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110TH CONGRESS
1ST SESSION

H. R. 2117

To amend the Federal Food, Drug, and Cosmetic Act concerning foods and dietary supplements, to amend the Federal Trade Commission Act concerning the burden of proof in false advertising cases, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 2, 2007

Mr. PAUL (for himself, Mr. BURTON of Indiana, Mr. SHAYS, Mr. BARTLETT of Maryland, and Mr. DUNCAN) 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 concerning foods and dietary supplements, to amend the Federal Trade Commission Act concerning the burden of proof in false advertising cases, 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 ''Health Freedom Protection Act''.

SEC. 2. DEFINITIONS.

The second sentence of subparagraph (1) of section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)) is amended by inserting ''including a claim to cure, mitigate, treat, or prevent disease,'' after ''for which a claim,''.

SEC. 3. MISBRANDED FOOD.

Section 403(r) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)) is amended—

(1) in subparagraph (1)(B), by striking ''to a disease or a health-related condition'' and inserting ''to the cure, mitigation, treatment, or prevention of any disease or any health-related condition'';

(2) in subparagraph (2)—

(A) by amending clause (G) to read as follows:

''(G) Publications of the United States Government shall not be subject to this subparagraph, subparagraph (3), or subparagraph 5(D). The Secretary shall take no action under this Act to restrict, limit, or impede the reprinting and distribution or sale of any publication of the United States Government (including ones published by or at the request of any department, agency, institute, center, or academy and including content characterizing the rela-

tionship of any nutrient to the cure, mitigation, treatment, or prevention of any disease). The Secretary shall not construe the distribution or sale of a publication of the United States Government in connection with the sale of a food or dietary supplement as evidence of an intent to sell that food or dietary supplement as a drug.''; and

(B) by amending clause (H) to read as follows:

''(H) Accurate quotations from a publication of the United States Government referred to in clause (G) shall not be subject to this subparagraph, subparagraph (3), or subparagraph 5(D). The Secretary shall take no action under this Act to restrict, limit, or impede the use of accurate quotations from a United States Government publication that characterize the relationship of any nutrient to the cure, mitigation, treatment, or prevention of any disease. The Secretary shall not construe accurate quotations from a United States Government publication used in connection with the sale of a food or dietary supplement as evidence of an intent to

sell that food or dietary supplement as a drug.'';

(3) in subparagraph (3), by adding at the end the following:

''(E) The Secretary shall allow with reasonable and concise disclaimers not to exceed three sentences claims of the type described in subparagraph (1)(B) not authorized under this subparagraph or subparagraph (5)(D) unless the Secretary determines that—

''(i) there is no scientific evidence that supports the claim; and

''(ii) the claim is inherently misleading and incapable of being rendered nonmisleading through the addition of a disclaimer.

The Secretary shall not use tests of consumer perception of product health benefits as a basis for a determination under subclause (ii). The Secretary shall bear the burden of proof by clear and convincing evidence on each element of this clause.

''(F) The Secretary shall not exclude studies concerning the treatment effects of nutrients on disease from the evaluation of any health

claims under this subparagraph or subparagraph (1)(B) or (5)(D).

''(G) Notwithstanding any other provision of law, a member of an advisory committee under this Act may not, with respect to service on a committee evaluating a claim of the type described in subparagraph (1)(B), be granted an exemption under section 208(b) of title 18, United States Code (relating to personal financial interests).

''(H) Notwithstanding any prior decisions of the Secretary concerning the relationship of saw palmetto to benign prostatic hyperplasia, the relationship of omega-3 fatty acids and coronary heart disease, the relationship of omega-3 fatty acids and sudden death heart attack, the relationship of glucosamine or chondroitin sulfate and osteoarthritis, or the relationship of calcium and bone fractures, the following health claims are authorized for use on labels and in the labeling of all foods and dietary supplements containing those nutrients:

''(i) Saw Palmetto may improve urine flow, reduce nocturia and reduce voiding

urgency associated with mild benign prostatic hyperplasia (an enlarged prostate).

''(ii) Omega-3 Fatty Acids may reduce the risk of coronary heart disease.

''(iii) Omega-3 Fatty Acids may reduce the risk of sudden death heart attack.

''(iv) Glucosamine may reduce joint stiffness and pain associated with osteoarthritis.

''(v) Chondroitin Sulfate may reduce joint stiffness and pain associated with osteoarthritis.

''(vi) Glucosamine and Chondroitin Sulfate may reduce joint stiffness and pain associated with osteoarthritis.

