

111TH CONGRESS
1ST SESSION

H. R. 3395

To amend the Federal Food, Drug, and Cosmetic Act concerning claims about the effects of foods and dietary supplements on health-related conditions and disease, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 29, 2009

Mr. PAUL (for himself and Mr. BURTON of Indiana) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act concerning claims about the effects of foods and dietary supplements on health-related conditions and disease, 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 “Health Freedom Act”.

1 **SEC. 2. LIMITATION ON SUPPRESSION BY FEDERAL GOV-**
2 **ERNMENT OF CLAIMS IN FOOD AND DIETARY**
3 **SUPPLEMENTS.**

4 The Federal Government may not take any action to
5 prevent use of a claim describing any nutrient in a food
6 or dietary supplement (as such terms are defined in sec-
7 tion 201 of the Federal Food, Drug, and Cosmetic Act
8 (21 U.S.C. 321)) as mitigating, treating, or preventing
9 any disease, disease symptom, or health-related condition,
10 unless in a final order of a Federal court following a trial
11 on the merits finds clear and convincing evidence based
12 on qualified expert opinion and published peer-reviewed
13 scientific research that—

14 (1) the claim is false and misleading in any ma-
15 terial respect; and

16 (2) there is no less speech restrictive alternative
17 to claim suppression, such as use of disclaimers or
18 qualifications, that can render the claim non-mis-
19 leading.

20 **SEC. 3. DEFINITION OF DRUG.**

21 (a) IN GENERAL.—Subparagraph (1) of section
22 201(g) of the Federal Food, Drug, and Cosmetic Act (21
23 U.S.C. 321(g)) is amended by striking the second and
24 third sentences and inserting the following: “A food or die-
25 tary supplement for which a claim is made in accordance

1 with section 403(r)(1)(B) is not a drug solely because of
2 such claim.”.

3 (b) RULES.—All rules of the Food and Drug Admin-
4 istration in existence on the date of the enactment of this
5 Act prohibiting nutrient-disease relationship claims are re-
6 voked.

7 **SEC. 4. MISBRANDED FOOD.**

8 Section 403(r) of the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 343(r)) is amended—

10 (1) by striking clause (B) of subparagraph (1)
11 and inserting the following:

12 “(B) describes any nutrient as mitigating,
13 treating, or preventing any disease, disease symp-
14 tom, or health-related condition if, and only if, the
15 claim has been adjudicated false and misleading in
16 any material respect by final order of a Federal
17 court of competent jurisdiction in accordance with
18 section 2 of the Health Freedom Protection Act.”;

19 (2) by striking subparagraph (3);

20 (3) in the first sentence of subparagraph
21 (4)(A)(i)—

22 (A) by striking “or (3)(B)”; and

23 (B) by striking “or (1)(B)”;

24 (4) by striking clause (C) of subparagraph (4);

1 (5) by striking clause (D) of subparagraph (5);
2 and
3 (6) in subparagraph (6), by striking the second
4 sentence.

5 **SEC. 5. DIETARY SUPPLEMENT LABELING EXEMPTIONS.**

6 Section 403B of the Federal Food, Drug, and Cos-
7 metic Act (21 U.S.C. 343–2) is amended to read as fol-
8 lows:

9 “FOOD AND DIETARY SUPPLEMENT LABELING
10 “SEC. 403B. The Federal Government shall take no
11 action to prevent distribution of any publication in connec-
12 tion with the sale of a food or dietary supplement to con-
13 sumers unless it establishes that a claim contained in the
14 publication—

15 “(1) names the specific food or dietary supple-
16 ment sold by the person causing the publication to
17 be distributed;

18 “(2) represents that the specific food or dietary
19 supplement mitigates, treats, or prevents a disease;
20 and

21 “(3) proves the claim to be false and misleading
22 in any material respect by final order of a Federal
23 court of competent jurisdiction in accordance with
24 section 2 of the Health Freedom Protection Act.”.

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