THE FREE SPEECH ABOUT SCIENCE ACT (FSAS)

The premise is to provide food producers, manufacturers, and dietary supplement manufacturers a means to make well-substantiated disease or health-related claims on the label without FDA involvement. The existing options to make a health-related claim require FDA review and approval (21 U.S.C. 343(r)(3)): a claim based on a 'significant scientific agreement;' an 'authoritative statement' (not available to dietary supplement manufacturers); or 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)*. This option has been available since 2003, and a mere 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 still have the absolute authority to pursue a cause of action for any fraudulent and misleading statements.

The key subject provision, 21 U.S.C. § 343(r)(1)(B), provides that food, including a dietary supplement, is misbranded if a claim is made in the label or labeling of the food which 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 food into a drug per FDA regulations. 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 available for purchase. Thus, to avoid classification as a drug by FDA, manufacturers of dietary supplements and foods must avoid disseminating scientific literature about their products or ingredients in their products in association with the sale of their products—which is highly valuable information to the American public.

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 really are healthy and helpful for good health.

FDA currently outlaws any reference to a scientific study relating to the health effects of a food or dietary supplement by any seller of the food and dietary supplement. Since the producers have the incentive and the means to spread the word about respected scientific research, the effect of FDA's actions is to censor science and prevent people from learning about it. There are no such barriers to learning about 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 caused those products to be drugs. Among other violations cited, the FDA objected to claims that tart cherries possess anti-inflammatory properties and therefore, 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 transform the products into unapproved new drugs. FDA regulations prohibit dietary supplements from citing a publication if the citation refers to a disease use, and if, in the context of the labeling as a whole, the citation implies treatment or prevention of a disease (*e.g.*, through placement on the immediate product label or packaging, inappropriate prominence, or lack of relationship to the product's express claims). 21 C.F.R. §101.93(g)(2)(iv)(C).

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 therefore, the FDA unapproved health-related claims transform the products into drugs. Accordingly, the cherry orchards 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 current legislation, 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 language 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 disclose each party that funded said study. The full citation must be disclosed to better enable the consumer to access the study if they so choose. To encourage transparency each party that funded the study must be disclosed, as this information is valuable to determine partiality or bias in study outcomes.

The definition of 'legitimate scientific research' was carefully drafted to ensure 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 want to assist in their decision making process of which products to purchase.

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; adds research noted in recognized textbooks and U.S. Government publications. The definition expands the sources from where research 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 being made 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 to include the full citation of the scientific study and to disclose each party that funded the study. (Page 6, line 12).

As is current law, a dietary supplement manufacturer must notice the FDA within thirty (30) days of asserting a structure-function claim, and this provision extends to 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.'