## Sengamala Thayaar Educational Trust Women’s College

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**FUNCTIONAL FOODS AND NUTRACEUTICALS**

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**FUNCTIONAL FOODS & NUTRACEUTICALS**

**Introduction**

Research into the health benefits of foods has been escalating during the last five to seven years, driven by consumers aware of the relationship of diet to optimal health, ever-increasing health care costs, the aging baby boomer population and others motivated to take control of their own health.  
  
A 1998 nationwide survey of 1,000 randomly selected consumers, commissioned by the International Food Information Council (IFIC) in Washington, D.C., found that 95 percent of Americans believe certain foods have health benefits that go beyond basic nutrition and may reduce the risk of disease, 92 percent believe they have control over their own health, and 78 percent can name a particular food or component and the health benefit associated with it. Broccoli, oranges and orange juice, carrots, fish and fish oil, garlic, green leafy vegetables, milk, and fiber were most often mentioned by consumers, in that order. [**1**]  
  
These beliefs are well founded. Recent scientific research increasingly supports the notion that foods, food ingredients and ingredient components have many potential health benefits. Food and dietary supplements marketers are adding health claims and structure/function claims on products based on the good science developing about them.  
  
In the marketplace, however, there is some confusion as to the difference among various categories of healthful foods as well as the increasingly fine-line difference between dietary supplements and foods. The following definitions should help clarify the issues.

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Dietary supplements are defined as any product (other than tobacco) that is intended to supplement the diet and contains one or more of the following: a vitamin, mineral, herb or other botanical; an amino acid or metabolite; an extract; or any combination of the previously mentioned items. According to U.S. Food and Drug Administration (FDA) regulations, a dietary supplement may be marketed in food form if it is not "represented" as a conventional food and is clearly labeled as a dietary supplement. Specific health or structure/function claims are allowed on dietary supplements provided the FDA deems adequate scientific substantiation exists for the claim.  
  
Fortified foods are enriched with vitamins and minerals, usually at a range up to 100 percent of the Dietary Reference Intake (DRI, formally called the Recommended Daily Allowance or RDA) for that nutrient. Often, these foods are mandated by law to be fortified to a level that replaces nutrients lost during processing, as in adding B vitamins to many baked goods. Breakfast cereals is a food category that has been fortified since the 1940s.  
  
Functional foods, according to their generally accepted definition, are "any food or food ingredient that may provide a health benefit beyond the traditional nutrients it contains." [**2**] This is a tricky definition because the term "traditional nutrients" refers *only*to vitamins and minerals. The reason is that these are considered essential to the diet and/or correct a classical nutrient deficiency disease; for instance, vitamin C corrects scurvy. Hence, the vitamin D content in sardines, which alleviates rickets, is not an example of a functional food, while soy, which contains soy protein associated with a reduction in cardiovascular disease, is one because soy protein is not considered to be essential. Other functional foods include red grapes and cranberry juice (for the oligomeric proanthocyanidins, OPCs) and oat bran (for the fiber content), all with health benefits attributed to "non-nutrient" compounds as classified by standard agreement of the term.  
  
So-called "super-fortified" foods--those fortified with more than 100 percent of the DRI and/or foods that have added botanicals or other supplements--also fall into the category of functional foods. Two examples of the latter are orange juice with echinacea (*Echinacea angustifolia* or *E. purpurea*) and salad dressing with omega-3 polyunsaturated fatty acids (PUFAs). Functional foods may carry health or structure/function claims provided adequate scientific evidence supports the claim.

Medical foods refer to a food formulated to be consumed or administered internally while under the supervision of a physician. The food product is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements are established by medical evaluation. Medical foods may be used to treat diabetes, obesity or heart disease, for example, and may carry specific claims, but in a strict sense are sold through physicians and not through conventional retail outlets.  
  
Nutraceuticals are often defined synonymously with functional foods in the media and literature. In fact, the term *nutraceutical*, as coined by Stephen DeFelice, M.D., founder of the Foundation for Innovation in Medicine in Cranford, N.J., covers the gamut--including dietary supplements, those fortified foods that are enriched with nutrients not natural to the food such as orange juice with added calcium, functional foods and medical foods. Thus, nutraceuticals are more correctly defined as parts of a food or a whole food that have a medical or health benefit, including the prevention and treatment of disease. Historically, the FDA has defined any specific foods used for the prevention or treatment of disease as drugs. DeFelice has been instrumental in promoting the October 1999 Nutraceutical Research and Education Act (NREA) legislation, which would legally define nutraceuticals as a separate regulatory category, thus allowing them to carry specific disease treatment or prevention claims previously allowed only for drugs.  
  
