Where Do Functional Foods Fit in the Diet?

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I will address what has been called the "functional foods revolution" and discuss some of the driving factors in this field. Let me begin by defining the term "functional food." Certainly all foods are functional because they provide taste, aroma, and/or nutritive value, but there is a definition that is becoming generally accepted, for example by the International Life Sciences Institute and the International Food Information Council: a food that by virtue of physiologically active components provides health benefits that go beyond basic nutrition. Those with a grounding in nutrition will realize that we are talking about the essential nutrients—vitamins, minerals, macronutrients and micronutrients—that are essential for metabolism and for maintenance and repair of body tissue. Calcium, for example, is a mineral that is very important for skeletal health, but scientific discovery indicates that calcium may be linked to reduced risk of colon cancer, it may reduce PMS, and it may be linked to blood-pressure regulation. There has been a lot of information in the news recently on folate with regard to cardiovascular disease. Homocysteine metabolism is very closely linked to this, and in early 2002 a paper was published on the fact that those with a compromised folate status may be at risk for Alzheimer's disease. Clearly, nutrients long known to be essential may have broader importance.

MEDICINE'S SHIFT OF FOCUS

Over the past 100 years there has been a shift of focus from prevention of nutrient-deficiency diseases to interest in prevention of chronic disease. We now suffer not from diseases of deficiency but of excess, and the Surgeon General's report first highlighted this in 1988:

> *Over-consumption of certain dietary components is now a major concern [as is] disproportionate consumption of foods high in fats, often at the expense of foods high in complex carbohydrates and fiber such as vegetables, fruits and whole grain products that may be more conducive to health.*

We recommend a plant-based diet for the prevention of chronic disease because there is accumulating evidence that many plants contain physiologically active "phytochemicals" that may be linked to chronic disease risk reduction. Examples are soybean phytosterols, resveretrol in grapes, lycopene in processed tomato products for possible prevention of prostate cancer. Also lutein in spinach, which received GRAS (generally regarded as safe) status in May 2001, and which will probably go into food products for age-related macular degeneration, the limonoids in citrus products, the indoles and glucosinolates in the brassica family vegetables such as broccoli, the organo-sulfur compounds such as allicin in garlic and shallots, and the proanthocyanidins in cranberries and even in chocolate. Yes, chocolate—my favorite—especially with a glass of red wine, which also has a lot of polyphenolics. And there are animal products that contain physiologically active "zoo-chemicals": conjugated linoleic acid in milk and the omega 3 fatty acids, for example.

If physiologically-active components are extracted from whole foods and put in capsule form, we can refer to them as "nutraceuticals." In my opinion, broccoli is not a nutraceutical whereas the extracted component is a nutraceutical. Steven Zeisel, Head of the University of North Carolina's Department of Nutrition, has defined nutraceuticals as diet supplements that deliver a concentrated form of a presumed bioactive agent from a food presented in a non-food matrix and used to enhance health in dosages that exceed those that can be obtained from normal food. An example is soy isoflavones.

The American Dietetic Association published a revised position paper in 1999 and I was privileged to be one of the three authors of this document. We felt that there are a number of foods that may be considered to be "functional," although it's an area of controversy. They certainly include whole foods, and also fortified, enriched or enhanced foods that have potentially beneficial effects on health when consumed as part of a varied diet on a regular basis at effective levels. The latter point is where regulations become critical, because the Food and Drug Administration (FDA) appraises health claims under the Nutrition Labeling and Education Act (NLEA) in terms of daily intake levels for foods such as soy, oats, *etc*.

Functional Foods: Examples

One of the best documented groups of functional foods are fruits and vegetables. Without question, one of the best things that we can all do to

reduce cancer risk is to consume at least five servings of fruits and vegetables per day. In 1997, the World Cancer Research Fund and the American Institute for Cancer Research published an excellent summary of data linking dietary modifications to cancer risk—including the consumption of fruits and vegetables—and demonstrated once again that dietary modification can reduce cancer risk by 30 to 40%.

Another well known functional food that meets a health need is calcium-fortified orange juice. Obviously, native orange juice does not contain calcium. However, since women still do not get nearly enough calcium, and for those who do not consume animal products (for whatever reason) orange juice is an excellent vehicle to provide calcium in the diet. Orange juice is high in potassium and the Food and Drug Administration (FDA) Modernization Act (FADAMA) of 1997 now allows two health claims on food. Potassium in relation to reduced blood pressure and stroke is the newest FADAMA claim allowed, and this information is important for public health as high blood pressure is largely undiagnosed.

