103D CONGRESS
2D SESSION

S. 784

To amend the Federal Food, Drug, and Cosmetic Act to establish standards with respect to dietary supplements, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 7 (legislative day, MARCH 3), 1993

Mr. HATCH (for himself, Mr. REID, Mr. MURKOWSKI, Mr. CRAIG, Mr. DURENBERGER, Mr. GORTON, Mr. WALLOP, Mr. GRASSLEY, Mr. THURMOND, Mr. D'AMATO, Mr. COATS, Mr. SIMPSON, Mr. KEMPTHORNE, Mr. BENNETT, Mr. DOMENICI, Mr. SMITH, Mr. JEFFORDS, Mr. GREGG, Mr. BURNS, Mr. NICKLES, Mr. PELL, Mr. MCCAIN, Mr. FAIRCLOTH, Ms. MIKULSKI, Mr. HELMS, Mr. DOLE, Mr. GRAMM, Mr. BINGAMAN, Mr. CAMPBELL, Mr. DASCHLE, Mr. INOUYE, Mr. MACK, Mr. COVERDELL, Mr. SIMON, Ms. MOSELEY-BRAUN, Mr. HATFIELD, Mr. HOLLINGS, Mr. PRESSLER, Mrs. HUTCHISON, Mr. DORGAN, Mr. MCCONNELL, Mr. BOND, Mr. STEVENS, Mr. SPECTER, Mr. HEFLIN, Mr. MATHEWS, Mr. LOTT, Mr. BROWN, Mr. DECONCINI, Mr. JOHNSTON, Mr. AKAKA, Mr. BOREN, Mr. CHAFEE, Mrs. BOXER, Mr. EXON, Mr. SHELBY, Mr. FORD, Mr. SASSER, Mr. LEAHY, Mr. ROTH, Mr. NUNN, Mr. DANFORTH, Mr. KOHL, Mr. WOFFORD, Mr. FEINGOLD, and Mr. HARKIN) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

AUGUST 13 (legislative day, AUGUST 11), 1994
Committee discharged

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish standards with respect to dietary supplements, 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 ''Dietary Supplement Health and Education Act of 1993''.

SEC. 2. FINDINGS AND PURPOSE.

(a) FINDINGS.—Congress finds that—

(1) improving the health status of United States citizens ranks at the top of the national priorities of the Federal Government;

(2) the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies;

(3)(A) there is a definitive link between the ingestion of certain nutrients or dietary supplements and the prevention of chronic diseases such as cancer, heart disease, and osteoporosis; and

(B) clinical research has shown that several chronic diseases can be prevented simply with a healthful diet, such as a diet that is low in fat, saturated fat, cholesterol, and sodium, with a high proportion of plant-based foods;

(4) healthful diets may mitigate the need for expensive medical procedures, such as coronary bypass surgery or angioplasty;

(5) preventive health measures, including education, good nutrition, and appropriate use of safe nutritional supplements will limit the incidence of chronic diseases, and reduce long-term health care expenditures;

(6)(A) promotion of good health and healthy lifestyles improves and extends lives while reducing health care expenditures; and

(B) reduction in health care expenditures is of paramount importance to the future of the country and the economic well-being of the country;

(7) there is a growing need for emphasis on the dissemination of information linking nutrition and long-term good health;

(8) consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements;

(9)(A) recent national surveys have revealed that almost 50 percent of the 260,000,000 Americans regularly consume dietary supplements of vita-

mins, minerals, or herbs as a means of improving their nutrition; and

(B) nearly all consumers indicate that dietary supplements should not be regulated as drugs;

(10) studies indicate that consumers are placing increased reliance on the use of nontraditional health care providers to avoid the excessive costs of traditional medical services and to obtain more holistic treatment of patients;

(11) the United States will spend over $900,000,000,000 on health care in 1993, which is about 12 percent of the Gross National Product of the United States, and this amount and percent will continue to increase unless significant efforts are undertaken to reverse the increase;

