Nutritional products for specific health benefits—
Foods, pharmaceuticals, or something in between?

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A category of compounds called nutraceuticals has been proposed as a new regulatory category separate from current US Food and Drug Administration (FDA) regulations for food or drugs. The Nutraceutical Research and Development Bill, proposed by the Foundation For Innovation in Medicine, would, if enacted, substantially loosen current criteria for health claims to consumers about nutritional products. However, the proposal conflicts with FDA regulations and the Nutrition Labeling and Education Act of 1990, which allow products to make health claims to consumers only when supported by significant scientific agreement. The nutraceutical proposal would also allow exclusivity of health claims based on proprietary research, in contrast to FDA regulations that health claims for foods should be based on public information and should not be brand specific. Federal regulations and funding should be encouraged to promote human research and clinical testing of the health benefits of foods and food components, in amounts available in the diet, without classifying these substances as drugs. Consumers will best be served by prohibiting health claims without sufficient research and prior approval and by allowing scientifically based health claims for all qualifying foods in a varied diet.

The term nutraceutical has been used nonspecifically. For instance, it has been said to include four types of food: "genetically engineered foods (tomatoes, for example), raw food (carrots with β-carotene), processed food without added ingredients (oat-bran cereal), and processed food with added ingredients (calcium-fortified juice)" (2, p 7).

Nutraceutical was proposed by The Foundation For Innovation in Medicine as a new regulatory term, "outside of the traditional regulatory concept of either a food or a drug" (3, p 77) to establish a new process for the review and approval of products and related health claims, and to provide exclusive marketing rights to such claims based on proprietary research.

The term nutraceutical is not recognized by the FDA (4), is not used in medical science literature, and did not appear in any titles or abstracts in the Medline database as of June 1993. On the other hand, it does appear in the Agricola database and in publications related to food technology and food marketing. It has also been used in the popular press by such publications as The New York Times and USA Today, which reflects an extensive media campaign by The Foundation For Innovation in Medicine.

In Japan and in some European countries, food products sold for health benefits have been termed functional foods, or "processed foods, defined by the main functional ingredient (oligosaccharides, fibres, minerals, etc.), that are claimed to perform specific health roles such as preventing, treating and curing various diseases, and which fall into a category somewhere between food, dietary supplements and drugs" (5, p 78).

FDA defines foods as “products primarily consumed for their taste, aroma, or nutritive value,” and drugs as products “intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure or a function of the body” (6, p 33692). Specific FDA regulations apply to medical foods, which are defined as products “intended for use under the supervision of a physician for specific dietary management of a disease or condition” (7, p 2151). Examples include enteral feeding solutions and products for individuals with phenylketonuria. The FDA plans to develop specific regulations for medical foods in the near future (7). Food additives, substances added to foods for specific physical or technical effects, require FDA approval of data that

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establish safety, including evidence that the additive will accomplish its intended effect (6).

MARKET OPPORTUNITIES AND OBSTACLES
Sales of food products with health claims have been forecast as a major growth area in the food industry. Forty percent of new food products carry some kind of general or specific health claim (8). From reduced-calorie foods to foods purported to prevent cancer and cardiovascular diseases, to "mood foods," the current retail market for all nutraceuticals has been estimated at $2.5 billion in 1988, with a projected annual growth rate of 17% to 20% (8).

Current FDA regulations allow only a few specific health claims that are well supported by publicly available scientific evidence and that can be used by all qualifying food products. There is no mechanism for exclusive health claims based on proprietary research, as exists for drugs. The Nutrition Labeling and Education Act mandates that "publicly available evidence" be used to support health claims for food, and the FDA has specified that such claims will not be brand specific (9). Proponents of nutraceuticals claim that this removes the financial incentive for companies to invest in research and development of nutritional products.

Examples of nutraceuticals include the use of beta carotene to prevent lung cancer, vitamin A to treat measles, fish oil for hypertension, and antioxidants for heart attacks.

REGULATORY CHANGES PROPOSED
The Foundation For Innovation in Medicine proposes that Congress enact a Nutraceutical Research and Development Bill that would permit 7 years of exclusivity in health claims for nutritional products based on proprietary research. A Nutraceutical Commission housed within FDA specifically for the review and approval of nutraceuticals would review, approve, and regulate new products and claims. The commission would be open and flexible in establishing study requirements and would classify submitted applications as either a medical nutraceutical (promoted to physicians only) or a consumer nutraceutical (promoted to physicians and consumers), depending on the request of its sponsor and the subsequent evaluation. A nutraceutical research grants program would be created specifically for nutraceutical clinical research, and would be administered by the National Institutes of Health (1).

Although DeFelice prefers the nutraceutical initiative, he has indicated that he "would support the passage of a Hatch/ Richardson-type bill, which would allow the companies to make claims without pre-marketing clearing, and the FDA challenging them afterwards" (10, p 25). This Dietary Supplement Bill (S 784/HR 1709), which was introduced by the Food and Drug Administration, and Rep Bill Richardson (D, NM) on April 7, 1993, would exempt dietary supplements from the health claims provisions of the Nutrition Labeling and Education Act of 1990. The American Dietetic Association (ADA) has lobbied against this bill.

