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Substantiation Still Matters:

The Importance of Science Behind Functional Food Claims

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These days, it feels like every time you open the newspaper, listen to the radio or watch television, the media is reporting on the latest study showing a connection between a food substance and health and wellness. Consumers are constantly learning about the ways in which particular foods may be useful in treating disease or in reducing the likelihood of developing a particular disease. As a result, consumers are looking for foods and dietary supplements that will help them manage their health. Conventional food and dietary supplement manufacturers are responding by developing new products and repositioning old ones in an effort to meet this demand. So-called "functional food," foods intended to provide health benefits beyond basic nutrition—are seemingly everywhere.

But as manufacturers seek to promote their products, they need not only ensure that their claims are properly phrased, but also that they possess adequate substantiation for them. In the absence of visible enforcement by the Food and Drug Administration (FDA), private citizens, consumer groups, the National Advertising Division (NAD) of the Council of Better Business Bureaus, the Federal Trade Commission (FTC), consumer groups, and class action lawyers are increasingly challenging the scientific basis for claims. If you are a conventional food or dietary supplement manufacturer already touting the health benefits of your product, or are looking to develop new functional foods, here is what you should know about promoting those products.

Basic Claims Available For Functional Foods

Because there is no legal or regulatory definition for functional foods, these foods fall under the same general FDA requirements that apply to foods, dietary supplements and other FDA regulated products. Therefore, depending on

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the claims made for a product and its positioning in the marketplace, it may be regulated as a conventional food, a dietary supplement or a drug. There are three basic types of health-related claims that can be made for conventional foods and supplements: nutrient content claims, health claims and structure/function claims.

Nutrient Content Claims

Nutrient content claims are claims that expressly or by implication characterize the level of any nutrient that is of the type required to be in nutrition labeling. Nutrient content claims may be express (e.g., "low sodium") or implied (e.g., "healthy"). Nutrient content claims may not be made unless the product meets the FDA definition and criteria for the term. In addition, a nutrient content claim generally may not be made for a food unless there is an established daily value for the nutrient. If a daily value is not established, FDA will allow quantitative statements disclosing the level of the substance in the food, but will not allow the use of consumer-friendly terms such as "high in" or "good source of" the substance.

FDA restrictions create challenges for companies that are trying to highlight the content of a substance in their food when FDA has not established a daily value for that substance. For example, there are many substances in foods with recognized antioxidant activity such as flavonoids, catechins, polyphenols and others. FDA has established a nutrient content claim for antioxidants that limits terms such as "good source" or "excellent source" antioxidant claims to those foods that contain the antioxidant vitamins C, E or A (when in the form of beta-carotene), at the levels specified in the nutrient content claim regulation. A product containing a significant level of a catechin antioxidant can disclose the level, such as "500 mg of catechins per serving," but the claim cannot use other terms such as "low" or "high" that would allow the consumer to place the level in the proper context.

Health Claims

Health claims are statements that characterize the relationship between a food (or substance in a food) and a disease or health-related condition. Accordingly, health claims are permitted claims regarding the relationship between a substance in a food or dietary supplement and a reduced risk of disease that do not subject a product to regulation as a drug.

Generally, health claims may be made only if specifically authorized by FDA by regulation and if they are made in accordance with FDA's conditions for making the claim. These conditions include the language that must be present in the claim and the nature of the food that may bear the claim. Similarly, though qualified health claims do not technically require FDA authorization, the agency maintains that it may take enforcement action against such claims if they do not track the language and conditions set out by the agency after review of the evidence supporting the claim.

The last type of claim under the health claim framework are so-called "FDAMA claims." The Food and Drug Modernization Act of 1997 (FDAMA) allows certain health claims to be made as a result of a successful notification to FDA of a health claim based on an "authoritative statement" from a scientific body of the U.S. Government or the National Academy of Sciences. Again, FDA often wields a strong hand in shaping the content and conditions for making FDAMA health claims.

