

111TH CONGRESS  
1ST SESSION

# H. R. 3394

To amend the Federal Trade Commission Act concerning the burden of proof in false advertising cases involving dietary supplements and dietary ingredients.

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## IN THE HOUSE OF REPRESENTATIVES

JULY 29, 2009

Mr. PAUL (for himself and Mr. BURTON of Indiana) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Trade Commission Act concerning the burden of proof in false advertising cases involving dietary supplements and dietary ingredients.

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 “Freedom of Health  
5 Speech Act”.

6 **SEC. 2. HEALTH INFORMATION.**

7 Section 5 of the Federal Trade Commission Act (15  
8 U.S.C. 45) is amended by adding at the end the following:

1       “(o) ADVERTISING OF DIETARY SUPPLEMENTS AND  
2 DIETARY INGREDIENTS.—

3               “(1) DEFINITIONS.—In this subsection—

4                       “(A) the term ‘dietary supplement’ has the  
5 meaning given to that term in section 201(ff)  
6 (21 U.S.C. 321(ff)) of the Federal Food, Drug,  
7 and Cosmetic Act; and

8                       “(B) the term ‘dietary ingredient’ means  
9 an ingredient listed in subparagraph (A)  
10 through (F) of section 201(ff)(1) (21 U.S.C.  
11 321(ff)(1)) of the Federal Food, Drug, and  
12 Cosmetic Act that is included in, or that is in-  
13 tended to be included in, a dietary supplement.

14               “(2) EXEMPTIONS FROM REGULATION AS AD-  
15 VERTISING.—No content of any publication shall be  
16 considered advertising regulable under this Act un-  
17 less the content is intended by the seller of a prod-  
18 uct to promote the sale of that product and the con-  
19 tent includes (A) the name of the product offered for  
20 sale; (B) an express offer to sell the named product;  
21 and (C) a purchase price for the product. No con-  
22 tent excerpted in whole or part from a peer-reviewed  
23 scientific publication shall be considered advertising  
24 regulable under this Act.

1           “(3) NO IMPLIED CLAIMS.—In any investiga-  
2           tion commenced by the Commission and in any adju-  
3           dicative proceeding in which the Commission is a  
4           party, the Commission shall not attribute to an ad-  
5           vertiser accused of false advertisement any adver-  
6           tising statement not actually made by that adver-  
7           tiser.

8           “(4) NOTICE, OPPORTUNITY TO CURE, AND  
9           BURDEN OF PROOF FOR INVESTIGATION.—Before  
10          the Commission authorizes an investigation of false  
11          advertisement by an advertiser of a dietary supple-  
12          ment or a dietary ingredient, the Commission shall  
13          send the advertiser a written ‘Notice of Suspected  
14          Violation and Opportunity to Cure’ informing the  
15          advertiser of—

16               “(A) the precise advertising statement that  
17               the Commission suspects may be false or mis-  
18               leading;

19               “(B) the scientific basis for the Commis-  
20               sion’s view that any statement of health benefit  
21               may be false or misleading; and

22               “(C) a date certain, not less than 30 days  
23               after the date of the advertiser’s receipt of the  
24               notice, by which the advertiser may voluntarily  
25               discontinue further use of the statement the

1 Commission suspects may be false or mis-  
2 leading and, upon so doing, the advertiser shall  
3 not be subject to an investigation of false adver-  
4 tisement by the Commission for the statement.

5 The Commission shall not commence any investiga-  
6 tion of an advertiser of a dietary supplement or a di-  
7 etary ingredient to determine whether the advertiser  
8 has disseminated a false advertisement unless it pos-  
9 sesses before the commencement of such investiga-  
10 tion clear and convincing evidence that the advertise-  
11 ment is false and misleading.

12 “(5) BURDEN OF PROOF FOR FALSE ADVER-  
13 TISEMENT CASES.—In every proceeding before a  
14 court or the Commission in which an advertiser of  
15 a dietary supplement or a dietary ingredient is  
16 charged with false advertising, the burden of proof  
17 shall be on the Commission to establish by clear and  
18 convincing evidence that the advertisement is false,  
19 that the advertisement actually caused consumers to  
20 be misled into believing to be true that which is  
21 false, and that but for the false advertising content  
22 the consumer would not have made the purchase at  
23 the price paid. If a claimed health benefit of a die-  
24 tary supplement or dietary ingredient is alleged to  
25 be false advertising, the Commission must addition-

1       ally establish based on expert scientific opinion and  
2       published peer-reviewed scientific evidence that the  
3       claim is false. No order adverse to the advertiser  
4       shall be entered except upon the Commission satis-  
5       fying this burden of proof.”.

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