



NUTRACEUTICALS: IMPORTANCE AND ADVANCES IN MEDICINE AND HEALTH

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ABSTRACT

Nutraceutical is a term coined to describe substances which are not traditionally recognized nutrients but which have positive physiological effects on the human body. They do not easily fall into the legal category of food and drug and often inhabit a grey area between the two. Risk of toxicity or adverse effect of drugs led us to consider safer nutraceutical and functional food based approaches for the health management. This resulted in a world wide nutraceutical revolution. The nutraceutical revolution will lead us into a new era of medicine and health, in which the food industry will become a research, oriented one similar to the pharmaceutical industry.

KEY WORDS: Nutraceutical, Medicine, Health

INTRODUCTION

Consumers are deeply concerned about how their health care is managed, administered and priced. They are frustrated with the expensive, high-tech, disease-treatment approach predominant in modern medicine; the consumer is seeking complementary or alternative beneficial products and the red tape of managed care makes nutraceuticals particularly appealing. Nutraceuticals (often referred to as phytochemicals or functional foods) are natural bioactive, chemical compounds that have health promoting, disease preventing or medicinal properties. Nutraceuticals are found in a mosaic of products emerging from (a) the food industry, (b) the herbal and dietary supplement market, (c) pharmaceutical industry, and (d) the newly merged pharmaceutical/ agribusiness/ nutrition conglomerates. It was defined as 'a food or part of food that provides medical or health benefits, including the prevention and treatment of disease'¹. Nutraceuticals may range from isolated nutrients, herbal products, dietary supplements and diets to genetically engineered "designer" foods and processed products such as cereals, soups and beverages. Doubtlessly, many of these products possess pertinent physiological functions and valuable biological activities². With the passage of the Dietary Supplement Health and Education Act of 1994, the definition of nutraceuticals has been expanded to include vitamins, minerals, herbs and other botanicals, amino acids and any dietary substance for use by humans to supplement the diet by increasing total dietary intake and subsequently increased the use of nutraceuticals dramatically^{3,4}. However, functional food concept is different from nutraceuticals and can be defined as food products to be taken as part of the usual diet in order to have beneficial effects that go beyond what are known as traditional nutritional effects⁵. The goal of achieving an optimal or maximal state of nutrition and health is becoming an increasing challenge with the introduction of many nutraceuticals⁶. The ascribed health benefits of nutraceuticals are legion. Various products are claimed not only to reduce the risk of cancer and heart disease but also to prevent or treat hypertension, high cholesterol, excessive weight, osteoporosis, diabetes, arthritis, macular degeneration (leading to irreversible blindness), cataracts, menopausal symptoms, insomnia, diminished memory and concentration,

digestive upsets and constipation and not to mention headaches⁴. Nutraceuticals are marketed in concentrated forms as pills, capsules, powders and tinctures either as a single substance or as combination preparations⁷.

CONCEPTS OF NUTRACEUTICALS⁸

In the pharmaceutical development process, it is a requirement to have clinical test results from animal tests and studies, for verification of the effects. On the other hand, in the case of nutrition, there was no verification method for foods in preventing diseases in the past. In recent years however, as food composition has been scientifically proven to cause lifestyle-related diseases, and has become a social issue as figure 1.

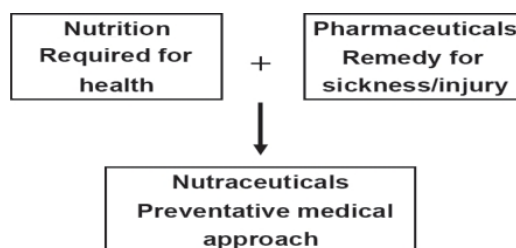


Figure 1: Concept of Nutraceuticals

Hippocrates highlighted around 2000year ago "Let food be your medicine and medicine be your food"⁹. Nutraceuticals are foods or food ingredients that provide medical or health benefits. This emerging class of products blurs the line between food and drugs¹⁰. They do not easily fall into the legal categories of food or drug and often inhabit a grey area between the two¹¹. Within European Union (EU) law the legal categorization of a nutraceutical is, in general, made on the basis of its accepted effects on the body. Thus, if the substance contributes only to the maintenance of healthy tissues and organs it may be considered to be a food ingredient. If, however, it can be shown to have a modifying effect on one or more of the body's physiological processes, it is likely to be considered to be a medicinal substance¹². Within European Medicines law a nutraceutical can be defined as a medicine for two reasons:

- 1) It can be used for the prevention, treatment or cure of a condition or disease or
- 2) It can be administered with a view to restoring, correcting or modifying physiological functions in human beings.¹³

CATEGORIES OF NUTRACEUTICALS¹⁴

Nutraceuticals are non-specific biological therapies used to promote wellness, prevent malignant processes and control symptoms. These can be grouped into the following three broad categories:

1. substances with established nutritional functions, such as vitamins, minerals, amino acids and fatty acids – Nutrients
2. herbs or botanical products as concentrates and extracts - Herbals
3. reagents derived from other sources (e.g. pyruvate, chondroitin sulphate, steroid hormone precursors) serving specific functions, such as sports nutrition, weight-loss supplements and meal replacements – Dietary supplements.

IMPORTANCE OF NUTRACEUTICAL

Malnutrition is a leading cause of disease in both emerging and developed economies.¹⁵ While the spectrum of health problems resulting from calorie-protein undernutrition is different from the “empty-calorie” overfeeding, both can have devastating consequences on both quality of life and longevity (Table 1).

Table 1. Some health consequences of malnutrition: Protein-calorie under nutrition and obesity

Emerging economies	Developed economies
Decrease in Muscle mass, cardiac and renal mass cell-mediated immunity, Fertility. Numerous skin changes, Normocytic, normochromic anemia, Fatigue, listlessness, cell-mediated immunity Pneumonia, opportunistic infections, Impaired wound healing Fertility	Protein-Calorie Under nutrition Obesity Metabolic syndrome with increase risk of CVD, CHF, PVD, ESRD, gall bladder disease, cancer risk especially, endometrial, breast, prostate and colon. Osteoarthritis, gout, Polycystic ovaries, infertility Sleep apnea, Fatigue

CVD = cardiovascular disease, CHF = congestive heart failure, PVD = peripheral vascular disease, ESRD = end-stage renal disease

Nutritional needs have changed as we have evolved from a pre-agricultural, hunter-gatherer milieu to a highly technological agricultural industry dependent on mechanical processing for our food supply.^{1,2} Movement from the Paleolithic diet with low sodium, high potassium, high fiber, low fat, lean animal protein, low refined carbohydrate, and low cholesterol intake composed of fruits, vegetables, berries, nuts, fiber, fish, fowl, and wild game to our modern diet has resulted in an epidemic of nutritionally-related diseases. These diseases include hypertension, atherosclerosis and target organ diseases (TOD) such as coronary heart disease (CHD), congestive heart failure (CHF), cerebrovascular accidents (CVA), myocardial infarction (MI), renal insufficiency (RI), and renal failure (RF).¹⁶

NUTRACEUTICALS REVOLUTION¹⁷

The nutraceuticals revolution began in the early 1980s, sparked off when the actual or potential clinical benefits of calcium, fiber and fish oil were supported by clinical studies published in distinguished medical journals, and when physicians began to educate their colleagues and consumers about these substances via the mass media.

FACTORS EFFECTING REVOLUTION^{18,19}

Physician - Increased physician acceptance of the medical benefits of nutritional products increased market demand of nutraceuticals.

Media- The mass media have emerged as the primary sources of medical claims, mass media has now become the powerful and legitimate promotion agency of nutraceutical products.

