NUTRACEUTICALS: AN AREA OF TREMENDOUS SCOPE
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ABSTRACT
Dr Stephen DeFelice coined the term "Nutraceutical" from "Nutrition" and "Pharmaceutical" in 1989. The term nutraceutical is being commonly used in marketing but has no proper definition. An attempt to redefine nutraceuticals and functional foods is made in this article. The proposed definitions can help distinguish between functional foods, nutraceuticals, and dietary supplements. The advantages and disadvantages of nutraceuticals along with the classification, emergence of nutraceuticals, nutraceutical development and future of the nutraceuticals are discussed.

KEY WORDS : Nutraceuticals, Dietary supplements, functional foods, medical food, farmaceutical

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INTRODUCTION
The term nutraceutical was coined from “nutrition” and “pharmaceutical” in 1989 by Stephen DeFelice , founder and chairman of foundation for innovation in medicine , Cranford, an American organization which encourages medical health.1-4

According to DeFelice, nutraceutical is any substance that is a food or a part of food that 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 food and herbal products.1,5

The concept of nutraceutical was started from the survey in U.K, Germany and France. However, the term nutraceutical as commonly used in marketing has no regulatory definition.

Health ministry of Canada which defines nutraceuticals 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 and provide protection against chronic disease.”6

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, carbohydrates, etc. for healthy survival.

When functional food aid in the prevention and/or treatment of disease(s) and/or disorder(s) other than anemia, it is called a nutraceutical. Eg; fortified dairy products( eg. Milk), and citrus fruits(eg. Orange juice).7

NUTRACEUTICAL STATUS
The Indians, Egyptians, Chinese and Sumerians are just a few civilization that have provided evidence suggesting the food can be effectively used as medicine Fig:1 to treat and prevent diseases. Hippocrates, highlighted around 2000 years, ago “let food be thy medicine”.5

Nutraceuticals are food or food ingredients that provides medical or health benefits. The emerging class of products blurs the line between food and medicine Fig:2

CLASSIFICATION OF NUTRACEUTICALS
Nutraceutical is a broad umbrella term. There is minimal separation over which products are allowed to display the nutraceutical term on their labels. Because of this, the term is often used to market products with varying uses and effectiveness.

The definition of nutraceuticals and related products often depend on the source established in order to distinguish between the wide varieties of products out there.7 There are multiple different types of products that fall under the category of nutraceuticals.
(1). Dietary supplements
(2). Functional foods
(3). Medicinal food
(4). Farmaceuticals.

**DIETARY SUPPLEMENTS**

A dietary supplement is a product that contains nutrients derived from food products that are concentrated in liquid, capsule, pills and tablet form. The dietary supplement health and education act (DSHE) of 1994 defined generally what constitutes a dietary supplement. “A dietary supplement 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 the use by man to supplement the diet by increasing the total dietary intake or a concentrate; metabolite, constituent extract, or combinations of these ingredients.

It is not represented for use as a conventional food or as the role item of a meal or diet and is labeled as a “dietary supplement”.

**FUNCTIONAL FOOD**

Functional food have been either enriched or fortified, a process called nutrification. This practice restores the nutrient content in a food back to similar levels from before the food was processed. Sometimes, additional complementary nutrients are added, such as vitamin D to milk.

Health Canada defines functional food as “ordinary food that has components or ingredients added to give it a specific medical or physiological benefit, other than a purely nutritional effect.”

In Japan, all functional foods must meet three established requirements: food should

- Prevent in their naturally occurring form, rather than a capsule, tablet, or powder.
- Consumed in the diet as often as daily and
- Should regulate a biological process in hopes of preventing or controlling diseases.

**MEDICAL FOOD**

The FDA considers medical foods to be “formulated to be consumed or administered internally under the supervision of a physician, and which is intended for the specific dietary management of a disease or conditions for which distinctive nutritional requirements, on the basis of recognized scientific principle, are established by the medical evaluation.”

Nutraceuticals and supplements do not meet these requirements and are not classified as medical food. Medical food can be ingested through the mouth or for people diagnosed with specific illness. Medical foods are regulated by the FDA and will be prescribed or monitored by medical supervision.

**FARMACEUTICALS**

According to a report written for the United States Congress entitled "Agriculture: A Glossary of Terms, Programs, and Laws", (Farmaceuticals) is a melding of the words farm and pharmaceuticals. It refers to medically valuable compounds produced from modified agricultural crops or animals (usually through biotechnology). Proponents believe that using crops and possibly even animals as pharmaceutical factories could be much more cost effective than conventional methods (i.e., in enclosed manufacturing facilities) and also provide agricultural producers with higher earnings.

