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**AMENDMENT TO _____**

**OFFERED BY MR. PAUL OF TEXAS**

At the end of part 1 of subtitle C of title V of division C, insert the following:

**SEC. 2574. CLAIMS ABOUT THE EFFECTS OF FOOD AND DIETARY SUPPLEMENTS.**

(a) LIMITATION ON SUPPRESSION BY FEDERAL GOVERNMENT OF CLAIMS IN FOOD AND DIETARY SUPPLEMENTS.—The Federal Government may not take any action to prevent use of a claim describing any nutrient in a food or dietary supplement (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) as mitigating, treating, or preventing any disease, disease symptom, or health-related condition, unless in a final order of a Federal court following a trial on the merits finds clear and convincing evidence based on qualified expert opinion and published peer-reviewed scientific research that—

(1) the claim is false and misleading in any material respect; and

(2) there is no less speech restrictive alternative to claim suppression, such as use of disclaimers or

qualifications, that can render the claim non-misleading.

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

"(o) ADVERTISING OF DIETARY SUPPLEMENTS AND DIETARY INGREDIENTS.—

"(1) DEFINITIONS.—In this subsection—

"(A) the term 'dietary supplement' has the meaning given to that term in section 201(ff) (21 U.S.C. 321(ff)) of the Federal Food, Drug, and Cosmetic Act; and

"(B) the term 'dietary ingredient' means an ingredient listed in subparagraph (A) through (F) of section 201(ff)(1) (21 U.S.C. 321(ff)(1)) of the Federal Food, Drug, and Cosmetic Act that is included in, or that is intended to be included in, a dietary supplement.

"(2) EXEMPTIONS FROM REGULATION AS ADVERTISING.—No content of any publication shall be considered advertising regulable under this Act unless the content is intended by the seller of a product to promote the sale of that product and the content includes (A) the name of the product offered for sale; (B) an express offer to sell the named product;

and (C) a purchase price for the product. No content excerpted in whole or part from a peer-reviewed scientific publication shall be considered advertising regulable under this Act.

"(3) NO IMPLIED CLAIMS.—In any investigation commenced by the Commission and in any adjudicative proceeding in which the Commission is a party, the Commission shall not attribute to an advertiser accused of false advertisement any advertising statement not actually made by that advertiser.

"(4) NOTICE, OPPORTUNITY TO CURE, AND BURDEN OF PROOF FOR INVESTIGATION.—Before the Commission authorizes an investigation of false advertisement by an advertiser of a dietary supplement or a dietary ingredient, the Commission shall send the advertiser a written 'Notice of Suspected Violation and Opportunity to Cure' informing the advertiser of—

"(A) the precise advertising statement that the Commission suspects may be false or misleading;

"(B) the scientific basis for the Commission's view that any statement of health benefit may be false or misleading; and

"(C) a date certain, not less than 30 days after the date of the advertiser's receipt of the notice, by which the advertiser may voluntarily discontinue further use of the statement the Commission suspects may be false or misleading and, upon so doing, the advertiser shall not be subject to an investigation of false advertisement by the Commission for the statement. The Commission shall not commence any investigation of an advertiser of a dietary supplement or a dietary ingredient to determine whether the advertiser has disseminated a false advertisement unless it possesses before the commencement of such investigation clear and convincing evidence that the advertisement is false and misleading.

"(5) BURDEN OF PROOF FOR FALSE ADVERTISEMENT CASES.—In every proceeding before a court or the Commission in which an advertiser of a dietary supplement or a dietary ingredient is charged with false advertising, the burden of proof shall be on the Commission to establish by clear and convincing evidence that the advertisement is false, that the advertisement actually caused consumers to be misled into believing to be true that which is false, and that but for the false advertising content

the consumer would not have made the purchase at the price paid. If a claimed health benefit of a dietary supplement or dietary ingredient is alleged to be false advertising, the Commission must additionally establish based on expert scientific opinion and published peer-reviewed scientific evidence that the claim is false. No order adverse to the advertiser shall be entered except upon the Commission satisfying this burden of proof.".

(c) DEFINITION OF DRUG.—

(1) IN GENERAL.—Subparagraph (1) of section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)) is amended by striking the second and third sentences and inserting the following: "A food or dietary supplement for which a claim is made in accordance with section 403(r)(1)(B) is not a drug solely because of such claim.".

(2) RULES.—All rules of the Food and Drug Administration in existence on the date of the enactment of this Act prohibiting nutrient-disease relationship claims are revoked.

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

(1) by striking clause (B) of subparagraph (1) and inserting the following:

"(B) describes any nutrient as mitigating, treating, or preventing any disease, disease symptom, or health-related condition if, and only if, the claim has been adjudicated false and misleading in any material respect by final order of a Federal court of competent jurisdiction in accordance with section 2 of the Health Freedom Protection Act.";

(2) by striking subparagraph (3);

(3) in the first sentence of subparagraph (4)(A)(i)—

(A) by striking "or (3)(B)"; and

(B) by striking "or (1)(B)";

(4) by striking clause (C) of subparagraph (4);

(5) by striking clause (D) of subparagraph (5); and

(6) in subparagraph (6), by striking the second sentence.

(e) DIETARY SUPPLEMENT LABELING EXEMPTIONS.—Section 403B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343–2) is amended to read as follows:

"FOOD AND DIETARY SUPPLEMENT LABELING

"SEC. 403B. The Federal Government shall take no action to prevent distribution of any publication in connection with the sale of a food or dietary supplement to consumers unless it establishes that a claim contained in the publication—

"(1) names the specific food or dietary supplement sold by the person causing the publication to be distributed;

"(2) represents that the specific food or dietary supplement mitigates, treats, or prevents a disease; and

"(3) proves the claim to be false and misleading in any material respect by final order of a Federal court of competent jurisdiction in accordance with section 2 of the Health Freedom Protection Act.".

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