For thousands of years, humans have used food and botanical sources as therapeutic remedies. Today, we know that diet plays a role in about half of the leading causes of death, including heart disease, certain types of cancer, stroke and diabetes, and research suggests that consumption of certain foods is linked to health more generally. As consumers take greater responsibility for their own well-being, and as the population ages, it makes sense that people look to their diet to improve their quality of life.

As the health claims associated with functional foods proliferate, the support for these claims has become a topic of increasing concern. How can the consumer figure out if a claim is realistic or not? The goals of this article are to explain how food manufacturers make health claims for their products and to provide some guidelines for making good choices with respect to functional foods.

What Are Functional Foods?
Foods that provide health benefits beyond basic nutrition (e.g., vitamins and minerals) are referred to as “functional foods.” Some functional foods are whole foods that carry added health benefits. In other cases, manufacturers may add extra ingredients or modify a food in some way that allows for a “health claim” on the label or in advertising materials. As interest in the healing properties of diet has grown, selling foods that claim curative properties has become a profitable business, with sales currently in excess of $25 billion per year and growing. As manufacturers chase these dollars, the public has been inundated with advertisements for foods that have been modified or supplemented in some way intended to reduce disease risk and improve health. Some of these additions are now commonplace: Iodine is added to salt to prevent goiter; and vitamin D is added to milk to improve bone mineralization. The first functional food claim recognized by the Food and Drug Administration (FDA) was the link between oat bran and reduced risk of heart disease, but many other functional food claims have never been tested systematically.

What Is a Health Claim?
A “health claim” is any claim on a label (package or advertisement) that suggests a relationship between an ingredient in a food and a disease-related condition. Health claims can be explicit and clearly stated or implicit and unspoken. For example, an implied claim can appear as a third-party endorsement, such as “The American Heart Association recommends eating a variety of grain products to reduce heart disease.”

Why Is There Concern About Certain Functional Food Claims?
Although functional foods have great potential to improve the health of the public, the recent history of functional foods has been marked by difficulties with regulatory compliance. When you use a medication, the product insert provides you with information about the drug and the prescription tells you how much to take and for what duration. In contrast, when you use a functional food, there is rarely a product insert or prescription and consumers are left to navigate their own way. This is frequently the case when herbal ingredients are added to functional foods, rather than being sold separately as dietary supplements. For example, the Center for Science in the Public Interest (CSPI) notes that labels on echinacea, when it is sold as a food supplement, warn users against taking it for an extended period of time. Other botanical
advertisements also caution consumers who live with weakened immune systems, autoimmune disorders or take medication. However, these warnings are hardly ever found on functional foods that contain these potentially harmful ingredients. (For this reason, an astute anesthesiologist or surgeon will always ask their patient if he or she uses any herbal ingredients—supplements or functional foods—before doing any procedures.) Table 1 presents some examples of historic functional food health claims, which came under scrutiny in 2001. None of these products remain on the market.

To protect the public from potentially misleading health claims, the FDA, until the 1990s, prohibited manufacturers from claiming that a food could reduce risk of disease. If a label mentioned a disease, the food was considered “unregulated” and treated as an unapproved drug. A few years later, the FDA got into the business of regulating specific health claims. This worked well until food makers developed creative ways to sidestep regulations. For example, instead of making a health claim about the benefits of a specific product, companies began associating their products with general claims about the structure or function of the body. So consumers started to see products reminding them that “calcium can build strong bones” or “fiber maintains bowel regularity.” The manufacturer was responsible for ensuring the accuracy and truthfulness of such statements.

About five years ago, consumer interest groups began to raise concerns about whether unsubstantiated claims about the health benefits of functional foods risked harming the public. For example, in 2001, CSPI and the Council of the Better Business Bureau urged the FDA to prohibit misleading health claims on herbal teas because these claims were not authorized for the botanical ingredients the teas contained. At that time, Arizona Rx Memory Mind Elixir contained ginkgo biloba, an ingredient not recognized as safe and one that has not been proven to improve memory. Yet, despite these concerns, the FDA was unable to enforce compliance and the tea claims continued for more than

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Table 1: Historic Functional Food Health Claims

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Product</th>
<th>Claim</th>
</tr>
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<tbody>
<tr>
<td>Snapple</td>
<td>Gravity Echinacea</td>
<td>Provides &quot;strength&quot; to &quot;maintain endurance and support the immune system.&quot;</td>
</tr>
<tr>
<td>Apple &amp; Eve</td>
<td>&quot;Tribal Tonics,&quot; Immune Boon, Echinacea</td>
<td>&quot;This herbal tonic enhances immunity and bolsters the body’s defense system.&quot;</td>
</tr>
<tr>
<td>Hansen’s Beverage Co.</td>
<td>&quot;Healthy Start&quot;: Immune ox Juice echinacea purpurea</td>
<td>&quot;May help stimulate the body’s production of interferon, a cell protecting protein.&quot;</td>
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one year. While that was happening, CSPI conducted a review that identified more than 100 functional foods making misleading or unsafe health claims. The General Accounting Office (GAO) also criticized the FDA for failing to protect consumers from the possible dangers of unproven ingredients.

