

107TH CONGRESS  
2D SESSION

# H. R. 3811

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

FEBRUARY 27, 2002

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; REFERENCE; TABLE OF CON-**

4       **TENTS.**

5       (a) SHORT TITLE.—This Act may be cited as the

6       “Health Information Independence Act of 2001”.

7       (b) REFERENCE.—Whenever in this Act an amend-

8       ment or repeal is expressed in terms of an amendment

1 to, or repeal of, a section or other provision, the reference  
2 shall be considered to be made to a section or other provi-  
3 sion of the Federal Food, Drug, and Cosmetic Act.

4 (c) TABLE OF CONTENTS.—The table of contents of  
5 this Act is as follows:

Sec. 1. Short title; reference; table of contents.  
Sec. 2. Findings.  
Sec. 3. Definitions.  
Sec. 4. Health claims.  
Sec. 5. Independent scientific review.  
Sec. 6. Legal effect of health claim recommendation by Independent Scientific  
Reviewers.  
Sec. 7. Department of Health and Human Services budget allocation for inde-  
pendent scientific reviews.

6 **SEC. 2. FINDINGS.**

7 Congress finds as follows:

8 (1) Access to accurate information at the point  
9 of sale concerning the effect of nutrients on disease  
10 is indispensable to the exercise of informed con-  
11 sumer choice in the marketplace and to the health  
12 and welfare of the American people.

13 (2) In 1999, 2000, and 2001, Federal courts  
14 have held that Food and Drug Administration sup-  
15 pression of nutrient-disease information is a viola-  
16 tion of the First Amendment to the United States  
17 Constitution.

18 (3) Despite those holdings and despite the  
19 courts' orders, the Food and Drug Administration  
20 continues to suppress nutrient-disease information  
21 that could improve public health, reduce the costs of

1       health care, and promote the welfare of the Amer-  
2       ican people.

3                   (4) The history of the Food and Drug Adminis-  
4       tration review of nutrient-disease relationships re-  
5       veals a strong and unscientific bias against food and  
6       dietary supplement health claims in direct violation  
7       of the constitutional mandates of Federal courts and  
8       the intent of Congress.

9                   (5) The Food and Drug Administration favors  
10      suppression of health claims over disclosure, despite  
11      court imposed constitutional requirements to the  
12      contrary.

13                   (6) To ensure that health claims are evaluated  
14      rationally, fairly, and in compliance with constitu-  
15      tional requirements and the intent of Congress, ju-  
16      risdiction over health claims evaluation must be re-  
17      moved from the Food and Drug Administration and  
18      placed in the hands of Independent Scientific Re-  
19      viewers who do not harbor a bias against food and  
20      dietary supplement health claims.

21 **SEC. 3. DEFINITIONS.**

22       Section 201 (21 U.S.C. 321) is amended by adding  
23      at the end the following:

24                   “(kk) The term ‘Independent Scientific Reviewer’  
25      means a person who—

1           “(1) holds a Ph.D., an M.D., or both, and has  
2           been employed full-time for at least the past 5 con-  
3           secutive years as a professor or assistant or asso-  
4           ciate professor in a department of medicine, bio-  
5           chemistry, epidemiology, pharmacology, pharmacog-  
6           noscis, or nutrition at a university that is accredited  
7           by an organization recognized by the Department of  
8           Education of the United States;

9           “(2) has never been employed by, and has never  
10           been contracted to do work for, the Food and Drug  
11           Administration or any other agency or office of the  
12           Department of Health and Human Services (except  
13           to review health claim petitions under section  
14           403D);

15           “(3) has never been employed by, and has never  
16           been contracted to do work for, the health claim pe-  
17           titioner;

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

22           “(5) signs an oath pledging not to discuss with  
23           any person the fact that he or she is reviewing the  
24           health claim petition or the substance of the petition  
25           or the substance of the evaluation before the results

1 of the scientific review are supplied in a complete  
2 written evaluation to the Secretary;

3 “(6) signs an oath pledging to supply complete  
4 copies of all publicly available scientific evidence re-  
5 viewed along with a complete written evaluation of  
6 the health claim to the Secretary no later than 180  
7 days after receipt of the health claim petition from  
8 the Secretary; and

