

112TH CONGRESS
1ST SESSION

H. R. 1364

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

APRIL 5, 2011

Mr. CHAFFETZ (for himself and Mr. POLIS) introduced the following bill;
which was referred to the Committee on Energy and Commerce

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Free Speech About
5 Science Act of 2011”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds the following:

8 (1) Federal regulators have forbidden—

1 (A) cherry growers and food producers to
2 cite independent and respected scientific re-
3 search on their produce that references health
4 benefits; and

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

9 (2) Americans want access and have a right to
10 access legitimate scientific information about foods
11 and dietary supplements to ensure informed deci-
12 sions about diet and health care. While the Amer-
13 ican public is inundated daily with advertisements
14 about prescription drugs for health conditions, many
15 of which could be prevented through lifestyle
16 changes, proper nutrition, and informed use of die-
17 tary supplements, Americans are denied access to
18 the very information that assists in making informed
19 lifestyle and health care decisions.

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

1 (4) The United States has a long commitment
2 to the free dissemination of scientific research with
3 the exception of limited extreme situations for na-
4 tional security. This commitment goes back to the
5 First Amendment to the Constitution and has con-
6 tributed vitally to the Nation’s economic progress.

7 **SEC. 3. MISBRANDED FOOD AND DIETARY SUPPLEMENTS.**

8 Section 403(r) of the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 343(r)) is amended—

10 (1) in subparagraph (3)—

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

13 (B) by inserting after clause (C) the fol-
14 lowing:

15 “(D) Notwithstanding the provisions of clauses (A)(i)
16 and (B), a claim of the type described in subparagraph
17 (1)(B) which is not authorized by the Secretary in a regu-
18 lation promulgated in accordance with clause (B) shall be
19 authorized and may be made with respect to a food if—

20 “(i) the claim is based on legitimate scientific
21 research;

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

1 “(iii) the claim is stated in a manner so that
2 the claim—

3 “(I) is an accurate balanced summary of
4 such research; and

5 “(II) enables the public to comprehend the
6 information provided in the claim and the rel-
7 ative significance of such information in the
8 context of a total daily diet;

9 “(iv) the claim includes a citation to such re-
10 search; and

11 “(v) the claim identifies each party that funded
12 such research.”;

13 (C) in clause (E), as so redesignated, by
14 striking “clause (C)” each place it appears and
15 inserting “clause (C) or (D)”; and

16 (D) by adding at the end the following:

17 “(F) In this subparagraph, the term ‘legitimate sci-
18 entific research’ means scientific research, whether per-
19 formed in vitro, in vivo, in animals, or in humans, that—

20 “(i) is conducted in accordance with sound sci-
21 entific principles;

22 “(ii) has been evaluated and accepted by a sci-
23 entific or medical panel; and

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

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

3 “(I) a peer-reviewed article or book;

4 “(II) a recognized textbook;

5 “(III) a peer-reviewed scientific publica-
6 tion; or

7 “(IV) any publication of the United States
8 Government (including ones published by or at
9 the request of a Federal department, agency,
10 institute, center, or academy).”;

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

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

15 “(i) the statement claims a benefit related to a
16 classical nutrient deficiency condition and discloses
17 the prevalence of such condition in the United
18 States, describes the role of a nutrient or dietary in-
19 gredient intended to affect the structure or function
20 in humans, characterizes the documented mechanism
21 by which a nutrient or dietary ingredient acts to
22 maintain such structure or function, or describes
23 general well-being from consumption of a nutrient or
24 dietary ingredient;

1 “(ii) the manufacturer of the dietary supple-
2 ment has substantiation that such statement is
3 truthful and not misleading;

4 “(iii) the statement contains, prominently dis-
5 played and in boldface type, the following: ‘This
6 statement has not been evaluated by the Food and
7 Drug Administration. This product is not intended
8 to diagnose, treat, cure, or prevent any disease.’; and

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

12 “(B) Notwithstanding subparagraph (1)(B), a state-
13 ment for a dietary supplement may be made if—

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

18 “(ii) the manufacturer of the dietary supple-
19 ment has substantiation that such statement is
20 truthful and not misleading;

21 “(iii) the statement contains, prominently dis-
22 played and in boldface type, the following: ‘This
23 statement has not been evaluated by the Food and
24 Drug Administration.’;

1 “(iv) the claim includes a citation to the re-
2 search referred to in subclause (i); and

3 “(v) the claim identifies each party that funded
4 such research.

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

11 (3) by adding at the end the following:

12 “(8) Subject to subparagraph (1) (relating to claims
13 in the label or labeling of food), the Secretary shall take
14 no action to restrict in any way the distribution of infor-
15 mation that is not false or misleading on legitimate sci-
16 entific research (as defined in subparagraph (3)(F)) in
17 connection with the sale of food.”.

18 **SEC. 4. FALSE ADVERTISING.**

19 (a) **DISSEMINATION OF LEGITIMATE SCIENTIFIC RE-**
20 **SEARCH IN CONNECTION WITH SALE OR DISTRIBUTION**
21 **OF FOOD OR DIETARY SUPPLEMENT.**—Section 12 of the
22 Federal Trade Commission Act (15 U.S.C. 52) is amended
23 by adding at the end the following:

24 “(c)(1) The dissemination of legitimate scientific re-
25 search in connection with the sale or distribution of a food

1 or dietary supplement to consumers shall not be deter-
2 mined to be false advertising by virtue of the fact that
3 the research does not directly correlate to the type of food
4 or dietary supplement (including any component thereof)
5 being sold or distributed if the dissemination includes a
6 clear disclosure that the research does not directly cor-
7 relate to such type of food or dietary supplement.

8 “(2) In any proceeding under section 13, the burden
9 of proof shall be on the Commission to establish that the
10 literature being disseminated is not legitimate scientific
11 research.”.

12 (b) DEFINITIONS.—Section 15 of the Federal Trade
13 Commission Act (15 U.S.C. 55) is amended by adding at
14 the end the following:

15 “(g) The term ‘dietary supplement’ has the meaning
16 given to such term in section 201 of the Federal Food,
17 Drug, and Cosmetic Act.

18 “(h) The term ‘legitimate scientific research’ has the
19 meaning given to such term in section 403(r) of the Fed-
20 eral Food, Drug, and Cosmetic Act.”.

○