“At issue in the United States has been whether the current system for regulating biotechnology is adequate for ensuring the safety (to humans, animals and crops, and the environment) of newly emerging applications, such as farmaceuticals... The term farmaceuticals is more frequently associated, in agricultural circles, with medical applications of genetically engineered crops or animals.”

**NUTRACEUTICAL MARKET**

Indian nutraceutical market is estimated to be USD one 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 two to USD four billion with almost 148 million potential customers, states the FICCI- Ernst and Young study titled ‘nutraceuticals-Critical supplement for building a healthy India’ released at the FICCI and Health Foods and Dietary Supplements Association conference. Of the global nutraceuticals market of USD 117 billion, India has less than one % share. Globally, this market is expected to reach USD 177 billion in 2013, growing at a CAGR of seven % driven by the fast growing dietary supplements category.

Sushil Jiwarajka, chairman FICCI’S Western Regional Council said, “There are 0.18 million food processing units and seven millions retail outlets. However, the country has only 2000 food safety officers and 250 food sample testing laboratories, which is not at all sufficient. In fact, it is well below international norms. India therefore needs to take immediate action to increase the number of testing laboratories and food safety officers so that the country is well prepared to enforce the regulations after these are established in the near future. The need of the hour is to develop clinical documentation and scientific basis to support claims of...
Indian nutraceuticals market in 2008, is estimated at USD 1.0 billion. Of this the functional foods market is the largest with 54% market share followed closely by the dietary supplements market which has a 32% market share. The functional beverages market in India is revealately nascent at 24%. The functional food and beverages categories consisting of nutrition fortified foods, sports and energy drinks, fortified juices and probiotic foods are growing faster, driven by wider distribution across FMCG channels as well as aggressive mass marketing.

The Indian market nutraceutical market is dominated primarily by pharmaceuticals and FMCG companies with very few pure play nutraceutical companies. Pharmaceutical and FMCG players’ active in the nutraceutical space have diversified by introducing product extensions and developing variants under existing brand names. Many new players have announced aggressive investment plans.13

**AREA COVERED BY NUTRACEUTICAL PRODUCTS**

All therapeutic areas such as anti-arhritic, pain killers and cough, sleeping disorders, digestion and prevention of certain cancers, osteoporosis, blood pressure, cholesterol, depression, diabetes and beauty care have been covered by nutraceuticals.14

**MILESTONES IN THE DEVELOPMENT OF NUTRACEUTICALS**

- The herb Kava has been formed to be useful in the anesthetic management of the preoperative patient, after recent investigation.15
- The consumption of Kava has potential CV consequences that could manifest in the pre – operative period. Kava may act through inhibition of Na and Ca channel to cause divert decrease in systemic vascular resistance and B.P kava has been reported to inhibit cycloxygenase to cause potential decrease in renal blood flow and to interfere with platelet aggregation also.15
- The neurologic effects of Kava are expressed in the form of anesthetic potency of BDZ and induction of anesthetic potency results in excessive preoperation sedation.
- The extracts off dried pomegranate peels have been reported to show the antioxidant capacity by the formation of phosphomolydbenum complex and antimutagenicity against the mutagenicity of sodium azide in salmonella typhimurium strains.16
- In recent investigation it has been reported that as little as 100g of cruciferous vegetables (cabbage, cauliflowers, sprouts etc) per day can play an important role in the prevention of colorectal cancer.17
- The cruciferous vegetables contain a lot of active ingredients such as incloles, isothiocyanates and sulforaphane. These anticancer components have been reported to prevent cancer by mechanisms such as inactivating carcinogens, activating the detoxification enzymes for inhibition of cancer and interfering in replication process of cells causing cancer.
- The green tea has been reported to show medicinal activity due to which, it has been placed in the category of nutraceuticals. The polyphenols present in green tea have been exhibited the property to reduce UV light induce oxidative stress and immunosuppression.18
- Cranberries have been separated to have antioxidant activity, according to Amy Howell, a researcher at Rutgers University. It is found to be effective against cancer, stroke, and viral infections. Researcher has found drinking cranberry juice can block urinary infection by binding to bacteria so that they adhere to cell wall.
- Proanthocamid, a good compound present in cranberries, prevents plaque formation on teeth. Regular cranberry juice consumption kills H. pylori bacteria, which is responsible for stomach cancer and ulcer.
- Studies have been conducted on nutraceuticals such as chondroitin sulphate and glucosamine to demonstrate their efficacy in the symptomatic treatment of Osteoarthritis(OA). Recent meta analysis reviewed clinical trials of glucosamine and chondroitin in the treatment of Osteoarthritis. Both showed substantial benefit in the treatment of OA.19
- Recent innovation, NEO Beauty from Wimm-Bill-Dann in the Russian market-a dairy with aloe vera, antioxidants, minerals and vitamins, Nestle SA in Mexico has also unveiled a new yogurt called Svelty Piel Diaay Noche. It contains CoQ10, which is reported to make skin softer.20
- Perfectil, a beauty supplement from Vitabiotics that supports the development of skin, hair and nails. It contains, among many other ingredients, grape seed extract, caeotenoids, vitamin D, biotin and manganese.20
- Nutraceuticals could prevent diabetics. The risk of diabetics can be reduced by a combination of weight loss, exercise, dietary changes and use of supplements containing extracts of certain foods reported to have a physiological benefit or provide protection from diseases. (Table:1)21
CAUSES OF RAPID EMERGENCE OF NUTRACEUTICALS

