

108TH CONGRESS  
2D SESSION

# H. R. 4004

To amend the Federal Food, Drug, and Cosmetic Act to establish a system independent of the Food and Drug Administration for the review of health claims, to define health claims, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 18, 2004

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 establish a system independent of the Food and Drug Administration for the review of health claims, to define health claims, 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 Information  
5 Independence Act”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

1           (1) Access to accurate information at the point  
2 of sale concerning the effect of nutrients on disease  
3 is indispensable to the exercise of informed con-  
4 sumer choice in the marketplace and to the health  
5 and welfare of the American people.

6           (2) In 1999, 2000, and 2001, Federal courts  
7 have held that Food and Drug Administration sup-  
8 pression of nutrient-disease information is a viola-  
9 tion of the First Amendment to the United States  
10 Constitution.

11           (3) Despite those holdings and despite the  
12 courts' orders, the Food and Drug Administration  
13 continues to suppress nutrient-disease information  
14 that could improve public health, reduce the costs of  
15 health care, and promote the welfare of the Amer-  
16 ican people.

17           (4) The history of the Food and Drug Adminis-  
18 tration review of nutrient-disease relationships re-  
19 veals a strong and unscientific bias against food and  
20 dietary supplement health claims in direct violation  
21 of the constitutional mandates of Federal courts and  
22 the intent of Congress.

23           (5) The Food and Drug Administration favors  
24 suppression of health claims over disclosure, despite

1 court imposed constitutional requirements to the  
2 contrary.

3 (6) To ensure that health claims are evaluated  
4 rationally, fairly, and in compliance with constitu-  
5 tional requirements and the intent of Congress, the  
6 federal government must be denied authority to deny  
7 the public access to health information absent prob-  
8 able cause that the claims are untrue, misleading or  
9 pose a danger to human health and jurisdiction over  
10 health claims evaluation must be removed from the  
11 Food and Drug Administration and placed in the  
12 hands of Independent Scientific Reviewers who do  
13 not harbor a bias against food and dietary supple-  
14 ment health claims.

15 **SEC. 3. AUTHORITY FOR MAKING HEALTH CLAIMS.**

16 (a) LIMITATION ON AGENCY AUTHORITY TO RE-  
17 STRICT DISTRIBUTION.—Notwithstanding any other pro-  
18 vision of Federal law, the Federal Government shall have  
19 no authority to restrict the distribution of any dietary sup-  
20 plement or other nutritional food on the basis that the  
21 manufacturer is making health claims unapproved by the  
22 Food and Drug Administration if—

23 (1) the product has a label clearly stating that  
24 its health claims are not FDA approved; and

1           (2) such Administration lacks evidence estab-  
2           lishing probable cause that the claims contain mis-  
3           leading information posing a threat to the safety and  
4           well-being of those who use such product.

5           (b) INDEPENDENT REVIEW OF AGENCY DETERMINA-  
6           TION OF EXISTENCE OF PROBABLE CAUSE.—In the event  
7           that the Food and Drug Administration determines that  
8           there is probable cause that the claims for a dietary sup-  
9           plement or other nutritional food contain misleading infor-  
10          mation posing a threat to the safety and well-being of  
11          those who use such product, such Administration shall, be-  
12          fore acting against the product carrying the allegedly of-  
13          fensive claims, submit the claims to review before an inde-  
14          pendent review board as described in the following sections  
15          of this Act.

16       **SEC. 4. DEFINITIONS.**

17          Section 201 of the Federal Food, Drug, and Cosmetic  
18          Act (21 U.S.C. 321) is amended by adding at the end the  
19          following:

20          “(nn) The term ‘Independent Scientific Reviewer’  
21          means a person who—

22                 “(1) holds a Ph.D., an M.D., or both, and has  
23                 been employed full-time for at least the past 5 con-  
24                 secutive years as a professor or assistant or asso-  
25                 ciate professor in a department of medicine, bio-

1 chemistry, epidemiology, pharmacology, pharmacog-  
2 nosy, or nutrition at a university that is accredited  
3 by an organization recognized by the Department of  
4 Education of the United States;

5 “(2) has never been employed by, and has never  
6 been contracted to do work for, the Food and Drug  
7 Administration or any other agency or office of the  
8 Department of Health and Human Services (except  
9 to review health claim petitions under section  
10 403D);

11 “(3) has never been employed by, and has never  
12 been contracted to do work for, the health claim pe-  
13 titioner;

14 “(4) signs an oath pledging to evaluate the  
15 health claim petition provided to him or her by the  
16 Secretary in strict accordance with the criteria speci-  
17 fied in section 403D;

18 “(5) signs an oath pledging not to discuss with  
19 any person the fact that he or she is reviewing the  
20 health claim petition or the substance of the petition  
21 or the substance of the evaluation before the results  
22 of the scientific review are supplied in a complete  
23 written evaluation to the Secretary;

24 “(6) signs an oath pledging to supply complete  
25 copies of all publicly available scientific evidence re-

1 viewed along with a complete written evaluation of  
2 the health claim to the Secretary no later than 180  
3 days after receipt of the health claim petition from  
4 the Secretary; and

5 “(7) signs an oath pledging to exercise inde-  
6 pendent professional judgment, free of any external  
7 influence and any unscientific bias that might inter-  
8 fere with the objective evaluation of the health  
9 claim.”.

