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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.

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.

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 Information Independence Act''.

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) Access to accurate information at the point of sale concerning the effect of nutrients on disease is indispensable to the exercise of informed consumer choice in the marketplace and to the health and welfare of the American people.

(2) In 1999, 2000, and 2001, Federal courts have held that Food and Drug Administration suppression of nutrient-disease information is a violation of the First Amendment to the United States Constitution.

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

(4) The history of the Food and Drug Administration review of nutrient-disease relationships reveals a strong and unscientific bias against food and dietary supplement health claims in direct violation of the constitutional mandates of Federal courts and the intent of Congress.

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

court imposed constitutional requirements to the contrary.

(6) To ensure that health claims are evaluated rationally, fairly, and in compliance with constitutional requirements and the intent of Congress, the federal government must be denied authority to deny the public access to health information absent probable cause that the claims are untrue, misleading or pose a danger to human health and jurisdiction over health claims evaluation must be removed from the Food and Drug Administration and placed in the hands of Independent Scientific Reviewers who do not harbor a bias against food and dietary supplement health claims.

SEC. 3. AUTHORITY FOR MAKING HEALTH CLAIMS.

(a) LIMITATION ON AGENCY AUTHORITY TO RESTRICT DISTRIBUTION.—Notwithstanding any other provision of Federal law, the Federal Government shall have no authority to restrict the distribution of any dietary supplement or other nutritional food on the basis that the manufacturer is making health claims unapproved by the Food and Drug Administration if—

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

(2) such Administration lacks evidence establishing probable cause that the claims contain misleading information posing a threat to the safety and well-being of those who use such product.

(b) INDEPENDENT REVIEW OF AGENCY DETERMINATION OF EXISTENCE OF PROBABLE CAUSE.—In the event that the Food and Drug Administration determines that there is probable cause that the claims for a dietary supplement or other nutritional food contain misleading information posing a threat to the safety and well-being of those who use such product, such Administration shall, before acting against the product carrying the allegedly offensive claims, submit the claims to review before an independent review board as described in the following sections of this Act.

SEC. 4. DEFINITIONS.

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

''(nn) The term 'Independent Scientific Reviewer' means a person who—

''(1) holds a Ph.D., an M.D., or both, and has been employed full-time for at least the past 5 consecutive years as a professor or assistant or associate professor in a department of medicine, bio-

chemistry, epidemiology, pharmacology, pharmacognosy, or nutrition at a university that is accredited by an organization recognized by the Department of Education of the United States;

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

''(3) has never been employed by, and has never been contracted to do work for, the health claim petitioner;

''(4) signs an oath pledging to evaluate the health claim petition provided to him or her by the Secretary in strict accordance with the criteria specified in section 403D;

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

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

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

''(7) signs an oath pledging to exercise independent professional judgment, free of any external influence and any unscientific bias that might interfere with the objective evaluation of the health claim.''.

SEC. 5. HEALTH CLAIMS.

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

(1) in subparagraph (1)—

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

(i) by striking ''food intended'' and inserting ''food or dietary supplement intended''; and

(ii) by striking ''food which'' and inserting ''food or dietary supplement which''; and

(B) in clause (B)—

(i) by inserting after ''health-related condition'' the following: ''(including any statement that the nutrient prevents, treats, or cures a disease)''; and

(ii) by striking ''or (5)(D)'';

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

''(B)(i) The Secretary shall promulgate no later than 30 days after receiving an evaluation from an Independent Scientific Reviewer regulations that authorize use on labels and in labeling of all claims of the type described in subparagraph (1)(B) recommended for approval by the Independent Scientific Reviewer together with such disclaimer or disclaimers as the Independent Scientific Reviewer may also recommend.

''(ii) The duties of the Secretary described in subclause (i) are nondelegable and may be discharged only by the Secretary.'';

(3) by striking subparagraph (4) and redesignating subparagraph (5) as subparagraph (4); and

(4) in subparagraph (4) (as so redesignated), by striking clause (D).

SEC. 6. INDEPENDENT SCIENTIFIC REVIEW.

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

''SEC. 403D. INDEPENDENT SCIENTIFIC REVIEW.

