

**AMENDMENT IN THE NATURE OF A SUBSTITUTE  
TO H.R. 2117  
OFFERED BY M . \_\_\_\_\_**

Strike all after the enacting clause and insert the following:

**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 after  
9 section 317T of such Act (42 U.S.C. 247b–22) the fol-  
10 lowing new section:

**11 “SEC. 317U. 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

1 the National Health and Nutrition Examination  
2 Survey and the National Health Interview Survey;

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

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

8 “(b) BIOMARKERS.—Any research conducted pursu-  
9 ant to subsection (a)(3) shall include—

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

12 “(2) the investigation of the use of identified  
13 biomarkers and tests in national surveys conducted  
14 as part of that research.”.

15 (b) ALLERGEN LABELING.—

16 (1) MAJOR FOOD ALLERGEN DEFINITION.—

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

22 (B) EFFECTIVE DATE.—The amendment  
23 made by subparagraph (A) shall apply with re-  
24 spect to food introduced or delivered for intro-

1           duction into interstate commerce on or after  
2           January 1, 2022.

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

7           “(3) Any other food ingredient that the Sec-  
8           retary determines by regulation to be a major food  
9           allergen, based on the scientific criteria determined  
10          by the Secretary (including the prevalence and sever-  
11          ity of allergic reactions to the food ingredient) that  
12          establish that such food ingredient is an allergen of  
13          public health concern.”.

14          (3) **TECHNICAL CORRECTIONS.**—Section  
15          201(qq)(2) of the Federal Food, Drug, and Cosmetic  
16          Act (21 U.S.C. 321(qq)(2)) is amended by striking  
17          “paragraph” each place it appears and inserting  
18          “subparagraph”.

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

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

24                  (1) by striking “Not later than” and inserting  
25          the following:

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

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

3 “(b) TREATMENTS FOR PATIENTS WITH FOOD AL-

4 LERGIES.—Each report under subsection (a) shall include

5 a synopsis of the use by the Food and Drug Administra-

6 tion in regulatory decisionmaking of patient experience

7 data on products with an indication for the treatment of

8 a food allergy.”.