(12)(A) the nutritional supplement industry is an integral part of the economy of the United States;

(B) the industry consistently projects a positive trade balance; and

(C) the estimated 600 dietary supplement manufacturers in the United States produce approximately 3,400 products, with total annual sales of such products alone reaching $4,000,000,000;

(13) although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose regulatory barriers limiting or slowing the flow of safe products and needed information to the marketplace and consumers;

(14) dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare; and

(15)(A) legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness; and

(B) a rational Federal framework must be established to supersede the current ad hoc, patchwork regulatory policy on dietary supplements.

(b) PURPOSE.—It is the purpose of this Act to—

(1) improve the health status of the people of the United States and help constrain runaway health care spending by ensuring that the Federal Government erects no regulatory barriers that impede the ability of consumers to improve their nutrition through the free choice of safe dietary supplements;

(2) clarify that—

(A) dietary supplements are not drugs or food additives;

(B) dietary supplements should not be regulated as drugs; and

(C) regulations relating to food additives should only be applied to dietary supplement ingredients used for food additive purposes, such as stabilizers, processing agents or preservatives;

(3) establish a new definition of a dietary supplement that differentiates dietary supplements from conventional foods, while recognizing the broad range of food ingredients used to supplement the diet;

(4) strengthen the current enforcement authority of the Food and Drug Administration by providing to the Administration additional mechanisms to take enforcement action against unsafe or fraudulent products;

(5) establish a series of labeling requirements that will provide consumers with greater information and assurance about the quality and content of dietary supplements, while at the same time assuring the consumers the freedom to use the supplements of their choice;

(6) establish dietary intake standards based on the amount of nutrients needed to prevent disease;

(7) provide new administrative and judicial review procedures to affected parties if the Administration takes certain actions to enforce dietary supplement requirements;

(8) specify the standards applicable to disease and other health-related claims for dietary supplements;

(9) reaffirm that dietary supplement labeling may bear information, other than health claims, about the vitamin, mineral, or other dietary properties of the supplement; and

(10) establish a new Office of Dietary Supplements within the National Institutes of Health to initiate and coordinate research on dietary supplements and advise the Secretary and other officials of the Department of Health and Human Services on dietary supplement issues.

SEC. 3. DEFINITIONS.

(a) DEFINITION OF CERTAIN FOODS AS DIETARY SUPPLEMENTS.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

''(gg) The term 'dietary supplement' means a food for special dietary use, as defined in section 411(c)(3), that—

''(1) includes—

''(A) a vitamin;

''(B) a mineral;

''(C) an herb;

''(D) an amino acid;

''(E) another ingredient for use by man to supplement the diet by increasing the total dietary intake; or

''(F) a concentrate or extract of any ingredient described in clause (A), (B), (C), (D), or (E); and

''(2)(A) is intended for ingestion in a form described in section 411(c)(1)(B)(i); or

''(B) complies with section 411(c)(1)(B)(ii).''.

(b) EXCLUSION FROM DEFINITION OF DRUG.—Section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)) is amended by adding at the end the following new sentence: ''The term 'drug' does not include a dietary supplement or an ingredient described in clause (A), (B), (C), (D), (E), or (F) of paragraph (gg)(1) in, or intended for use in, a dietary supplement.''.

(c) EXCLUSION FROM DEFINITION OF FOOD ADDITIVE.—Section 201(s) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(s)) is amended—

(1) by striking ''or'' at the end of subparagraph (4);

(2) by striking the period at the end of subparagraph (5) and inserting ''; or''; and

(3) by adding at the end the following:

''(6) an ingredient described in clause (A), (B), (C), (D), (E), or (F) of paragraph (gg)(1) in, or intended for use in, a dietary supplement.''.