Viactiv™ chews are another example of a functional food for women's health—currently a hot topic for marketers because women make most of the purchasing decisions in the grocery store. They are living longer past menopause—30 years in an estrogen-compromised state—which has implications for bone loss, for increased cancer risk and for increased heart-disease risk. So this is an excellent functional food for those who want to get calcium and other bioactive components for bone health, such as vitamin K, vitamin D, and magnesium.

Other functional foods available in the marketplace are Benecol® and its competitor product Take Control®. They are margarines containing stanol and sterol esters, respectively, that have been shown in numerous clinical trials to be effective in lowering cholesterol. The FDA approved an interim final health claim on these products in the year 2000.

And of course we have processed foods such as ketchup that marketers are using to increase awareness of the role of certain foods in chronic disease reduction. However, there is still some controversy over communicating the benefits of lycopene as a cancer chemoprevention agent, as the data are largely epidemiological.

Drivers

A number of books have been written on this subject over the past few years, starting in 1994 with *Functional Foods* edited by Israel Goldberg. Also Ted Labuza, who is at this meeting, and his wife, Mary Schmidl, edited an excellent text, *Essentials of Functional Foods*, a couple of years ago. Why is it such a hot topic? It is driven by a number of factors: consumer demand, technology advances, liberalized regulations, certainly scientific research linking diet and health, and the business-opportunity component.

Consumer demand is being further driven by aging demographics, rising healthcare costs, and what we refer to as the "self-care" trend. In their annual reports over the past several years, the Food Marketing Institute (FMI) has shown that a significant portion of consumers feel that eating healthfully is a better way to manage their illness than even taking medication. Thus, consumers are turning to the kitchen cabinet rather than the medicine cabinet to meet their health needs.

The percentage of shoppers more likely to treat themselves before seeing a physician rose from 31% in 1998 to 64% in 2001. In a survey by Sloan Trends & Solutions, Inc., eyesight was the number-one concern—maintaining healthy eyesight as we age. Heart disease, the leading cause of death is also a major health concern, and it is not surprising to see a number of cholesterol-fighting functional foods on the market with attendant health claims. Oat beta-glucan, soluble fiber, psyllium fiber—these functional foods have NLEA-approved health claims. I mentioned the sterol and stanol esters. Soy protein had an NLEA health claim approved in 1999 and there is currently a qualified health claim for dietary supplement sources of omega-3 fatty acids.

The sequencing of the human genome has driven an area of study referred to as "nutritional genomics," which is certainly one of the forefront biomedical developments: the interaction of the human genome, nutrition, and biochemistry. However, it must be remembered that about 70% of colon cancer, stroke, more than 80% of coronary heart disease and over 90% of type-2 diabetes are preventable by the right life-style choices. Walter Willett addressed this issue in the April 26, 2002, issue of *Science*, and stated:

> *Overly enthusiastic expectations regarding the benefits of genetic research for disease prevention have the potential to distort research priorities and spending for health. However, integration of new genetic information into epidemiologic studies can help clarify causal relations between both lifestyle and genetic factors and risks of disease.*

Clearly we must keep the role of nutritional genomics in perspective. However, indications are that nutritional genomics has huge potential for designing diets and identifying specific genetic links to disease.

Business Opportunities

Certainly there are huge business opportunities for manufacturers of functional foods. Benecol® is significantly more expensive than typical margarine, about $5/lb. There is interest on the part of food manufacturers to get into the functional-foods arena because products that deliver health benefits are growing at a much higher annual rate than are conventional foods. According to the *Nutrition Business Journal*, conventional foods have been growing between 2 and 4% annually over the last 4 years, whereas functional or health-enhanced foods have been growing at 7 to 9%—a trend that is expected to continue.

With respect to food manufacturing, there has been a shift away from removing negative ingredients to adding positive ingredients, which resonates well with the consumer. Consumers want to hear positive messages, so there is a focus on positive eating. Therefore, rather than focusing as much as we did 10 years ago on removing negative ingredients, we are adding the more positive ingredients to foods. For example, from the early 1990s to 2000, the number of low- or no-cholesterol products on the market has diminished, whereas the number of calcium-fortified products has increased.

No Magic Bullet

There is a very narrow gap between foods, drugs, and dietary supplements and the Center for Science and Public Interest has called for scrutiny in this area particularly because of concerns over the positioning of conventional foods as dietary supplements and over herbal-fortified products because they may interact with certain drugs.

Functional foods need to be safe and their efficacy proven. Their health benefits need to be effectively communicated to consumers with the caveat that they are no magic bullets.