

106TH CONGRESS
2^D SESSION

H. R. 4604

To amend the Federal Food, Drug, and Cosmetic Act to compel Food and Drug Administration compliance with the first amendment to the United States Constitution and to protect freedom of informed choice in the dietary supplement marketplace consistent with the decision of the United States Court of Appeals for the District of Columbia Circuit in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), reh'g denied en banc, 172 F.3d 72 (D.C. Cir. 1999).

IN THE HOUSE OF REPRESENTATIVES

JUNE 8, 2000

Mrs. CHENOWETH-HAGE (for herself, Mr. PAUL, Mr. STUMP, Mr. MCINTOSH, and Mr. DOOLITTLE) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to compel Food and Drug Administration compliance with the first amendment to the United States Constitution and to protect freedom of informed choice in the dietary supplement marketplace consistent with the decision of the United States Court of Appeals for the District of Columbia Circuit in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), reh'g denied en banc, 172 F.3d 72 (D.C. Cir. 1999).

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE; REFERENCE.**

2 (a) **SHORT TITLE.**—This Act may be cited as the
3 “Consumer Freedom Protection Act”.

4 (b) **REFERENCES.**—Each amendment to or repeal of
5 a section or other provision of law that is made by this
6 Act shall be considered to be an amendment to or repeal
7 of, respectively, that provision of the Federal Food, Drug,
8 and Cosmetic Act (21 U.S.C. 301 et seq.), unless another
9 public law is specified as being the subject of the amend-
10 ment or repeal.

11 **SEC. 2. FINDINGS.**

12 The Congress finds as follows:

13 (1) The Food and Drug Administration has
14 only authorized three health claims for dietary sup-
15 plements since enactment of the Nutrition Labeling
16 and Education Act of 1990 despite the publication
17 of tens of thousands of peer reviewed scientific jour-
18 nal articles on the effect of nutrients on disease and
19 health-related conditions.

20 (2) Scientific information on the nutrient-dis-
21 ease relationship contained in peer reviewed sci-
22 entific journals is indispensable to the exercise of in-
23 formed choice in the food and dietary supplement
24 marketplaces.

25 (3) The Food and Drug Administration’s fail-
26 ure to authorize health claims has violated the first

1 amendment rights of health claimants and American
2 consumers alike and is injurious to public health be-
3 cause it denies consumers access to information nec-
4 essary to exercise informed choice at the point of
5 sale.

6 (4) Contrary to the will of Congress, on re-
7 peated occasions the Food and Drug Administration
8 has denied and suppressed health claims that would
9 otherwise convey to consumers important informa-
10 tion on the association between nutrients and dis-
11 eases.

12 (5) Contrary to the will of Congress, the Food
13 and Drug Administration's treatment of dietary sup-
14 plements and its implementation of the Nutrition
15 Labeling and Education Act of 1990 and the Food
16 and Drug Administration Modernization Act of 1997
17 health claims provisions has hindered, rather than
18 fostered, the dissemination of truthful and nonmis-
19 leading information about the nutrient-disease rela-
20 tionship.

21 (6) The Food and Drug Administration has
22 failed to implement faithfully and fully the first
23 amendment mandate in *Pearson v. Shalala*, 164
24 F.3d 650 (D.C. Cir. 1999), and continues to sup-
25 press, rather than authorize, health claims.

1 **SEC. 3. FOOD AND DIETARY SUPPLEMENT CLAIMS.**

2 (a) CONFORMING AMENDMENTS.—Section 403 (21
3 U.S.C. 343) is amended—

4 (1) in paragraph (r)(1), by inserting “or a die-
5 tary supplement” after “food” but before “intended”
6 and by inserting “or dietary supplement” after
7 “food” but before “which”;

8 (2) in paragraph (r)(1)(A), by inserting “or die-
9 tary supplement” after “food”;

10 (3) in paragraph (r)(1)(B), by inserting “or di-
11 etary supplement” after “food” and by adding at the
12 end of the paragraph the following: “For purposes
13 of this subparagraph, a claim that characterizes
14 such a relationship includes claims to diagnose, cure,
15 mitigate, treat, or prevent any disease or health-re-
16 lated condition.”;

17 (4) in paragraph (r)(2)(G), by inserting “or di-
18 etary supplement” after “food”;

19 (5) in paragraph (r)(2)(G)(iii), by inserting “or
20 dietary supplement” after “food”;

21 (6) by striking subclause (iv) of subparagraph
22 (r)(2)(G);

23 (7) by striking paragraph (r)(2)(H);

24 (8) in paragraph (r)(3)(A)(ii), by inserting “or
25 dietary supplement” after “food” but before “for”;

1 (9) in paragraph (r)(3)(C), by inserting “or die-
2 tary supplement” after “food”;

3 (10) in paragraph (r)(3)(C)(iii), by inserting
4 “or dietary supplement” after “food”;

5 (11) by striking subclause (iv) of paragraph
6 (r)(3)(C);

7 (12) by striking subclause (A)(i) of paragraph
8 (r)(4);

9 (13) by striking subclause (D) of paragraph
10 (r)(5); and

11 (14) by striking subparagraph (7) of paragraph
12 (r).