(d) FORM OF INGESTION.—Section 411(c)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350(c)(1)(B)) is amended—

(1) in clause (i), by inserting ''powder, softgel,'' after ''capsule,''; and

(2) in clause (ii), by striking ''does not simulate and''.

SEC. 4. SAFETY OF DIETARY SUPPLEMENTS.

Section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) is amended by adding at the end the following:

''(f) If it is a dietary supplement that contains an ingredient that is intended to be consumed for its dietary properties and—

''(1) the Secretary finds, after rulemaking, that the ingredient presents a substantial and unreasonable risk of illness or injury; or

''(2) no manufacturer of the supplement, or manufacturer of the raw material comprising the ingredient, has adequately substantiated the safety of the ingredient—

''(A) through evidence of a history of safe use of the ingredient (as part of any intended use prior to the use of the ingredient in such dietary supplement), and through the absence of substantial information that brings the safety of the ingredient into question;

''(B) by well-designed scientific studies conducted in a manner that is consistent with generally recognized scientific procedures and principles; or

''(C) by other appropriate means,

unless—

''(i) the Secretary has established, in consultation with the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, and the National Academy of Sciences, a recommended dietary allowance, or an estimated safe and adequate dietary intake level, with respect to the ingredient;

''(ii) the Secretary has determined, prior to the date of enactment of this paragraph, that the ingredient has been generally recognized as safe; or

''(iii) the ingredient is used in conformity with a regulation relating to food additives that is described in section 409(a)(2) and is issued prior to the date of enactment of this paragraph.''.

SEC. 5. REPORT ON IMPACT OF SIGNIFICANT CHANGES IN MANUFACTURING PRACTICES.

(a) STUDY.—The Director of the Office of Dietary Supplements shall conduct a study relating to significant changes in the manufacturing practices of manufacturers of raw materials utilized in dietary supplements. In conducting the study, the Director shall analyze the extent to which such changes pose a risk to public safety.

(b) REPORT.—Not later than 3 years after the date of enactment of this Act, the Director of the Office of Dietary Supplements shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report containing—

(1) the results of the study described in subsection (a); and

(2) any recommendations for legislative reform.

SEC. 6. DIETARY INTAKE STANDARDS.

(a) NUTRITION INFORMATION.—Section 403(q)(1) (21 U.S.C. 343(q)(1)) is amended—

(1) by striking the period at the end of clause (E) and inserting ‘‘, or’’; and

(2) by adding after clause (E) the following:

‘‘(F) a declaration of the percent of a daily reference amount for each nutrient specified in clauses (D) and (E), stated as a ‘Percent Daily Value’ provided by a serving of the food.’’.

(b) REGULATIONS.—

(1) IN GENERAL.—

(A) DAILY VALUE.—Subject to subparagraph (B), the Secretary of Health and Human Services shall, by regulation, determine, based on the dietary guidance provided by the Department of Agriculture, the Department of Health and Human Services, the Centers for Disease Control and Prevention, the National Institutes of Health, and other authoritative public health organizations, a daily value for each nutrient specified in clauses (D) and (E) of section 403(q)(1) of the Federal Food, Drug, and Cosmetic Act. The daily value shall reflect the daily intake of each such nutrient that will promote

optimal health and minimize the risk of disease or other health-related conditions.

(B) LIMITATION.—The daily value determined by the Secretary under subparagraph (A) shall, in every appropriate case, be no less than the United States Recommended Daily Allowances established by the Food and Nutrition Board of the National Academy of Sciences for the age and sex group most at risk of nutritional deficiencies of any particular nutrient.

(2) TIMING.—Except as provided in paragraph (4), the Secretary of Health and Human Services shall issue proposed regulations under paragraph (1) no later than 12 months after the date of the enactment of this Act and shall issue final regulations no later than 24 months after such date.

