



Nutraceuticals :The future of intelligent food and medicine

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ABSTRACT

The term 'nutraceuticals' was coined in the late 1980s to describe food products that have a medicinal benefit. This fast growing sector includes functional foods (such as vitamin enriched products), nutritional supplements, sport drinks, and medically formulated foods. Functional foods and nutraceuticals provide a chance to enhance the human health, reduce health care costs and support economic development in rural communities. The phrase "Let food be the drugs and medicine be the food," coined by Hippocrates over 2500 years ago is receiving tons of interest today as food scientists and consumers realize the various health benefits of certain foods. This review article focused on the definition and the challenges and opportunities, motivating the development and regulations of functional foods and nutraceuticals were discussed. This article also focused on some samples of the functional foods and nutraceuticals and their health benefits

Keywords: Definition, Nutraceutical product hot spots, Regulations, Health Benefits

INTRODUCTION

Background

Nutraceuticals is predicted to play a central role in preventative healthcare. The logic seems simple: an ageing population gives rise to lifestyle related diseases, whose impact can be lessened by making healthier choices earlier in life. This results in a sharper specialise in measures, like a healthpromoting diet, to stop people from ever getting ill. Healthcare research, both publicly and privately funded, will got to consider the implications: not just new 'superfoods', to require one example, but also ways to influence people to form better choices about their diet. The emphasis of the research may, that remind and incentivize people to form better dietary choices and promote exercise, these pill replacing could invigorate demand

for new nutraceutical products designed to promote wellness.

Competitive landscape

Convergence of drugs, food and technology is probably going to make a battleground during which food and pharma companies compete for dominance of the world. The global market for functional foods certainly presents a big opportunity: sales are predicted to reach US\$250 billion by 2020(1), roughly five times larger than in 1999(2). This is substantial when compared with the \$900 billion pharmaceuticals market (3), but it is small in relation to the \$5 trillion worldwide food industry (4). Food companies have strong expertise in largescale manufacturing and global logistics that reach mass markets of consumers, but their research expertise doesn't go as deep as that of the pharmaceuticals industry. Successful companies will need to hit the

bullseye in six main areas: technology, product strategy, compliance, marketing, supply chain management and company dealmaking.

Achieving success

Technology goes to play an important role in success. Companies who thrive are likely to be those that place bold bets and wait patiently for results. Product cycles are much longer in nutraceuticals than in food, and this should play to the strengths of pharma which is accustomed to long lead times. The potential gains, though, are going to be considerable: Future 'superfoods' could tackle the underlying causes of conditions like diabetes, obesity and disorder, by linking diet to health. Competitive advantage will be gained by those companies with a superior product strategy, juggling ingredients, technology and labelling to optimize the product portfolio in each country. The potential market for nutraceuticals may be large, but a global blockbuster product will require top class regulation compliance with a patchwork of regulations in each country plus tenacious marketing to navigate the vagaries of national tastes. As the industry expands, the most players need to assure a gentle supply of such ingredients as plant extracts, dairy products, whey proteins, and omega3 fish oils. Supply chains will gradually become vertically integrated to make sure stability. The nutraceuticals industry is probably going to ascertain food and pharma companies collaborating for an advantageous position. There will be many mergers, many divestments and tons of incubation of future winners. Dealmaking skills will be at a premium. Big pharma and big food companies are not known for being nimbly entrepreneurial, so they will have to do a number of things that go against their corporate cultures: be bold, supple and patient, all at the same time.

KEY NUTRACEUTICAL PRODUCT HOT SPOTS

Brain Health and Aging

Background: The WHO predicts that by 2020 over 65 million people will have dementia and that the prevalence of other neurodegenerative brain diseases, like Alzheimer's, is also increasing (5). The pressure to produce successful treatments is rising but has proved unsuccessful so far. Scientists are increasingly looking to food products to assist slow disease progression and treat symptoms.

Pipeline: There are a variety of products within the pipeline that plan to improve cognitive function. Enhancing brain glucose metabolism to delay cognitive decline has been the target of some products, like Accera. There is also an increasing number of products which claim to enhance normal brain function, such as Neurozan. As adults become

more conscious of cognitive disease there'll be a greater marketplace for preventative treatments. With large investments happening during this area, there'll be innovative products hitting the market within five years.

Gastrointestinal Health

Background: Gut health issues, from indigestion through to more serious conditions like celiac disease motivate consumers to look to over the counter symptom relief. It is estimated that over 100 million people globally are effected by 'gut health' problems and the prevalence is rising (6). Household products help to provide some symptom relief. They have a positive effect on the millions of organisms that live in the human intestine (known as gut flora)(7). Many consumers purchase some form of 'probiotic' product and the market is growing(8).