13 (b) HEALTH CLAIMS IN GENERAL.—Section 403 (21
14 U.S.C. 343) is amended in paragraph (r)(3) by amending
15 clause (B) to read as follows:

16 “(B)(i) The Secretary shall promulgate no later than
17 100 days after the Secretary receives a claim of the type
18 described in subparagraph (1)(B) regulations authorizing
19 the claim in a form that accurately reflects the degree of
20 scientific evidence supporting the claim unless the Sec-
21 retary determines based on all publicly available scientific
22 evidence that no scientific evidence supports the claim and
23 that the claim is inherently misleading. The Secretary may
24 require that the claim be accompanied by a disclaimer dis-
25 closing the absence of conclusive evidence, the presence of

1 conflicting evidence, or such other information about the
2 claim as is needed to avoid a misleading connotation.

3 “(ii) If within 100 days after the Secretary receives
4 a claim, the Secretary promulgates neither regulations au-
5 thorizing the claim nor a final decision denying the claim,
6 the claim shall be deemed authorized and shall be accom-
7 panied by the following disclaimer until such time as the
8 Secretary complies with the requirements of subparagraph
9 (3)(B)(i): ‘The Food and Drug Administration has not
10 evaluated the scientific evidence concerning this claim.’.

11 “(iii) If the Secretary denies a claim of the type de-
12 scribed in subparagraph (1)(B) and the claimant informs
13 the Secretary in writing that the claimant objects to the
14 Secretary’s denial, no later than 30 days after the Sec-
15 retary receives the objection, the Secretary shall file a peti-
16 tion to review the order with the United States Court of
17 Appeals for the D.C. Circuit, naming the claimant as a
18 defendant and seeking a declaratory judgment on whether
19 the Secretary’s denial complies with subparagraph
20 (3)(B)(i) and the first amendment to the United States
21 Constitution. For purposes of subparagraph (3)(B) the
22 United States Court of Appeals for the D.C. Circuit has
23 exclusive jurisdiction and venue. If the United States
24 Court of Appeals for the D.C. Circuit declares the Sec-
25 retary’s denial invalid, the Court shall order the Secretary

1 to pay the claimant from funds appropriated by Congress
2 to the Food and Drug Administration no later than 60
3 days after the Court's decision is filed with the Clerk of
4 the Court the actual costs and fees incurred by the claim-
5 ant for participating in the proceedings before the United
6 States Court of Appeals, exclusive of all other recompense
7 to which the claimant would otherwise be entitled under
8 Federal law.”.

9 (c) HEALTH CLAIMS BASED ON GOVERNMENT
10 STATEMENTS.—Section 403 (21 U.S.C. 343) is amended
11 by striking subclauses (i) and (ii) of paragraph (r)(3)(C)
12 and inserting the following:

13 “(i) the claim is a verbatim quotation of a
14 statement published by a scientific body of the
15 United States Government about the relationship be-
16 tween a nutrient, including a dietary supplement,
17 and a disease or health-related condition and in-
18 cludes a citation to the author, the title of the publi-
19 cation, the date of publication, and the page on
20 which the statement appears, provided that the
21 claimant submits to the Secretary a written notice of
22 the exact words used in the claim and of the citation
23 at least 30 days before first introducing the food or
24 dietary supplement into interstate commerce with
25 the claim; or

1 “(ii) the claim paraphrases in a nonmisleading
2 manner a statement published by a scientific body of
3 the United States Government about the relation-
4 ship between a nutrient and a disease or health-re-
5 lated condition and includes a citation to the author,
6 the title of the publication, the date of publication,
7 and the page on which the statement appears, pro-
8 vided that the claimant submits to the Secretary a
9 written notice of the exact words used in the claim
10 and of the citation at least 30 days before first in-
11 troducing the food or dietary supplement into inter-
12 state commerce with the claim; and”.

13 (d) DISCLAIMERS FOR HEALTH CLAIMS BASED ON
14 GOVERNMENT STATEMENTS.—Section 403 (21 U.S.C.
15 343) is amended by adding at the end of subclause (iii)
16 of paragraph (r)(3)(C) the following: “The Secretary may
17 not deny authorization of a claim made in compliance with
18 the provisions of subclause (i) or (ii) of clause (C) but
19 may require that the claim be accompanied by a disclaimer
20 disclosing the absence of conclusive evidence, the presence
21 of conflicting evidence, or such other information about
22 the claim as is needed to avoid a misleading connotation.
23 The Secretary shall authorize use of the claim no later
24 than 100 days after the date it is submitted to the Sec-
25 retary. If the Secretary does not act to authorize the claim

1 within 100 days after it is submitted to the Secretary, the
2 claim shall be considered authorized.”.