10 **SEC. 5. HEALTH CLAIMS.**

11 Section 403(r) of the Federal Food, Drug, and Cos-  
12 metic Act (21 U.S.C. 343(r)) is amended—

13 (1) in subparagraph (1)—

14 (A) in the matter preceding clause (A)—

15 (i) by striking “food intended” and in-  
16 sserting “food or dietary supplement in-  
17 tended”; and

18 (ii) by striking “food which” and in-  
19 sserting “food or dietary supplement  
20 which”; and

21 (B) in clause (B)—

22 (i) by inserting after “health-related  
23 condition” the following: “(including any  
24 statement that the nutrient prevents,  
25 treats, or cures a disease)”; and

1 (ii) by striking “or (5)(D)”;

2 (2) in subparagraph (3), by amending clause  
3 (B) to read as follows:

4 “(B)(i) The Secretary shall promulgate no later than  
5 30 days after receiving an evaluation from an Independent  
6 Scientific Reviewer regulations that authorize use on la-  
7 bels and in labeling of all claims of the type described in  
8 subparagraph (1)(B) recommended for approval by the  
9 Independent Scientific Reviewer together with such dis-  
10 claimer or disclaimers as the Independent Scientific Re-  
11 viewer may also recommend.

12 “(ii) The duties of the Secretary described in sub-  
13 clause (i) are nondelegable and may be discharged only  
14 by the Secretary.”;

15 (3) by striking subparagraph (4) and redesign-  
16 ating subparagraph (5) as subparagraph (4); and  
17 (4) in subparagraph (4) (as so redesignated),  
18 by striking clause (D).

19 **SEC. 6. INDEPENDENT SCIENTIFIC REVIEW.**

20 Chapter IV of the Federal Food, Drug, and Cosmetic  
21 Act (21 U.S.C. 341 et seq.) is amended by inserting after  
22 section 403C the following new section:

23 **“SEC. 403D. INDEPENDENT SCIENTIFIC REVIEW.**

24 “(a) INVITATIONS TO PARTICIPATE.—No later than  
25 30 days after the date of the enactment of the Health In-

1 formation Independence Act, and every 180-days there-  
2 after, the Secretary shall send to every department of  
3 medicine, biochemistry, epidemiology, pharmacology,  
4 pharmacognosy, and nutrition at every university that is  
5 accredited by an organization recognized by the Secretary  
6 of Education a notice and invitation to participate, stating  
7 the following:

8           “(1) Scientists employed by the university in its  
9           departments of medicine, biochemistry, epidemiology,  
10          pharmacology, pharmacognosy, or nutrition who pos-  
11          sess a Ph.D. or an M.D., or both, and have been ei-  
12          ther a full-time professor or a full-time assistant or  
13          associate professor for at least the past 5 consecu-  
14          tive years are invited to apply to the Secretary to be  
15          Independent Scientific Reviewers in assessing health  
16          claims made without a label clearing stating its  
17          health claims are not approved by the Food and  
18          Drug Administration or such Administration has  
19          evidence establishing probable cause that the claims  
20          contain misleading information posing a threat to  
21          the safety and well-being of those who use the prod-  
22          uct. Health claims are statements of nutrient-disease  
23          association.

24           “(2) Scientists who qualify to be Independent  
25          Scientific Reviewers will be selected at random by

1 the Secretary to review all publicly available sci-  
2 entific evidence on a particular nutrient-disease as-  
3 sociation, must supply copies of all evidence reviewed  
4 to the Secretary, and must supply a written evalua-  
5 tion of that evidence and the health claim to the  
6 Secretary no later than 180 days after receipt of the  
7 health claim petition. The Independent Scientific Re-  
8 viewer shall state whether the claim is supported by  
9 scientific evidence and is, therefore, recommended  
10 for approval. The Independent Scientific Reviewer  
11 should only conclude that the health claim is not  
12 supported by scientific evidence, and, therefore, not  
13 recommended for approval, if the reviewer finds—

14 “(A) no credible scientific evidence sup-  
15 porting the claim; and

16 “(B) no disclaimer that could accompany  
17 the claim that could eliminate any potentially  
18 misleading connotation conveyed by the claim.