Pipeline: there's continued investment into 'free from' products. This is driven by the increasing number of people claiming to be intolerant to certain ingredients, for example gluten and lactose, although few people have a diagnosed intolerance(9). One example is Alpo's successful almond milk product offering

Cardio & Heart Health

Background: The impact of disorder (CVD) is critical. It is the number one cause of death globally (10). The risk of contracting CVD is related to lifestyle choices including a poor diet. There are three main opportunities for nutraceuticals in heart health. The first is to scale back cholesterol, the second is to scale back the circulation of freeradicals (which contribute to plaque formation in arteries), and therefore the third is Fibrinolytic activity (plaque break down). Any food and drink which will demonstrate progress in these areas will have wide reaching impacts on the disease.

Pipeline: There is already a suite of products that focus on cholesterol reduction, with most evidence supporting the role of Vitamin E and omega3 (11). CardioMax is an omega3 based nutraceutical produced by SevenSeas which claims to support a healthy heart. Preliminary research is being conducted to endorse products like Naticor, which use a mixture of 'natural enzymes' to assist promote fibrinolysis. Products which may demonstrate even alittle health benefit during this area will convince achieve success.

Endocrine Health & Diabetes

Background: The WHO estimate that 347 million people worldwide have diabetes(12). Sustained exposure to high blood glucose is linked to the consumption of high fat and high sugar content foods. Foods which release sugars slowly enable better glucose control which may reduce the impact

of diabetes for sufferers, and may also help to stop the onset of type 2 diabetes.

Pipeline: Recent success stories include European Food Standards Authority (EFSA) approved Benecarb; a coffee glycaemic index sugar substitute for diabetics. There are also a number of studies looking at food products that resensitize the body to insulin (13). One product developing traction may be a soluble fibre gum that has registered approval to say it can increase insulin sensitivity following successful trial results.

Food versus pharmaceuticals

Food companies have a greater understanding than pharmaceuticals of nutrition and food formulation, plus decades of marketing research and relationships with massmarket distributors. Food companies who do well in nutraceuticals include people who have created separate health divisions, acquired successful brands, and launched global health improvement plans. However, despite a commitment to innovation, food businesses lack a number of the in-depth scientific resources that are needed to return up with major breakthroughs. Innovation in food tends to involve modest improvements such as reduced sugar, salt or fat levels, or novel tasting products. As a result, food companies may struggle to realize the type of gamechanging breakthroughs necessary to open up new nutraceutical markets. Furthermore, shareholders might be impatient over the longer development times related to nutraceutical products. Pharmaceuticals companies face a different set of difficulties. They have strong research departments, stakeholder relationships and regulatory structures that enable them to get new compounds, plus wider ties to the scientific community. Yet, despite their large sales and marketing resources, most of their efforts are aimed toward medical professionals and pharmacists instead of consumers. Only a little number of pharmaceutical companies have a consumer arm. An organizational culture dedicated to blockbuster drugs and long research cycles may struggle to adapt to the faster pace of the nutraceuticals market. Among the pharmaceuticals companies with a robust presence in nutraceuticals, Abbott owns a number of the leading nutritional product brands. Pfizer sells a range of dietary supplements. Johnson & Johnson makes products to lower cholesterol and dietary supplements for people who are lactose intolerant. Some pharmaceuticals companies have attempted wider public awareness campaigns for nutraceuticals, but few, if any, have the competence to influence behavioral change on a good scale. There is also the question of the way to accommodate consumer-oriented brands within existing portfolios, with such products typically delivering smaller margins than traditional drugs. By