IFIC's 1998 survey found that a large majority (69 percent) of consumers preferred the term functional foods to the terms optimum foods (60 percent) or nutraceuticals (30 percent).

**Regulatory and Perception Issues**  
  
Functional foods are regulated as either foods or dietary supplements, depending on how they are labeled. Functional foods may carry either health claims, which are usually FDA preapproved, or structure/function claims, depending on the most recent regulations promulgated by FDA as a result of the Dietary Supplement Health and Education Act (DSHEA) of 1994. The FDA regulates medical foods somewhat loosely within their own regulatory category.  
  
Health claims describe the relationship of diet to a disease, and only 11 health claims are approved by FDA. An example is, "Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord defect." Health claims traditionally have been approved based on the concept of "significant scientific agreement," which the FDA has only recently defined in a guidance document as an agreement among qualified scientific experts that a substance/disease relationship exists based on a sound body of scientific evidence. The level of evidence must be strong enough that it would be unlikely to be reversed by further study. Using a health claim that is not approved by the FDA may render the functional food a drug, according to the FDA.  
  
Structure/Function claims are statements of health-promoting or nutritional benefit allowed on dietary supplement labels. They are not allowed to mention disease conditions; they must describe the support or maintenance of the normal functioning of the body. "Cranberry supports the health of the urinary tract," is an example of a model structure/function claim.  
  
Scientific associations, such as the Institute of Food Technologists (IFT), [**3**] based in Chicago, Ill., and the American Dietetic Association (ADA) [**4**] in Washington, D.C., support the potential benefits of functional foods provided that the claims for them are substantiated by good scientific criteria.  
  
However, a prominent consumer organization, the Washington, D.C.-based Center for Science in the Public Interest (CSPI), recently published a report decrying functional foods. It was prompted by the increasing introduction of many functional foods in the marketplace that are high in fat, calories and sodium. CSPI noted that "if governments do not require functional ingredients to be proven effective (and safe) before they are added to the food supply, if claims are not required to be adequately substantiated, if functional ingredients are simply added to foods high in fat, cholesterol, sodium or sugar, then dubious functional foods may merely amount to 21 [st ] century quackery." [**5**]  
  
In addition, consumer reaction has been mixed when it comes to new functional foods introductions. For example, a line of frozen foods designed to meet the dietary recommendations of both the Washington, D.C.-based American Heart Association (AHA) and ADA as well as a line of products containing psyllium fiber (*Plantago psyllium*) to lower cholesterol were highly publicized--and expensive--failures. The failures were attributed to broad new product introductions that were often outside of the specific competitive marketing, sales and distribution advantages of the respective companies. Other more evolutionary products, such as orange juice fortified with vitamins C and E, sauces fortified with vitamin E, and beverages with added nutraceutical ingredients, have had more commercial success. Large food and pharmaceutical companies remain committed to the potential of functional foods and are continuing to pursue clinical research to substantiate the efficacy of these functional products.

**Scientific Substantiation**  
  
There are many examples of functional foods, medical foods and dietary supplements in food form that have been introduced to the marketplace with scientific substantiation. Some examples are detailed below.  
  
Cranberry Juice  
  
Recent studies show that the OPCs in cranberry juice prevent the adhesion of bacteria to urinary tract cell walls. [**6**] A 1994 clinical trial by Harvard Medical School researchers in Boston compared 153 elderly women who consumed either 10 ounces per day of a low-calorie cranberry juice cocktail or a similarly colored, flavored and vitamin C-fortified placebo. The study demonstrated cranberry juice's efficacy. The women who drank the cranberry juice cocktail were less than half as likely to have bacteria in their urine and only a quarter as likely to have their urine remain infected from one month to the next. [**7**]  
  
Cranberry juice cocktail is now marketed as a functional food with a structure/function claim regarding support of urinary tract health. Recent research has shown that cranberry may also inhibit plaque-forming bacteria in the mouth by the same basic mechanism, [**8**] and marketers are looking for new applications of cranberry in products such as toothpaste, dental floss, mouthwash and rinses.  
  
