Are Nutritional Claims Appropriate for Muscle Foods?

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A revolutionary change is taking place in the way we view food in America, and indeed in much of the developed world. For the first few hundred thousand years of human existence, the only real issue involving food was, "Is there any?" Much of the course of civilization, from the formation of socialization patterns to support hunting groups, through the first beginnings of communities to facilitate agriculture, to the development of organized governmental structures to manage the storage and distribution of food concerned itself with assuring a dependable food supply.

Once a sufficient quantity of food was available, interests turned to hedonism: people wanted food that provided sensory pleasure, and they wanted to avoid food that tasted bad. Spices and sauces made their appearance as a means of covering up off tastes of putrefying foods. The microbiological safety of food was not, and is still not an issue.People want their food to be safe–make no mistake about that–but they don't want that to be in their hands or a matter of their choice; it is up to the supplier and the government to "do something" to make sure the food will be safe, no matter what.

It is only within the past two hundred years or so that interest has focused on the health benefits of foods. Until about the last decade the only health benefits seen were prevention of frank nutrient deficiency disease-scurvy, rickets, goiter, and so forth. This orientation was, and still is the basis for virtually all government regulation of food labeling and advertising. The food label introduced in 1973 after the 1969 White House Conference was heavily targeted to micronutrients–the mandatory nutrients were vitamins A and C, three B-complex vitamins, iron, and calcium, and there was an optional list of many more.

What could a food manufacturer say good about the product, other than "Mmmm good!" or "They're grrrreeaaaat!?" Any indication that the product might be useful in the cure, mitigation, prevention, treatment, or diagnosis of any disease was (and is) regarded as a drug claim, and the product was immediately transformed from a useful food into an illegal drug.

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The first successful assault on this wall was launched by Kellogg in 1984 with their introduction of All-bran®, a high-fiber breakfast cereal that carried a carefully worded claim that the National Cancer Institute recommends that a diet high in fiber and low in fat may help reduce the risk of some kinds of cancer. After several failures to force Kellogg to remove this statement, the FDA finally conceded partial defeat in a *Federal Register* notice in 1987, which provided for truthful health-related statements on foods. While the FDA proposal called for an interagency committee chaired by FDA to develop health messages, this still represented the first admission by a Federal regulatory authority of the appropriateness of label statements regarding health benefits of food products.

The Nutrition Labeling and Education Act (NLEA) provided for health claims to be based on a determination by FDA, based on the totality of publicly available scientific evidence, that there is significant scientific agreement that the claim is supported by such evidence. FDA has been something less than enthusiastic about making such determinations, and at the urging of the food industry, Congress included in the FDA Modernization Act of 1997 (FDAMA) an amendment to the Food Drug and Cosmetic Act (FDCA) that authorizes food labeling to include certain health claims without approval by an FDA regulation. Such a health claim must be the subject of a published authoritative statement, currently in effect, issued by a scientific body of the U.S. government with official responsibility for public health protection or research directly relating to human nutrition or by the National Academy of Sciences. However, the claim and its basis must be submitted to FDA 120 days in advance, and FDA can terminate the right to use the claim simply by publishing a proposal for public comment prohibiting or modifying the claim or finding that the requirements to make the claim have not been met. In point of fact this is what has happened with all of the FDAMA claims submitted to date.

NLEA and FDAMA are amendments to the FDCA and consequently have no direct impact on USDA, which operates under different laws–primarily the Federal Meat Inspection Act and the Federal Poultry Products Inspection Act. However, USDA has endeavored to ensure some degree of consistency across products labeled under FDA and under USDA jurisdiction. In April 1994, USDA issued a proposed rule (which paralleled FDA's final rule of January 1993) to provide for the appropriate use on USDA-regulated products of health claims, approved by FDA as of that date. However, when FDA continued to approve additional health claims and when FDAMA established new procedures for health claims, USDA's proposed rule became

obsolete and was withdrawn in April 1998. Nevertheless, USDA policy will permit health claims approved by FDA on USDA-regulated products which meet the required conditions (such as maximum fat or saturated fat content) established by FDA for use of the claim.

In addition, USDA has accepted the concept of third-party endorsements of muscle foods. The only specific manifestation of this policy is the agency's decision to allow regulated products to bear the American Heart Association (AHA) heart-check mark logo, which certifies that the product meets the AHA criteria for fat, saturated fat, cholesterol, sodium, and nutrient content.

However, there is one strongly held restriction regarding the use of health claims on meat and poultry products: ingredients may not be added to the product in order to qualify for the claim. This position is based on a much older policy that has consistently been expressed by USDA, that "meat and poultry products are not appropriate for fortification."

This restriction may be tempered if one phrases the question in terms of "USDA regulated products" rather than specifically "meat and poultry products." USDA regulates mixed dishes (referred to as "meal-type products") that contain more than 3% meat or 2% poultry. While USDA would disapprove adding (for example) psyllium to the meat or poultry component of the mixed dish, there might be no objection to adding it to the non-meat or poultry component. An example might be a frozen breakfast containing pancakes and sausages. It is possible that psyllium could be added to the pancakes in order to provide the basis for a health claim (assuming that the claim is not disqualified due to the fat, saturated fat, or cholesterol content of the meal), but the label would be required to reveal that the claim was based on the pancake component rather than the sausage component.