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

14 **SEC. 4. HEALTH CLAIMS.**

15 Section 403(r) (21 U.S.C. 343(r)) is amended—

16 (1) in subparagraph (1)—

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

18 (i) by striking “food intended” and in-  
19 serting “food or dietary supplement in-  
20 tended”; and

21 (ii) by striking “food which” and in-  
22 serting “food or dietary supplement  
23 which”; and

24 (B) in clause (B)—

1 (i) by inserting after “health-related  
2 condition” the following: “(including any  
3 statement that the nutrient prevents,  
4 treats or cures a disease)”; and

5 (ii) by striking “or (5)(D)”:

6 (2) in subparagraph (3), by amending clause

7 (B) to read as follows:

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

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

19 (3) by striking subparagraph (4) and redesignating subparagraph (5) as subparagraph (4); and  
20 (4) in subparagraph (4) (as so redesignated),  
21 by striking clause (D).

## 23 SEC. 5. INDEPENDENT SCIENTIFIC REVIEW.

24 Chapter IV (21 U.S.C. 341 et seq.) is amended by  
25 inserting after section 403C the following new section:

1                   “INDEPENDENT SCIENTIFIC REVIEW

2                   “SEC. 403D. (a) INVITATIONS TO PARTICIPATE.—

3                   No later than 30 days after the date of the enactment

4                   of the Health Information Independence Act of 2001, and

5                   every 180-days thereafter, the Secretary shall send to

6                   every department of medicine, biochemistry, epidemiology,

7                   pharmacology, pharmacognosy, and nutrition at every uni-

8                   versity that is accredited by an organization recognized by

9                   the Secretary of Education a notice and invitation to par-

10                   ticipate, stating the following:

11                   “(1) Scientists employed by the university in its

12                   departments of medicine, biochemistry, epidemiology,

13                   pharmacology, pharmacognosy, or nutrition who pos-

14                   sess a Ph.D. or an M.D., or both, and have been ei-

15                   ther a full-time professor or a full-time assistant or

16                   associate professor for at least the past 5 consecu-

17                   tive years are invited to apply to the Secretary to be

18                   Independent Scientific Reviewers in assessing health

19                   claims filed with the Food and Drug Administration.

20                   Health claims are statements of nutrient-disease as-

21                   sociation.

22                   “(2) Scientists who qualify to be Independent

23                   Scientific Reviewers will be selected at random by

24                   the Secretary to review all publicly available sci-

25                   entific evidence on a particular nutrient-disease as-

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

12               “(A) no credible scientific evidence sup-  
13               porting the claim; and

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

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

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

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

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

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

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

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

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

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

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

22                 “(b) CONFIRMATION OF INDEPENDENT SCIENTIFIC  
23                 REVIEWER STATUS.—No later than 30 days after the Sec-  
24                 retary’s receipt of a request, including the certifications  
25                 required under subsection (a)(4), from a person who seeks

1 to serve as an Independent Scientific Reviewer, the Sec-  
2 retary shall notify that person whether he or she satisfies  
3 the qualification criteria specified in such subsection and  
4 is, thereby, eligible to be selected to serve as an Inde-  
5 pendent Scientific Reviewer.

6       “(c) RANDOM SELECTION OF INDEPENDENT SCI-  
7 ENTIFIC REVIEWER TO EVALUATE HEALTH CLAIM.—No  
8 later than 15 days after a health claim petition is filed  
9 with the Secretary, the Secretary shall select an Inde-  
10 pendent Scientific Reviewer at random and shall provide  
11 that person with a complete copy of the health claim peti-  
12 tion for evaluation. The Secretary shall not reveal the  
13 name of the Independent Scientific Reviewer to the public  
14 or to the health claim petitioner until after the Secretary  
15 receives from the Independent Scientific Reviewer all pub-  
16 licly available scientific evidence reviewed and a complete  
17 evaluation of the health claim.

18       “(d) ALL PUBLICLY AVAILABLE SCIENTIFIC EVI-  
19 DENCE SHALL BE REVIEWED.—Upon receipt of a health  
20 claim petition, the Independent Scientific Reviewer shall  
21 acquire and evaluate all publicly available scientific evi-  
22 dence relevant to the claim. The Independent Scientific  
23 Reviewer shall determine whether credible scientific evi-  
24 dence supports the health claim.

