WHAT'S WRONG WITH FUNCTIONAL FOODS?

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ABSTRACT: A "functional food" is a food-based product that provides a demonstrable physiological benefit beyond its dietary or nutritional value. This class of foods for specific health uses are designed to assist in the prevention or treatment of disease, or to enhance and improve human capacities. They include products like vitamin-fortified grains, energy bars, low-fat or low-sodium foods, and sports drinks. Three sets of concerns about functional foods deserve attention. 1) Their health benefits are greatly exaggerated and, in many cases, non-existent; practical questions remain about their efficacy. 2) Their medicinal properties blur the boundaries between food and drugs; public health questions remain about their appropriate use, distribution, and regulation. 3) Their proliferation is fueled by the food industry, not by the medical profession; political questions remain about the role of market forces that too often benefit producers more than consumers.

FUNCTIONAL FOODS DEFINED

All food is in some sense functional insofar as it contains calories and nutrients that support health. The more narrowly construed sense of functional foods are those that have added ingredients believed to provide additional health benefits. Functional foods are not new. They have existed since the early 1900s when iodine was first added to salt to prevent goiter. Vitamin D has been added to milk since the 1930s, extra vitamins and minerals to breakfast cereals since the

1940s, and water fluoridated shortly thereafter. The difference between these fortified foods and the newer generation of functional foods is that more recent ones are designed to replace medicine with food, or sometimes to eliminate qualities from the food to make them (seem) more healthy. Examples of include *Benecol* (a cholesterol-lowering margarine), *Kitchen Prescription Soup* (with the herbal supplement Echinacea), *EggsPlus* (nutritionally enhanced eggs with extra omega-3 fatty acids), *Viactiv* (calcium chews), *Gatorade* and *Vitamin Water* (supplement beverages), *Wow Potato Chips* (fat free, fewer calories), *Ensemble* food products (with soluble fiber to promote heart health), low-carb food products (from beer to frozen food to fast food), and products geared toward the specific health needs of infants, toddlers, and the aging.

Often genetically-modified foods are engineered to be nutritionally enhanced. The most notable example is the highly publicized, Vitamin-A enriched, *Golden Rice*, which has been touted for its ability to reduce blindness in malnourished children. Other genetically-modified products currently promised are high-protein and vitamin-enriched cassavas, milk and peanuts that are allergen-free, tomatoes with three-times the usual amount of lycopene, a cancer-fighting anti-oxidant, carrots with a hepatitis-B vaccine, and potatoes with a vaccine for cholera.

What counts as a functional food varies from nation to nation. But in each instance the definition is bound up with the kind of health claims a product is allowed by law to make. For example, Japan, where the very concept of contemporary functional foods was invented, is the only nation in which functional foods have their own legal designation and regulatory body. Foods for Specific Health Uses (FOSHU) are defined as those foods and beverages with ingredients added for a determined health effect or to reduce the risk of disease or health-related condition. Applications for FOSHU certification are reviewed by the Japan's Ministry of Health and Welfare and must include scientific documentation established by clinical trials performed by approved research institutions. Only FOSHU-approved products are permitted to make health claims on food labels. They are a separate category in the Japanese food system. Participation in FOSHU is, however, voluntary. Food companies can produce items that make *general* health claims (to promote health) so long as they make no *specific* claims (to treat diseases). Products making general, unregulated health claims make up 90 percent of the health food market in Japan.[1] To encourage greater participation in FOSHU, the government lowered the scientific requirements, allowed private-sector laboratories to make legitimate health claims, and streamlined the application process. Still, non-FOSHU-approved functional foods dominate the Japanese market.

In the United Kingdom, there is no legal definition of functional foods, only a working definition by the Ministry of Agriculture Fisheries and Food (MAFF). It defines functional foods as those foods enhanced to have additional health benefits beyond their nutritive benefits.[2] As in Japan, food products are allowed to make general, but not specific, health claims. If a product claims to be capable of preventing, treating, or curing human disease then the food must be licensed as

medicine. Food manufacturers are prohibited from making any medicinal claims. They are, however, allowed to make claims which refer to possible disease factors ("can lower cholesterol"), to nutrient function ("Vitamin A is essential for normal vision"), or to recommended dietary practice ("part of a nutritious breakfast"). Other EU countries have adopted a similar strategy: they allow a wide range of generic health claims and have established procedures to assess the evidence for specific health claims. Common to all definitions of functional foods in the EU are that they be recognizable as food, not pills, capsules, or other drug-like forms.

