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106TH CONGRESS
1ST SESSION

# H. R. 3001

To amend the Federal Food, Drug, and Cosmetic Act to promote clinical research and development on dietary supplements and foods for their health benefits; to establish a new legal classification for dietary supplements and foods with health benefits, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

OCTOBER 1, 1999

Mr. PALLONE introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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# A BILL

To amend the Federal Food, Drug, and Cosmetic Act to promote clinical research and development on dietary supplements and foods for their health benefits; to establish a new legal classification for dietary supplements and foods with health benefits, 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 AND REFERENCE.**

(a) SHORT TITLE.—This Act may be cited as the ''Nutraceutical Research and Education Act''.

(b) REFERENCE.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

**SEC. 2. FINDINGS AND STATEMENT OF PURPOSE.**

(a) FINDINGS.—The Congress finds the following:

(1) Consumers spend annually an estimated $12,000,000,000 on dietary supplements and billions more on medical and similar foods. Nevertheless, the health benefits of these products have not, in most cases, been demonstrated by clinical testing or other means. In consequence, specific health claims may not be advanced for them. Consumers are thus left uncertain as to the value of these products in promoting health and well-being, and preventing or reducing the risk of disease, including the management of a disease or condition. The companies that produce these products desire to provide them to consumers with specific health claims based on clinical testing. The Federal Government demands sound scientific evidence of safety and effectiveness in order to fulfill its statutory mandate to protect and promote the public health.

(2) Because dietary supplements and similar foods are natural products widely available without a strong proprietary position, a person who now finances the cost of research successfully demonstrating the health benefits of such a product receives no special economic benefit in the marketplace to repay that cost. Others, who have not contributed to those research costs, may nevertheless embrace the findings of that research to support identical claims for their own versions of the product. Without economic incentive to research and develop new products, those who would finance the cost of research are presently focusing their efforts on promotional activities to the disservice of the public interest and health.

(3) It is in the national interest to encourage clinical research into the health benefits of dietary supplements, medical foods, and other foods.

(4) Current regulatory and epistemological chaos exists with regard to health claims for foods, dietary supplement, and medical foods. It is in the national interest to provide a category of products that have recognized health benefits but are not drugs and to recognize that these products are safe when used as indicated on their labeling.

(5) It is necessary to promote research into the health benefits of dietary supplements, medical foods, and other foods and to require that these health benefits be established by the results of clinical studies.

(6) It is necessary to establish a regulatory system within the Food and Drug Administration for reviewing health claims of health benefits of such products which is less burdensome than the traditional regulatory scheme for drugs and to stimulate the industry to devote resources to proving the health claims anticipated under this Act since such claims relate to the possibility of preventing or reducing the risk of disease, including the management of a disease or health condition.

(7) It is necessary to update the present regulatory scheme to reflect the fact that such products can safely prevent disease and health conditions, manage or improve health, or reduce the risk of disease.

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

(1) promote research into the health benefits of dietary supplements, medical foods, and other foods;

(2) establish a simplified process within the Food and Drug Administration for reviewing, on a case by case method, health claims of health benefits of such nutraceutical products made under a petition under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(3));

(3) prescribe a period of exclusive marketing protection for a person that demonstrates the health benefits of a dietary supplement, medical food, or other food, and who markets such product in association with approved labeling that describes its contribution to human health; and

(4) confirm the health benefits of these products as determined by clinical trials, and disseminate this information to the public and the health care profession, so that the public and the health care profession may integrate this knowledge into practice.

**SEC. 3. DEFINITIONS.**

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

''(kk) The term 'nutraceutical' means a dietary supplement, food, or medical food, as respectively defined in paragraphs (f) and (ff) and section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)), that—

''(1) possesses health benefits; and

''(2) is safe for human consumption in such quantity, and with such frequency, as required to realize such properties.

''(ll) The term 'health benefit', when used with reference to a nutraceutical, means a benefit which prevents or reduces the risk of a disease or health condition, including the management of a disease or health condition or the improvement of health.

**SEC. 4. HEALTH CLAIMS.**

(a) NUTRACEUTICAL HEALTH CLAIM.—Section 403(r)(5)(D) (21 U.S.C. 343(r)(5)(D)) is amended by inserting before the period the following: ''except that in the case of a claim made with respect to a nutraceutical, the regulation shall be issued by the Secretary under subparagraph (4)(D)''.

