

109<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 2352

To amend the Federal Food, Drug, and Cosmetic Act to ensure that health claims for foods and dietary supplements include accurate statements of the curative, mitigation, treatment, and prevention effects of nutrients on disease or health-related conditions, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 12, 2005

Mr. PAUL introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to ensure that health claims for foods and dietary supplements include accurate statements of the curative, mitigation, treatment, and prevention effects of nutrients on disease or health-related conditions, 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 “Consumers’ Access to  
5 Health Information Act”.

1 **SEC. 2. FINDINGS.**

2 The Congress finds as follows:

3 (1) When the Congress included health claims  
4 provisions in the Nutrition Labeling and Education  
5 Act of 1990, amending the Federal Food, Drug, and  
6 Cosmetic Act (“FDCA” or “Act”), the Congress in-  
7 tended for those provisions to permit use of accurate  
8 label and labeling claims of the curative, mitigation,  
9 treatment, and prevention effects of foods and die-  
10 tary supplements on disease and health-related con-  
11 ditions.

12 (2) In the 2004 decision, *Whitaker v. Thomp-*  
13 *son*, 353 F.3d 947 (2004), rehearing den. 2004 U.S.  
14 App. LEXIS 4617 (D.C. Cir. March 9, 2004), the  
15 United States Court of Appeals for the D.C. Circuit  
16 erroneously construed the health claims provisions of  
17 the FDCA to prohibit accurate curative, mitigation,  
18 and treatment health claims.

19 (3) The health claims provisions of the Act  
20 should be amended to clarify their meaning and en-  
21 sure that accurate health claims are not suppressed;  
22 that consumers are given truthful and full informa-  
23 tion about the disease curative, mitigation, treat-  
24 ment, and prevention effects of foods and dietary  
25 supplements; that the intent of the Congress is hon-  
26 ored; and that the erroneous construction of the

1 health claims provisions of the Act by the United  
2 States Court of Appeals for the D.C. Circuit in such  
3 2004 decision does not remain the law.

4 **SEC. 3. HEALTH CLAIMS; EXCEPTION FROM DRUG DEFINI-**  
5 **TION.**

6 (a) HEALTH CLAIMS.—The Federal Food, Drug, and  
7 Cosmetic Act is amended—

8 (1) in section 403(r)(1)(B) (21 U.S.C.  
9 343(r)(1)(B))—

10 (A) by striking “the relationship of any  
11 nutrient which” and inserting “the curative,  
12 mitigation, treatment, or prevention effect of  
13 any nutrient (which ”; and

14 (B) by striking “the food to a disease or  
15 a health-related condition” and inserting “the  
16 food) on any disease or health-related condi-  
17 tion”; and

18 (2) in section 403(r)(3)(B)(ii)(I) (21 U.S.C.  
19 343(r)(3)(B)(ii)(I))—

20 (A) by striking “the relationship between a  
21 nutrient” and inserting “the curative, mitiga-  
22 tion, treatment, or prevention effect of a nutri-  
23 ent”; and

24 (B) by striking “and a disease” and insert-  
25 ing “on any disease”.

1 (b) EXCEPTION FROM DRUG DEFINITION.—Section  
2 201(g)(1) of the Federal Food, Drug, and Cosmetic Act  
3 (21 U.S.C. 321(g)(1)) is amended by striking the second  
4 and third sentences and inserting the following: “A claim  
5 on the label or in the labeling of a food or dietary supple-  
6 ment, subject to sections 403(r)(1)(B) and 403(r)(3) or  
7 sections 403(r)(1)(B) and 403(r)(5)(D), made in accord-  
8 ance with the requirements of section 403(r), shall not  
9 cause the food or dietary supplement to be a drug. A  
10 truthful and not misleading statement on the label or in  
11 the labeling of a food or a dietary supplement made in  
12 accordance with section 403(r)(6) shall not cause the food  
13 or dietary supplement to be a drug.”.

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