The case in the United States is somewhat more vague. Functional foods are part of an overlapping family that includes food additives, food supplements, and genetically-modified foods. The Food and Drug Administration (FDA) defines a "food additive" as any substance designed to help prevent spoilage, contamination, or make food look and taste better. Additives are things like flavor enhancers (MSG), artificial colors and flavors, preservatives, stabilizers, sulfites, and nitrates. The FDA defines a "dietary supplement" (somewhat unhelpfully) as additional ingredients with either *nutritional* or *non-nutritional* properties, such as vitamins, minerals, proteins, herbs, enzymes, or extracts. They can either take drug-like forms or they can be added to foods. Finally, the FDA defines function foods as any food product fortified with dietary supplements, food additives, genetically-modified organisms, or vaccines with health benefits beyond that of conventional foods. These categories of modified foods are very rough and vague. It does not help clarify things when food technology industry representatives say things like, "fruits and vegetables, being natural sources of beneficial nutrients like vitamins, antioxidants, and fiber, are in essence the ultimate functional food."[3]

There is no legal definition for functional foods in the United States. Although food additives must receive pre-market FDA approval as "Generally Regarded As Safe" (GRAS), dietary supplements and functional foods do not. Under the Dietary Supplement Health and Education Act of 1994 (DSHEA) no pre-market approval is required for dietary supplements and extra-nutritional ingredients. In fact, the FDA must demonstrate that a product is *unsafe* for a product to be pulled from the market. Functional foods are often marketed as dietary supplements to avoid proving their ingredients are GRAS. Yet, only dietary supplements labels must include the disclaimer: "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease." Functional food labels need not include a disclaimer about proven effectiveness. Given that functional foods are most often conventional foods with dietary supplement ingredient added, the lack of consistency in labeling is, if nothing else, puzzling.

Health claims, however, are more carefully regulated than ingredients. The FDA regulates "foods for special dietary use," which includes products used for supplying a special dietary need that exists "by reason of a physical, physiological, pathological, or other condition including but not limited to the conditions of disease, convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, or the need to control the intake of sodium."[4] Health

claims for foods for special dietary use must have pre-market approval. Because compliance is voluntary and more strict than what is required for functional foods, very few food products are identified as "for special dietary use." Incredibly, the FDA does not regulate "medical foods." These foods are prescribed by a physician for a patient with "special nutrient needs" in order to manage a disease or health condition. They are not intended for the general public. Examples of medical foods include *UltraClear* (for liver failure), *Vistrum* (for gastrointestinal balance), and *Nephrovite* (vitamin supplements for dialysis patients). The FDA does not require that medical foods have nutritional information labeled, nor must their health claims meet specified standards. In 1996, the FDA conceded that the lack of regulation is a problem and it has relied too much on the medical profession to regulate itself to prescribe and oversee the safety of medical foods.[5] As of 2006, the FDA's webpage continues to states that it is "exploring ways to more specifically regulate medical foods. This might include safety evaluations, standards for claims, and requiring specific information on the labels."[6]

As in Japan and the EU, food and supplement companies in the United States are permitted to make general health claims ("Structure/Function Claim") without FDA approval, whereas a specific health claim ("Disease Claim") does require approval. Unlike other countries, the U.S. permits health claims to be made for nutrients already contained in conventional food. Nothing has to be added to food to warrant a health claim. Another difference between the U.S. and other countries is in the language used to distinguish between a general and specific health claim: it is parsed exceptionally thin. According to the FDA:

> An example of an acceptable claim is "a good diet promotes good health and prevents the onset of disease" or "better dietary and exercise patterns can contribute to disease prevention and better health."
>
> An example of a disease claim is "Promotes good health and prevents the onset of disease" because the claim infers (sic) that the product itself will achieve the intended effect.[7]

It is hard to imagine that language like this does anything but confuse consumers.