complementing each other's strengths (and weaknesses), a merger of the nutraceuticals portfolios of an enormous company and an enormous pharmaceuticals company might add up, but there hasn't been a significant one yet. Instead, there has been a blurring of the road demarcating the 2 industries and a lively marketplace for corporate transactions involving relatively small acquisitions and selloffs. These maneuvers are preliminary skirmishes; the battle for dominance within the nutraceuticals market seems an extended way off. But the war against chronic and lifestyle related diseases is already fully swing. Functional 'superfoods' probably have an important role to play in the struggle, and it's only a matter of time before the fight spills over into corporate takeover wars. At some point, a nutraceuticals powerhouse will emerge, but what is going to it fancy build one? Whether it grows organically or by acquisitions or a mixture of the 2, certain key attributes are going to be required. Technological boldness. Much of the technological progress within the field of nutraceuticals would require patience, deep pockets and a willingness to put risky bets. Companies will got to achieve genuine breakthroughs to tackle a good range of conditions. Nutraceuticals is perhaps getting to take advantage of the trend of personalized medicine, therefore using and creating technology which aids this movement are getting to be key. Consumer companies are already experts in collecting data, analyzing behavior and lifestyle, and using the knowledge to focus on their customers with tailored offers supported their shopping habits. In 2013 Tesco unveiled plans to use their Clubcard data to tackle obesity, by looking at shoppers' baskets and tailoring suggestions for healthier eating (14). Consumer companies have the intelligence available to personalize dietary advice, and with prudent partnerships, pharmaceutical companies could also be ready to personalize over the counter nutraceutical products to supplement consumer lifestyles.

Personalization is also exemplified by genomics, which tailors treatments closely to an individual's genetic profile. Epigenetics and nutrigenomics recognize that each individual has different nutritional requirements and responds to food in different ways. By linking diet to the genome it's going to be possible to not only boost health, but also reduce the prospect of developing conditions like disorder, obesity, diabetes and inflammatory bowel disease. Physicians are going to be ready to predict patients' reactions to different compounds, and – with the assistance of pharmaceuticals companies – devise holistic regimes incorporating things like behavioral change and biofeedback. Consumers are already being given the chance to require this into their own hands, with personalized DNA and genomics reports widely available. Pharmaceutical companies must establish a route to focus on these

health conscious individuals with personalized solutions. Using technology, foods themselves will also become healthier. The (often controversial) use of genetic modification and marker-assisted selection helps farmers breed stronger, fortified, pest and disease-resistant crops, like vitamin A enriched 'golden rice' and oilseeds containing 'healthier' oil. Nutraceuticals may seem too pricey for emerging economies, but they are the prime beneficiaries of these innovations, where programs such as the nonprofit HarvestPlus (15) are using biofortification to produce crops containing higher amounts of vitamins and minerals.

Compliant marketing

The marketplace for nutraceuticals isn't global, and any company that fails to acknowledge this is often likely to fail. One reason is that buyers cannot agree whether nutraceuticals are food or drugs, and that they are highly suspicious of exaggerated health claims. Another is that each country regulates nutraceuticals differently. In the EU, any product that claims to be a nutraceutical has got to be certified first by the EU Food Safety Authority, which tests the merchandise to ascertain whether it lives up to its claims. Canada operates a similarly demanding process. In both cases, only a little proportion of claims are approved. In the U.S. and Japan, against this, nutraceuticals don't need to pass stringent government tests, as long as they are doing not claim to treat or prevent a selected disease. Japan was the first country to recognize functional food officially, in 1984 (16), and has the world's second largest nutraceuticals market. In the U.S., the largest market, a company can make a claim about a structure or function – for example that pomegranate juice, helps the heart and blood vessels (17). But for a label to assert that it "prevents cardiovascular disease" requires the approval of the FDA. The lack of harmonized rules means companies must adapt their marketing strategies to the regulations of every country, varying the nutritional claims and even the ingredients, counting on the rules and consumer preferences. This involves sophisticated and complex logistics to provide the precise ingredients and print the acceptable packaging. The most successful companies invest considerable resources in lobbying and interacting with the varied food and supplement bodies at a national and, where necessary, regional level, to organize for changes ahead of any new laws. Government policies don't just deter; they can sometimes help to promote the consumption of functional foods as a byproduct of national public education campaigns for healthy eating. They can also steer the market towards skilled offerings, by applying schemes like so-called 'fat taxes' on products containing excessive amounts of sugar or fat. Both food and pharmaceuticals companies are

conversant in handling complex regulations, but unless projected sales justify the difficulty, they have often dropped nutraceutical products during a given market, or withdrawn them if the rules change.

A snapshot of global regulations

United States

In the U.S., nutraceuticals mainly come under the category of vitamins and dietary supplements. A range of regulations apply, notably the Dietary Supplement Health and Education Act (DSHEA) from 1994, which covers dietary supplements, the Federal Food Drug and Cosmetic Act, which covers all foods and food additives, and Good Manufacturing Practice regulations from 2007. Under these the manufacturer:

- is responsible for ensuring the safety of supplements it makes or distributes
- must make no false or misleading claims
- cannot claim the product will diagnose, cure, mitigate, treat or prevent a disease
- must notify the FDA if wishing to use any ingredient not sold before October 15 1994, with the notification containing information the manufacturer/distributor has wanted to certify the product's safety
- must guarantee the identity, purity, strength and composition of their supplements (deadline for compliance by all manufacturers was June 2010).

