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(Original Signature of Member)

119TH CONGRESS
1ST SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to establish certain labeling requirements for caffeine, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. MENENDEZ introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish certain labeling requirements for caffeine, 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 “Sarah Katz Caffeine
5 Safety Act”.

6 **SEC. 2. CAFFEINE LABELING REQUIREMENTS.**

7 (a) INFORMATION REQUIRED TO BE DISCLOSED BY
8 RESTAURANTS AND RETAIL FOOD ESTABLISHMENTS.—

1 (1) IN GENERAL.—Section 403(q)(5)(H) of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 343(q)(5)(H)) is amended—

4 (A) by amending subclause (i) to read as
5 follows:

6 “(i) GENERAL REQUIREMENTS FOR RES-
7 TAURANTS AND SIMILAR RETAIL FOOD ESTABLISH-
8 MENTS.—

9 “(I) STANDARD MENU ITEMS.—Except for
10 food described in subclause (vii), in the case of
11 food that is a standard menu item that is of-
12 fered for sale in a restaurant or similar retail
13 food establishment that is part of a chain with
14 20 or more locations doing business under the
15 same name (regardless of the type of ownership
16 of the locations) and offering for sale substan-
17 tially the same menu items, the restaurant or
18 similar retail food establishment shall disclose
19 the information described in subclauses (ii) and
20 (iii).

21 “(II) TEMPORARY MENU ITEMS.—

22 “(aa) IN GENERAL.—In the case of
23 food that is a temporary menu item that is
24 offered for sale in a restaurant or similar
25 retail food establishment that is part of a

1 chain with 20 or more locations doing busi-
2 ness under the same name (regardless of
3 the type of ownership of the locations) and
4 offering for sale substantially the same
5 menu items, the restaurant or similar re-
6 tail food establishment shall disclose the
7 information described in subclause (ii)(III).

8 “(bb) TEMPORARY MENU ITEM DE-
9 FINED.—In this item, the term ‘temporary
10 menu item’ means a food that appears on
11 a menu or menu board for less than a total
12 of 60 days per calendar year. The 60 days
13 includes the total of consecutive and non-
14 consecutive days the item appears on the
15 menu.”;

16 (B) in subclause (ii)—

17 (i) by redesignating items (III) and
18 (IV) as items (IV) and (V), respectively,
19 and moving the margins of such items 2
20 ems to the right;

21 (ii) by inserting after item (II) the fol-
22 lowing:

23 “(III) in the case of a standard menu item
24 or temporary menu item that contains any
25 added caffeine (as the Secretary shall by regu-

1 lation define) and at least 150 milligrams of
2 total caffeine per serving, the statement ‘High
3 caffeine’, or such other similar statement or
4 symbol as the Secretary determines appropriate,
5 adjacent to the name of the standard menu
6 item or temporary menu item, so as to be clear-
7 ly associated with such menu item, on the menu
8 listing the item for sale and on the menu board,
9 including a drive through menu board;” and

10 (iii) in item (IV) (as so redesignated),
11 by inserting before the semicolon the fol-
12 lowing: “and the number of milligrams of
13 caffeine in the item”; and

14 (C) in subclause (vii)(I), by striking “Sub-
15 clauses (i) through (vi)” and inserting “Subject
16 to subclause (i)(II), subclauses (i) through
17 (vi)”.

18 (2) CONFORMING AMENDMENTS.—Section
19 403(q)(5) of the Federal Food, Drug, and Cosmetic
20 Act (21 U.S.C. 343(q)(5)) is amended—

21 (A) in clause (A)—

22 (i) in subclause (i), by striking
23 “clause (H)(ii)(III)” and inserting “clause
24 (H)(ii)(IV)”; and

1 (ii) in subclause (ii), by striking
2 “clause (H)(ii)(III)” and inserting “clause
3 (H)(ii)(IV)”;
4 and
5 (B) in clause (H)—

6 (i) in subclause (ii)(V) (as redesign-
7 nated by subsection (a)(1)(B)(i) of this
8 section), by striking “item (III)” and in-
9 serting “item (IV)”;

10 (ii) in subclause (vi), by striking “sub-
11 clause (ii)(III)” each place it appears and
12 inserting “subclause (ii)(IV)”;

13 (iii) in subclause (vii)(II), by striking
14 “subclauses (ii)(III) and (vi)” and insert-
15 ing “subclauses (ii)(IV) and (vi)”.

16 (b) CAFFEINE LABELING REQUIREMENTS FOR FOOD
17 AND DIETARY SUPPLEMENTS.—Section 403 of the Fed-
18 eral Food, Drug, and Cosmetic Act (21 U.S.C. 343) is
19 amended by adding at the end the following:

20 “(z) If it is a food (including a dietary supplement)
21 that contains more than 10 milligrams of caffeine, unless
22 the label of such food includes—

23 “(1) the number of milligrams of caffeine in the
24 food;

25 “(2) a statement of whether the caffeine in the
food is naturally occurring or an additive; and

1 “(3) an advisory statement indicating that the
2 daily recommended limit of caffeine for healthy
3 adults is 400 milligrams (or such other limit as the
4 Secretary determines appropriate).”.

5 **SEC. 3. FDA AND NIH REVIEWS OF SAFETY OF CAFFEINE.**

6 (a) FDA REVIEW OF CAFFEINE AS GRAS.—

7 (1) IN GENERAL.—The Secretary of Health and
8 Human Services, acting through the Commissioner
9 of Food and Drugs, (in this subsection referred to
10 as the “Commissioner”) shall conduct a review of
11 the safety of caffeine and other stimulants, as the
12 Commissioner determines appropriate, in food (in-
13 cluding beverages) and dietary supplements.