Because of the prescriptive nature of nutrient content claims and health claims, conventional food and dietary supplement manufacturers are increasingly turning to statements of nutritional support (structure/function claims) to tout the health benefits of their products.

The Dietary Supplement Health and Education Act of 1994 (DSHEA) authorized dietary supplements to bear statements that describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or that characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, provided that such statements are not disease claims. Given the statutory definition for "drug" ("articles (other than food) that are intended to affect the structure or any function of the body"), conventional foods are also permitted to bear structure/function claims. Structure/function claims are decidedly more flexible than health claims or nutrient content claims and enable manufacturers to communicate the health benefits of their products

to consumers in a concise and consumer-friendly way.

At the same time, manufacturers must keep in mind that, outside of health claims as described above, neither supplements nor conventional foods may bear disease claims. If they do, the products will be regulated as drugs. Disease claims include those that explicitly or implicitly state that a product has an effect on a specific disease or on characteristic signs or symptoms of a disease.

Structure/Function Claims

Although the line between structure/function claims and disease claims is not always clear, in general, FDA will permit those structure/function claims that address the normal functioning of the body. Claims that address an abnormal function present some regulatory risk.

Due to the fine line between disease claims and structure/function claims, many conventional food and dietary supplement manufacturers have been primarily concerned with whether structure/function claims are properly phrased, rather than whether they can be substantiated. Indeed, the requirement that dietary supplement manufacturers notify FDA of any structure/function claims no later than 30 days after the first marketing of the product focuses on whether those claims are properly phrased—dietary supplement manufacturers are not required to demonstrate to FDA that they possess adequate substantiation for them.

However, the relative ease with which structure/function claims can be made and the lack of visible enforcement from FDA ensuring that manufacturers have a reasonable basis for their claims do not mean that substantiation is not important. Not only must all claims be substantiated, but increasingly other "enforcers" are stepping in to regulate in this area.

Filling FDA's Void

The FTC, for example has initiated a number of enforcement actions in recent years concerning substantiation for structure/function claims made on dietary supplements and conventional foods. For example, the FTC has entered into consent agreements requiring substantiation for claims concerning: weight loss (Goen Technologies Corp.), improved memory/prevention of memory loss (Nutramax Laboratories, Inc.), and alleviation of stress (Vital Basics, Inc.). In addition, the FTC undertakes numerous investigations of claim substantiation every year that do not result in public enforcement actions. State attorneys general will also on occasion investigate substantiation of claims under the authority of state food labeling laws and consumer protection statutes.

Companies can also be required to provide substantiation for claims in industry arbitrations at the NAD of the Council of Better Business Bureaus. NAD issues dozens of decisions a year concerning substantiation of structure/function claims made for foods and dietary supplements. For example, from July 2008 to September 2008, NAD issued decisions concerning the following types of claims: long lasting energy, increased metabolism, improved cognitive development, blood sugar maintenance, stress alleviation, mood enhancement, immunity strengthening, fat-burning and appetite suppression. Many of these arbitrations are initiated by competitors, but NAD can also initiate challenges itself. NAD reserves the right to refer matters to the FTC if an advertiser does not comply with NAD's decision.

Private lawsuits, brought by public interest organizations or as class actions, are increasingly being used to challenge the substantiation of claims. These lawsuits typically allege violations of state consumer protection statutes. Indeed, the Center for Science in the Public Interest (CSPI) has filed and threatened to file lawsuits involving claims appearing on products CSPI believes are lacking in substantiation. In addition, in the last year, CSPI has asked FDA and/or the FTC to investigate substantiation for claims on numerous products, including: immunity claims on frozen vegetables, "supports a healthy digestive system" claims on grape juice, and "heart healthy" claims on eggs containing omega-3 fatty acids.

