



# Congressman Jared Polis

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## H.R. 4913 – The Free Speech About Science Act

### SUMMARY

The goal of the legislation is to increase the availability of information to the American public on healthy foods and dietary supplements so that consumers can make informed choices related to their personal health and well being. The bill allows food producers and dietary supplement manufacturers to cite legitimate, peer-reviewed scientific studies on the health benefits of these products without being classified as a new, unapproved drug by the FDA. The existing options to make a health-related claim require FDA review and approval (21 U.S.C. 343(r)(3)): 1) a claim based on a ‘significant scientific agreement; 2) an ‘authoritative statement’ (not available for dietary supplement manufacturers); or 3) petition the FDA for a ‘qualified health claim,’ where the amount of scientific evidence is below that of a significant scientific agreement (*Consumer Health Information for Better Nutrition Initiative*). Qualified health claims have been available since 2003, and only 17 claims have made the list.

FSAS allows a disease or health-related claim to be made based on ‘legitimate scientific research.’ This piece of legislation creates a new standard for permissible health-related claims without FDA’s review yet FDA and FTC would still have the absolute authority to pursue a cause of action for any fraudulent and misleading statements.

The key provision, 21 U.S.C. § 343(r)(1)(B), provides that a food, including a dietary supplement, is misbranded if a claim is made on the label or labeling of the food that expressly or by implication characterizes the relationship of any nutrient to a disease or a health-related condition—unless such claim is pre-approved by FDA. Making such a claim, without FDA approval, transforms a dietary supplement or a food into a drug. Additionally, discussion of a nutrient-disease relationship in a scientific study or article—even if the article does not mention a product by name—may be considered a product claim by FDA if the article is disseminated in association with the product or appears on the product website where the product is promoted or available for purchase. Thus, to avoid classification as a drug by FDA, manufacturers of dietary supplements and foods cannot disseminate scientific literature about their products or ingredients in their products in association with the sale of their products. This limits the availability of this important and valuable information to the American public.

### SECTION 1. SHORT TITLE

The short title of the act is the “Free Speech About Science Act.”

### SECTION 2. FINDINGS

More and more Americans are taking charge of their personal health and consumers are determined to improve their diets in order to stay or get healthy. In order to make informed decisions, consumers are looking for reliable scientific information. Access to this information is key to knowing which foods and food supplements are healthy and beneficial for the needs of individual consumers.

Current law outlaws any reference to a scientific study relating to the health benefits of a food or dietary supplement by producers, manufacturers and sellers of these products. Since these entities have the incentive and the means to disseminate legitimate scientific research and studies on these health benefits, the effect of current law is to censor science and prevent people from accessing this information. There are no such barriers to disseminating similar information for prescription drugs.

In October of 2005, FDA issued twenty-nine (29) Warning Letters to cherry orchards stating that claims being made by the orchards for their cherries, cherry juices, and other cherry products converted those products to unapproved new drugs. The claims were based on respected, peer-reviewed scientific studies. Among other violations cited, the FDA objected to claims that tart cherries possess anti-inflammatory properties that could help relieve the symptoms of gout and arthritis, as well as claims that tart cherries may inhibit the growth of certain cancers.

FDA has also issued Warning Letters to dietary supplement makers for including “offending” citations to independent scientific research on their websites, stating that such citations transformed the products into unapproved new drugs.

Many of the above referenced claims appeared on websites, which often posted or linked to scientific studies to substantiate the claims. FDA argued that websites constitute labeling and transformed the products into unapproved new drugs. Accordingly, the cherry growers and dietary supplement makers were forced to remove the highly valuable citations and links to scientific research from their websites.

### **SECTION 3. MISBRANDED FOOD AND DIETARY SUPPLEMENTS**

This provision amends the current statute, 21 U.S.C. 343(r)(3), to enable food producers and dietary supplement manufacturers to make a disease or health-related claim based on ‘legitimate scientific research.’

This first section addresses *food products* and includes the definition of ‘legitimate scientific research.’ The legislation tracks existing statutory language that allows food products to make a disease or health-related claim based on an ‘authoritative statement’ with the added requirements to include the full citation of said scientific study and to promote transparency by requiring the disclosure of any entity that funded the study. The full citation must be disclosed to better enable the consumer to access the study if they so choose.

The definition of ‘legitimate scientific research’ was carefully drafted to ensure that industry understands what is permissible and to ensure the courts have an articulate standard to readily interpret and apply. The definition is specific enough to weed out “junk science” and still permit a wide variety of “real” scientific research, which consumers desire to assist in their decision making process.

The definition includes the types of publications currently exempted from the dietary supplement labeling requirements (21 U.S.C. 343-2) and adds clarifying language on the type of acceptable research (*i.e.*, in vitro, in vivo, in animals or humans); allows accurate, balanced summaries of research as long as a complete citation is included; and adds research noted in recognized textbooks and U.S. Government publications. The definition expands the sources of research that can be cited and includes appropriate safeguards to ensure validity (*i.e.*, the research must be conducted in accordance with sound scientific principles and evaluated and accepted by a scientific or medical panel).

Dietary supplements are addressed next and the first provision restates current law with no changes to the provisions on when and how a structure-function statement can be made. (21 U.S.C. 343(r)(6)). (Page 5, line 13).

New language is then included to *permit a disease or health-related claim for dietary supplements* based on

'legitimate scientific research.' Again, the language tracks existing statutory language on the requirements that must be met to make a structure-function claim, with the added requirements that the full citation of the scientific study must be included and to disclose each party that funded the study must be disclosed. (Page 6, line 12). A structure-function claim describes 'the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans.'

As is current law, a dietary supplement manufacturer must notice the FDA within thirty (30) days of asserting a structure-function claim. Under FSAS, this obligation extends to a manufacturer that makes a health-related claim based on 'legitimate scientific research.' (21 U.S.C. 343(r)(6)). (Page 7, line 5).

The final provision prohibits the FDA from restricting the dissemination of information based on 'legitimate scientific research' in connection with the *sale of food*. FDA currently considers anything that "accompanies" a product to be labeling for a product, including scientific research that is disseminated in association with the product. This language bars FDA from restricting the distribution of said information as long as the information is based on 'legitimate scientific research.'