14 (2) ELEMENTS.—In conducting the review
15 under paragraph (1), the Commissioner shall con-
16 sider the following:

17 (A) Whether caffeine should be considered
18 to be generally recognized to be safe, with re-
19 spect to consumption by healthy populations,
20 under section 201(s) of the Federal Food,
21 Drug, and Cosmetic Act (21 U.S.C. 321(s)).

22 (B) The safety of added caffeine or other
23 stimulants, or a complex blend containing a
24 combination of caffeine and other stimulants, in
25 food and dietary supplements.

1 (C) The safety of guarana, taurine, and
2 similar substances in food and dietary supple-
3 ments with added caffeine.

4 (D) Thresholds for the amount of caffeine,
5 or the amount of a complex blend containing a
6 combination of caffeine and other stimulants,
7 that should be generally recognized as safe
8 when included in food or dietary supplements.

9 (E) Whether any regulations relating to
10 caffeine in food and dietary supplements should
11 be issued or updated.

12 (3) REPORT.—Not later than 6 months after
13 the date of enactment of this Act, the Commissioner
14 shall submit to Congress and make publicly available
15 a report detailing the results of the review under
16 paragraph (1).

17 (4) CONSIDERATION OF RESULTS.—Following
18 the completion of the review under paragraph (1),
19 the Secretary of Health and Human Services—

20 (A) shall, in considering the results of such
21 review, make a determination regarding wheth-
22 er caffeine is generally recognized to be safe,
23 with respect to consumption by healthy popu-
24 lations, under section 201(s) of the Federal

1 Food, Drug, and Cosmetic Act (21 U.S.C.
2 321(s)); and

3 (B) may consider the results of such re-
4 view in making a determination pursuant to
5 paragraph (q)(5)(H)(ii)(III) or (z)(3) of section
6 403 of the Federal Food, Drug, and Cosmetic
7 Act (21 U.S.C. 343) (as inserted by subsection
8 (a)(1)(B)(ii), and added by subsection (b), of
9 section 2 of this Act).

10 (b) NIH REVIEW OF CAFFEINE IN VULNERABLE
11 POPULATIONS.—

12 (1) IN GENERAL.—The Secretary of Health and
13 Human Services, acting through the Director of the
14 National Institutes of Health, (in this subsection re-
15 ferred to as the “Director”) shall conduct or support
16 a review of the effect of the consumption of caffeine
17 and other stimulants, as the Director determines ap-
18 propriate, on the vulnerable populations described in
19 paragraph (2). The Director may enter into a con-
20 tract with an appropriate entity under which such
21 entity will conduct such review.

22 (2) VULNERABLE POPULATIONS.—The “vulner-
23 able populations” described in this paragraph are
24 the following:

25 (A) Children and adolescents.

1 (B) Individuals with underlying heart con-
2 ditions.

3 (C) Pregnant and breast-feeding women.

4 (D) Individuals with seizure disorders.

5 (E) Individuals with mental health condi-
6 tions that may be worsened by stimulants.

7 (F) Caffeine-sensitive individuals.

8 (G) Such other individuals as the Director
9 determines appropriate.

10 (3) REPORT.—Not later than 6 months after
11 the date of enactment of this Act, the Director shall
12 submit to Congress and make publicly available a re-
13 port detailing the results of the review under para-
14 graph (1).

15 (c) AUTHORIZATION OF APPROPRIATIONS.—There is
16 authorized to be appropriated—

17 (1) \$1,000,000 for the purpose of carrying out
18 subsection (a); and

19 (2) \$1,000,000 for the purpose of carrying out
20 subsection (b).

21 **SEC. 4. PUBLIC EDUCATION CAMPAIGN ON CAFFEINE SAFE-**
22 **TY.**

23 The Secretary of Health and Human Services, acting
24 through the Commissioner of Food and Drugs, in con-
25 sultation with the Director of the Centers for Disease Con-

1 trol and Prevention, and working with consumer advocacy
2 and patient groups, shall conduct a public education cam-
3 paign on the safe consumption of caffeine and caffeinated
4 food (including beverages) and dietary supplements. Such
5 campaign shall pay special attention to the following:

6 (1) The dangers of the overconsumption of caf-
7 feine.

8 (2) The health impacts caffeine can have on
9 certain vulnerable populations, including—

10 (A) children and adolescents;

11 (B) individuals with underlying heart con-
12 ditions;

13 (C) pregnant and breast-feeding women;

14 (D) individuals with seizure disorders;

15 (E) individuals with mental health condi-
16 tions that may be worsened by stimulants; and

17 (F) caffeine-sensitive individuals.

18 (3) How caffeine is marketed to children and
19 adolescents.

20 (4) How guarana, taurine, and similar sub-
21 stances impact safety.

22 (5) How to safely consume caffeine.

1 **SEC. 5. GAO STUDY AND REPORT ON MARKETING OF**
2 **CAFFEINATED BEVERAGES.**

3 (a) IN GENERAL.—The Comptroller General of the
4 United States shall conduct a study on the marketing of
5 caffeinated beverages in restaurants, in stores, and online
6 (including on social media and by social media
7 influencers). In conducting such study, the Comptroller
8 General shall focus on—

9 (1) ways in which the marketing of caffeinated
10 beverages (including to children and adults) may be
11 misleading; and

12 (2) how the marketing of such caffeinated bev-
13 erages is targeted at children and teens.

14 (b) REPORT.—Not later than 180 days after the date
15 of enactment of this Act, the Comptroller General of the
16 United States shall submit to Congress a report describing
17 the results of the study conducted under subsection (a),
18 including any recommendations for legislative or adminis-
19 trative action to address the misleading marketing of
20 caffeinated beverages or the targeted marketing of such
21 beverages to children and teens.