In 1988 the FDA awarded 'orphan drug' status to medical foods to encourage their development and a few U.S. healthcare plans reimburse medical foods.

EU

A complex range of regulations applies to nutraceuticals within the EU, counting on the merchandise type. These are mainly overseen by the EU Food Safety Authority (EFSA), which also evaluates claims and features a public Register of Nutrition and Health Claims. If a product isn't on this certified list it can't be used until approved for inclusion following detailed scientific testing by the corporate and subsequent review by the EFSA. The EFSA also sets maximum and minimum levels of ingredients to be added to supplements. Labels cannot contain claims that their product will diagnose, cure, mitigate, treat or prevent a disease; nutrition and health claims must be authorized at an EU level. Between 2008 and 2011 the EFSA evaluated 2,758 food-related general health claims to ascertain if they were supported by scientific evidence. Only around 10 percent of the claims could be substantiated.

China

China features a lengthy and dear registration process, with three main entities involved in policing

the industry. The State Food and Drug Administration (SFDA) is responsible of dietary supplements and registration. The Ministry of Health (MOH), oversees the SFDA and therefore the approval of latest novel food ingredients. Finally, the Administration of Quality Supervision Inspection and Quarantine (AQSIQ) controls all the imports and exports.

Japan

Foods with nutrient function claims are not heavily regulated and simply must satisfy the standards for the minimum and maximum daily levels of twelve vitamins and five minerals. Foods for specified health uses (FOSHU) require premarketing approval, and ask products containing dietary ingredients that have reported beneficial physiological effects and promote health. Disease risk reduction claims are not allowed.

India

The manufacture, storage, distribution, sale and import of nutraceuticals in India are regulated under the Food Safety and Standards Act (FSSA). The required manufacturing oversight is a smaller amount strong than for pharmaceuticals, which can impact Indian producers' ability to supply nutraceuticals for export.

Supply Chain

Technological prowess and marketing smarts aren't all that's required to create a nutraceuticals powerhouse. Manufacturers of functional foods must also pay close attention to every stage in the supply chain. With increasing consumer concerns about food safety, the standard of the raw materials went to create nutraceutical supplements have come under intense scrutiny, so companies must consider carefully how to access and assure supplies of essential ingredients or flavorings. In the U.S., nutraceutical companies collect detailed information about suppliers using the Standardized Information on Dietary Ingredients protocol (18), which provides data on the (wild or cultivated) sources of ingredients, the methods of agricultural process and manufacture, and of sterilization. Supply chain risks are often high: sundried materials, for instance, could also be subject to the expansion of mold or maybe toxins. A number of recent acquisitions of food and beverage companies are aimed toward securing stable, highquality supplies of raw materials. Having acquired nutritional supplements manufacturer Complian Food UK in 2011(19), for example, Danone purchased a 40 percent stake in Kenya's Brookside Dairy in 2014, which has around 140,000 milk farms in East Africa(20). Such vertical combination not only gives greater certainty of supply; it also lays a

foundation for developing new uses of existing materials, or to supply new, related ingredients.

Investigating Nutraceuticals

Faced with technological, regulatory and logistical challenges, food and pharmaceuticals companies are taking advantage of the expansion of nutraceuticals in several ways. Some are investing in startups. Nestle has found out a risk capital fund with the aim of investing in early stage nutraceuticals businesses. The fund takes varying stakes in these entities then tries to shop for a majority share at a later date, should the startup prove successful. On the pharmaceuticals side, Alliance Boots (now part of Walgreens Boots Alliance(21), a global pharmacy chain created at the end of 2014) launched a specialized investment fund, B&B Investment Partners, which focuses on small and medium sized consumer brand businesses within health, wellness, beauty and personal care. One of its first deals, announced in November 2014, was the US\$30 million acquisition of PhD Nutrition, a leading producer of protein powder and nutrition bars(22). Other companies have been rebalancing their product portfolio, abandoning companies that don't fit their strategy. In 2013, GSK sold its nutritional drinks brands Lucozade and Ribena to Japan's Suntory (23). More recently Nestle unloaded its sports nutrition PowerBar brand to cereal maker Post Holdings of the U.S.(24) in order to focus on a few winning products. Unilever said in July 2014 that it sold its SlimFast diet unit to Kainos Capital, a private equity firm (25). Danone, against this, said in December 2014 that it might keep its medical nutrition business, ending months of speculation that it might sell the unit (26).