- Consumers dissatisfied with drug cost and conventional health care are turning to unproven and untested natural product for treatment and prevention.
- Chronic diseases with poor therapeutics alternatives.
- Desired for personalized medicines.
- Large proportion try to get rid of the effects of aging.
- New focus on preventing medicine.
- Public perception that “natural is good”.
- Use of nutraceuticals before long runs and routinely during a season of training may reduce the incidence of effusions, leading to less training days lost to swollen joints.\(^2\)
- Preparations that enhance meniscal healing, especially after surgical repair, are sure to developed as the meniscus is the main protector of the knee joint.\(^2\)
- More than 40% of American use alternative medical therapies,(Table:2) nutraceutical account for a significant population.

FUTURE DEVELOPMENTS OF NUTRACEUTICALS

Increasing awareness levels about fitness and health, spread by media coverage are promoting the majority of people to lead healthier lifestyles, exercise more, and eat healthy.

The expanding nutraceuticals market indicates that end users are seeking minimally processed food with extra nutritional benefits and organoleptic value. This development, in term, is propelling expansion in the nutraceutical market globally. The emerging nutraceuticals industry seems destined to occupy the landscape in the new millennium. Its tremendous growth has implications for the food, pharmaceutical, health care, and agricultural industries.\(^2\)

- Many scientists believe that enzymes represent another exciting frontier in nutraceuticals. “enzymes have been underemployed. They are going to be a hot area in the future”.
- Fermentation technology using microbes to create new food products also represent potential.
- Use of nutraceuticals in sports medicine application is appealing.
- Action sports Hub is the world’s premier action incubation for future champions and future industry leaders. Action Sports Hub (ASH) bring together two industries that are currently changing the next generation’s future in sports, Action Sports and Mixed Martial Arts (MMA).\(^2\)
- Carotenoids will certainly play a critical role in nutraceutical product development. There is an abundance of scientific information supporting the benefits of natural carotenoids versus disease states. Also, it appears that the two most powerful antioxidant natural carotenoids are lutein and lycopene.\(^2\)
- Lutein is a natural carotenoid that offers protection against age related macular degeneration (AMD), the leading cause of adult blindness in the western world. Unfortunately there is no care or medicine available, but science advises that six mg per day of lutein may help, protect against AMD. This condition can occur at 50-60 years. Thus making the aging Baby Boomers prime targets. Lutein has additional scientific support with regard to protective benefits against lung cancer, breast cancer and cervical cancer in women.\(^2\)
- Lycopene offers tremendous nutraceuticals opportunities.
- Tocotrienol is promising for nutraceuticals because of its health benefits, “suggest Eileen mourry, business manager for nutrition, Eastman Chemical, Kingsport,TN. “ Studies shows tocotrienols are powerful antioxidants. Preliminary results indicate that it may have an anti-cancer benefit as well”.\(^2\)
- Gerry McKiernan sees interest growing beta glucan. “we had a lot of inquiries about our natural fermentation- grade beta glucans. It is important for cholesterol reduction .in soluble form it targets colon cancer”\(^2\).
- In the field of sports medicine, athletes are always looking for an edge to avoid injury and when injured, to recuperate quickly. Natural treatment preparations appeal to athletes, and may now use nutraceuticals as an adjunct in the treatment regimens for aching joints.
- Future use of nutraceuticals in these areas is exciting and opens an opportunity for extensive study of efficacy. There is an enormous concern for health care cost and the impact of managed care. This result is an opportunity called nutraceuticals.

