

116TH CONGRESS
2^D SESSION

H. R. 2117

IN THE SENATE OF THE UNITED STATES

NOVEMBER 18, 2020

Received; read twice and referred to the Committee on Health, Education,
Labor, and Pensions

AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Food Allergy Safety,
3 Treatment, Education, and Research Act of 2020” or the
4 “FASTER Act of 2020”.

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

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

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

12 “(a) **IN GENERAL.**—The Secretary, acting through
13 the Director of the Centers for Disease Control and Pre-
14 vention, shall—

15 “(1) expand and intensify the collection of in-
16 formation on the prevalence of food allergies for spe-
17 cific allergens in the United States, such as through
18 the National Health and Nutrition Examination
19 Survey and the National Health Interview Survey;

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

23 “(3) encourage research to improve the accu-
24 racy of food allergy prevalence data.

25 “(b) **BIOMARKERS.**—Any research conducted pursu-
26 ant to subsection (a)(3) shall include—

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

3 “(2) the investigation of the use of identified
4 biomarkers and tests in national surveys conducted
5 as part of that research.”.

6 (b) ALLERGEN LABELING.—

7 (1) MAJOR FOOD ALLERGEN DEFINITION.—

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

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

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

22 “(3) Any other food ingredient that the Sec-
23 retary determines by regulation to be a major food
24 allergen, based on the scientific criteria determined
25 by the Secretary (including the prevalence and sever-

1 ity of allergic reactions to the food ingredient) that
2 establish that such food ingredient is an allergen of
3 public health concern.”.

4 (3) TECHNICAL CORRECTIONS.—Section
5 201(qq)(2) of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 321(qq)(2)) is amended by striking
7 “paragraph” each place it appears and inserting
8 “subparagraph”.

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

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

14 (1) by striking “Not later than” and inserting
15 the following:

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

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

18 “(b) TREATMENTS FOR PATIENTS WITH FOOD AL-
19 LERGIES.—Each report under subsection (a) shall include
20 a synopsis of the use by the Food and Drug Administra-
21 tion in regulatory decisionmaking of patient experience

- 1 data on products with an indication for the treatment of
- 2 a food allergy.”.

Passed the House of Representatives November 17,
2020.

Attest: CHERYL L. JOHNSON,
Clerk.