19 Recommended disclaimers must be accurate and  
20 concise. Disclaimers should reveal the extent of sup-  
21 port for the claim by stating whether evidence in  
22 support of the claim is less than conclusive, e.g.,  
23 that evidence in support of the claim is preliminary  
24 and inconclusive, suggestive but not conclusive, or

1 generally accepted but not yet proven to a conclusive  
2 degree.

3 “(3) Independent Scientific Reviewers must  
4 complete their reviews within 180 days of receipt of  
5 a health claim petition from the Secretary.

6 “(4) To qualify to be an Independent Scientific  
7 Reviewer you must certify in writing under penalty  
8 of perjury that—

9 “(A) you hold a Ph.D., an M.D., or both,  
10 and have been employed full-time for at least  
11 the past 5 consecutive years as a professor, as-  
12 sistant professor, or associate professor in a de-  
13 partment of medicine, biochemistry, epidemi-  
14 ology, pharmacology, pharmacognosy, or nutri-  
15 tion at a university that is accredited by an or-  
16 ganization recognized by the Department of  
17 Education of the United States;

18 “(B) you have never been employed by,  
19 and have never been contracted to do work for,  
20 the Food and Drug Administration or any other  
21 agency or office of the Department of Health  
22 and Human Services (except to review health  
23 claim petitions) or for the health claim peti-  
24 tioner;

1           “(C) you will evaluate any health claim pe-  
2           tition submitted to you in strict accordance with  
3           the criteria specified in section 403D;

4           “(D) you will not discuss with any person  
5           the fact that you are reviewing the health claim  
6           petition or the substance of the petition or the  
7           substance of the evaluation before you submit a  
8           complete written evaluation of the health claim  
9           to the Secretary;

10          “(E) you will complete your review of the  
11          health claim petition and will supply your com-  
12          plete written evaluation of it along with all sci-  
13          entific evidence reviewed to the Secretary no  
14          later than 180 days after receipt of the health  
15          claim petition from the Secretary; and

16          “(F) you will exercise independent profes-  
17          sional judgment, free of any external influence  
18          and any unscientific bias that might interfere  
19          with the objective evaluation of the health  
20          claim.

21          “(5) Failure to abide by the above rules will re-  
22          sult in disbarment from the Independent Scientific  
23          Review program and disallowance of all compensa-  
24          tion for any review undertaken.

1           “(b) CONFIRMATION OF INDEPENDENT SCIENTIFIC  
2 REVIEWER STATUS.—No later than 30 days after the Sec-  
3 retary determines that a health claim meets the criteria  
4 established in section 3 of the Health Information Inde-  
5 pendence Act for government approval, including the cer-  
6 tifications required under subsection (a)(4) of this section,  
7 from a person who seeks to serve as an Independent Sci-  
8 entific Reviewer, the Secretary shall notify that person  
9 whether he or she satisfies the qualification criteria speci-  
10 fied in such subsection and is, thereby, eligible to be se-  
11 lected to serve as an Independent Scientific Reviewer.

12           “(c) RANDOM SELECTION OF INDEPENDENT SCI-  
13 ENTIFIC REVIEWER TO EVALUATE HEALTH CLAIM.—Not  
14 later than 15 days after the Secretary determines that a  
15 health claim meets the criteria established in section 3 of  
16 the Health Information Independence Act for government  
17 approval, the Secretary shall select an Independent Sci-  
18 entific Reviewer at random and shall provide that person  
19 with a complete copy of the health claim petition for eval-  
20 uation. The Secretary shall not reveal the name of the  
21 Independent Scientific Reviewer to the public or to the  
22 health claim petitioner until after the Secretary receives  
23 from the Independent Scientific Reviewer all publicly  
24 available scientific evidence reviewed and a complete eval-  
25 uation of the health claim.

1       “(d) ALL PUBLICLY AVAILABLE SCIENTIFIC EVI-  
2 DENCE SHALL BE REVIEWED.—Upon receipt of a health  
3 claim petition, the Independent Scientific Reviewer shall  
4 acquire and evaluate all publicly available scientific evi-  
5 dence relevant to the claim. The Independent Scientific  
6 Reviewer shall determine whether credible scientific evi-  
7 dence supports the health claim.

8       “(e) EVERY HEALTH CLAIM SHALL BE REC-  
9 OMMENDED FOR APPROVAL THAT IS SUPPORTED BY  
10 CREDIBLE SCIENTIFIC EVIDENCE.—If the Independent  
11 Scientific Reviewer finds that credible scientific evidence  
12 supports the health claim, the Independent Scientific Re-  
13 viewer shall recommend to the Secretary that the health  
14 claim be approved. If the Independent Scientific Reviewer  
15 finds the scientific evidence in support of the claim less  
16 than conclusive, suggestive but not conclusive, preliminary  
17 and inconclusive, or generally accepted but not yet proven  
18 to a conclusive degree, or if the Independent Scientific Re-  
19 viewer finds the claim to convey a potentially misleading  
20 connotation, the Independent Scientific Reviewer shall  
21 also recommend that the health claim be approved accom-  
22 panied by a concise disclaimer carefully worded to render  
23 the claim nonmisleading.

