

Nutraceuticals: new era of medicine and health

Manisha Pandey *, Rohit K Verma, Shubhini A Saraf

Department of Pharmaceutics, Babu Banarasi Das National Institute of Technology and Management, Lucknow, Uttar Pradesh – 227105, India.

Address for correspondence: Manisha Pandey, Department of Pharmaceutics, Babu Banarasi Das National Institute of Technology and Management, Lucknow, Uttar Pradesh – 227105, India. E-mail: manisha_2929@yahoo.co.in

The concept of nutraceutical was started from the survey in U.K., Germany and France which concluded that diet is rated more highly by consumers than exercise or hereditary factors for achieving good health. 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.

Keywords: Nutraceuticals, Medicine, Functional foods.

INTRODUCTION

The quality of life in terms of income, spending and lifestyle has improved with economic development. However, it has also thrown up a major challenge in the form of 'lifestyle diseases'. The first victim of this lifestyle change has been food habits. Consumption of junk food has increased manifold, which has led to a number of diseases related to nutritional deficiencies. Nutraceuticals can play an important role in controlling them. No wonder more and more people are turning to nutraceuticals.

The term nutraceutical was coined from nutrition and pharmaceutical (Figure 1) in 1989 by Stephen Defelice, founder and chairman of foundation for innovation in medicine, an American organization which encourages medical health [1, 2, 3, 4]. According to him "a nutraceutical is any substance that is a food or a part of food and provides medical or health benefits, including the prevention and treatment of disease". Such products may range from isolated nutrients, dietary supplements and specific diets to genetically engineered designer foods and herbal products [1, 5]. The concept of nutraceutical was started from the survey in U.K., Germany and France and it concluded that diet is rated more highly by consumer than exercise or hereditary factors to achieving a good health. In the U.S. "nutraceutical"

was commonly used, but no regulatory definition existed. Its meaning was modified by health ministry of Canada which defines nutraceutical as "a product isolated or purified from the food, generally sold in medicinal form not associated with food and demonstrated to have a physiological benefit. It also provides benefit against chronic disease" [7].

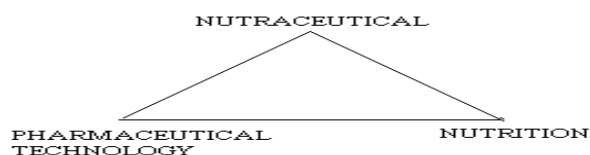


Figure 1. Nutraceutical was coined from nutrition and pharmaceutical

In Britain, the Ministry of Agriculture, Fisheries and Food has developed a definition of a functional food as "a food that has a component incorporated into it to give it a specific medical or physiological benefit, other than purely nutritional benefit" [8].

There is a slight difference between the functional foods and nutraceuticals. When food is being cooked or prepared using "scientific intelligence" with or without knowledge of how or why it is being used, the food is called "functional food". Thus, functional food provides

the body with the required amount of vitamins, fats, proteins, carbohydrates, etc. needed for its healthy survival. When functional food aids in the prevention and/or treatment of disease(s) and/or disorder(s) other than anemia, it is called a nutraceutical. Examples of nutraceuticals include fortified dairy products (e.g. milk) and citrus fruits (e.g. orange juice)^[9].

The DSHEA formally defined "dietary supplement" using several criteria. A dietary supplement:^[10]

- is a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients- a vitamin, a mineral, a herb or other botanicals, amino acids or a dietary substance for use by man to supplement the diet by increasing the total daily intake or a concentrate, metabolite, constituent, extract, or combinations of these ingredients.
- is intended for ingestion in pill, capsule, tablet or liquid form.
- is not represented for use as a conventional food or as the sole item of a meal or diet.
- is labeled as a "dietary supplement".

Benefits

From the consumers' point of view, functional foods and nutraceuticals may offer many benefits:

- May increase the health value of our diet.
- May help us live longer.
- May help us to avoid particular medical conditions.
- May have a psychological benefit from doing something for oneself.
- May be perceived to be more "natural" than traditional medicine and less likely to produce unpleasant side-effects.
- May present food for populations with special needs (e.g. nutrient-dense foods for the elderly)^[11].

Bridging the gap between food and medicine

Hippocrates highlighted around 2000year ago "Let food be your medicine and medicine be your food"^[5]. Nutraceuticals are foods or food ingredients that provide medical or health benefits. This emerging class of products blurs the line between food and drugs^[12]. They do not easily fall into the legal categories of food or drug and often inhabit a grey

area between the two^[13].

