103D CONGRESS
2D SESSION

# S. 784

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

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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 1994''.

**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) national surveys have revealed that almost 50 percent of the 260,000,000 Americans regularly consume dietary supplements of vitamins, 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 consideration of their needs;

(11) the United States will spend over $1,000,000,000,000 on health care in 1994, which is about 12 percent of the Gross National Product of the United States, and this amount and percentage 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 4,000 products, with total annual sales of such products alone reaching at least $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 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;

(C) regulations relating to food additives are not applicable to dietary supplements and their ingredients used for food additive purposes, including stabilizers, processing agents, or preservatives; and

(D) the burden of proof is on the Food and Drug Administration to prove that a prod-

uct is unsafe before it can be removed from the marketplace;

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

(7) establish a Commission on Dietary Supplement Labels within the executive branch to develop recommendations on a procedure to evaluate health

claims for dietary supplements and provide recommendations to the President and the Congress.

**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:

''(ff) The term 'dietary supplement' means—

''(1) a product intended to supplement the diet by increasing the total dietary intake that bears or contains one or more of the following dietary ingredients:

''(A) a vitamin;

''(B) a mineral;

''(C) an herb or other botanical;

''(D) an amino acid;

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

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

''(2) a product that—

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

''(ii) complies with section 411(c)(1)(B)(ii); and

''(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

''(C) is labeled as a dietary supplement.''.

(b) EXCLUSION FROM DEFINITION OF DRUG.—Section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)) is amended by adding at the end the following new subparagraph:

''(3) The term 'drug' does not include a dietary supplement as defined in paragraph (ff), except that—

''(A) an article that is approved as a new drug, certified as an antibiotic (under section 355 or 357), or licensed as a biologic (under section 351 of the Public Health Service Act (42 U.S.C. 262 et seq.)) and was, prior to such approval, certification or license, marketed as a dietary supplement or as a food, may continue to be offered for sale as a dietary supplement unless the Secretary has issued a regulation, after notice and comment, finding that the article when used as or in a dietary supplement under the conditions of use and dosages set forth in the la-

beling for such dietary supplement, is unlawful under section 402(f); and

''(B) an article that is approved as a new drug, certified as an antibiotic (under section 355 or 357), or licensed as a biologic (under section 351 of the Public Health Service Act (42 U.S.C. 262 et seq.)) and was not prior thereto marketed as a dietary supplement or as a food, may not be considered as a dietary ingredient or dietary supplement unless the Secretary has issued a regulation, after notice and comment, finding that the article would be lawful under section 402(f) under the conditions of use and dosages set forth in the recommended labeling for such article.''.

(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 new subparagraph:

''(6) an ingredient described in paragraph (ff) 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, gelcap,'' after ''capsule,''; and

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

**SEC. 4. SAFETY OF DIETARY SUPPLEMENTS AND BURDEN OF PROOF ON FDA.**

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—

''(1) the Secretary finds, after rulemaking, presents a substantial and unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling;

''(2) the Secretary declares to pose an imminent and substantial hazard to public health or safety, except that the authority to make such declaration shall not be delegated and the Secretary shall promptly thereafter convene rulemaking pursuant to section 701(e), (f), and (g) to affirm or withdraw the declaration; or

''(3) is or contains a dietary ingredient that renders it adulterated under paragraph (a)(1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.

In any proceeding under this section, the United States bears the burden of proof on each element to show that a dietary supplement is adulterated.''.

**SEC. 5. DIETARY SUPPLEMENT CLAIMS.**

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

''DIETARY SUPPLEMENT LABELING EXEMPTIONS

''SEC. 403B. An article, another publication, a chapter in books, or the official abstract of a peer-reviewed scientific publication that appears in the article and was prepared by the author or the editors of the publication, reprinted in its entirety, shall not be defined as labeling when used in connection with the sale of dietary supplements to consumers when it—

''(1) is not false or misleading;

''(2) does not promote a particular brand of a dietary supplement;

''(3) is displayed or presented, or is displayed or presented with other such items on the same subject matter, so as to present a balanced view of the

available scientific information on a dietary supplement; and

''(4) if displayed in an establishment, is physically separate from the dietary supplements.