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

formation Independence Act, and every 180-days thereafter, the Secretary shall send to every department of medicine, biochemistry, epidemiology, pharmacology, pharmacognosy, and nutrition at every university that is accredited by an organization recognized by the Secretary of Education a notice and invitation to participate, stating the following:

''(1) Scientists employed by the university in its departments of medicine, biochemistry, epidemiology, pharmacology, pharmacognosy, or nutrition who possess a Ph.D. or an M.D., or both, and have been either a full-time professor or a full-time assistant or associate professor for at least the past 5 consecutive years are invited to apply to the Secretary to be Independent Scientific Reviewers in assessing health claims made without a label clearing stating its health claims are not approved by the Food and Drug Administration or such Administration has evidence establishing probable cause that the claims contain misleading information posing a threat to the safety and well-being of those who use the product. Health claims are statements of nutrient-disease association.

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

the Secretary to review all publicly available scientific evidence on a particular nutrient-disease association, must supply copies of all evidence reviewed to the Secretary, and must supply a written evaluation of that evidence and the health claim to the Secretary no later than 180 days after receipt of the health claim petition. The Independent Scientific Reviewer shall state whether the claim is supported by scientific evidence and is, therefore, recommended for approval. The Independent Scientific Reviewer should only conclude that the health claim is not supported by scientific evidence, and, therefore, not recommended for approval, if the reviewer finds—

''(A) no credible scientific evidence supporting the claim; and

''(B) no disclaimer that could accompany the claim that could eliminate any potentially misleading connotation conveyed by the claim.

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

generally accepted but not yet proven to a conclusive degree.

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

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

''(A) you hold a Ph.D., an M.D., or both, and have been employed full-time for at least the past 5 consecutive years as a professor, assistant professor, or associate professor in a department of medicine, biochemistry, epidemiology, pharmacology, pharmacognosy, or nutrition at a university that is accredited by an organization recognized by the Department of Education of the United States;

''(B) you have never been employed by, and have never been contracted to do work for, the Food and Drug Administration or any other agency or office of the Department of Health and Human Services (except to review health claim petitions) or for the health claim petitioner;

"(C) you will evaluate any health claim petition submitted to you in strict accordance with the criteria specified in section 403D;

"(D) you will not discuss with any person the fact that you are reviewing the health claim petition or the substance of the petition or the substance of the evaluation before you submit a complete written evaluation of the health claim to the Secretary;

"(E) you will complete your review of the health claim petition and will supply your complete written evaluation of it along with all scientific evidence reviewed to the Secretary no later than 180 days after receipt of the health claim petition from the Secretary; and

"(F) you will exercise independent professional judgment, free of any external influence and any unscientific bias that might interfere with the objective evaluation of the health claim.

"(5) Failure to abide by the above rules will result in disbarment from the Independent Scientific Review program and disallowance of all compensation for any review undertaken.

''(b) CONFIRMATION OF INDEPENDENT SCIENTIFIC REVIEWER STATUS.—No later than 30 days after the Secretary determines that a health claim meets the criteria established in section 3 of the Health Information Independence Act for government approval, including the certifications required under subsection (a)(4) of this section, from a person who seeks to serve as an Independent Scientific Reviewer, the Secretary shall notify that person whether he or she satisfies the qualification criteria specified in such subsection and is, thereby, eligible to be selected to serve as an Independent Scientific Reviewer.

''(c) RANDOM SELECTION OF INDEPENDENT SCIENTIFIC REVIEWER TO EVALUATE HEALTH CLAIM.—Not later than 15 days after the Secretary determines that a health claim meets the criteria established in section 3 of the Health Information Independence Act for government approval, the Secretary shall select an Independent Scientific Reviewer at random and shall provide that person with a complete copy of the health claim petition for evaluation. The Secretary shall not reveal the name of the Independent Scientific Reviewer to the public or to the health claim petitioner until after the Secretary receives from the Independent Scientific Reviewer all publicly available scientific evidence reviewed and a complete evaluation of the health claim.

''(d) ALL PUBLICLY AVAILABLE SCIENTIFIC EVIDENCE SHALL BE REVIEWED.—Upon receipt of a health claim petition, the Independent Scientific Reviewer shall acquire and evaluate all publicly available scientific evidence relevant to the claim. The Independent Scientific Reviewer shall determine whether credible scientific evidence supports the health claim.

