

109TH CONGRESS
1ST SESSION

H. R. 4282

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

NOVEMBER 9, 2005

Mr. PAUL (for himself, Mr. JONES of North Carolina, Mr. DUNCAN, Mr. DEFAZIO, Mr. BARTLETT of Maryland, Mr. BURTON of Indiana, Mr. MILLER of Florida, and Mr. BISHOP of Utah) 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 foods and dietary supplements, to amend the Federal Trade Commission Act concerning the burden of proof in false advertising cases, 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 Pro-
5 tection Act”.

1 **SEC. 2. DEFINITIONS.**

2 The second sentence of 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 inserting “including a claim
5 to cure, mitigate, treat, or prevent disease,” after “for
6 which a claim,”.

7 **SEC. 3. 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) in subparagraph (1)(B), by striking “to a
11 disease or a health-related condition” and inserting
12 “to the cure, mitigation, treatment, or prevention of
13 any disease or any health-related condition”;

14 (2) in subparagraph (2)—

15 (A) by amending clause (G) to read as fol-
16 lows:

17 “(G) Publications of the United States
18 Government shall not be subject to this sub-
19 paragraph, subparagraph (3), or subparagraph
20 5(D). The Secretary shall take no action under
21 this Act to restrict, limit, or impede the reprint-
22 ing and distribution or sale of any publication
23 of the United States Government (including
24 ones published by or at the request of any de-
25 partment, agency, institute, center, or academy
26 and including content characterizing the rela-

1 tionship of any nutrient to the cure, mitigation,
2 treatment, or prevention of any disease). The
3 Secretary shall not construe the distribution or
4 sale of a publication of the United States Gov-
5 ernment in connection with the sale of a food
6 or dietary supplement as evidence of an intent
7 to sell that food or dietary supplement as a
8 drug.”; and

9 (B) by amending clause (H) to read as fol-
10 lows:

11 “(H) Accurate quotations from a publica-
12 tion of the United States Government referred
13 to in clause (G) shall not be subject to this sub-
14 paragraph, subparagraph (3), or subparagraph
15 5(D). The Secretary shall take no action under
16 this Act to restrict, limit, or impede the use of
17 accurate quotations from a United States Gov-
18 ernment publication that characterize the rela-
19 tionship of any nutrient to the cure, mitigation,
20 treatment, or prevention of any disease. The
21 Secretary shall not construe accurate quotations
22 from a United States Government publication
23 used in connection with the sale of a food or di-
24 etary supplement as evidence of an intent to

1 sell that food or dietary supplement as a
2 drug.”;

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

5 “(E) The Secretary shall allow with rea-
6 sonable and concise disclaimers not to exceed
7 three sentences claims of the type described in
8 subparagraph (1)(B) not authorized under this
9 subparagraph or subparagraph (5)(D) unless
10 the Secretary determines that—

11 “(i) there is no scientific evidence that
12 supports the claim; and

13 “(ii) the claim is inherently mis-
14 leading and incapable of being rendered
15 nonmisleading through the addition of a
16 disclaimer.

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

23 “(F) The Secretary shall not exclude stud-
24 ies concerning the treatment effects of nutrients
25 on disease from the evaluation of any health

1 claims under this subparagraph or subpara-
2 graph (1)(B) or (5)(D).

3 “(G) Notwithstanding any other provision
4 of law, a member of an advisory committee
5 under this Act may not, with respect to service
6 on a committee evaluating a claim of the type
7 described in subparagraph (1)(B), be granted
8 an exemption under section 208(b) of title 18,
9 United States Code (relating to personal finan-
10 cial interests).

11 “(H) Notwithstanding any prior decisions
12 of the Secretary concerning the relationship of
13 saw palmetto to benign prostatic hyperplasia,
14 the relationship of omega-3 fatty acids and cor-
15 onary heart disease, the relationship of omega-
16 3 fatty acids and sudden death heart attack,
17 the relationship of glucosamine or chondroitin
18 sulfate and osteoarthritis, or the relationship of
19 calcium and bone fractures, the following health
20 claims are authorized for use on labels and in
21 the labeling of all foods and dietary supple-
22 ments containing those nutrients:

23 “(i) Saw Palmetto may improve urine
24 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

1 claims under subparagraph (3)(B), shall publish
2 notice of claims allowed or disallowed under
3 subparagraph (3)(C) or (3)(E) no later than
4 100 days after the petition for such claims is
5 received by the Secretary, and shall not seek or
6 grant any extensions of that deadline. Any fail-
7 ure by the Secretary to act within the 100-day
8 period described in the preceding sentence shall
9 result in authorization or allowance, as applica-
10 ble, of the petitioned claim by operation of
11 law.”; and