This section shall not apply to or restrict a retailer or wholesaler of dietary supplements in any way whatsoever in the sale of books or other publications as a part of the business of such retailer or wholesaler. In any proceeding under this section, the burden of proof shall be on the United States to establish that an article or other such matter is false or misleading.''.

**SEC. 6. STATEMENTS OF NUTRITIONAL SUPPORT.**

Section 403(r)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(1)) is amended by adding the following new sentence at the end:''For purposes of this subparagraph, a statement for a dietary supplement shall not be considered a claim of the relationship of a nutrient or dietary ingredient to a disease or health-related condition if the statement does not claim to diagnose, prevent, mitigate, treat, or cure a specific disease or class of diseases. A statement for a dietary supplement may be made if the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the

structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient.''.

**SEC. 7. CONFORMING AMENDMENTS.**

(a) SECTION 201.—The next to the last sentence of section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)) (as amended by section 3(b)) is amended to read as follows: ''A food or dietary supplement for which a claim, subject to section 403(r)(1)(B) and 403(r)(3) or section 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and nonmisleading statement is made in accordance with section 403(r)(1) is not a drug solely because the label or the labeling contains such a statement.''.

(b) SECTION 403.—Section 403 (21 U.S.C. 343) is amended by adding at the end the following:

''A dietary supplement shall not be deemed misbranded solely because its label or labeling contains directions or conditions of use or warnings.''.

**SEC. 8. 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 new section:

**"SEC. 311. WARNING LETTERS.**

''Any warning letter or similar written threat of enforcement under the Federal Food, Drug, and Cosmetic Act constitutes final agency action for the purpose of obtaining judicial review under chapter 7 of title 5, United States Code, if the matter with respect to such letter or threat is not resolved within 60 days from the date such letter or threat is delivered to any person subject to this Act. In any proceeding for judicial review of a warning letter or similar written threat of enforcement under the Act, the United States bears the burden of proof on each element of each alleged violation of law described.''.

**SEC. 9. WITHDRAWAL OF THE REGULATIONS AND NOTICE.**

(a) IN GENERAL.—The advance notice of proposed rulemaking concerning dietary supplements published in the Federal Register of June 18, 1993 (58 FR 33690–33700), the notices of proposed rulemaking concerning nutrition labeling for dietary supplements and nutrient content claims for dietary supplements published in the Federal Register of June 18, 1993 (58 FR 33715–33731 and 58 FR 33731–33751), and the final rules and notices published in the Federal Register of January 4, 1994 con-

cerning nutrition labeling for dietary supplements and nutrient content claims for dietary supplements (59 FR 354–378 and 378–395) are null and void and of no force or effect insofar as they apply to dietary supplements. Final regulations and notices published in the Federal Register of January 4, 1994 concerning health claims for dietary supplements under the Nutrition Labeling and Education Act of 1990 (59 FR 395–426) shall not be affected by this section and shall remain in effect until 120 days after the date of the submission of the final report of the Commission established under section 11 to the President and to Congress, or 28 months after the date of enactment of this Act, whichever is earlier.

(b) NOTICE OF REVOCATION.—The Secretary of Health and Human Services shall publish notices in the Federal Register to revoke all of the items declared to be null and void and of no force or effect under subsection (a).

(c) ISSUANCE OF REGULATIONS.—Notwithstanding any provision of the Nutrition Labeling and Education Act of 1990—

(1) no regulation is required to be issued pursuant to such Act with respect to dietary supplements of vitamins, minerals, herbs, amino acids, or other similar nutritional substances; and

(2) no regulation that is issued in whole or in part pursuant to such Act shall have any force or effect with respect to any dietary supplement of vitamins, minerals, herbs, amino acids, or other similar nutritional substances unless such regulation is issued pursuant to rulemaking proceedings that are initiated by an advance notice of proposed rulemaking that is published no earlier than 2 years after the date of enactment of this Act, and followed by, at least, a notice of proposed rulemaking prior to issuance of the final regulation, except insofar as the regulation authorizes the use of labeling about calcium, folic acid, or other matters and does not prohibit the use of any labeling.