FUNCTIONAL FOOD EFFECTIVENESS

The first concern about functional foods is practical, not philosophical. The fundamental practical problem with functional foods is that they do not work very well, and when they do work their health and nutritive affects are far less significant than their advocates would have us believe. That is because the very reductivist premise of functional foods—that food is the kind of thing that can be understood in terms of its component parts—is mistaken. When food is understood in terms of parts rather than wholes it usually does not deliver its promised effect as well as conventional food. There is increasing evidence that food broken down into its component parts and then reassembling as processed food is less nutritious than conventional food. It has been shown that ingredients isolated in laboratories do

not function in the same way they do in whole foods.[8] The Center for Science in the Public Interest warns that too often manufacturer claims about functional ingredients are "misleading and unsubstantiated by scientific evidence," and until governments establish adequate regulatory controls "functional foods may merely amount to little more than 21st Century quackery."[9] Even the nutritionists and industry experts who contribute to *Food Technology*, the leading industry journal, caution that the "single-nutrient approach is too simplistic."[10] Food, it appears, is more than the sum of its chemical parts, therefore treating it as collections of single nutrients to be mixed and matched, rather than as the complex biological system it is, simply may not work.

It is true, however, that food fortification for some nutrients does work. The fluoridation of drinking water in the U.S. has helped prevent tooth decay, vitamin-D fortified milk has eliminated rickets, iodized salt reduced goiter, and niacin-enriched flour, pellagra.[11] The increased fortification of these nutrients has very effectively prevented deficiencies of the nutrients added and eliminated a number of sources of disease. Yet, in complex matters of public health, it is often difficult to isolate single causal explanations. For example, is impossible to know precisely how effective niacin fortification was in the reduction of pellagra deaths in the 1940s since the decrease corresponds with changes in social and economic mobility, food safety, and food availability. If more people were eating healthier, more nutritious diets anyway, it is difficult to explain the reduction of the disease exclusively by niacin fortification. The situation is similar today with grain products fortified with folic acid to reduce the number of infants born with neural tube defects (anencephaly and spina bifida). On the one hand, higher levels of folate are now present in adults in the U.S. since fortification began in the 1980s, and fewer babies have been born with birth defects. On the other hand, the public is already more informed about the link between diet and fetal health—especially wealthier, more educated members of society. It is difficult to determine the effects of fortification on people who are already concerned about maintaining a healthy diet. Other causal factors may explain the reduction in birth defects.[12]

Some nutritionists worry that the single-nutrient approach drives functional food research and marketing, misleading the public to believe that there are dietary magic bullets in their food that will ensure a healthy diet regardless of what they eat. Enhancing food with dietary supplements is a quick techno-fix for more complicated issues of dietary patterns, lifestyle, and public health.

> Can we really accept that super-fortification will eliminate our need to select widely from conventional foods to balance nutrient intake? Americans are intrigued with the notion that a pill or a portion can settle all nutritional needs. Thus, we regard fortified cupcakes and synthesized orange juice as necessary steps in achieving that goal. . . . Dumping nutrients into such foods will not neutralize their detrimental effects or make them more healthful. Furthermore, fortification schemes serve primarily to add to the public's confusion about nutrition. By their nature, fortification practices discourage the most desirable modifications in food selection behavior.[13]

Although techno-solutions are often a short-cut, they should not be dismissed out of hand. It is much easier and more effective to supplement food than to address the more persistent underlying causes of malnutrition, such as poverty or insufficient education. But the small number of successful examples of food fortification should not lead us to assume that all food fortification will work as well. The single-nutrient approach to diet works only on rare occasions. The majority of functional foods are market-driven consumer goods that have not been proven to work at all.