(3) PENDING DAILY VALUES.—Pending the issuance of final regulations under paragraph (1), the daily values for the nutrients declared under section 403(q)(1)(F) of the Federal Food, Drug, and Cosmetic Act shall be the values specified in sections 101.9(c)(8) and 101.9(c)(9) of title 21, Code of Federal Regulations, as in effect on the date of the enactment of this Act.

(4) ASSISTANCE.—

(A) REVIEW AND STUDIES.—To assist the Secretary of Health and Human Services in issuing regulations under paragraph (1), the Director of the Congressional Research Service, in consultation with the Director of the Office of Technology Assessment, shall review existing scientific data and conduct any necessary studies.

(B) PURPOSE.—Such review and studies shall determine the amount of each nutrient specified in clauses (D) and (E) of section 403(q)(1) of the Federal Food, Drug, and Cosmetic Act that would be provided by the diets recommended by the Department of Agriculture, the Department of Health and Human Services, the Centers for Disease Control and Prevention, the National Institutes of Health, and other authoritative public health organizations, to minimize the risk of disease and other health-related conditions and to promote optimal health.

(C) TIMING.—Such review and studies shall be completed no later than 9 months after the date of the enactment of this Act. If the Congressional Research Service does not com-

plete such review and studies within 9 months after the date of enactment of this Act, the time prescribed by paragraph (2) for the issuance of proposed and final regulations shall be extended by a period equal to the additional time required by such Office to complete such review and studies.

SEC. 7. DIETARY SUPPLEMENT CLAIMS.

Section 403(r) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)) is amended by striking subparagraph (5)(D) and inserting the following:

''(D) A subparagraph (1)(B) claim made with respect to a dietary supplement shall not be subject to subparagraph (3).

''(6)(A) A claim made in the label or labeling of a dietary supplement may characterize the relationship between the supplement and a disease or other health-related condition if—

''(i)(I) the Secretary has authorized, under subparagraph (3)(B), a claim of the type described in subparagraph (1)(B) for any nutrient contained in the supplement, with respect to the disease or other health-related condition;

''(II) such characterization is consistent with the claim authorized by the Secretary; and

''(III) the Secretary has not determined, after rulemaking based on the totality of scientific evidence (including evidence from well-designed studies conducted in a manner consistent with generally recognized scientific principles), that consumption of the nutrient in a dietary supplement would not tend to reduce the risk of the disease or other health-related condition in a similar manner as would consumption of the nutrient in conventional foods; or

''(ii) such characterization accurately represents the state of scientific evidence, as of the date of the evaluation of the claim, concerning the relationship between the supplement or ingredient of the supplement and the disease or other health-related condition, taking into account the totality of scientific evidence (including evidence from well-designed studies conducted in a manner consistent with generally recognized scientific principles).

''(B) Nothing in this subparagraph shall—

''(i) prohibit the inclusion, in the label or labeling of a dietary supplement, of truthful and nonmisleading information concerning the vitamin, mineral, or other dietary properties of the supplement (including nutritional information about the manner in which the dietary properties affect proc-

esses of the body, or prevent or repair damage caused by diet or other environmental factors); or

''(ii) permit the Secretary to establish any requirement that such a claim made in the label or labeling of a dietary supplement be approved by the Secretary before the claim may be used.''.

SEC. 8. REPORT ON NOTIFICATION REGARDING NEW CLAIMS.

(a) STUDY.—

(1) IN GENERAL.—The Director of the Office of Dietary Supplements shall conduct a study regarding the desirability of a notification requirement relating to new claims about dietary supplements.

(2) CONTENT.—Such study shall examine—

(A) the need for a requirement that a person responsible for marketing a dietary supplement provide notification to the Secretary of Health and Human Services before making such a claim;

(B) the feasibility of such a requirement;

(C) the effect of such a requirement on the marketing of dietary supplements and on the ability of consumers to purchase dietary supplements; and

(D) such other issues related to the desirability of such a requirement as the Director of the Office of Dietary Supplements may determine to be appropriate.

