

110TH CONGRESS
2D SESSION

H. R. 7120

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

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 26, 2008

Mr. CANNON 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 and citation of 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 “Science Free Speech
5 Act”.

6 **SEC. 2. DEFINITION OF A DRUG.**

7 Section 201(g)(1) of the Federal Food, Drug, and
8 Cosmetic Act (21 U.S.C. 321(g)(1)) is amended by adding

1 at the end the following: “A food or dietary supplement,
2 for which a claim regarding legitimate scientific research
3 is made in accordance with section 403B, is not a drug
4 solely because of such claim.”.

5 **SEC. 3. MISBRANDED FOOD.**

6 Section 403(r)(1)(B) of the Federal Food, Drug, and
7 Cosmetic Act (21 U.S.C. 343(r)(1)(B)) is amended by
8 striking “unless the claim is made in accordance with sub-
9 paragraph (3) or (5)(D)” and inserting “unless the claim
10 is made in accordance with subparagraph (3) or (5)(D)
11 or is a claim regarding legitimate scientific research made
12 in accordance with section 403B”.

13 **SEC. 4. FOOD AND DIETARY SUPPLEMENT LABELING EX-**
14 **EMPTIONS.**

15 Section 403B of the Federal Food, Drug, and Cos-
16 metic Act (21 U.S.C. 343–2) is amended to read as fol-
17 lows:

18 **“SEC. 403B. FOOD AND DIETARY SUPPLEMENT LABELING**
19 **EXEMPTION.**

20 “(a) **LEGITIMATE SCIENTIFIC RESEARCH.**—The use
21 of truthful and not misleading information on legitimate
22 scientific research in connection with the sale or distribu-
23 tion of a food or dietary supplement to consumers shall
24 not be treated as a violation of this Act and shall not be
25 deemed evidence of an intent to sell a drug.

1 “(b) ACTIONS BY SECRETARY.—The Secretary—

2 “(1) shall not restrict in any way the distribu-
3 tion of truthful and not misleading information on
4 legitimate scientific research described in subsection
5 (a); and

6 “(2) shall not prohibit manufacturers or dis-
7 tributors of foods or dietary supplements from in-
8 cluding citations to legitimate scientific research in
9 the labeling of a food or a dietary supplement, even
10 if the citation expressly or implicitly references a dis-
11 ease or a disease condition.

12 “(c) BURDEN OF PROOF.—In any administrative or
13 judicial proceeding in which the Secretary contests the use
14 of material being disseminated or cited as legitimate sci-
15 entific research, the burden of proof shall be on the Sec-
16 retary to disprove that the material is truthful and not
17 misleading information on legitimate scientific research.

18 “(d) DEFINITION.—In section 201(g) and this sec-
19 tion, the term ‘legitimate scientific research’ means sci-
20 entific research, whether performed in vitro, in vivo, in
21 animals, or in humans, that is—

22 “(1) conducted in accordance with sound sci-
23 entific principles; and

24 “(2) evaluated and accepted by a scientific or
25 medical panel or published in—

1 “(A) a recognized scholastic textbook or a
2 peer-reviewed scientific publication or database;

3 “(B) any publication of the United States
4 Government (including publications by or at the
5 request of any Federal department, agency, in-
6 stitute, center, or academy); or

7 “(C) an accurate balanced summary or sci-
8 entific review of information published in ac-
9 cordance with subparagraph (A) or (B).”.

10 **SEC. 5. DIAGNOSTIC TESTS.**

11 Chapter III of the Federal Food, Drug, and Cosmetic
12 Act (21 U.S.C. 331 et seq.) is amended by inserting after
13 section 301 the following:

14 **“SEC. 301A. PERMITTED ACTS.**

15 “The Secretary shall not prohibit or restrict a retailer
16 or wholesaler of any agricultural product, including fresh
17 produce, in any way from—

18 “(1) testing any of its agricultural products for
19 any pathogens, including bacteria, viruses, protozoa,
20 fungi, or parasites, that may—

21 “(A) potentially be transmitted to humans;

22 or

23 “(B) potentially cause illness or disease in
24 humans; or

1 “(2) communicating the results of the tests de-
2 scribed in paragraph (1) to the public.”.

○