12 (5) in the matter following clause (C) in sub-
13 paragraph (6), by adding at the end the following
14 “A statement for a dietary supplement under this
15 subparagraph may include words that are recognized
16 as signs or symptoms of disease or that among their
17 commonly understood meanings imply the cure, miti-
18 gation, treatment, or prevention of disease so long as
19 the statement does not include the name of a spe-
20 cific disease and is made in compliance with the re-
21 quirements of clause (C). A statement for a dietary
22 supplement under this subparagraph may in support
23 of the statement refer to or cite a scientific publica-
24 tion that has a title or contents that include the

1 name of a specific disease or a sign or symptom of
2 a specific disease.”.

3 **SEC. 4. DIETARY SUPPLEMENT LABELING EXEMPTIONS.**

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

7 “FOOD AND DIETARY SUPPLEMENT LABELING
8 EXEMPTION

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

16 **SEC. 5. HEALTH INFORMATION.**

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

19 “(o) ADVERTISING OF DIETARY SUPPLEMENTS AND
20 DIETARY INGREDIENTS.—

21 “(1) DEFINITIONS.—In this subsection:

22 “(A) DIETARY SUPPLEMENT.—The term
23 ‘dietary supplement’ has the meaning given to
24 that term in section 201(ff) of the Federal
25 Food, Drug, and Cosmetic Act.

1 “(B) DIETARY INGREDIENT.—The term
2 ‘dietary ingredient’ means an ingredient listed
3 in clause (A) through (F) of section 201(ff)(1)
4 of the Federal Food, Drug, and Cosmetic Act
5 that is included in, or that is intended to be in-
6 cluded in, a dietary supplement.

7 “(2) EXEMPTIONS FROM REGULATION AS AD-
8 VERTISING.—

9 “(A) Insofar as a publication is exempt
10 pursuant to Section 403B of the Federal Food,
11 Drug, and Cosmetic Act, the publication is also
12 exempt from regulation as ‘advertising’ under
13 this Act.

14 “(B) A truthful and accurate summary of
15 the findings of a peer-reviewed medical, nutri-
16 tional, or other scientific publication shall not
17 be subject to regulation as ‘advertising’ under
18 this Act.

19 “(3) NO IMPLIED CLAIMS.—In any investiga-
20 tion commenced by the Commission and in any adju-
21 dicative proceeding in which the Commission is a
22 party, the Commission shall not attribute to an ad-
23 vertiser accused of false advertisement any adver-
24 tising statement not actually made by that adver-
25 tiser.

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

3 “(A) Before the Commission authorizes an
4 investigation of false advertisement by an ad-
5 vertiser of a dietary supplement or a dietary in-
6 gredient, the Commission shall send the adver-
7 tiser a written ‘Notice of Suspected Violation
8 and Opportunity to Cure’ informing the adver-
9 tiser of—

10 “(i) the precise advertising statement
11 that the Commission suspects may be false
12 or misleading;

13 “(ii) the scientific basis for the Com-
14 mission’s view that any statement of health
15 benefit may be false or misleading; and

16 “(iii) a date certain, not less than 30
17 days after the date of the advertiser’s re-
18 ceipt of the notice, by which the advertiser
19 may voluntarily discontinue further use of
20 the statement the Commission suspects
21 may be false or misleading and, upon so
22 doing, the advertiser shall not be subject to
23 an investigation of false advertisement by
24 the Commission for the statement.

1 “(B) The Commission shall not commence
2 any investigation of an advertiser of a dietary
3 supplement or a dietary ingredient to determine
4 whether the advertiser has disseminated a false
5 advertisement unless it possesses before the
6 commencement of such investigation proof by a
7 preponderance of the evidence that the adver-
8 tisement is false and misleading.

9 “(5) BURDEN OF PROOF FOR FALSE ADVER-
10 TISEMENT CASES.—In any proceeding before a
11 Court or the Commission in which an advertiser of
12 a dietary supplement or a dietary ingredient is
13 charged with deceptive advertising, the burden of
14 proof shall be on the Commission to establish that
15 the advertisement is false and misleading and that
16 the advertisement actually causes consumers to be
17 misled into believing to be true that which is demon-
18 strably false. No order adverse to the advertiser
19 shall be entered except upon the Commission satis-
20 fying that burden of proof.”.

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