(b) PETITION.—Section 403(r)(4) (21 U.S.C. 343(r)(4)) is amended by adding at the end the following:

''(D)(i) Any person may file a petition with the Secretary to issue a regulation relating to a claim for a nutraceutical described in subparagraph (5)(D).

''(ii) A petition filed under subclause (i) shall be prepared in such form, and submitted in such manner, as the Secretary may prescribe, and, with respect to the prod-

uct sought to be introduced as a nutraceutical, shall contain the following:

''(I) A report of at least 1 clinical trial which has been conducted on the product which is the subject of the petition. Such clinical trial results shall address the potential health benefits of the product and its safety. The results of the clinical trial must demonstrate and characterize the beneficial relationship or the significance of the relationship of the nutraceutical in such product to a disease or its affects on a health related condition, health problem, or health status. The clinical trial must have a sufficient size to prove the benefits and may have as its endpoints either surrogate markers or clinical endpoints to support the claim. The application may also include epidemiological or preclinical studies in support of the clinical trial. The amount of evidence necessary to sustain a claim will be determined by the Secretary on a case by case basis.

''(II) Evidence that it is safe for human consumption in such quantity, and with such frequency, as required to provide the health benefits.

''(III) A complete description, in the case of a processed product, as to its ingredients or chemical composition.

''(IV) Information adequate to enable the Secretary to determine, where pertinent, that the methods used in, and the facilities and controls used for, processing and packing the product are sufficient to preserve its identity, strength, quality, and purity.

''(V) Such samples of the product as the Secretary may require.

''(VI) A specimen of the labeling proposed to be used with the product, when introduced or delivered for introduction into commerce as a nutraceutical, that accurately and completely describes its health benefits under its stated conditions of use.

''(iii) Within 7 days of the receipt of a petition, the Secretary shall cause it to be published in the Federal Register to provide notice to the public that the petition has been filed. Such notice shall contain the name of the petitioner, date and time of filing, a summary and description of the proposed product, and the nature of the proposed health claim.

''(iv) When a petition is filed for a nutraceutical claim under subparagraph (5)(D), no other petition for a product which is the same as or similar to the product for which a petition has been filed and no other petition for a claim which is the same or similar to the claim for which

a petition has been filed may be filed until final action has been taken on the first petition.

''(v) A person who files a petition for a claim for a nutraceutical claim under subparagraph (5)(D) may apply to the Secretary to amend the petition when the amendment is required by a change in the product due to new and unexpected findings in research on the product or the disease or condition for which the product is being proposed.

''(vi) The Secretary shall refer any petition filed for a nutraceutical claim under subclause (i) to the Advisory Council on Nutraceuticals established under section 7 of the Nutraceutical Research and Education Act.

''(vii) The Secretary shall take final action on a petition which—

''(I) was filed under subclause (i), and

''(II) was determined by such Advisory Council on Nutraceuticals to be worthy of review,

not later than 6 months after the date the petition is filed.''.

**SEC. 5. MARKET PROTECTION FOR NUTRACEUTICAL.**

(a) IN GENERAL.—Section 403(r) is amended by adding at the end the following:

''(8) If the Secretary issues a regulation in response to a petition filed under subparagraph (4) relating to a

claim for a nutraceutical described in subparagraph (5)(D), the Secretary may not issue another regulation for an essentially identical nutraceutical claim during the 10-year period that begins on the date that the Secretary approved the original petition, except that—

''(A) if a petition is submitted for an essentially identical nutraceutical claim for a nutraceutical the intended use of which provides greater effectiveness, greater safety, or otherwise a major contribution to patient care, the Secretary may issue a regulation under subparagraph (4)(D) for such claim; or

''(B) if a petition is subsequently revoked, another petition may be submitted to the Secretary for an essentially identical nutraceutical claim.''.

(b) MISBRANDING.—Section 402 (21 U.S.C. 342) is amended by adding at the end the following:

''(h) If it is a nutraceutical and it has not had a petition approved under section 403(r)(4)(D).''.

**SEC. 6. GOOD MANUFACTURING PRACTICES.**

Section 402(g) (21 U.S.C 342(g)) is amended by—

(1) inserting '', including a nutraceutical'' after ''dietary supplement'' in subparagraph (1); and

(2) inserting '', including nutraceuticals'' after ''dietary supplements'' in subparagraph (2).