CONCLUSION

Nutraceutical industry is growing at a rate far exceeding expansion in the food and pharmaceutical industries. In tomorrows market, the most successful nutraceutical players are likely to bethose companies in which functional product are just a part of a broad line of good satisfying both conventional and health value point. Future demand of nutraceuticals depends on consumer perception of the relationship between diet and disease.
Nutraceuticals are presenting excellent opportunities for research scholars and industry people to exploit their usefulness. The use of nutraceuticals, as an attempt to accomplish desirable therapeutic outcomes with reduced side effects or compound with other therapeutic agent has met with great monetary success.

REFERENCES
table 1: Examples of functional foods/ nutraceuticals

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Functional Ingredients</th>
<th>source</th>
<th>Medicinal use</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Carotenoids:-Alpha- Carotenoids Beta-Carotenoids</td>
<td>Carrots, Fruits Vegetables</td>
<td>Neutralize free radicals may cause damage to cells</td>
</tr>
<tr>
<td>2</td>
<td>Lutein</td>
<td>Green vegetables</td>
<td>Reduce the risk of muscular degeneration</td>
</tr>
<tr>
<td>3</td>
<td>Lycopene</td>
<td>Tomato products (ketch up, sauces)</td>
<td>Reduce the risk of prostate cancer.</td>
</tr>
<tr>
<td>4</td>
<td>Dietary fibre Insoluble fibre</td>
<td>Wheat, bran</td>
<td>Reduce the risk of breast or colon cancer.</td>
</tr>
<tr>
<td>5</td>
<td>Beta glucan Soluble fibre</td>
<td>Oats, barley, psyllium</td>
<td>Reduce the risk of cardiovascular disease. Protect against heart disease and some cancers, lower LDL and total cholesterol.</td>
</tr>
<tr>
<td>6</td>
<td>Fatty acids:- Long chain omega-3 fatty acid DHA/EPA</td>
<td>Salmon and other fish oil</td>
<td>Reduce the risk of cardiovascular diseases, improve mental, visual functions.</td>
</tr>
<tr>
<td>7</td>
<td>Conjugated linoleic acid (CLA)</td>
<td>Cheese, meat products</td>
<td>Improve body composition, decrease risk of certain cancers.</td>
</tr>
<tr>
<td>8</td>
<td>Phenolics:- Anthocyanidines Catechins, Flavonones, Lignans</td>
<td>Fruits, Tea, Citrus, vegetables Flax, rye</td>
<td>Neutralize free radicals, reduce the risk of cancer of stomach and oesophagus. Prevention of cancer, renal failure</td>
</tr>
<tr>
<td>9</td>
<td>Tannins (proanthocyanidines)</td>
<td>Cranberries, cranberry products, cocoa, chocolate</td>
<td>Improve urinary tract , reduce risk of cardiovascular diseases.</td>
</tr>
<tr>
<td>10</td>
<td>Plant sterols:- Stanol ester</td>
<td>Corn, soy, wheat, wood oil</td>
<td>Lower blood cholesterol levels by inhibiting cholesterol absorption.</td>
</tr>
<tr>
<td>11</td>
<td>Prebiotics/ Probiotics:- Fructo-oligosaccharides</td>
<td>Jerusalem artichokes, shallots, onion powder</td>
<td>Improve quality of intestinal microflora,gastrointestinal health</td>
</tr>
<tr>
<td>12</td>
<td>lactobacillus</td>
<td>Yogurt, other dairy products</td>
<td>Menopause symptoms such as hot flashes. Protect against heart disease and some cancers, lowers LDL and total cholesterol.</td>
</tr>
</tbody>
</table>

Table 2: Dietary factors linked with disease

<table>
<thead>
<tr>
<th>Disease</th>
<th>Total or saturated fat</th>
<th>Antioxidant</th>
<th>Folic acid</th>
<th>calcium</th>
<th>Complex CHO' fibre</th>
<th>Omega-3-fatty acids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular system</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+</td>
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<tr>
<td>Cancer</td>
<td>-</td>
<td>+</td>
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<tr>
<td>Diabetes</td>
<td>-</td>
<td>+</td>
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<tr>
<td>Cataract</td>
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<td>+</td>
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<tr>
<td>Obesity</td>
<td>-</td>
<td>+</td>
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<td>+</td>
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<tr>
<td>Osteoporosis</td>
<td>-</td>
<td>+</td>
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<tr>
<td>Birth outcomes</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
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<td>+</td>
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<tr>
<td>Immune function</td>
<td>-</td>
<td>+</td>
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<td>+</td>
</tr>
</tbody>
</table>

(+) = positive impact on health outcomes
(-) = negative impact on health outcomes

Fig 1: Bridging the gap between food and medicine (drug)

Fig 2: Nutraceutical inhibit a grey area between the food and drug