

The Time Has Come for Nutraceutical Cereals

BY STEPHEN L. DEFELICE



The recently passed Dietary Supplement Health & Education Act (DSHEA), as part of the ongoing nutraceutical revolution, clearly signals that the time has come for the development and marketing of nutraceutical cereals. This is necessary for three primary reasons: to significantly expand the cereal market, to increase product profit margins, and to set up part of a defense against oncoming competitors.

A nutraceutical is any substance that is a food or part of a food that provides medical and/or health benefits, including the prevention and treatment of disease. Such products may range from isolated nutrients, dietary supplements, and diets to genetically engineered “designer” foods, herbal products, and processed foods such as cereals, soups, and beverages. I coined the term *nutraceutical* to give this vast new area a defined identity.

Historically in the United States, the health food industry has been a consumer business largely based on traditional home and other remedies. Then, in the early 1980s, the potential medical benefits of calcium, fiber, and fish oil rose to prominence, supported by university-based clinical data. This initiated the nutraceutical revolution. Because of the published clinical data, physicians joined in their broad belief that what we eat has medicinal value. This marked the entry of nutraceuticals into the mainstream of medical practice and scientific/medical research and gave rise to an increasingly urgent need to rationalize the scientific development, commercial availability, and communications of those products to a dual audience of physicians and consumers.

Today, various foods or parts of foods are being studied for such far-reaching benefits as slowing the aging process and curtailing the adverse effects of pollution. Single and multiple deficiencies of natural substances never before measured in routine tests, such as magnesium and carnitine, have been found to have direct bearing on the malfunction of specific organ systems. Such chronic, subacute, and acute deficiencies can sometimes be remedied by appropriate diets but in most cases usually require supplementation.

Meanwhile, a stream of clinical studies continues to define the actual or potential clinical benefits of a rapidly growing range of nutraceuticals on an expanding array of specific disease processes and altered health states. Examples include the use of niacin to reduce plasma lipids, folic acid to prevent neural tube defects, fish oil to treat a specific type of nephropathy, magnesium to reduce insulin resistance, and vitamin A to treat measles. The National Cancer Institute considered a program to develop “designer” foods with increased contents of phytochemicals for the prevention of cancer, and USDA developed a computer program on potential chemopreventive compounds in foods.

Clinical studies on the potential or actual benefits of food and

parts of food products for the prevention or the treatment of widespread illnesses are being published in medical journals and then publicized to physicians and consumers. In effect, the product managers in the U.S. nutraceutical industry are the researchers who have conducted and published clinical studies and presented the results in an open forum. The marketing and sales force are the media that publicize it. And the customers are the physicians and consumers.

Before the DSHEA, corporations were not eager to conduct the necessary research to demonstrate the clinical utility of nutraceuticals because they were virtually prohibited by law to make such claims. The much-heralded Nutrition Labeling and Education Act (NLEA) further discouraged corporate research because although it provided rules for making claims, the right to each specific claim could not be proprietary. The following hypothetical scenario will help explain. If the First American Cereal Nutraceutical Corporation developed and performed the clinical research for a long-overdue cereal effective against colds and influenza, FDA could grant this corporation the right to make a cold or influenza claim under NLEA, but that right would also be available to other cereal corporations—ones that have not invested research dollars. Is there a more effective way to discourage research?

The DSHEA has changed all of this. Corporations now have the right to make such claims as regarding structure, function, deficiencies, and well-being without prior FDA approval. This presents an enormous opportunity to develop proprietary products and market such products with cautiously worded but effective and truthful claims. It is anticipated that amendments to the DSHEA will broaden the ground rules for claiming.

What is clear, however, is that the DSHEA as presently written serves in itself as a sufficient foundation for a dynamic nutraceutical cereal industry. The industry must now concentrate on producing specific patented or proprietary cereals and performing the necessary clinical research to demonstrate their medical and/or health benefits. If the cereal industry does not act quickly, it will lose an enormous market opportunity to other factions of the food industry.

The nutraceutical market currently contains two primary types of products: potential nutraceuticals and established nutraceuticals. A potential nutraceutical is one that holds promise of a health and/or medical benefit. It becomes an established nutraceutical only after sufficient clinical data demonstrate such a benefit. Thus, folic acid was a potential nutraceutical until the sufficient clinical evidence for the reduction of neural tube defects was generated to make it an established one. Ginseng remains a potential nutraceutical because of a lack of such evidence. It is important to note that the overwhelming majority of nutraceutical products, including cereals, are in the potential category and are waiting to become established.

The U.S. nutraceutical market size far exceeds the figures commonly quoted, which are almost all less than \$10 billion annually. The gross distortion of the true nutraceutical market is due principally to incorrect (and often unstated) definitions of a nutraceutical. If one would use the true definition of a nutraceutical, the potential market size leaps to levels of another dimension.

The total U.S. retail food market in 1992 was \$503 billion. The combined pharmaceutical (approximately \$70 billion) and over-

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the-counter (\$24 billion) 1992 retail markets, which total \$94 billion, are only a small portion. It is not unreasonable to estimate that 50% of the foods in the market are used—ustifiably or not—for medical and/or health benefits. They include dietary supplements, sugar substitutes, fat substitutes, fiber-enriched foods, vegetables, and reduced-fat and -calorie foods.

Using these numbers, we arrive at a \$250 billion potential nutraceutical market, which is approximately 2.5 times the combined pharmaceutical and over-the-counter markets! It is not unreasonable to assume that the potential nutraceutical market of the EEC is at least equal to that in the United States. This adds up to a combined market of \$500 billion. Couple this with the fact that 100 million Americans take dietary supplements daily, it then becomes evident that an enormous foundation for an established nutraceutical market exists.

Recently, the Foundation for Innovation in Medicine held a day-long conference, “Nutraceutical Research, Development & Marketing: Time to Move Forward?” in which legal, marketing, and medical experts explored the opportunities and pitfalls facing any company considering the introduction of a nutraceutical product in the United States. The conference took the form of a board meeting of a hypothetical company called the American Nutraceutical Corporation. The company's directors debated whether to undertake the costly launch of a nutraceutical product,

a specific proprietary mixture of soy protein and vegetable extracts, to be used as a preventive or therapeutic treatment for breast cancer. Ingredients of the proposed product were foods that contained demonstrated preclinical cancer-preventive or cancer-ameliorative effects and no known toxicity. Participants considered whether they should formulate the product as a pill or as a cookie, and how they should market it, in either case. The audience was the shareholders of the corporation. After lengthy discussion and debate regarding whether to proceed with the development and marketing of this nutraceutical, the board and the shareholders were polled by a go/no go vote. Five times as many board members and twice as many shareholders favored proceeding with the breast cancer nutraceutical over not proceeding, and three times as many shareholders voted in favor of undertaking additional nutraceutical projects as voted against. These final votes by the board and shareholders of the American Nutraceutical Corporation indicate that the nutraceutical revolution has arrived. (A videotape of the conference is available from F-D-C Reports, 301/657-9830; Fax 301/986-6443.)

In conclusion, it is not a matter of “if” established cereal nutraceuticals will play a major role in the U.S. health arena but when. As we enter this new era in health and medicine, those cereal corporations with vision and flexibility can become major players in the nutraceutical revolution.