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Nutraceuticals

Blurring the Line between Food and Drugs in the Twenty-first Century

Nutraceutical products constitute the fastest growing segment of the U.S. food industry. Nutraceuticals are foods or food ingredients that provide medical or health benefits, including disease prevention and treatment. This emerging class of products blurs the line between food and drugs. In an attempt to take greater responsibility for their health, Americans increasingly seek to derive medicinal benefits from food and pursue wellness through the use of herbals, dietary supplements, and other nutraceuticals.

Nutraceuticals challenge the traditional notion that foods nourish and entertain, while drugs prevent or treat disease. In this sense, nutraceuticals have caused a major shift in consumer views and business operations in the food, pharmaceutical, and health management industries. The nutraceuticals industry recognizes that foods may be the ultimate delivery mechanism for medicine and health. Historically, the counterculture provided the primary market for the majority of health food and herbs. Today, a much broader class of consumers recognizes the health and medicinal values of food products as the interest in nutraceuticals approaches a mainstream phenomenon.

Nutraceuticals has become the buzzword for food industry executives, especially those seeking to position their companies for the opportunities offered by the industry's equivalent of "high-tech." A new class of companies has emerged in recent years that produces functional and medical foods, herbal products, supplements, and natural foods. Large food and pharmaceutical companies are looking with interest at the middle ground between their industries as an area of opportunity. Some have created new divisions focused on nutraceuticals. Others have merged with or acquired nutraceutical companies. For example, pharmaceutical companies such as American Home Products, Smith-Kline Beecham, and Warner Lambert entered the botanical supplement market in 1997 and 1998. In the food industry, giants such as Kellogg, Nabisco, Ocean Spray, duPont,

Coca-Cola, General Mills, Lipton, and Pepsico seek to capitalize upon the nutraceuticals phenomenon by expanding into the functional foods arena.

Industry scope, size and growth

The nutraceutical industry's three main segments include functional foods, dietary supplements, and herbal/natural products (Adelaja et al.). Functional foods are modified foods or food ingredients that provide health benefits beyond their traditional nutrients (*Nutrition Business Journal* 1996). These include medical foods, prescription foods, pharmafoods, and specially formulated diets. The functional foods category also includes lifestyle-oriented foods such as fitness foods, nutritional foods, therapeutic foods, super foods, and longevity foods. MenuDirect Corporation, for example, is a recently formed New Jersey company that designs and markets specially formulated low-protein, gluten-free, and consistency-modified diets for individuals afflicted with phenylketonuria, celiac sprue, and dysphagia.

The dietary supplements category includes isolated nutrients and other supplements that enhance health and improve the nutritional value of food. Fortitech, for example, was formed to produce and distribute such products.

The herbal and natural products category includes botanicals and herbal remedies. Recent public interest in St. John's wort as an alternative to Prozac for the treatment of depression illustrates the entrance of herbal alternatives into the American mainstream. Companies such as Herbalist and Alchemist specialize in the manufacturing and distribution of herbal products.

Estimates of the size of the U.S. nutraceutical market range from \$64 to \$250 billion (Adelaja et al.). In comparison, U.S. retail food and pharmaceuticals sales in 1995 totaled roughly \$600 billion and \$77 billion, respectively (U.S. Bureau of the Census). The discrepancy in market size estimates arises from definitional differences. Stephen DeFelice, who coined the term *nutraceuticals* in the

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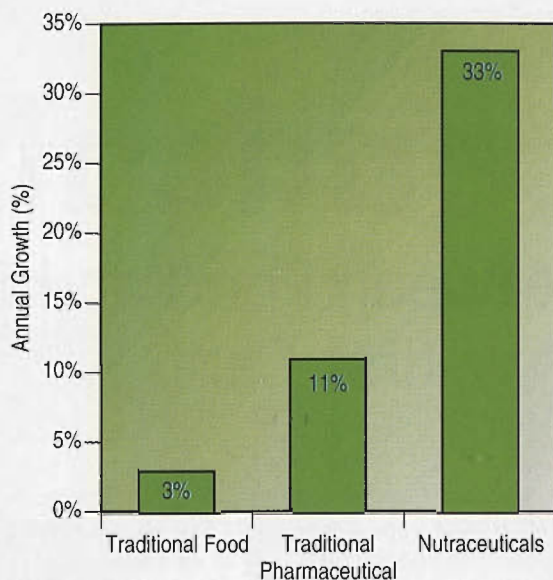


Figure 1. Estimated growth rates in the food, pharmaceutical, and herbal/natural product industries in the Mid-Atlantic region

late 1980s, defined nutraceuticals broadly to include processed healthy foods and items such as sugar and fat substitutes, fiber-enriched foods, vegetables, herbal remedies, virtually fatless meat, skim milk, low-calorie diets, and other products consumed for health reasons. His \$250 billion estimated market size far exceeds the existing retail market for ethical drugs and over-the-counter pharmaceuticals estimated at \$94 billion in 1992 (Adelaja et al.).