**SEC. 7. ADVISORY COUNCIL ON NUTRACEUTICALS.**

(a) ESTABLISHMENT.—There is established within the Food and Drug Administration an advisory council to be known as the ''Advisory Council on Nutraceuticals''.

(b) DUTIES.—The Advisory Council shall evaluate the merit of each petition filed for a nutraceutical health claim under section 403(r)(4)(D) of the Federal Food, Drug, and Cosmetic Act, including the proposed labeling of the product that is the subject of the petition, and submit its evaluation to the Secretary. The evaluation of the Advisory Council shall determine if a petition is worthy of review by the Food and Drug Administration and whether it conflicts with any other petition.

(c) MEMBERSHIP.—

(1) IN GENERAL.—The Advisory Council shall consist of ex officio members and not more than 6 additional members appointed by the Secretary. The ex officio members shall be nonvoting members.

(2) EX OFFICIO MEMBERS.—The ex officio members of the Advisory Council shall be the Secretary, the Director of the National Institutes of Health (hereinafter in this Act referred to as the ''Director of NIH''), and such additional officers or employees of the United States as the Secretary determines necessary for the Advisory Council to carry out its functions.

(3) OTHER MEMBERS.—The members of the Advisory Council who are not ex officio members shall be appointed by the Secretary from among individuals distinguished in the fields of health, nutrition, or biomedical research.

(d) COMPENSATION.—Members of the Advisory Council who are officers or employees of the United States shall serve on the Advisory Council as part of their official duties, and shall not receive additional compensation therefor. Other members of the Advisory Council shall receive, for each day (including traveltime) they are engaged in the performance of Advisory Council functions, compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade ES–1 (5 U.S.C. 5382). Such other members, when performing Advisory Council functions (including travel to and from Advisory Council meetings), shall be entitled to travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

(e) TERM.—The term of office of an appointed member of the Advisory Council is 4 years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term and the Secretary shall make appointments to the Advisory Coun-

cil in such a manner as to ensure that the terms of the members do not all expire in the same year. A member may serve after the expiration of the member's term for 180 days after the date of such expiration. A member who has been appointed for a term of 4 years may not be reappointed to the Advisory Council before 2 years from the date of expiration of such term of office. If a vacancy occurs in the Advisory Council among the appointed members, the Secretary shall make an appointment to fill the vacancy within 90 days from the date the vacancy occurs.

(f) CHAIR.—The Secretary shall select the chair of the Advisory Council from among the appointed members. The term of office of the chair shall be 2 years.

(g) MEETINGS AND PROCEDURES.—The Advisory Council shall meet at the call of the chair, or at the direction of the Director of the National Institutes of Health, but with sufficient frequency to ensure prompt evaluation of every nutraceutical petition referred to it by the Secretary. The Advisory Council shall adopt rules governing its procedures.

(h) FEDERAL ADVISORY COMMITTEE ACT.—Meetings and proceedings of the Advisory Council shall not be subject to the Federal Advisory Committee Act (5 U.S.C. Appendix).

**SEC. 8. NUTRACEUTICAL INDEX.**

The Secretary shall maintain, and periodically publish in the Federal Register, an index that shall list—

(1) the name and description of each nutraceutical for which there is an approved petition, the name and address of the applicant, and the date upon which the Secretary approved the petition; and

(2) each petition pending with the Secretary, the date upon which it was filed with the Secretary, the name and address of the applicant, and a description of the nutraceutical and the claim made for the nutraceutical that is the subject of that petition.

**SEC. 10. SMALL BUSINESS ANTITRUST EXEMPTION.**

(a) EXEMPTION.—It shall not be unlawful under the antitrust laws for 2 or more small businesses to agree to combine their resources to meet the requirements of section 403(r) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(r)) for claims of health benefits of a nutraceutical.

(b) DEFINITIONS.—

(1) ANTITRUST LAWS.—The term ''antitrust laws'' has the meaning given such term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), except that such term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45)

to the extent such section applies to unfair methods of competition.

(2) NUTRACEUTICAL.—The term ''nutraceutical'' has the meaning given such term in section 201(k)(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(k)(k)).

(3) SMALL BUSINESS.—The term ''small business'' has the meaning given such term in section 736(d)(3)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(d)(3)(A)).

**SEC. 11. EFFECTIVE DATE.**

This Act and the amendments made by this Act shall take effect 90 days after the date of its enactment.

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