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111TH CONGRESS
2D SESSION

H. R. 4913

To amend the Federal Food, Drug, and Cosmetic Act concerning the distribution of information on legitimate scientific research in connection with foods and dietary supplements, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 23, 2010

Mr. CHAFFETZ (for himself and Mr. POLIS of Colorado) 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 concerning the distribution of information on legitimate scientific research in connection with foods and 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 ''Free Speech About Science Act of 2010''.

SEC. 2. FINDINGS.

The Congress finds the following:

(1) Federal regulators have forbidden—

(A) cherry growers and food producers to cite independent and respected scientific research on their produce that references health benefits; and

(B) a variety of dietary supplement makers to cite independent scientific research on health benefits from supplements from respected, peer-reviewed scientific journals.

(2) Americans want access and have a right to access legitimate scientific information about foods and dietary supplements to ensure informed decisions about diet and health care. While the American public is inundated daily with advertisements about prescription drugs for health conditions, many of which could be prevented through lifestyle changes, proper nutrition, and informed use of dietary supplements, Americans are denied access to the very information that assists in making informed lifestyle and health care decisions.

(3) Providing access to scientific information promotes self-responsibility, thereby empowering Americans to exercise independent judgment in caring for themselves and ultimately reducing health care costs and improving quality of life.

(4) The United States has a long commitment to the free dissemination of scientific research with the exception of limited extreme situations for national security. This commitment goes back to the First Amendment to the Constitution and has contributed vitally to the Nation's economic progress.

SEC. 3. MISBRANDED FOOD AND DIETARY SUPPLEMENTS.

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

(1) in subparagraph (3)—

(A) by redesignating clause (D) as clause (E);

(B) by inserting after clause (C) the following:

''(D) Notwithstanding the provisions of clauses (A)(i) and (B), a claim of the type described in subparagraph (1)(B) which is not authorized by the Secretary in a regulation promulgated in accordance with clause (B) shall be authorized and may be made with respect to a food if—

''(i) the claim is based on legitimate scientific research;

''(ii) the claim and the food for which the claim is made are in compliance with clause (A)(ii) and are otherwise in compliance with paragraph (a) and section 201(n);

''(iii) the claim is stated in a manner so that the claim—

''(I) is an accurate balanced summary of such research; and

''(II) enables the public to comprehend the information provided in the claim and the relative significance of such information in the context of a total daily diet;

''(iv) the claim includes a citation to such research; and

''(v) the claim identifies each party that funded such research.'';

(C) in clause (E), as so redesignated, by striking ''clause (C)'' each place it appears and inserting ''clause (C) or (D)''; and

(D) by adding at the end the following:

''(F) In this subparagraph, the term 'legitimate scientific research' means scientific research, whether performed in vitro, in vivo, in animals, or in humans, that—

''(i) is conducted in accordance with sound scientific principles;

''(ii) has been evaluated and accepted by a scientific or medical panel; and

''(iii) has been published in its entirety, or as an accurate, balanced summary or scientific review

including a citation to the research in its entirety, in—

''(I) a peer-reviewed article or book;

''(II) a recognized textbook;

''(III) a peer-reviewed scientific publication; or

''(IV) any publication of the United States Government (including ones published by or at the request of a Federal department, agency, institute, center, or academy).'';

(2) by amending subparagraph (6) to read as follows:

''(6)(A) For purposes of subparagraph (1)(B), a statement for a dietary supplement may be made if—

''(i) the statement claims a benefit related to a classical nutrient deficiency condition and discloses the prevalence of such condition 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;

''(ii) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading;

''(iii) the statement contains, prominently displayed and in boldface type, the following: 'This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.'; and

''(iv) the statement does not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.

''(B) Notwithstanding subparagraph (1)(B), a statement for a dietary supplement may be made if—

''(i) the statement claims to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases, based on legitimate scientific research (as defined in subparagraph (3)(F));

''(ii) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading;

''(iii) the statement contains, prominently displayed and in boldface type, the following: 'This statement has not been evaluated by the Food and Drug Administration.';

''(iv) the claim includes a citation to the research referred to in subclause (i); and

''(v) the claim identifies each party that funded such research.

If the manufacturer of a dietary supplement proposes to make a statement described in clause (A) or (B) in the labeling of the dietary supplement, the manufacturer shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made.''; and

(3) by adding at the end the following:

''(8) Subject to subparagraph (1) (relating to claims in the label or labeling of food), the Secretary shall take no action to restrict in any way the distribution of information that is not false or misleading on legitimate scientific research (as defined in subparagraph (3)(F)) in connection with the sale of food.''.

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