The sale of product lines creates new opportunities for the acquirer, and therefore the fragmented structure of the nutraceuticals industry suggests that there'll be many mergers within the future. In April 2014, Integrity Nutraceuticals and Cornerstone Research & Development merged (27), combining the former's capability in the manufacture of powder and capsule products with the latter's production of vitamin supplements. In June 2014, Spanish pharmaceuticals multinational Laboratorio Reig Jofre merged with nutritional supplements specialist Natraceutical(28). The new entity plans to sell its science based nutritional products through its medical channels, although there is no apparent move to enter consumer markets. Such mergers are small as compared with the dimensions of the worldwide nutraceuticals market, but they're a harbinger of larger transactions to return. It only takes one sizeable acquisition to change the dynamics of the industry, and then other big companies in the field will be forced to respond. In a rapidly changing market, it may be better to take the initiative rather than wait for others to make their move. Whether or

not the primary company to maneuver, deal making skills of a high order are needed to realize the advantage, as companies scramble for the choicest assets.

Reshaping Nutraceuticals

Nutraceuticals offers opportunities for pharmaceuticals companies to make their products more consumer-oriented, and for food producers to create brands with a medical image. Adding vitamin supplements or omega3 could potentially transform a mainstream food substance, while brands traditionally related to pills could broaden into drinks and snack bars.

- *Yakult: From food to health*
- Beneficial health claims but does not purport to be a cure
- Branded with science and research and medically manufactured
- Set up a microbiological research center looking into probiotics
- Published research papers to demonstrate health benefit
- Began as a consumer 'healthy drink' and is now prescribed by physicians (although still available over the counter)

Accera ('Axona'): From health to food

- Medical claims about metabolism of sugars in the brain
- Associated itself with a specific medical condition: Alzheimer's
- Branded and aligned to scientific evidence
- Prescription only
- FDA warning due to regulatory uncertainty over medical claims

These examples show that innovation is coming from both directions, so successful nutraceutical companies will need to keep their eyes on competitors from both food and pharmaceuticals. Neither industry has sufficient advantages to corner this market; the sector is open.

Characteristics of success to win

To succeed in the brave new world of nutraceuticals, will have to excel in six areas:

Technology– Personalized healthcare is probably going to steer to a proliferation of nutraceutical products. Companies will need to place strategic bets on technological breakthroughs to realize results.

Product strategy – Only the best product strategists are going to make a profit by developing a powerful portfolio of technologies and brands. Blockbusters may be few and far between.

Regulation– Regulations around nutraceuticals vary from one country to another and are changing all the time. Manufacturers will have to work closely

with governments to anticipate market opportunities that arise when the rules are altered.

Marketing– Consumer tastes are likely to be fickle within the field of nutraceuticals. Successful companies will need to develop a highly nuanced global marketing campaign which will exploit economies of scale while adapting to national preferences.

Supply chain – As researchers explore evermore exotic locales for 'miracle' ingredients, only the most flexible supply chain is going to produce the goods. Avoid high risks by paying close attention to every stage of the chain.

Dealmaking

Companies may be able to make up for their weaknesses in certain areas by being quick and decisive corporate dealmakers. They can put together a robust product portfolio through a program of acquisitions and divestments. Speed will be of the essence. The Indian nutraceutical industry has great prospects. Over the last decade a good range of products are available, giving an insight into the tremendous growth. On one hand a booming economy has resulted in overall increase in income of population. Added to the present unhealthy, eating habits including sedentary lifestyle have led to extend incidence of diet and its related health issues. On the opposite hand, there's a growing awareness on the importance of nutrition and diet for future healthiness. These have contributed to a positive 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 materials 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 2 to fourfold the present 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 pharmaceuticals and Ranbaxy.

CONCLUSION

Many nutraceuticals, functional foods and naturally occurring compounds that have been investigated and reported in various studies revealed that these products are extremely active, have profound effect on cell metabolism and often have little adverse effect. It is natural that people's focus is shifting to a positive approach for prevention of diseases to remain healthy. Nutraceuticals is scientific area generated everywhere the planet . In

many cases nutraceuticals offer a plus over the synthetic drugs under development by the pharmaceuticals industry. It is novel pharmacological activity that are become interesting in their possible clinical use and thus helping in prevention and therapeutic in several diseases. Most of the pharmaceuticals companies often lack motivation to pursue these difficulties in obtaining the patents. It is hope that government agencies and research centers will give support for further research innutraceuticals.

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