FUNCTIONAL FOODS AS MEDICINE

The second concern about functional foods is that they blur the line between food and medicine. The FDA concedes that there is greater need for regulating the health claims made by functional food producers but has been negligent in its obligation to provide consumer protection. Meanwhile, the market in functional foods is booming. In 2004 sales of functional food products reached $22 billion in the U.S and $47 billion worldwide.[14] Millions of people in the U.S., Western Europe, and Japan manage their own health by eating dietary supplements and functional foods instead of using prescription or over-the-counter drugs. A nationwide survey conducted recently by the Centers for Disease Control and Prevention (CDC) found that 36 percent of American adults use complementary and alternative medicines ranging from diet to acupuncture to prayer. That means that a sizeable percentage of the public puts their health into their own hands. In 2003, 158 million Americans used some form of dietary supplements instead of over-the-counter drugs in order, they said, to save money, take control of their own lives, and to live healthier.[15] The trend is toward a public increasingly interested in maintaining better health through diet rather than spending money on health care and prescription medications. Under these conditions, the market for functional foods will only continue to grow.

In many ways, there is nothing new about this do-it-yourself approach to health care. It is a technologically-mediated version of long standing traditions that connect moral conduct with self-mastery of one's body. This connection between a self-imposed dietary regimen and moral conduct can be found in religious traditions throughout the world. For the ancient Greeks and Romans temperance and moderation of all of the appetites were central to moral conduct—especially sexual restraint but also control of diet, exercise, and strong emotions. Asian traditions also emphasized the relationship between diet, regimentation, and health. Taoism, Ayurveda, and Zen Buddhism are just some philosophical-religious systems that specify how bodily health connected to moral conduct leads to spiritual salvation. Although we have retained quite a bit from these traditions, the difference between our contemporary notions of diet and health and ancient and religious dietary practices is not only a greater understanding of physiology and nutrition but also the availability of technologies that extend our capacities in ways non-technological dietary and health practices cannot. Our current dietary practices are much better at reducing risk of disease, treating disorders, and fostering health.

The widespread use of dietary supplements, functional foods, and medical foods are twenty-first century versions of long-standing, tradition-bound, dietary/health/self-management practices.

Yet the regulatory oversight for these edible technologies is terrible: existing regulations do not provide clear guidance—much less enforceable laws—on products ingredients, safety, and health claims. The most serious problem is the lack of regulation on medical foods. Although they are supposed to be used by patients under medical supervision, there is nothing stopping a food producer from calling any product a medical food and making it available to the public. Even when a medical food is used properly, there are no guarantees that the specific health claims made are supported by adequate scientific evidence. The FDA needs to change its current approach to the regulation of medical and functional foods to ensure safety and truthful labeling. It needs to clearly distinguish between medical and functional foods in unambiguous language, establishing standards and procedures for product composition, manufacturing practice and controls, and labeling requirements. The FDA should require that manufacturers notify the agency before marketing the product, submit evidence it is GRAS, and that the claims made about its health benefits are supported by what it calls "sound science." The quantity and quality of scientific evidence required might be modeled after FOSHU. That would clearly distinguish between medical foods and functional foods, and establish standards for what kind of health claims functional foods can legitimately make.

As the line between food and drugs becomes increasingly blurry, the FDA should require that functional food labels carry the same disclaimer ("This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease") as dietary supplements. That would remove an arbitrary loophole in the food regulatory system and take a minimal step toward informing consumers of scientific validity of the health claims being made. It should require that all functional ingredients, like food additives, are GRAS before, not after, they are marketed.

The current burden of proof placed on the consumer to demonstrate a product is unsafe is unfair and unreasonable. Individuals lack the resources and know-how to provide scientific evidence for food safety. If "sound science" takes place in laboratories and large-scale research facilities, then it is the obligation of those with access to such places to ensure food safety and to verify health claims, not individuals. It is the obligation of the government to enforce laws and punish offenders for unsafe ingredients and false health claims. Only it has the legitimate power and authority to do so. Food safety is a matter of social justice. A government that fails to protect the safety of its citizens fails in its obligations to protect our rights—for what value do rights have if a citizen is unable to safely exercise those rights? How can we freely choose if the knowledge needed to make informed choices is hidden from us? Even the most minimal conceptions of social justice require the State to protect public safety. The market cannot guarantee food safety, health claims, and credible medical practice. That is the proper role of government.