**SEC. 10. DIETARY SUPPLEMENT INGREDIENT LABELING AND NUTRITION INFORMATION LABELING.**

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

''(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 section 201(ff); 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 dietary supplement fails to identify the product by using the term 'dietary supplement', which term may be modified with the name of such an ingredient;

''(C) the supplement contains an ingredient described in section 201(ff) (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.''.

(b) SUPPLEMENT LISTING ON NUTRITION LABELING.—Section 403(q)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(1)) is amended by adding at the end the following: ''A dietary supplement may bear on the nutrition label or in labeling a listing and quantity of ingredients that have not been deemed essential nutrients by the Secretary if such ingredients are prominently identified as not having been shown to be essential or not having an established daily value.''.

(c) DIETARY SUPPLEMENT LABELING EXEMPTIONS.—Section 403(q)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)) is amended by adding at the end the following new clause:

''(H) The labels of dietary supplements shall not be required to bear the nutrition information under subparagraph (1), but shall be required to list immediately above the ingredient listing the amount of nutrients required by

the Secretary to be listed pursuant to clause (C), (D) or (E) of subparagraph (1) or clause (A) of subparagraph (2) that are present in significant amounts in the supplement.''.

(d) VITAMINS AND MINERALS.—Section 411(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350(b)(2)) is amended—

(1) by striking ''vitamins and minerals'' and inserting ''dietary supplement ingredients described in section 201(ff)'';

(2) by striking ''(2)(A)'' and inserting ''(2)''; and

(3) by striking subparagraph (B).

**SEC. 11. COMMISSION ON DIETARY SUPPLEMENT LABELS.**

(a) ESTABLISHMENT.—There shall be established as an independent agency within the executive branch a commission to be known as the Commission on Dietary Supplement Labels (hereafter in this section referred to as the ''Commission'').

(b) MEMBERSHIP.—

(1) COMPOSITION.—The Commission shall be composed of 7 members who shall be appointed by the President.

(2) EXPERTISE REQUIREMENT.—The members of the Commission shall consist of individuals with

expertise and experience in dietary supplements and in the manufacture, regulation, distribution, and use of such supplements. At least three of the members of the Commission shall be qualified by scientific training and experience to evaluate the benefits to health of the use of dietary supplements and one of such three members shall have experience in pharmacognosy, medical botany, traditional herbal medicine, or other related sciences. No member of the Commission shall be biased against dietary supplements.

(c) FUNCTIONS OF THE COMMISSION.—The Commission shall conduct a study on, and provide recommendations for, the regulation of label claims for dietary supplements, including procedures for the evaluation of such claims. In making such recommendations, the Commission shall evaluate how best to provide truthful and nonmisleading information to consumers so that such consumers may make informed health care choices for themselves and their families.

(d) REPORTS AND RECOMMENDATIONS.—

(1) FINAL REPORT REQUIRED.—Not later than 24 months after the date of enactment of this Act, the Commission shall prepare and submit to the

President and to the Congress a final report on the study required by this section.

(2) RECOMMENDATIONS.—The report described in paragraph (1) shall contain such recommendations, including recommendations for legislation, as the Commission deems appropriate.

(e) ADMINISTRATIVE POWERS OF THE COMMISSION.—

(1) HEARINGS.—The Commission may hold hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Commission considers advisable to carry out the purposes of this section.

(2) INFORMATION FROM FEDERAL AGENCIES.—The Commission may secure directly from any Federal department or agency such information as the Commission considers necessary to carry out the provisions of this section.

(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may necessary to carry out the provisions of this section.

**SEC. 12. GOOD MANUFACTURING PRACTICES.**

Section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) (as amended by section 4) is further amended by adding at the end the following:

''(g)(1) If it is a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations issued by the Secretary under subparagraph (2).

''(2) The Secretary may by regulation prescribe good manufacturing practices for dietary supplements. Such regulations shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology. No standard of current good manufacturing practice may be imposed unless such standard is included in a regulation promulgated after notice and opportunity for comment in accordance with the Administrative Procedure Act.''.

**SEC. 13. 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(ff) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff)).

''(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.''.

Passed the Senate August 13 (legislative day, August 11), 1994.

Attest:

*Secretary.*

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