There are several points to note in this review of the history of label claims regarding benefits of foods. First, it seems in some respects that USDA is generally more conservative than FDA, especially in its opposition to the fortification of meat and poultry dishes. It must be recalled, however, that FDA has a long history of equal opposition to what the agency regards as "uncontrolled fortification," and its fortification policy guidelines lay out elaborate procedures to avoid any risk of "over-fortification." It might also be recalled that FDA delayed for years implementing a policy to promote fortification with folic acid–despite many documented cases of neural tube defects in the U.S.–alleging a relatively theoretical concern with the potential for masking detection of pernicious anemia.

As nutrition science identifies more and more beneficial food components beyond traditional vitamins and minerals, such as conjugated linoleic acid (CLA), it is likely that components will be found for which muscle-food products are the most appropriate vehicles. USDA's opposition to fortifying meat and poultry products is a matter of policy rather than of legislation or regulation that requires formal rule-making to overturn, and it may well crumble under the right assault.

A second point is related to the fact illustrated above: as compared to FDA, USDA has few regulations regarding labeling and label claims. Rather, the department has a lot of policies which can–not always do, but can–allow for flexibility and ready adaptability to changed conditions. As an example, it required the Dietary Supplements Health and Education Act (DSHEA) to force FDA to allow food labels to include claims of nutritional support—often referred to as "structure/function claims." (To avoid confusion, let me concede that DSHEA did not mandate this relaxation of FDA's control of food labels, but it still resulted in the change by providing for such labeling for dietary supplements. This was followed by the obvious question: "Why can a supplement make a nutritional support claim for component x while a food that contains the same component at the same level of concentration cannot?")

While USDA has no regulations in force regarding claims of nutritional support, as a matter of policy they will allow such claims if they meet the same criteria as are required for such claims on FDA regulated products. For example, a muscle food could almost certainly carry a claim that the product contains x amount of protein, and that protein is necessary to build and maintain muscle tissue–or any similar claim that is well supported by science. A meat or poultry product that is a good source of iron or zinc could most probably make an appropriate claim regarding the nutritional benefit of these minerals. Note, however, that I said the "nutritional benefit." USDA would be most unlikely to approve an antioxidant claim or immune function claim.

Another point is that USDA still has a policy of label pre-approval. This, combined with the relative paucity of detailed labeling regulations, gives a food manufacturer considerable opportunity to try out new ideas. There is clearly an opportunity for presentation to USDA of a proposed label claim, along with strong scientific substantiation for the claim, with a real possibility of approval. For example, in 9 CFR 317.369, USDA addresses procedures for submitting "labeling applications for a new (heretofore unauthorized) nutrient content claim." This submission must provide (*inter alia*):

"A detailed explanation supported by any necessary data of why use of the food component characterized by the claim is of importance in human nutrition by virtue of its presence or absence at the levels that such claim would describe."

USDA provides for the submission to be accompanied by clinical or non-clinical studies substantiating the alleged nutritional benefit.

Other speakers at this session are addressing issues related to emerging science regarding beneficial components of muscle foods. However, CLA may serve as an example of the potential that exists for using USDA's flexibility to modify its policies regarding labeling. At the present time, USDA forbids labeling the CLA content of a meat or poultry product on the argument that the "importance to human nutrition" of this component has not been demonstrated. I would speculate that the research on CLA will soon result in the development of an adequate science base to persuade USDA that labeling the CLA content of foods is appropriate. From there, it will be only a short step to the authorization of claims of nutritional support for CLA.

A final point regarding benefit claims for USDA regulated products v. those regulated by FDA is worth making. This is less a matter of public record than of individual perception based on the ten years I spent at FDA and four at USDA. FDA is part of the Public Health Service, and its enabling legislation reflects

that fact. The Food, Drug and Cosmetic Act is wholly risk-based; there is no provision for consideration of benefits in such things as food-additive approvals. But even beyond the legislation, the orientation of all of the public health agencies is to see food as merely a risk factor for cancer, coronary heart disease, hypertension, or other clinical endpoint. On the other hand, USDA tends to see food as basically good stuff. Not that the department is unaware of health concerns related to overconsumption of food or certain components, but it is perhaps more ready than is FDA to see the benefit side of the equation. What I am leading up to is a suggestion that USDA could be fertile territory for those who are ready to provide good science to back up their desire to formulate a functional meat or poultry based food, or to add claims regarding health benefits to the labels of muscle foods.

Finally, it must not be forgotten that there are powers beyond FDA and USDA. One of these is the First Amendment to the Constitution. An important decision came down from the U.S. DC Circuit Court of Appeals on January 15, 1999. Makers of dietary supplements petitioned FDA to authorize four health claims:

- "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers."
- "Consumption of fiber may reduce the risk of colorectal cancer."
- "Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease."
- "0.8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form."

FDA rejected the four claims, not due to a dearth of supporting evidence, but on the argument that the evidence was inconclusive and failed to give rise to "significant scientific agreement." FDA won in the U.S. District Court for the District of Columbia, but lost on appeal. The appeals court based its decision on two arguments:

- First, the court rejected FDA's claim that consumers are not capable of applying discretion to limited claims or claims with disclaimers if the claim is not a matter of scientific consensus.
- Second, the court regarded FDA's requirement for "significant scientific agreement" to constitute an "unarticulated standard" and thus to be so vague as to be unconstitutional.

Again, this decision directly addresses only FDA's rejection of four specific claims, but the effects of the decision are potentially extremely far-reaching. It might be argued that USDA, with its rather loose policies in place of regulations, is even more liable than is FDA to charges of vagueness and the application of "unarticulated standards." It will be most interesting to see what happens over the next year or so regarding the ability of manufacturers of meat and poultry based foods to make scientifically supported label statements regarding the health benefits of consumption of their products.