''(vii) Calcium may reduce the risk of bone fractures.'';

(4) in subclause (i) of subparagraph (4)(A)—

(A) in the first sentence, by striking ''or (3)(B)'' and inserting '', (3)(B), or (3)(E)''; and

(B) by striking ''Not later than 100 days'' and all that follows through the end of subclause (i) and inserting ''The Secretary shall promulgate regulations authorizing or denying

claims under subparagraph (3)(B), shall publish notice of claims allowed or disallowed under subparagraph (3)(C) or (3)(E) no later than 100 days after the petition for such claims is received by the Secretary, and shall not seek or grant any extensions of that deadline. Any failure by the Secretary to act within the 100-day period described in the preceding sentence shall result in authorization or allowance, as applicable, of the petitioned claim by operation of law.''; and

(5) in the matter following clause (C) in subparagraph (6), by adding at the end the following ''A statement for a dietary supplement under this subparagraph may include words that are recognized as signs or symptoms of disease or that among their commonly understood meanings imply the cure, mitigation, treatment, or prevention of disease so long as the statement does not include the name of a specific disease and is made in compliance with the requirements of clause (C). A statement for a dietary supplement under this subparagraph may in support of the statement refer to or cite a scientific publication that has a title or contents that include the

name of a specific disease or a sign or symptom of a specific disease.''.

SEC. 4. DIETARY SUPPLEMENT LABELING EXEMPTIONS.

Section 403B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343–2) is amended to read as follows:

''FOOD AND DIETARY SUPPLEMENT LABELING EXEMPTION

''SEC. 403B. A truthful and nonmisleading scientific publication reprinted in its entirety and used in connection with the sale of a food or dietary supplement to consumers shall not be defined as labeling and shall not be deemed evidence of an intent to sell a drug. The Secretary shall not restrict in any way whatsoever the distribution of any publication exempt from labeling under this section.''.

SEC. 5. HEALTH INFORMATION.

Section 5 of the Federal Trade Commission Act (15 U.S.C. 45) is amended by adding at the end the following:

''(o) ADVERTISING OF DIETARY SUPPLEMENTS AND DIETARY INGREDIENTS.—

''(1) DEFINITIONS.—In this subsection:

''(A) DIETARY SUPPLEMENT.—The term 'dietary supplement' has the meaning given to that term in section 201(ff) of the Federal Food, Drug, and Cosmetic Act.

"(B) DIETARY INGREDIENT.—The term 'dietary ingredient' means an ingredient listed in clause (A) through (F) of section 201(ff)(1) of the Federal Food, Drug, and Cosmetic Act that is included in, or that is intended to be included in, a dietary supplement.

"(2) EXEMPTIONS FROM REGULATION AS ADVERTISING.—

"(A) Insofar as a publication is exempt pursuant to Section 403B of the Federal Food, Drug, and Cosmetic Act, the publication is also exempt from regulation as 'advertising' under this Act.

"(B) A truthful and accurate summary of the findings of a peer-reviewed medical, nutritional, or other scientific publication shall not be subject to regulation as 'advertising' under this Act.

"(3) NO IMPLIED CLAIMS.—In any investigation commenced by the Commission and in any adjudicative proceeding in which the Commission is a party, the Commission shall not attribute to an advertiser accused of false advertisement any advertising statement not actually made by that advertiser.

''(4) NOTICE, OPPORTUNITY TO CURE, AND BURDEN OF PROOF FOR INVESTIGATION.—

''(A) Before the Commission authorizes an investigation of false advertisement by an advertiser of a dietary supplement or a dietary ingredient, the Commission shall send the advertiser a written 'Notice of Suspected Violation and Opportunity to Cure' informing the advertiser of—

''(i) the precise advertising statement that the Commission suspects may be false or misleading;

''(ii) the scientific basis for the Commission's view that any statement of health benefit may be false or misleading; and

''(iii) a date certain, not less than 30 days after the date of the advertiser's receipt of the notice, by which the advertiser may voluntarily discontinue further use of the statement the Commission suspects may be false or misleading and, upon so doing, the advertiser shall not be subject to an investigation of false advertisement by the Commission for the statement.

"(B) The Commission shall not commence any investigation of an advertiser of a dietary supplement or a dietary ingredient to determine whether the advertiser has disseminated a false advertisement unless it possesses before the commencement of such investigation proof by a preponderance of the evidence that the advertisement is false and misleading.

"(5) BURDEN OF PROOF FOR FALSE ADVERTISEMENT CASES.—In any proceeding before a Court or the Commission in which an advertiser of a dietary supplement or a dietary ingredient is charged with deceptive advertising, the burden of proof shall be on the Commission to establish that the advertisement is false and misleading and that the advertisement actually causes consumers to be misled into believing to be true that which is demonstrably false. No order adverse to the advertiser shall be entered except upon the Commission satisfying that burden of proof.".

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