Today, concerns about unsubstantiated health claims continue. New products that have raised concerns include, but are not limited to: (1) Enviga™, a carbonated drink from a Coca-Cola/Nestle partnership that claims that the ingredients (caffeine and EGCG from green tea) burn more calories than the drink provides; (2) Mars/Masterfoods CocoaVia®, a candy bar that claims to be heart healthy; and (3) DanActive™ Immunity, a dairy drink that Dannon claims will “strengthen your body’s defenses.”

Attorney Illene Ringel Heller, for the CSPI, points out that enforcement of existing regulations is challenging: “When the FDA has warned companies, such as the makers of Mars candy and Arizona Iced Tea, that they were violating the law, the firms largely ignored the agency and have continued to market their products,” (cited in CSPI Newsroom, 2006). Recognizing that some manufacturers have short-circuited the regulatory process, some worry that functional foods will become “about as dependable as 19th century snake oil.”

Is There a Place for Functional Foods?

Despite these concerns, there is a place for functional foods in health promotion. Functional foods have been used for the prevention of osteoporosis, cardiovascular disease, anemia and neural tube defects, among other conditions, and there is growing interest in how they might be used to improve immune function. Scientists have begun to study the role of diet and nutrition in hypersensitivity, atopic disease and food allergy. For those with health concerns, there may be real benefits of using functional foods (see Table 2).

At the same time, it is important to be selective and cautious. In a recent study, post-operative surgical patients were given a formula that contained arginine (an amino acid). Researchers found improvements in cellular immunity and recovery for those who were given the enhanced formula. However, the same amino acid that helped the surgical patients caused harm in other patients, leading the researchers to caution that the enhanced formula may increase risk of an inflammatory response and mortality among patients with underlying problems. Thus, the benefits for those who live with a primary immune deficiency, systemic inflammatory response syndromes or sepsis remain uncertain.

Even if food ingredients such as amino acids, probiotics, selenium, antioxidants, vitamins, etc. are shown to play a role in enhancing immune function and resistance to infection, the optimum intake level and recommended servings of functional foods have not been established for many disease-specific groups. For example, a few years ago, when studies suggested that diets high in soy decrease risk of heart disease, manufacturers of functional foods began in earnest to fortify food with soy isoflavones. Soon after, scientists reported that isoflavones actually increased risk among a unique disease-specific group—those with estrogen-dependent breast cancer.

In other words, when it comes to functional foods, one serving size does not fit all. The American Dietetic Association suggests that certain foods that have health benefits for some groups may be contraindicated for others. Increasing intake of whole-grain foods, for example, may reduce heart disease in adults but excess fiber may cause

| Table 2: Selected Examples of Functional Foods With Potential Health Benefits |
|---|---|---|
| **Functional Food** | **Ingredient/Component** | **Health Benefit** |
| Whole oat products, barley, certain yeasts and breakfast cereals | Beta glucan | May reduce risk of coronary heart disease (CHD) and some types of cancer; may contribute to maintenance of healthy blood glucose levels |
| Certain fortified margarines | Plant sterol and stanol esters | Reduces total and LDL cholesterol |
| Cold-water or fatty fish and their oils | Polyunsaturated fatty acids: Omega 3s, *Eicosapentaenoic Acid (EPA)/Docosahexaenoic Acid (DHA) | May reduce risk of CHD; may contribute to maintenance of mental and visual function |

*EPA and DHA are also found in breast milk.*
malnutrition in growing infants. Clearly, there is more work to be done before scientists identify functional foods that can be recommended to the public at large. Unless the benefits and record of safety are known, nutrition goals should focus on preventing or treating nutritional deficiencies rather than on attempting to modulate disease.

**How Can One Make Informed Choices?**

An important preliminary question that savvy consumers should always ask themselves about any health claim for functional foods is: “Is it too good to be true?” As with most things, if a claim sounds too good to be true, it is most likely misleading.

A second important question is whether a specific health claim is supported by any research. Addressing this question is actually a lot more complicated than it sounds, because some manufacturers conduct their own poorly designed studies as a way of justifying health claims for their products. Table 3 contrasts some of the distinguishing features of quality scientific research and pseudoscientific research, both of which may be used to test functional food claims.

Use caution when deciphering food claims and always consult with your healthcare providers about any herb, dietary supplement or questionable ingredients that you are using, including herbal beverages.

**Summary**

Technological advances in the food industry, in combination with clinical trials and governmental control, will eventually improve the credibility of nutrient content claims and the public’s confidence in functional foods. Until more is known, however, consumers must understand that, although functional foods show promise to improve health, many...