(b) REPORT.—Not later than 3 years after the date of enactment of this Act, the Director of the Office of Dietary Supplements shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report containing—

(1) the results of the study described in subsection (a); and

(2) any recommendations for legislative reform.

SEC. 9. DIETARY SUPPLEMENT LABELING.

Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

''(s) If—

''(1) it is a dietary supplement; and

''(2)(A) the label or labeling of the supplement fails to list—

''(i) the name of each ingredient of the supplement that is described in clause (A), (B), (C), (D), (E), or (F) of section 201(gg)(1); and

''(ii)(I) the quantity of each such ingredient; or

''(II) with respect to a proprietary blend of such ingredients, the total quantity of all ingredients in the blend;

''(B) the label or labeling of the supplement fails to identify the product by using the term 'supplement', which term may be modified with—

''(i) the name of such an ingredient; or

''(ii) by a general term such as the term 'dietary';

''(C) the supplement contains an ingredient described in section 201(gg)(1)(C), and the label or labeling of the supplement fails to identify any part of the plant from which the ingredient is derived;

''(D) the supplement—

''(i) is covered by the specifications of an official compendium;

''(ii) is represented as conforming to the specifications of an official compendium; and

''(iii) fails to so conform; or

''(E) the supplement—

''(i) is not covered by the specifications of an official compendium; and

''(ii)(I) fails to have the identity and strength that the supplement is represented to have; or

''(II) fails to meet the quality (including tablet or capsule disintegration), purity, or compositional specifications, based on validated assay or other appropriate methods, that the supplement is represented to meet.''.

SEC. 10. PROHIBITION ON CERTAIN REGULATORY ACTIONS.

Section 411 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350) is amended—

(1) in the title, by striking ''VITAMINS AND MINERALS'' and inserting ''VITAMINS, MINERALS, AND DIETARY SUPPLEMENTS''; and

(2) by adding at the end the following:

''(d)(1) Except as provided in paragraph (2)—

''(A) the Secretary may not establish, under section 201(n), 401, or 403, maximum limits on the potency of any dietary supplement, or any ingredient that is described in clause (A), (B), (C), (D), (E), or (F) of section 201(gg)(1) within such a supplement;

''(B) the Secretary may not classify any dietary supplement or any such ingredient as a drug; and

''(C) the Secretary may not limit, under section 201(n), 401, or 403, the combination or number of such ingredients within a dietary supplement.

''(2)(A) Subparagraphs (A) and (C) of paragraph (1) shall not apply in the case of such a dietary supplement or such an ingredient that is represented for use by—

''(i) individuals in the treatment or management of specific diseases or disorders;

''(ii) children; or

''(iii) pregnant or lactating women.

''(B) For purposes of this paragraph, the term 'children' means individuals who are under the age of 12 years.''.

SEC. 11. ADMINISTRATIVE AND JUDICIAL REVIEW.

The Federal Food, Drug, and Cosmetic Act is amended by adding at the end of chapter III (21 U.S.C. 331 et seq.) the following:

''SEC. 311. ADMINISTRATIVE AND JUDICIAL REVIEW.

''(a) DEFINITION.—As used in this subsection, the term 'affected party' means a manufacturer, processor, packer, distributor, or retailer, of a dietary supplement, or another appropriate person.

''(b) REVIEW OF VIOLATIONS.—

''(1) DETERMINATION OF VIOLATION.—

''(A) INFORMAL HEARING.—If the Secretary determines that an affected party has violated a provision of this Act with respect to a dietary supplement, whether the Secretary makes the determination in a warning letter issued by an officer or employee of the Department or in connection with another action to enforce a provision of this Act, the Secretary shall provide notice to the affected party of the opportunity to obtain a determination on the record after opportunity for an agency hearing regarding the alleged violation. The affected party may request such a hearing not later than 60 days after receiving the notice.