''(e) EVERY HEALTH CLAIM SHALL BE RECOMMENDED FOR APPROVAL THAT IS SUPPORTED BY CREDIBLE SCIENTIFIC EVIDENCE.—If the Independent Scientific Reviewer finds that credible scientific evidence supports the health claim, the Independent Scientific Reviewer shall recommend to the Secretary that the health claim be approved. If the Independent Scientific Reviewer finds the scientific evidence in support of the claim less than conclusive, suggestive but not conclusive, preliminary and inconclusive, or generally accepted but not yet proven to a conclusive degree, or if the Independent Scientific Reviewer finds the claim to convey a potentially misleading connotation, the Independent Scientific Reviewer shall also recommend that the health claim be approved accompanied by a concise disclaimer carefully worded to render the claim nonmisleading.

''(f) HEALTH CLAIMS NOT RECOMMENDED FOR APPROVAL.—If the Independent Scientific Reviewer finds

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

''(g) COMPENSATION FOR INDEPENDENT SCIENTIFIC REVIEWERS AND SANCTIONS FOR NONCOMPLIANCE.—The Secretary shall pay each Independent Scientific Reviewer the sum of $40,000 no later than 60 days after the Secretary receives all publicly available scientific evidence reviewed and a complete evaluation of the health claim. If the Secretary finds that the Independent Scientific Reviewer has submitted a false certification under subsection (a)(4), the Secretary may debar the Independent Scientific Reviewer from the Independent Scientific Review program and shall refrain from paying the $40,000 fee.''.

SEC. 7. LEGAL EFFECT OF HEALTH CLAIM RECOMMENDATION BY INDEPENDENT SCIENTIFIC REVIEWERS.

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

"SEC. 403E. LEGAL EFFECT OF HEALTH CLAIM RECOMMENDATIONS.

"(a) SECRETARY'S RESPONSE TO HEALTH CLAIM EVALUATIONS BY INDEPENDENT SCIENTIFIC REVIEWERS.—No later than 30 days after the Secretary receives from an Independent Scientific Reviewer copies of all publicly available scientific evidence reviewed and a complete written evaluation of a health claim, the Secretary shall—

"(1) make the evaluation and all scientific evidence reviewed publicly available; and

"(2) publish in the Federal Register as a final and binding order of the Department of Health and Human Services the recommendation of the Independent Scientific Reviewer verbatim and without any alteration in content whatsoever, including the claim, whether the claim is approved or disapproved, the reasons therefor, and whether the claim must be accompanied by a disclaimer and the content of the disclaimer, and the reasons therefor.

"(b) ORDER ON HEALTH CLAIMS RECOMMENDATIONS OF INDEPENDENT SCIENTIFIC REVIEWERS IMMEDIATELY APPEALABLE TO THE UNITED STATES COURT OF APPEALS FOR THE D.C. CIRCUIT.—Any health claim petitioner, or any other aggrieved party, may file an appeal for review of an order of the Secretary pursuant to subsection (a) directly to the United States Court of Ap-

peals for the District of Columbia Circuit within 90 days of the date of publication of the order in the Federal Register.''.

SEC. 8. DEPARTMENT OF HEALTH AND HUMAN SERVICES BUDGET ALLOCATION FOR INDEPENDENT SCIENTIFIC REVIEWS.

(a) COSTS OF IMPLEMENTATION.—All costs associated with implementing this Act shall be borne by the Department of Health and Human Services from its existing budget.

(b) OFFSETS.—This Act eliminates the need for the Food and Drug Administration to review health claim petitions for foods and dietary supplements. No later than six months after the date of the enactment of this Act, the Secretary of Health and Human Services shall eliminate staff, reduce operating expenses, and maximize cost savings in the Food and Drug Administration's Center for Food Safety and Applied Nutrition to offset the costs of implementing this Act.

SEC. 9. DEFINITION REGARDING DISTINCTION BETWEEN FOOD AND DRUGS.

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

(B) by inserting ''(other than food, including dietary supplements)'' after ''articles''.

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