FUNCTIONAL FOODS AS CONSUMER GOODS

The third concern about functional foods is with the role of the market. The food industry runs up against the troublesome fact, from its perspective, that each person can only eat so much food. On average we eat about 1,500 pounds of food in a year. Yet unlike other consumer goods there is a limit to how much we can consume. Although the epidemic of obesity might seem to suggest that this limit is flexible, the reason Americans are obese has less to do with the total mass of food consumed than with total calories, fats, and lack of exercise. Try as it might, the food industry has to convince us to eat more than we need to. The best way to do this is by adding value to cheap raw materials, usually in the form of convenience or fortification. The food industry has learned that selling unprocessed or minimally processed food is far less profitable than modifying existing food items by enhancing elements they already have in them (like vitamins and minerals) or by adding new elements to them. There is not a lot of money to be made selling oranges, somewhat more money to be made selling orange juice, but even more to be made selling orange juice that claims to provide the recommended daily allowance of calcium.[16]

Functional foods once played a crucial role in public health in eliminating nutritional deficiency disorders. It is conceivable that they may do so again. They may indeed, in some social context, be an intelligent way to support health and treat or prevent disease for people suffering from food restrictions and shortages. When functional foods do provide genuine public health solutions, they contribute immensely to the public welfare. They help to provide the very conditions for life; they help us to increase our capacities, to exercise our rights, and to live well together. The use of functional foods under these circumstances is, of course, a morally permissible policy for a government. In extreme cases, such as malnutrition or famine, a policy of functional food distribution might be required by a government to promote public health or even to protect our food rights.[17] Or, in less extreme circumstances, a government might be required to manage long-standing nutritional needs through the distribution of functional foods, if necessary for the public welfare. In the United States, the greatest challenges to nutritional health are currently obesity, chronic diseases (many of which are associated with obesity), the needs of an increasing aging population, and food safety. If functional foods can treat hypertension, diabetes, heart disease, arthritis, and eliminate the risks of food-borne illness and disease, then it would not only be wise to continue to develop and distribute them, but it is conceivable that it would be the obligation of the federal government to do so. This might take the form of food relief and food commodity distribution, school feeding programs, nutrition education programs, or incentives for private sector research and development.

It is morally defensible to rely on markets to provide functional foods to maintain public health, so long as no greater harms are inflicted, capacities diminished, or rights abused. If these conditions are met then markets and health are perfectly compatible. If individuals choose to support their health or treat

disease by purchasing functional foods, and they are safe, effective, and consumed with knowledge, then there again is little reason to oppose them. The current case with folate-fortified grains is instructive: the market might presently be serving a genuine public health need by providing a functional food that reduces the instances of neural tube birth defects (assuming for the moment that little or no government subsidies were involved). If this is the case, then privatized food production and distribution should be encouraged as matter of policy to support public health.

The problem with relying on market mechanisms is that they are fickle. Markets may or may not solve public health problems. That is not what they are designed to do. Consequently, to rely on them is, at best, unwise for a government, at worst, negligent and a failure to protect its citizens. The food industry very aggressively influences and distorts nutrition science, federal regulation, and consumer choice. It functions like any other industry: it seeks to maximize profit and increase market share. The food industry does so by creating a favorable sales environment for its products. This includes lobbying political representatives to eliminate unfavorable regulations and pressure regulatory agencies not to enforce regulations, co-opting nutrition experts by supporting favorable research, and marketing and advertising, often to children who are unable to read ads critically. The food industry is, of course, free to sell people whatever people want, but it also relies heavily on its influence on the political process, marketing, and its version of nutritional advice in order to persuade people that they want what the industry is selling. Sometimes the food industry succeeds in producing and publicizing goods that people actually want and need; other times its means are less honest and serve to deceive people into thinking they want and need things they really do not.[18] Once functional foods are seen as one among many products that are a part of a sprawling food industry, then there is reason to question how vital they truly are. Functional foods should be seen as commodities with exchange-value rather than goods with use-value, as Marx would explain it.