In an attempt to refine DeFelice's quantification, the *Nutrition Business Journal* (NBJ) identified an \$80 billion nutraceuticals market in 1995 by considering natural and organic foods (\$6.2 billion), functional foods (\$13.4 billion), certain lesser-evil foods with reduced or no unhealthy ingredients (\$23 billion), dietary supplements (\$8.9 billion), and selected market standard foods (\$28.3 billion). NBJ has begun tracking nutraceuticals industry growth. Since 1995, the industry, as defined by NBJ, has grown by an average of 7.1 percent per year. In 1997, industry sales totaled \$91.7 billion (NBJ 1998). The most rapidly growing segments of the industry were dietary supplements (19.5 percent per year) and natural/herbal products (11.6 percent per year).

Sloan and Stiedemann truncated the marketplace further by defining the "core" nutraceuticals market as a \$64.4 billion entity that includes healthy prepared foods; snacks and meal replacements (\$37.3 billion); sports, herbal, and fortified beverages (\$20.9 billion); vitamins, minerals, and herbals (\$5.7 billion); and diet, lactose intolerance, and fiber aids (\$510 million) (Adelaja et al.).

Nutraceuticals offer an impressive potential for future growth. As the concept of deriving health

from food enters the American consciousness, nutraceutical products once relegated to specialized health and natural products stores will occupy increasing shelf space in conventional grocery and drug stores. For example, in an analysis of the mid-Atlantic herbal/supplement component of the nutraceuticals retail market, Adelaja et al. reported an anticipated annual growth rate in retail sales of 33 percent. This compares to recent growth rates of 3 and 11 percent, respectively, in the sales of traditional food and pharmaceutical companies in the mid-Atlantic states (figure 1).

Drivers of nutraceutical industry growth

The surge in consumer demand for food-based health delivery has been dubbed one of the top ten trends in the food industry (Sloan). Several forces will promote rapid growth in the industry, including increased awareness of diet-disease relationships, demographic transitions, heightened interest in maintaining personal health, and changes in the structure of the healthcare system.

Improved diet-disease knowledge

According to the *Surgeon General's Report on Nutrition and Health*, diet is one of the top three personal factors affecting the health and longevity of Americans (U.S. Dept. of Health and Human Services). Many of the leading causes of death are diet-related (Adelaja, Nayga, and Wall). Frazao (1999) estimates that the adoption of healthier diets in the U.S. could prevent \$71 billion per year in medical costs, lost productivity, and premature deaths associated with coronary heart disease, cancer, stroke, and diabetes. Collectively, these conditions currently account for approximately \$220 billion per year in medical expenses and lost productivity alone. Frazao (1996) notes that improved diet could forestall 20 percent of deaths from heart disease, cancer, stroke, and diabetes. The possibility that improved diet could reduce escalating healthcare costs and improve public health interests public health officials. In recognition of the link between diet and health, the National Cancer Institute embarked on a five-year initiative to study and develop designer foods (Caragay).

The public's awareness of the relationship between diet and disease has increased dramatically. For example, 92 percent of respondents to the Food Marketing Institute's 1995 survey indicated that they had adopted healthier diets (Frazao 1996). Transitions to healthier diets include many of the traditional diet modifications (increased consumption of fiber, reduced-fat foods, and low-calorie diets) as well as a marked increase in the consumption of nutraceutical products.

Changing demographics

The "baby boom" is perhaps the most significant factor influencing domestic product markets since World War II. Baby-boomers are approaching ages at which health is of paramount importance. Many baby-boomers have reached their peak income-earning years but are "time starved" and seek avenues for continued health. While medical advances and increased scientific understanding of many diseases allow Americans to live longer, they also want to maintain a high quality of life in later stages of life. The aging baby boom generation is receptive to a wide range of alternative methods of disease treatment and prevention, including nutraceuticals. They have tremendous market muscle, capable of sustaining growth in the nutraceutical market.

Growing ethnic diversification also expands the demand for alternative health and medicinal products. Although the interest in nutraceuticals is a relatively new phenomenon in the U.S., many Asian, African, and European cultures have historically used food as a mechanism for improving health. Continued U.S. immigration will increase the demand for nutraceutical products both directly and indirectly by exposing Americans to these alternative products.