The recent settlements concerning claims for the dietary supplement Airborne illustrate the potential costs to companies from government investigations and private lawsuits concerning substantiation of claims. Airborne, which was marketed with "boost your immune system" claims as well as disease claims concerning prevention of colds and infections, has been under investigation by the FTC and several state attorneys general since 2007. Earlier this year, a private class action lawsuit was filed against Airborne, Inc. alleging violations of California's consumer protection law. In March 2008, the company settled the lawsuit for $23.3 million. In August 2008, Airborne, Inc. entered into a consent order with FTC in which the company agreed to pay up to $6.5 million more to eligible consumers, bringing the total settlement pool to close to $30 million. The company also agreed to stop using unsubstantiated claims on the product.

Substantiation is All About Science

These actions should serve as a reminder to supplement and conventional food manufacturers that they must possess adequate support for the claims made for their products. Manufacturers

should have this data on file *before* they begin making structure/function claims. Ingredient suppliers can be a manufacturer's first step in ensuring there is adequate support for a claim, but not the last. Manufacturers should consider whether the studies offered in support of a given structure/function claim are of sufficient quality, whether the surrounding body of evidence supports the claim, and the relationship of the evidence to the claims. It is essential that the claims match the underlying scientific support.

The claims appearing on the label and in the labeling and advertising of conventional foods and dietary supplements are subject to the requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Trade Commission Act (FTCA). According to the guidance established by both FDA and the FTC, structure/function claims must be supported by competent and reliable scientific evidence. Competent and reliable scientific evidence is defined as "tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results."

There is no established formula as to the number or type of scientific studies necessary to substantiate a structure/function claim. Although the FTC has never established any specific number of studies that should support a claim, the agency recognizes "the replication of research results in an independently-conducted study adds to the weight of the evidence." The agency also notes, "in most situations, the quality of the studies will be more important than the quantity."

Scientific quality is based on several criteria including the design and implementation of the study, its duration, how the data are collected, what endpoints or outcomes are measured, and whether the results are statistically significant. The "gold" standard is randomized, double blind, parallel group, placebo-controlled trial design.

In addition, published studies in peer-reviewed journals will carry more weight. Therefore, when evaluating whether a scientific study supports a particular structure/function claim, manufacturers should pay close attention to the study's methodology, making sure that the methodology is well-established and that the design of the study is reasonable.

Manufacturers should also examine the hypothesis of the study and the endpoints measured to ensure that the study is of sufficient quality.

Just as important as the validity of individual studies, however, is the surrounding body of scientific evidence. Supplement and conventional food manufacturers cannot rely solely on the support of one good study, but must also consider the totality of the evidence in support of a claim.

Manufacturers should consider all relevant research, both favorable and unfavorable. The strength of the surrounding evidence will affect how the claim should be presented—that is, how carefully it should be qualified to accurately reflect the strength of the support for it.

This last point should not be overlooked: the claim should match the underlying evidence. In other words, you may have valid studies and those studies may be consistent with the surrounding body of scientific evidence, but do the studies support your claim?

To help determine this, manufacturers should consider asking: Are the conditions of the study relevant to the advertising audience for my product? Are the parameters of the study such that allow for extrapolation to my product? Are there limitations in the study that require me to narrow or qualify my claim? How has the author characterized the study? How are the results framed? Remember: claims cannot extend beyond the level of substantiation that exists.

In sum, before making a structure/function claim, supplement and conventional food manufacturers should conduct a careful review of the support for the claim, making sure the evidence is scientifically sound, that it is sufficient in the context of surrounding evidence, and that it is relevant to both the product and claim advertised.

Conclusion

With their relative flexibility, supplement and conventional food manufacturers are increasingly turning to structure/function claims as a means to communicate the benefits of their products to health- and disease-conscious consumers. But as manufacturers focus on whether those claims are properly phrased, they should not lose sight of the importance of proper substantiation. Indeed, recent enforcement actions by the FTC, NAD, the plaintiffs bar, and others should serve to remind manufacturers that they must have adequate substantiation before marketing those claims.

With a new administration set to take charge in January, it is possible that we could see increased enforcement activity from FDA. Certainly a few targeted enforcement activities (even if in the form of warning letter or two) could send a strong message to industry. In the meantime, with other parties filling the void left by FDA, a careful review of the scientific support manufacturers have in their files would be prudent.