When food and medicine are treated like any other consumer goods there is a real danger that our very dietary and medical practices ultimately serve the interests of others more than our own interests. Commerce in functional foods, then, is a profoundly moral and political matter. The more dietary practice becomes a matter of consumer choice, the less it becomes a matter for mechanisms of distribution other than the market. Yet that is precisely the social context in which functional foods exists. On one hand, they are commodities like any other to be manufactured, sold, and consumed; on the other hand, they are uniquely situated at the nexus of diet, health, and commerce, spanning the worlds of optional consumer goods and vital human needs. This puts us all in a tenuous position: commercial interests have the potential to transform how we eat and how we care for ourselves, yet the very future of food and medicine is in the hands of those who may not have our best interests in mind. That may be the most important thing wrong with functional foods.

NOTES

1. Michael Heasman and Julian Mellentin, *The Functional Foods Revolution: Healthy People, Healthy Profits?* (London: Earthscan Publications, 2001), p. 134.

2. Ministry for Agriculture Fisheries and Food, Food Standards Agency, www.food.gov.uk/regulation_health_claims.

3. Linda Orh, "Nutraceuticals and Functional Foods," *Food Technology*, May 2004, vol. 58, no. 5, p. 64.

4. U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, "Food Labeling and Nutrition." www.cfsan.fda.gov/label.html.

5. "The agency believes that there is a need to reevaluate its policy for regulating medical foods because of a number of developments, including enactment of a statutory definition of 'medical food,' the rapid increase in the variety and number of products that are marketed as medical foods, safety problems associated with the manufacture and quality control of these products, and the potential for fraud as claims that are not supported by sound science proliferate for these products." U.S. Food and Drug Administration, "Regulation of Medical Foods," *Federal Register*, November 29, 1996 (vol. 61, no. 231).

6. www.cfsan.fda.gov/~dms/ds-medfd.html.

7. "Structure/Function Claims: Small Entity Compliance Guide." U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, January 9, 2002. www.cfsan.fda.gov/~dms/sclmguid.html.

8. Bruce Silverglade and Michael Jacobson, eds. *Functional Foods: Public Health Boon or 21st Century Quackery?* (New York: Center for Science in the Public Interest, 2000).

9. Ibid., p. 19.

10. Robert Ward and Herbert Watseka, "Bioguided Processing: A Paradigm Change in Food Production," *Food Technology*, May 2004, vol. 58, no. 5, pp. 44–48.

11. Centers for Disease Control and Prevention, "Ten Great Public Health Achievements in the 20th Century," *Morbidity and Mortality Weekly Report*, October, 15, 1999: 48(40), pp. 905–913.

12. For an analysis of food fortification, see, Marion Nestle, *Food Politics* (Berkeley: University of California Press, 2002), pp. 298–314.

13. C. Christopher, "Is Fortification Unnecessary Technology?" *Food Product Development*, 1978: 12 (4), pp. 24–25. Quoted in Nestle, *Food Politics*, p. 314.

14. A. Elizabeth Sloan, "Top 10 Functional Food Trends 2004," *Food Technology*, April 2004, vol. 58, no. 4, p. 32.

15. "Complementary and Alternative Health Medicine Use Among Adults, United States, 2002." Centers for Disease Control and Prevention National Center for Health Statistics, *U.S. Department of Health and Human Services Publications*, 2004.

16. For more of this argument, see, Greg Critser, *Fat Land: How Americans Became the Fattest People in the World* (New York: Mariner Books, 2003).

17. "Universal Declaration of Human Rights," http://www.un.org/rights, p. 5. The right to food is recognized directly or indirectly by every country in the world, either written into

their constitutions or by virtue of their membership in the United Nations. Article 25 of the 1948 Universal Declaration of Human Rights states that "everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing, medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control."

18. For evidence of precisely how the food industry creates a favorable sales environment through lobbying, marketing, and co-opted nutrition experts, see, Marion Nestle, *Food Politics*, pp. 95–136, 175–218.