Cholesterol-Lowering Breakfast Cereals and Margarines  
  
Several companies have marketed breakfast cereals as functional foods when enriched with inulin (an oligosaccharide) or psyllium. Plasma total cholesterol was reduced by 7.9 percent and total triglycerides by 21.2 percent in young men consuming a 50 g serving of a breakfast cereal fortified with 18 percent inulin for four weeks during a study conducted at the University of Milan, Italy. [**9**] Bifidobacteria in the stools also increased and appeared to explain the lipid-lowering effect. A University of Sydney, Australia, study of a breakfast cereal containing 50 g of soluble fiber as psyllium, oat and barley showed that it significantly reduced total cholesterol and low density lipoprotein (LDL) concentrations in the blood as compared to a wheat bran cereal for middle-aged mildly hypercholesterolemic men who were already eating a diet low in saturated fat. [**10**]  
  
Plant sterol-enriched margarines, originally positioned as dietary supplements but now marketed in the United States as functional foods, were shown to reduce blood cholesterol levels in mildly hyper-cholesterolemic subjects in a human trial conducted at the TNO Nutrition and Food Institute, Zeist, Netherlands. [**11**] In another study, conducted at the University of Kuopio, Finland, plant stanol esters, similar to plant sterols although chemically modified and nonabsorbable, were also shown to reduce LDL cholesterol by 10 to 15 percent when consumed in three servings of margarine per day as part of a low-fat diet. [**12**] A 25 percent risk reduction in heart disease has been estimated based on the level of cholesterol reduction provided by consuming these margarine products. [**13**]  
  
Food Bar for Arterial Disease Prevention  
  
A pharmaceutical company has developed a medical food bar for the dietary management of vascular disease. The bar, available in pharmacies nationwide, has a soy protein base and contains L-arginine as well as the preferred amounts of vitamins C, E, B6, B12, niacin and folate for those with coronary artery disease. L-arginine is an amino acid that is required for the production of nitric oxide, a potent vasodilator. A clinical study of the food bar among patients with lower limb atherosclerosis, conducted at Stanford University, Palo Alto, Calif., showed that it provided a significant (66 percent) improvement in pain-free walking distance and an increase (23 percent) of total walking distance for those patients taking two bars per day for two weeks vs. placebo. In addition, the effects were maintained through 10 weeks of consuming two bars daily. [**14**] What has not been evaluated is whether this bar, containing 3 grams of L-arginine/bar, provides any benefit over an equal amount of arginine taken as a dietary supplement. Although this dose (as tablets or capsules) would involve eight to 12 tablets or capsules per day, consumption of the bar twice daily may foster weight and fat gain and could produce "taste fatigue."  
  
Eggs Enriched with Pufas  
  
There are currently eggs on the market enriched with PUFAs that function as dietary supplements in food form. Rather than adding PUFAs directly to the eggs, the nutritional benefit is obtained by feeding hens a diet enriched with fish oils, vegetable oils or an algal source of docosahexaenoic acid (DHA). This provides a more cost-effective way for consumers to obtain omega-3 fatty acids in the diet over servings of cold-water fish.  
  
In a study conducted at the University of New England, Armidale, Australia, significant increases in blood omega-3 PUFAs and HDL cholesterol were shown in subjects consuming seven enriched eggs per week as compared to controls. [**15**] The subjects showed a significant gain in body weight and HDL levels, but merely adding one egg per day to the diet should not result in weight or HDL changes.  
  
Probiotic Beverages  
  
A dietary supplement beverage containing *Lactobacillus casei, Streptococcus thermophilus*and *Lactobacillus bulgaricus* has been marketed as a dietary supplement with the following structure/function claim: "[This product], with its unique combination of cultures, including *L. casei,*has been clinically proven to fortify your natural defenses." A patented probiotic bacterium, *L. casei*ssp. *GG,* has been shown in human trials to produce an optimized humoral response in the immune system [**16**] and a heightened immune response to rotavirus-induced diarrhea in children. [**17**] However, another study carried out by TNO Nutrition Food and Research Institute showed no effect on natural killer cell activity, phagocytosis or cytokine production in healthy males drinking a milk cultured with a different strain of the same organism. [**18**]  
  
It is clear that food and pharmaceutical companies are committed to the study and development of functional foods and other nutraceuticals. They also have demonstrated that a sound scientific base for the efficacy of these products combined with good marketing leads to acceptance by consumers for various types of products. The future certainly looks bright for these categories.