California, Ms. SPANBERGER, Mrs. AXNE, Mr. STEIL, Mrs. KIRKPATRICK, Mr. PERLMUTTER, Ms. JACKSON LEE, Mr. NEGUSE, Mr. LIPINSKI, Mr. MALINOWSKI, Mrs. HAYES, Ms. VELÁZQUEZ, Mr. GALLAGHER, Mr. REED, Mr. PETERS, Mr. CARBAJAL, Mr. O'HALLERAN, Mr. NADLER, Ms. TORRES SMALL of New Mexico, Mr. MCADAMS, Ms. STEVENS, Mrs. CAROLYN B. MALONEY of New York, Mr. SCHNEIDER, Mr. NORCROSS, Mr. CISNEROS, Ms. NORTON, Mr. DELGADO, Mr. PANETTA, Mr. RIGGLEMAN, Mr. STAUBER, Mr. LANGEVIN, Mr. AMODEI, Mr. JOHNSON of South Dakota, Mr. JOHNSON of Ohio, Mr. CASTEN of Illinois, Mr. BACON, Mrs. TRAHAN, Mr. KEATING, Ms. JAYAPAL, Mr. SEAN PATRICK MALONEY of New York, Mr. HORSFORD, Mrs. BROOKS of Indiana, Mr. MITCHELL, Mr. MEUSER, Mr.

GONZALEZ of Ohio, Mr. HURD of Texas, Mr. THOMPSON of Pennsylvania, Mr. WITTMAN, Mr. LEVIN of Michigan, Mr. CICILLINE, Ms. BROWNLEY of California, Mr. PAPPAS, Mr. VARGAS, and Mr. TAYLOR

NOVEMBER 16, 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.

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 “Food Allergy Safety,*
5 *Treatment, Education, and Research Act of 2020” or the*
6 *“FASTER Act of 2020”.*

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

9 *(a) COLLECTION OF FOOD ALLERGY DATA.—The Pub-*
10 *lic Health Service Act is amended by inserting before sec-*
11 *tion 318 of such Act (42 U.S.C. 247c) the following new*
12 *section:*

13 **“SEC. 317W. COLLECTION OF FOOD ALLERGY DATA.**

14 *“(a) IN GENERAL.—The Secretary, acting through the*
15 *Director of the Centers for Disease Control and Prevention,*
16 *shall—*

17 *“(1) expand and intensify the collection of infor-*
18 *mation on the prevalence of food allergies for specific*
19 *allergens in the United States, such as through the*
20 *National Health and Nutrition Examination Survey*
21 *and the National Health Interview Survey;*

22 *“(2) include such information within annual or*
23 *other periodic reporting to the Congress and the pub-*
24 *lic on other surveillance activities; and*

1 “(3) encourage research to improve the accuracy
2 of food allergy prevalence data.

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

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

7 “(2) the investigation of the use of identified bio-
8 markers and tests in national surveys conducted as
9 part of that research.”.

10 (b) *ALLERGEN LABELING*.—

11 (1) *MAJOR FOOD ALLERGEN DEFINITION*.—

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

16 (B) *EFFECTIVE DATE*.—The amendment
17 made by subparagraph (A) shall apply with re-
18 spect to food introduced or delivered for intro-
19 duction into interstate commerce on or after
20 January 1, 2022.

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

1 “(3) Any other food ingredient that the Secretary
2 determines by regulation to be a major food allergen,
3 based on the scientific criteria determined by the Sec-
4 retary (including the prevalence and severity of aller-
5 gic reactions to the food ingredient) that establish that
6 such food ingredient is an allergen of public health
7 concern.”.

8 (3) **TECHNICAL CORRECTIONS.**—Section
9 201(qq)(2) of the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C. 321(qq)(2)) is amended by striking
11 “paragraph” each place it appears and inserting
12 “subparagraph”.

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

16 Section 3004 of the 21st Century Cures Act (21 U.S.C.
17 355 note) is amended—

18 (1) by striking “Not later than” and inserting
19 the following:

20 “(a) **IN GENERAL.**—Not later than”; and

21 (2) by adding at the end the following:

22 “(b) **TREATMENTS FOR PATIENTS WITH FOOD ALLER-**
23 **GIES.**—Each report under subsection (a) shall include a
24 synopsis of the use by the Food and Drug Administration
25 in regulatory decisionmaking of patient experience data on

- 1 *products with an indication for the treatment of a food al-*
- 2 *lergy.”.*

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