Japan, Europe, and the United States, are currently considering how best to regulate such products. In Japan, regulations were approved in July 1991 for Food for Specified Health Use (FOSHU). These foods must have a clear medical and health benefit, should be a product that is normally consumed in ordinary diets (not pills or supplements), and must be labeled with medical benefits and precautions for cooking, use, and storage. The Japanese government is considering requiring sales of FOSHU products only in certified stores staffed by FOSHU nutritionists. No FOSHU products were approved in the first 18 months of the regulations (11).

Nutraceuticals promoters cite instances in Europe of exclusivity granted for research-based health claims. Maxepa (Laboratories, Lincoln, France), a product containing long-chain n-3 fatty acids, was refused by the French government as a food with specific therapeutic claims, but was subsequently approved as a drug with market exclusivity to claims that it is effective in treating isolated or combined hypertriglyceridemia. The product can only be supplied as a prescription drug in pharmacies, and patients are 70% reimbursed by the government. "Sales have taken off, and seven out of 12 EEC [European Economic Community] countries have accepted Maxepa as a drug" (11, p 60).

EVIDENCE FOR HEALTH CLAIMS
The white paper describing the nutraceutical initiative calls for research requirements that are open and flexible, indicating that epidemiological data may frequently provide significant evidence in addition to clinical studies...the focus will be on preventive or therapeutic results, and not necessarily the often economically prohibitive task of identifying whether or not any specific product component is the active one in isolation. The overriding requirement for supporting data will be that they must be appropriate and sufficient for accurate and reliable health claims, and demonstrate an acceptable level of risk to public safety. Whenever nutraceuticals are substances that are routinely consumed by the public and generally recognized as safe, there can be little or no requirement for pre-clinical testing (1, p 9).

Examples of nutraceuticals and clinical research support cited in the nutraceutical white paper (1) are: the use of beta carotene to prevent lung cancer (12), niacin to prevent recurrent heart attacks (13), pyridoxine to treat and prevent depression (14), niacin to prevent recurrent heart attacks (13), pyridoxine to treat and prevent depression (14), vitamin A to treat measles (15), magnesium to treat hypertension (16), garlic to reduce arteriosclerosis (17), fish oil for hypertension (18), calcium for hypertension as well as osteoporosis (19), and antioxidants to reduce damage from heart attacks (20) (references 12-20 were cited in reference 1). The references cited as evidence for these examples suggest that claims could be approved based on single scientific papers, review articles, or even an abstract.

DeFelice has further indicated that: ...the products must be effective, or probably effective, as demonstrated by published clinical trials. Clinical studies must be published in respected clinical journals. But they do not necessarily have to demonstrate definitive clinical activity, such as the effect of vitamin C in patients with scurvy. Strongly suggestive data are sufficient as we have seen with a pyrimidine-based cereal that lowers blood lipids and a mineral such as magnesium, which inhibits platelet aggregation and reduces insulin resistance in certain diabetics (21).

Although most scientific, professional, or consumer organizations have not expressed a position on nutraceuticals, Bruce Silverglade, legal director of the Center for Science in the Public Interest, expressed concern about reducing the requirements for health claims: "With weaker scientific proof necessary to make health claims for nutraceuticals, you may end up with so many claims that consumers won't be able to make heads or tails of them" (22, p 40).
CONCLUSIONS

Scientific criteria for making health claims

In comments on FDA labeling regulations, ADA has supported FDA’s proposal to require regulations for supplements to be as similar as possible to labeling regulations for food products. Independently, and as a member of the Food and Nutrition Labeling Group, ADA has written to senators and congressmen against passage of the Hatch/Richardson bill, on the grounds that it would provide consumers with less protection against unsafe dietary supplements and misleading labeling claims than is provided with the Nutrition Labeling and Education Act of 1990. The Nutraceutical Research and Development Bill proposed by the Foundation For Innovation in Medicine, which would weaken the scientific criteria for making health claims, conflicts with ADA’s continued support of FDA regulation of consumer health claims (in accordance with the Nutrition Labeling and Education Act).

Open, academic research has been fundamental to the development of nutrition science; we should not discourage research by requiring investigative new drug procedures for substances in amounts available in the diet.

Exclusivity for making health claims based on proprietary research

Nutrition research has generally followed an open, academic process, free of proprietary claims. Exclusivity of health claims on products based on proprietary research when other products commonly consumed may be equally associated with the claimed health benefits could lead to consumer confusion. For example, if health claims of reduced risk of cancer were allowed for ß-carotene, consumers may be best served if such claims are allowed for all foods with substantial amounts of bioavailable ß-carotene, not just for the products of a single producer who funded supportive research. FDA regulations require that health claims made to consumers are based on public information and are not brand specific. Before developing a position on exclusivity of health claims for foods based on proprietary research, the ADA may wish to further explore the existing laws and regulations related to the patent process and the use of proprietary research, in particular regarding foods, medical foods, food additives, and drugs.

Classification (food vs drug) of research using purified food components

Open, academic research, including human testing of isolated food components (e.g., vitamins, minerals, amino acids, fatty acids, sugars, dietary fibers, and many other food components), has been fundamental to the development of nutrition science. Federal regulations (through FDA) and funding should be encouraged to promote human research and clinical testing of the health benefits of foods and food components, consistent with good science, safety, and the Nutrition Labeling and Education Act of 1990. Although compounds in foods that must be concentrated to obtain physiologic effects should be regulated as drugs, foods and purified food constituents in amounts commonly consumed should not be classified as drugs simply because they are being tested for potential health effects or disease prevention. Research should not be discouraged by requiring investigative new drug procedures for substances in amounts available in the diet.

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