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

17       “(f) HEALTH CLAIMS NOT RECOMMENDED FOR AP-  
18 PROVAL.—If the Independent Scientific Reviewer finds  
19 that no credible scientific evidence supports the health  
20 claim and that no disclaimer can eliminate a misleading  
21 connotation conveyed by the claim, then the Independent  
22 Scientific Reviewer shall recommend that the Secretary  
23 not approve the health claim.

24       “(g) COMPENSATION FOR INDEPENDENT SCIENTIFIC  
25 REVIEWERS AND SANCTIONS FOR NONCOMPLIANCE.—

1 The Secretary shall pay each Independent Scientific Re-  
2 viewer the sum of \$40,000 no later than 60 days after  
3 the Secretary receives all publicly available scientific evi-  
4 dence reviewed and a complete evaluation of the health  
5 claim. If the Secretary finds that the Independent Sci-  
6 entific Reviewer has submitted a false certification under  
7 subsection (a)(4), the Secretary may debar the Inde-  
8 pendent Scientific Reviewer from the Independent Sci-  
9 entific Review program and shall refrain from paying the  
10 \$40,000 fee.”.

11 **SEC. 6. LEGAL EFFECT OF HEALTH CLAIM RECOMMENDA-**  
12 **TION BY INDEPENDENT SCIENTIFIC REVIEW-**  
13 **ERS.**

14 Chapter IV (21 U.S.C. 341 et seq.), as amended by  
15 section 5 of this Act, is amended by inserting after section  
16 403D the following new section:

17 “**LEGAL EFFECT OF HEALTH CLAIM RECOMMENDATIONS**  
18 “**SEC. 403E.** (a) **SECRETARY’S RESPONSE TO**  
19 **HEALTH CLAIM EVALUATIONS BY INDEPENDENT SCI-**  
20 **ENTIFIC REVIEWERS.**—No later than 30 days after the  
21 Secretary receives from an Independent Scientific Re-  
22 viewer copies of all publicly available scientific evidence re-  
23 viewed and a complete written evaluation of a health  
24 claim, the Secretary shall—

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

1               “(2) publish in the Federal Register as a final  
2       and binding order of the Department of Health and  
3       Human Services the recommendation of the Inde-  
4       pendent Scientific Reviewer verbatim and without  
5       any alteration in content whatsoever, including the  
6       claim, whether the claim is approved or disapproved,  
7       the reasons therefor, and whether the claim must be  
8       accompanied by a disclaimer and the content of the  
9       disclaimer, and the reasons therefor.

10       “(b) ORDER ON HEALTH CLAIMS RECOMMENDA-  
11       TIONS OF INDEPENDENT SCIENTIFIC REVIEWERS IMME-  
12       DIATELY APPEALABLE TO THE UNITED STATES COURT  
13       OF APPEALS FOR THE D.C. CIRCUIT.—Any health claim  
14       petitioner, or any other aggrieved party, may file an ap-  
15       peal for review of an order of the Secretary pursuant to  
16       subsection (a) directly to the United States Court of Ap-  
17       peals for the District of Columbia Circuit within 90 days  
18       of the date of publication of the order in the Federal Reg-  
19       ister.”.

20 **SEC. 7. DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
21               **BUDGET ALLOCATION FOR INDEPENDENT**  
22               **SCIENTIFIC REVIEWS.**

23       (a) COSTS OF IMPLEMENTATION.—All costs associ-  
24       ated with implementing this Act shall be borne by the De-

1 partment of Health and Human Services from its existing  
2 budget.

3 (b) OFFSETS.—This Act eliminates the need for the  
4 Food and Drug Administration to review health claim pe-  
5 titions for foods and dietary supplements. No later than  
6 six months after the date of the enactment of this Act,  
7 the Secretary of Health and Human Services shall elimi-  
8 nate staff, reduce operating expenses, and maximize cost  
9 savings in the Food and Drug Administration's Center for  
10 Food Safety and Applied Nutrition to offset the costs of  
11 implementing this Act.

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