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109TH CONGRESS
1ST 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.

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Consumers' Access to Health Information Act''.

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) When the Congress included health claims provisions in the Nutrition Labeling and Education Act of 1990, amending the Federal Food, Drug, and Cosmetic Act (''FDCA'' or ''Act''), the Congress intended for those provisions to permit use of accurate label and labeling claims of the curative, mitigation, treatment, and prevention effects of foods and dietary supplements on disease and health-related conditions.

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

(3) The health claims provisions of the Act should be amended to clarify their meaning and ensure that accurate health claims are not suppressed; that consumers are given truthful and full information about the disease curative, mitigation, treatment, and prevention effects of foods and dietary supplements; that the intent of the Congress is honored; and that the erroneous construction of the

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

SEC. 3. HEALTH CLAIMS; EXCEPTION FROM DRUG DEFINITION.

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

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

(A) by striking ''the relationship of any nutrient which'' and inserting ''the curative, mitigation, treatment, or prevention effect of any nutrient (which ''; and

(B) by striking ''the food to a disease or a health-related condition'' and inserting ''the food) on any disease or health-related condition''; and

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

(A) by striking ''the relationship between a nutrient'' and inserting ''the curative, mitigation, treatment, or prevention effect of a nutrient''; and

(B) by striking ''and a disease'' and inserting ''on any disease''.

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

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