24       “(f) HEALTH CLAIMS NOT RECOMMENDED FOR AP-  
25 PROVAL.—If the Independent Scientific Reviewer finds

1 that no credible scientific evidence supports the health  
2 claim and that no disclaimer can eliminate a misleading  
3 connotation conveyed by the claim, then the Independent  
4 Scientific Reviewer shall recommend that the Secretary  
5 not approve the health claim.

6 “(g) COMPENSATION FOR INDEPENDENT SCIENTIFIC  
7 REVIEWERS AND SANCTIONS FOR NONCOMPLIANCE.—  
8 The Secretary shall pay each Independent Scientific Re-  
9 viewer the sum of \$40,000 no later than 60 days after  
10 the Secretary receives all publicly available scientific evi-  
11 dence reviewed and a complete evaluation of the health  
12 claim. If the Secretary finds that the Independent Sci-  
13 entific Reviewer has submitted a false certification under  
14 subsection (a)(4), the Secretary may debar the Inde-  
15 pendent Scientific Reviewer from the Independent Sci-  
16 entific Review program and shall refrain from paying the  
17 \$40,000 fee.”.

18 **SEC. 7. LEGAL EFFECT OF HEALTH CLAIM RECOMMENDA-**  
19 **TION BY INDEPENDENT SCIENTIFIC REVIEW-**  
20 **ERS.**

21 Chapter IV of the Federal Food, Drug, and Cosmetic  
22 Act (21 U.S.C. 341 et seq.), as amended by section 6 of  
23 this Act, is amended by inserting after section 403D the  
24 following new section:

1 **“SEC. 403E. LEGAL EFFECT OF HEALTH CLAIM REC-**  
2 **COMMENDATIONS.**

3 “(a) SECRETARY’S RESPONSE TO HEALTH CLAIM  
4 EVALUATIONS BY INDEPENDENT SCIENTIFIC REVIEW-  
5 ERS.—No later than 30 days after the Secretary receives  
6 from an Independent Scientific Reviewer copies of all pub-  
7 licly available scientific evidence reviewed and a complete  
8 written evaluation of a health claim, the Secretary shall—

9 “(1) make the evaluation and all scientific evi-  
10 dence reviewed publicly available; and

11 “(2) publish in the Federal Register as a final  
12 and binding order of the Department of Health and  
13 Human Services the recommendation of the Inde-  
14 pendent Scientific Reviewer verbatim and without  
15 any alteration in content whatsoever, including the  
16 claim, whether the claim is approved or disapproved,  
17 the reasons therefor, and whether the claim must be  
18 accompanied by a disclaimer and the content of the  
19 disclaimer, and the reasons therefor.

20 “(b) ORDER ON HEALTH CLAIMS RECOMMENDA-  
21 TIONS OF INDEPENDENT SCIENTIFIC REVIEWERS IMME-  
22 DIATELY APPEALABLE TO THE UNITED STATES COURT  
23 OF APPEALS FOR THE D.C. CIRCUIT.—Any health claim  
24 petitioner, or any other aggrieved party, may file an ap-  
25 peal for review of an order of the Secretary pursuant to  
26 subsection (a) directly to the United States Court of Ap-

1 peals for the District of Columbia Circuit within 90 days  
2 of the date of publication of the order in the Federal Reg-  
3 ister.”.

4 **SEC. 8. DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
5 **BUDGET ALLOCATION FOR INDEPENDENT**  
6 **SCIENTIFIC REVIEWS.**

7 (a) COSTS OF IMPLEMENTATION.—All costs associ-  
8 ated with implementing this Act shall be borne by the De-  
9 partment of Health and Human Services from its existing  
10 budget.

11 (b) OFFSETS.—This Act eliminates the need for the  
12 Food and Drug Administration to review health claim pe-  
13 titions for foods and dietary supplements. No later than  
14 six months after the date of the enactment of this Act,  
15 the Secretary of Health and Human Services shall elimi-  
16 nate staff, reduce operating expenses, and maximize cost  
17 savings in the Food and Drug Administration’s Center for  
18 Food Safety and Applied Nutrition to offset the costs of  
19 implementing this Act.

20 **SEC. 9. DEFINITION REGARDING DISTINCTION BETWEEN**  
21 **FOOD AND DRUGS.**

22 Section 201(g)(1) of the Federal Food, Drug, and  
23 Cosmetic Act (21 U.S.C. 321(g)(1)) is amended in clause

1 (B) by inserting “(other than food, including dietary sup-  
2 plements)” after “articles”.

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