''(B) NOTIFICATION.—Not later than 30 days after the date on which the hearing is held, the Secretary shall notify the affected party whether the determination of the violation has been affirmed, modified, or revoked. Such notification shall constitute final agency action.

''(C) PROHIBITION ON ACTION.—The United States may not bring an action in any Federal court relating to the matter that is the subject of the determination until 60 days after the Secretary provides notification under subpara-

graph (B), unless the Secretary demonstrates that the dietary supplement involved in the matter poses an imminent hazard to health.

''(D) RIGHT OF ACTION.—Not later than 60 days after receipt of the notification under subparagraph (B), an affected party who receives notification of an adverse decision under subparagraph (B) may—

''(i) bring an action in a district court of the United States in any appropriate judicial district under section 1391 of title 28, United States Code, seeking de novo review of the final agency action regarding the validity of the determination; or

''(ii) bring any other action authorized by law seeking judicial review of the final agency action.

''(E) INFERENCE.—The absence of any request for a hearing under subparagraph (A), or of an action described in subparagraph (D), with respect to such a determination shall not establish any inference that the determination is valid.

''(2) SEIZURES.—

''(A) INSTITUTION OF LIBEL OF INFORMATION.—The institution by the United States of a libel of information for condemnation of a dietary supplement, on the basis of a determination that an affected party has violated a provision of this Act with respect to the supplement, shall constitute final agency action by the Secretary or the delegate of the Secretary.

''(B) RIGHT OF ACTION.—Not later than 60 days after the United States institutes such a libel of information with respect to a dietary supplement, the affected party may—

''(i) bring an action described in paragraph (1)(D)(i) seeking de novo review of the final agency action regarding the validity of the determination; or

''(ii) obtain any other means authorized by law of judicial review of the final agency action.''.

SEC. 12. OFFICE OF DIETARY SUPPLEMENTS.

(a) IN GENERAL.—Title IV of the Public Health Service Act is amended by inserting after section 486 (42 U.S.C. 287c–3) the following:

''Subpart 4—Office of Dietary Supplements

"SEC. 486E. DIETARY SUPPLEMENTS.

''(a) ESTABLISHMENT.—The Secretary shall establish an Office of Dietary Supplements within the National Institutes of Health.

''(b) PURPOSE.—The purposes of the Office are—

''(1) to explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to improve health care; and

''(2) to promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions.

''(c) DUTIES.—The Director of the Office of Dietary Supplements shall—

''(1) conduct and coordinate scientific research within the National Institutes of Health relating to dietary supplements and the extent to which the use of dietary supplements can limit or reduce the risk of diseases such as heart disease, cancer, birth defects, osteoporosis, cataracts, or prostatism;

''(2) collect and compile the results of scientific research relating to dietary supplements, including

scientific data from foreign sources or the Office of Alternative Medical Practice;

''(3) serve as the principal advisor to the Secretary and to the Assistant Secretary for Health, and to provide advice to the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs, on issues relating to dietary supplements including—

''(A) dietary intake regulations;

''(B) the safety of dietary supplements;

''(C) claims characterizing the relationship between—

''(i) dietary supplements; and

''(ii)(I) prevention of disease or other health-related conditions; and

''(II) maintenance of health; and

''(D) scientific issues arising in connection with the labeling and composition of dietary supplements;

''(4) compile a database of scientific research on dietary supplements and individual nutrients; and

''(5) coordinate funding relating to dietary supplements for the National Institutes of Health.

''(d) DEFINITION.—As used in this section, the term 'dietary supplement' has the meaning given the term in section 201(gg) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(gg)).

''(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $5,000,000 for fiscal year 1994 and such sums as may be necessary for each subsequent fiscal year.''.

(b) CONFORMING AMENDMENT.—Section 401(b)(2) of the Public Health Service Act (42 U.S.C. 281(b)(2)) is amended by adding at the end the following:

''(E) The Office of Dietary Supplements.''.

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