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 substance (Figure 2)^[14]. Within European Medicines law a nutraceutical can be defined as a medicine for two reasons:

- 1) It can 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^[15].

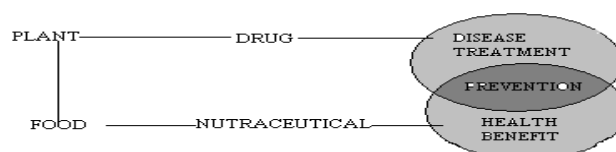


Figure 2. Nutraceutical inhabit a grey area between the food and drug

CLASSIFICATION OF NUTRACEUTICALS

Regarding the promise of nutraceuticals, they should be considered in two ways:

- Potential nutraceuticals
- Established nutraceuticals

A potential nutraceutical is one that holds a promise of a particular health or medical benefit; such a potential nutraceutical only becomes an established one after there are sufficient clinical data to demonstrate such a benefit. It is disappointing to note that the overwhelming majority of nutraceutical products are in the 'potential' category, waiting to become established^[1]. The food products used as nutraceutical are categorized as^[16].

- Probiotic

- Prebiotic
- Dietary fiber
- Omega 3 fatty acid
- Antioxidant

AREA COVERED BY NUTRACEUTICAL PRODUCTS

All therapeutic areas such as anti-arthritic, pain killers, cold and cough, sleeping disorders, digestion and prevention of certain cancers, osteoporosis, blood pressure, cholesterol, depression and diabetes have been covered by nutraceuticals (Figure 3) ^[17].

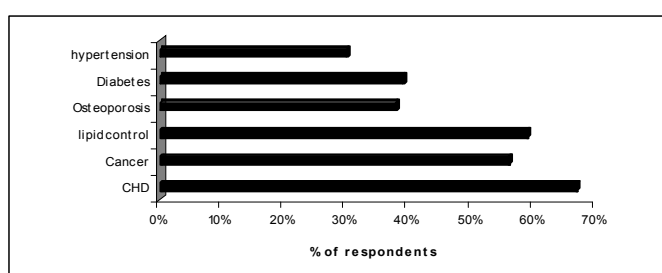


Figure 3. Percentage area covered by nutraceutical products

NUTRACEUTICALS REVOLUTION

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 ^[1].

Factors effecting Revolution

- 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 ^[18, 19].

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 nutraceutical ^[21]

- 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.

MARKET TRENDS OF NUTRACEUTICALS

The nutraceutical industry's three main segments include functional foods, dietary supplements, and herbal/natural products ^[5]. 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) ^[22]. According to BCC Research - The global nutraceuticals market grew to \$46.7 billion in 2002,

at an AAGR of nearly 7%. In 2007 nutraceuticals sale is projected to reach \$74.7 billion at an AAGR of 9.9%. This assumes a world economic recovery in 2003 and an end to price competition (Figure 4)^[23].

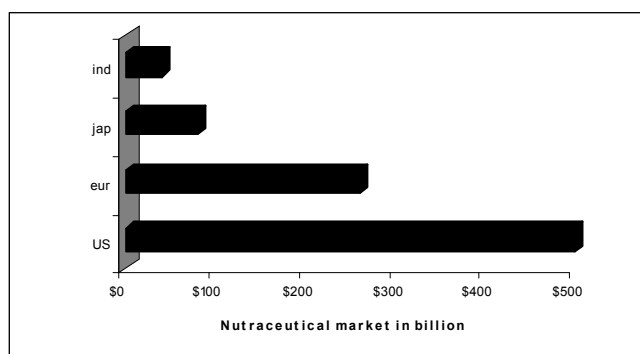


Figure 4. Nutraceutical market in different countries

THE FUTURE OF NUTRACEUTICALS

Increasing awareness levels about fitness and health, spurred by media coverage are prompting the majority of people to lead healthier lifestyles, exercise more, and eat healthy. The expanding nutraceutical market indicates that end users are seeking minimally processed food with extra nutritional benefits and organoleptic value. This development, in turn, is propelling expansion in the nutraceutical markets globally. 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

Many scientists believe that enzymes represent another exciting frontier in nutraceuticals. "Enzymes have been underemployed... they're going to be a hot area in the future." Fermentation technology using microbes to create new food products also represents potential.