Greater personal responsibility for health

Americans are assuming greater responsibility for maintaining personal health and adopting a "wellness" perspective that emphasizes disease prevention over disease treatment. Increasingly time-starved Americans aggressively pursue nontraditional alternatives to maintain good health. In addition to treatments such as

acupuncture, yoga, and aromatherapy, more consumption-based alternatives for promoting health have increased significantly in popularity.

Changes in the healthcare system

As baby-boomers age, traditional healthcare institutions will face new challenges—especially the growing discontentment of consumers with the expense of traditional high-tech medical cures and reliance on synthetic chemicals. Consumers seem less tolerant of the side effects of synthetic pharmaceuticals and are opting for natural alternatives that maintain healthy lifestyles. Increasing reliance on alternative wellness programs and alternative medicine has emerged as one of the major trends in the healthcare system (Gravzer). Roughly half of patients in the U.S., according to some estimates, now rely on alternative as well as modern western healthcare methods (*Complementary Medicine*). Many of these alternative treatments include herbs, botanicals and natural products.

Increasingly, managed care and health maintenance organizations acknowledge the value of preventive approaches to medicine. Managed care organizations already explore the possibility of including nutraceuticals in their formularies and some already reimburse members for "complementary" medical treatments. According to a Rutgers University study, at least thirty-four states require insurance reimbursement of medical foods expenses for people with special dietary needs. Some insurance companies, even in the absence of a legislative mandate, voluntarily reimburse expenditures for prescribed diets that reduce expected medical costs.



UDON/MS

Nutraceuticals in the twenty-first century

The nutraceuticals industry holds tremendous growth potential. Changes in the composition and consciousness of the American public appear capable of sustaining industry growth well into the twenty-first century. However, the industry faces significant challenges. The rapid emergence of the industry caught regulators, industry, and the public off guard. Federal regulators are unsure how to view newly emerging nutraceutical products, the public wants more information, and many of the large food and pharmaceutical companies are guarded in their approach to nutraceuticals because they face an ambiguous regulatory framework.

Regulatory structure

The Nutrition Labeling and Education Act of 1990 (NLEA) forms the backbone of U.S. food regulation. NLEA prohibits the use of health claims in advertising unless such claims are scientifically substantiated and approved by the Food and Drug Administration (FDA). The Dietary Supplement Health and Education Act (DSHEA) passed in 1994, however, allows dietary supplements to be regulated differently than other foods. Dietary supplements are not subject to the rigorous scien-

tific substantiation required of traditional drugs and can be marketed on the basis of structure-function claims, provided that such claims do not specifically connote disease treatment or prevention.

The regulation of nutraceutical products is among the most contentious issues facing the industry. It is unclear how the regulatory landscape will evolve. Some consumer groups are pressuring the FDA to resolve the ambiguity that presently surrounds nutraceutical products. Industry, too, worries about the present murkiness of nutraceuticals regulation. For example, McNeil Pharmaceuticals recently attempted to market a margarine product which lowers cholesterol. The FDA ruled that the company needed scientific proof of the product's cholesterol-reducing effects. But, McNeil contended that FDA approval of the product was unnecessary because it was a dietary supplement. Given the uncertainty of the regulatory climate, some companies are initiating clinical trials to scientifically document the efficacy of their products in order to legally make health claims.

Consumer education

The ambiguous regulatory climate presents some interesting consumer challenges. Despite the public's interest in maintaining health, consumers have inadequate understanding of many types of nutraceutical products. Swayed, however, by the prospect of achieving improved health, Americans consume many types of herbal and other dietary supplements, for example, despite limited knowledge of dosage, side effects, and product interactions.