3 (e) NUTRIENT CONTENT CLAIMS BASED ON GOV-
4 ERNMENT STATEMENTS.—Section 403 (21 U.S.C. 343) is
5 amended by striking subclauses (i) and (ii) of paragraph
6 (r)(2)(G) and inserting the following:

7 “(i) the claim is a verbatim quotation of a statement
8 published by a scientific body of the United States Govern-
9 ment which identifies the nutrient level to which the claim
10 refers and includes a citation to the author, the title of
11 the publication, the date of publication, and the page on
12 which the statement appears, provided that the claimant
13 submits to the Secretary a written notice of the exact
14 words used in the claim and of the citation at least 30
15 days before first introducing the food or dietary supple-
16 ment into interstate commerce with the claim; or

17 “(ii) the claim paraphrases in a nonmisleading man-
18 ner a statement published by a scientific body of the
19 United States Government which identifies the nutrient
20 level to which the claim refers and includes a citation to
21 the author, the title of the publication, the date of publica-
22 tion, and the page on which the statement appears, pro-
23 vided that the claimant submits to the Secretary a written
24 notice of the exact words used in the claim and of the
25 citation at least 30 days before first introducing the food

1 or dietary supplement into interstate commerce with the
2 claim; and”.

3 (f) **DISCLAIMERS FOR NUTRIENT CONTENT CLAIMS**
4 **BASED ON GOVERNMENT STATEMENTS.**—Section 403 (21
5 U.S.C. 343) is amended by adding at the end of subclause
6 (iii) of paragraph (r)(2)(G) the following: “The Secretary
7 may not deny authorization of a claim made in compliance
8 with the provisions of subparagraph (G)(i) or (G)(ii) but
9 may require that the claim be accompanied by a disclaimer
10 containing such information about the claim as is needed
11 to avoid a misleading connotation.”.

12 (g) **DEFINITION OF PUBLISHED STATEMENT.**—Sec-
13 tion 403 (21 U.S.C. 343) is amended by adding at the
14 end of paragraph (r)(2)(G) the following: “For purposes
15 of this clause, a statement published by a scientific body
16 of the United States is any statement contained in a docu-
17 ment available to the public published by any one or more
18 United States Government offices, departments, commis-
19 sions, agencies, institutes, centers, divisions, academies, or
20 other subdivisions thereof.”.

21 **SEC. 4. STATEMENTS OF NUTRITIONAL SUPPORT.**

22 Section 403 (21 U.S.C. 343) is amended by striking
23 the last sentence of paragraph (r)(6).

1 **SEC. 5. WITHDRAWAL OF ORDERS AND RULES; AUTHORIZA-**
2 **TION OF SPECIFIC CLAIMS.**

3 (a) The health claims references in Pearson v.
4 Shalala, 164 F.3d 650 (D.C. Cir. 1999) are approved. No
5 later than 30 days after the effective date of this Act, the
6 Secretary of Health and Human Services shall publish a
7 notice in the Federal Register granting each of the health
8 claims referenced in that decision with the following dis-
9 claimer: “The Food and Drug Administration has deter-
10 mined that the evidence supporting this claim is inconclu-
11 sive.”.

12 (b) The interim final rules concerning health claims
13 based on authoritative statement published in the Federal
14 Register of June 22, 1998 (63 Fed. Reg. 34084; 63 Fed.
15 Reg. 34092; 63 Fed. Reg. 34097; 63 Fed. Reg. 34101;
16 63 Fed. Reg. 34104; 63 Fed. Reg. 34107; 63 Fed. Reg.
17 34110; 63 Fed. Reg. 34112; and 63 Fed. Reg. 34115)
18 are null and void and of no further force or effect. The
19 health claims referenced therein are approved. No later
20 than 30 days after the effective date of this Act the Sec-
21 retary of Health and Human Services shall publish a no-
22 tice in the Federal Register revoking the interim final
23 rules, declaring them null and void and of no further force
24 or effect, and granting each of the health claims ref-
25 erenced therein with the following disclaimer: “The Food

1 and Drug Administration has determined that the evi-
2 dence supporting this claim is inconclusive.”.

3 (c) All orders issued by the Food and Drug Adminis-
4 tration after April 20, 1999, but before the effective date
5 of this Act, that have denied health claims are hereby null
6 and void. The Food and Drug Administration shall re-
7 evaluate those claims in accordance with the provisions of
8 this Act and the amendments made by this Act.

○