RESEARCH AND DEVELOPMENT

The greatest scientific need in nutraceuticals pertains to standardization of compounds and/or products, to carefully develop and execute clinical studies/trials to provide the basis for health claims for nutraceuticals that impact consumers as well as companies making strategic investments.²⁰ Powerful market forces are fueling the interest in nutraceuticals:²¹

- Rapid advances in scientific knowledge supporting the vital role of diet in health and disease prevention.
- Skyrocketing health care costs.
- An aging population.
- Technical advances in the food industry that are allowing the development of health promoting
- foods that can be marketed to health-conscious consumers at a premium.
- The changing regulatory environment.

ROLE OF R AND D IN NUTRACEUTICAL²¹

- To test safety, purity and potency of products.
- To develop more effective and efficient means of producing ingredients for use in products.
- To develop testing methods for ensuring and verifying the consistency of the dosage of
- ingredients included in the company's products.
- Develop the new products either by combining existing ingredients used in nutritional
- supplements or identifying new ingredients that can be used in nutritional supplements.

NUTRACEUTICAL SCENARIO IN INDIA

The Indian nutraceutical industry has great prospects. Over the last decade a wide range of products have been available, giving an insight into the tremendous growth. On one hand a booming economy has resulted in overall increase in disposable income of population. Added to this unhealthy, eating habits coupled with sedentary lifestyle have led to increase incidence of diet and its related health issues. On the other hand, there is a growing awareness on the importance of nutrition and diet for long term good health. These have contributed to a favorable market conditions for Nutraceutical industry in India. India has a lot of advantages like qualified human resources, world class R & D facilities and varied raw material-aspects that give our country a leading edge. The Indian Nutritional market is estimated to be USD 1 Billion. While the global market is growing at a CAGR of 7%, the Indian market has been growing much faster at a CAGR of 18% for the last three years, driven by Functional food and beverages categories. However the latent market in India is two to four times the current market size and is between USD 2 to USD 4 billion with almost 148 million potential customers. In USD 1 billion market size functional food having 54% market share followed by 32% market share of Dietary supplement and 14% share of Functional beverages. The Indian nutraceutical market is dominated primarily by pharmaceuticals and FMCG companies with very few pure play nutraceutical companies. Some major companies Marketing Nutraceuticals in India are GlaxoSmithKline

consumer healthcare, Dabur India, Cadila Health care, EID Parry's, Zandu Pharmaceuticals, Himalaya herbal Healthcare, Amway, Sami labs, Elder harmaceuticals and Ranbaxy.²²

Regulatory aspects

In USA, watershed legislation was passed in 1994 to regulate the manufacture and marketing of Nutraceutical. This law, known as the Dietary Supplement Health and Education Act, reversed 45 years of increasing FDA regulation of health related products. The FDA may establish good manufacturing practices for Nutraceutical as long as these regulations are molded after the less stringent regulations for foods as opposed to those for drugs. A draft law reminiscent of the Dietary Supplement Health and Education Act is in development in India to regulate manufacturing, importing and marketing of health foods/dietary supplements and other nutraceuticals. Also the country's central drug control department has put some structures in place for dietary supplements, but it is taking a long time for states to cooperate and some states have rejected the structures when their own rules and regulations conflict. Also a new independent association has been formed in India to address some of these issues. The Indian Health and Dietary Supplement Association was created to represent pharmaceutical, nutraceutical, herbal, direct selling and other service oriented industry companies and plans to affiliate with the International Alliance of Dietary Supplement Associations in the near future. The association is planning a scientific conference to bring the industry and government together to share information, experience and perspectives on the use and regulation of dietary supplements.²³

CONCLUSION

The nutraceutical industry is growing at a rate far exceeding expansion in the food and pharmaceutical industries. In tomorrow's market, the most successful nutraceutical players are likely to be those companies in which functional product are just a part of a broad line of goods satisfying both conventional and health value point. Future demand of nutraceutical depends on consumer perception of the relationship between diet and disease.

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