Global trends to healthy products cannot be reversed. Companies taking the lead by investing strategically in science, product development, marketing and consumer education will not go unrewarded.

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.

Although nutraceuticals have significant promise in the promotion of human health and disease prevention, health professional, nutritionists and regulatory toxicologist should strategically work together to plan appropriate regulation to provide the ultimate health and therapeutic benefit to mankind. Long-term clinical studies are required to scientifically validate the nutraceuticals in various medical conditions. The interaction of nutraceuticals with food and drugs is another area, which should be taken into consideration. The effect of different processing methods on the biological availability and effectiveness of nutraceuticals remains to be determined. As like drugs, there should be strict regulatory controls for nutraceuticals.

REFERENCES

1. De Felice L Stephen. The nutraceutical revolution, its impact on food industry. *Trends in Food Sci. and Tech* 1995; 6:59-61.
2. Jack DB. Keep taking the tomatoes - the exciting world of nutraceuticals. *Mol Med Today* 1995; 1(3):118-21.
3. Brower B. Nutraceuticals: poised for a healthy slice of the market. *Nat Biotechnology* 1998; 16: 728-33.
4. Mannion M. Nutraceutical revolution continues at foundation for innovation in medicine conference. *Am J Nat Med* 1998; 5:30-3.
5. Rishi RK. Nutraceutical: borderline between food and drug. *Pharma Review* 2006, Available from: <http://www.kppub.com/articles/herbal-safety-pharma-review-004/nutraceuticals-borderline-between-food-and-drugs.html>. Accessed on date Feb 12, 2009.
6. Gil Hardy. Nutraceuticals and functional foods: introduction and meaning. *Nutr.* 2000; 16: 718-719.
7. Bull Esther. What is nutraceutical? *Pharm. J.* 2000; 265:57-58.
8. Cockbill CA. Food law and functional foods. *Br Food J* 1994; 96:3-4.
9. Kalra EK. Nutraceutical-definition and introduction. *AAPS PharmSci.* 2003; 5:2-3.
10. FDA/CFSAN resources page. Food and Drug Administration website. Dietary Supplement Health and Education Act of 1994. Available from: <http://vm.cfsan.fda.gov/~dms/dietsupp.html>.
11. Consumer Association of Canada. Available from: <http://www.consumermanitoba.ca/resources.html>. Accessed on date March 8, 2009

12. Adelaja Adesoji O, Schilling Brian J. Nutraceutical: blurring the line between food and drugs in the twenty-first century. *The Magazine of Food, Farm and Resource Issues* 1999; 14: 35-40.
13. Om P Gulati, Peter Berry Ottaway. Legislation relating to nutraceuticals in the European Union with a particular focus on botanical-sourced products. *Toxicol.* 2006; 221:75-87.
14. Richardson DP. Functional foods—shades of grey: an industry perspective. *Nutr. Rev.* 1996; 54: 174-180.
15. Dietary Supplement Health Education Act (DSHEA) of 1994. Public Law 103-417, available from FDA website: <http://www.fda.gov>.
16. Kokate CK, Purohit AP, Gokhale SB. Nutraceutical and Cosmeceutical. *Pharmacognosy*, 21st edition, Pune, India: Nirali Prakashan, 2002; p 542-549.
17. Sami Labs — pioneer in nutraceuticals. *The Hindu Newspaper*; Aug 05, 2002, Available from: <http://www.hinduonnet.com/thehindu/biz/2002/08/05/stories/2002080500040200.htm>.
18. Nutraceutical reality on the horizon-cover story. *Food Product Design*. Available from: <http://www.pharmabiz.com/article/detnews.asp?articleid=22127§ionid=46>
19. De Felice L Stephen. The nutraceutical evolution: fueling a powerful, new international market. *The Foundation for Innovation in Medicine*. Available from: <http://www.fimdefelice.org/archives/arc.fueling.html>.
20. The Nutraceutical Institute. Available from: <http://foodsci.rutgers.edu/nci>.
21. De Busk Ruth. Functional Food. *Vegitarian Nutrition*. Available from: <http://www.andrews.edu/NUFS/functionalfoods.html>.
22. *Nutrition Business Journal*, 1:2, September 1996.
23. GA-085R. Evolving nutraceutical, Available from: <http://www.bccresearch.com/food/GA085R.html>.