

112TH CONGRESS
1ST SESSION

H. R. 2044

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

MAY 26, 2011

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

14 (1) the claim is false and misleading in a mate-
15 rial 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 (b) DEFINITION.—In this section, the term “mate-
21 rial” means that the Food and Drug Administration has
22 identified a competent consumer survey demonstrating
23 that consumers decided to purchase the food or dietary
24 supplement based on the portion of the claim alleged to
25 be false or misleading.

1 **SEC. 3. DEFINITION OF DRUG.**

2 (a) IN GENERAL.—Subparagraph (1) of section
3 201(g) of the Federal Food, Drug, and Cosmetic Act (21
4 U.S.C. 321(g)) is amended by striking the second and
5 third sentences and inserting the following: “A food or die-
6 tary supplement for which a claim is made in accordance
7 with section 403(r)(1)(B) is not a drug solely because of
8 such claim.”.

9 (b) RULES.—All rules of the Food and Drug Admin-
10 istration in existence on the date of the enactment of this
11 Act prohibiting nutrient-disease relationship claims are re-
12 voked.

13 **SEC. 4. MISBRANDED FOOD.**

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

16 (1) by striking clause (B) of subparagraph (1)
17 and inserting the following:

18 “(B) describes any nutrient as mitigating,
19 treating, or preventing any disease, disease symp-
20 tom, or health-related condition if, and only if, the
21 claim has been adjudicated false and misleading in
22 a material respect by final order of a Federal court
23 of competent jurisdiction in accordance with section
24 2 of the Health Freedom Act.”;

25 (2) by striking subparagraph (3);

1 (3) in the first sentence of subparagraph
2 (4)(A)(i)—
3 (A) by striking “or (3)(B)”; and
4 (B) by striking “or (1)(B)”;
5 (4) by striking clause (C) of subparagraph (4);
6 (5) by striking clause (D) of subparagraph (5);
7 and
8 (6) in subparagraph (6), in the matter following
9 clause (C), by striking the first sentence.

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

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

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

20 “(1) names the specific food or dietary supple-
21 ment sold by the person causing the publication to
22 be distributed;

23 “(2) represents that the specific food or dietary
24 supplement mitigates, treats, or prevents a disease;
25 and

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

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