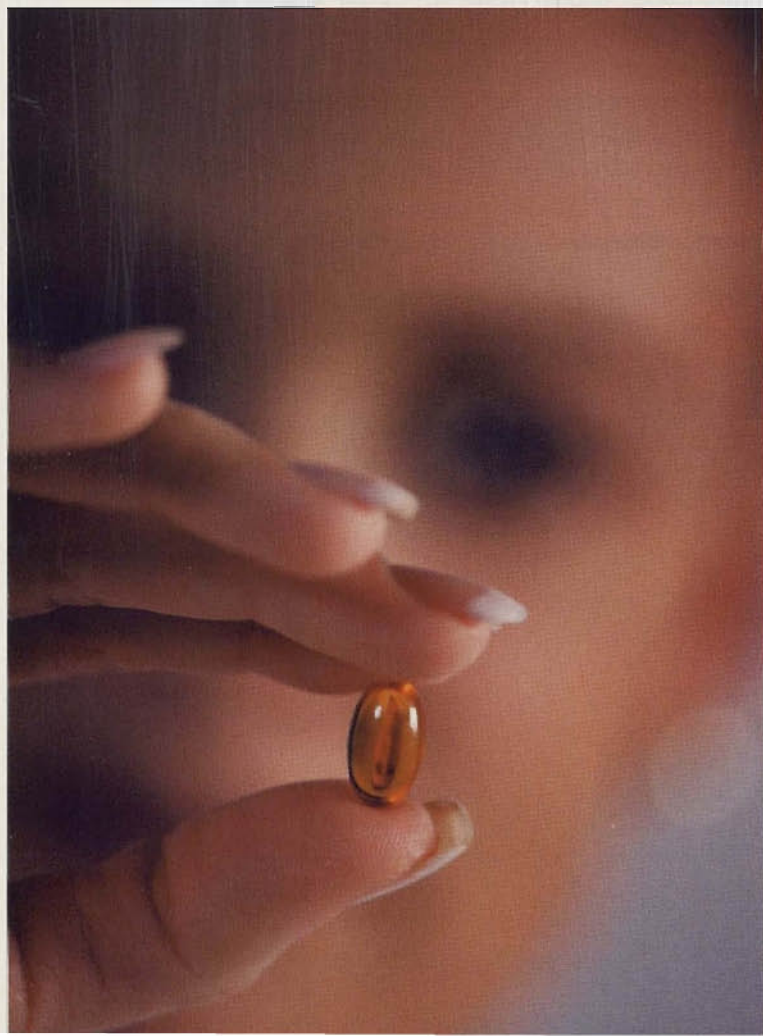
Product adulteration and fraudulent claims

Given limited consumer awareness and a loose regulatory system, unethical manufacturers can introduce products lacking specified active ingredients or containing unspecified ingredients. Further, the practice of overtly or tacitly advertising nonexistent or exaggerated health claims has caused some critics to label nutraceuticals as the snake oil of the 1990s.

Insurance coverage

As demand for nutraceuticals grows, an important policy question emerges: Should consumer expenditures on these products be reimbursed by health insurance companies? While anecdotal evidence and widespread use of such products in other countries lends an air of credibility to the efficacy of certain nutraceuticals, scientific evidence is often limited. Consequently, insurance companies are often reluctant to provide reimbursement.

According to a 1999 study at Rutgers University, thirty-four states require reimbursement to individuals who require special medical diets. For example, many states require that insurance compa-



nies reimburse expenditures on low-protein formula for infants afflicted with inborn errors of metabolism. But what about the consumption of prescribed foods that greatly enhance the quality of life of persons afflicted with certain conditions—for example, gluten-free products for individuals suffering from celiac sprue? What about expenditures on herbal products and dietary supplements designed to maintain health? Reimbursement for these products remains unclear.

As the American mindset shifts toward disease prevention and reliance upon natural remedies, insurance companies will be pressured to reimburse expenditures on nontraditional products. Increasingly, advocates assert that disease prevention costs less than disease treatment. Extensive clinical trials and cost-benefit analysis are needed to validate or refute such arguments.

Technology versus naturalness

Growing demand for nutraceutical products may eventually lead to genetically altered crops and animal products that accentuate health-promoting components or remove undesired components (gluten-free wheat, for example). The emergence of the nutraceuticals phenomenon in the U.S., however, has been rooted in an interest in natural products and lifestyles. The development of genetically modified products would test the public's desire to achieve improved health *vis-à-vis* its commitment to naturalness and skepticism about genetically modified products.

The future of nutraceuticals

The nutraceutical industry is growing at a rate far exceeding expansion in the food and pharmaceutical industries. Nutraceuticals now blur the heretofore clear distinction between food and drugs. As the new millennium approaches, a number of pressing issues face the industry. Consumers hope that nutraceuticals will provide personal health, longevity, and quality of life benefits. However, the nascency of the industry makes its future difficult to clearly envision.

The emerging nutraceuticals industry seems destined to occupy the landscape in the new millennium. Its tremendous growth has implications for the food, pharmaceutical, healthcare, and agricultural industries. But what forces will shape the industry? Will continued growth be largely consumer-driven? What is the appropriate role of the government in industry regulation and development? Given the implications for public health and safety, as well as cost containment in the health care industry, public attention seems warranted. Nutraceuticals may well be one of the most important industries to watch in the new millennium. ■

■ For more information

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