IADSA
Product Innovation in Functional Foods & Dietary Supplements

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What are Nutraceuticals?

"Food, or parts of food, that provide medical or health benefits, including the prevention and treatment of disease."

Dr. Stephen DeFelice,
Foundation for Innovation in Medicine
The Marketplace

Nutraceuticals help maintain health and, when combined with a healthy lifestyle, help prevent the onset of disease.

The global nutraceuticals product market is comprised of functional foods and beverages as well as dietary/food/health supplements.

The global nutraceutical market continues to experience significant growth.
The global market will experience a positive growth rate in protein and peptides segment of the dietary supplement market. The non-herbal segment of the supplement market will have a steady growth rate during 2012-2017. The omega fatty acid fortified food segment of functional food market will have a moderate growth rate during the forecasted period.
The Marketplace

The North American and Asia Pacific nutraceutical market is expected to have a market share of 39.2% and 30.4% in 2017. The dietary supplement market will be fastest growing market during 2012 – 2017 as it helps in improving the body ability to heal and protect itself.
The Marketplace

The Asia-Pacific nutraceutical product market is an emerging market as regards supplements and functional food segment.

Japan is the largest consumer of nutraceuticals. China is second largest consumers of nutraceutical products as people are more conscious about their food habits and they have the largest population in the world.
The Marketplace

The functional food market in India is expected to grow moderately as compared to the overall dietary supplement in the region.

The functional food and beverage market in India is expected to have 70.74% as compared to the dietary supplement in 2017.
The Target of Optimal Health

People in the world taking a range of food, beverage and food supplement products as appropriate to achieve optimal health.
How does IADSA help achieve that vision?

Partnership with government on policy, regulation, science and quality standards

World-leading guidance: IADSA has produced a range of publication on nutrition and the benefits and safety of supplementation:

• To guide policy efforts to develop soundly based and proportionate laws for food supplements.

• To increase awareness of the importance of food supplements for public health
Section 22 of FSS Act mandates

“manufacturing, selling, distributing or importing of new type of foods like **Novel Foods**, foods from **GM articles**, **irradiated Foods**, organic **Foods**, **Foods for special dietary uses**, **Functional foods**, **Nutraceuticals**, **Health Supplements**, **Proprietary foods** shall be guided by specific regulations”

Have not considered:
1. Use of and possible labeling of genetically modified ingredients
2. Use of and possible labeling of ionizing irradiation on ingredients or finished products
3. Certification, use and labeling of organic ingredients or products
The Indian Picture

Food Supplements, Nutraceuticals, Foods for Special Dietary Uses and Functional Foods defined under general definition:

“Foods which are specifically processed or formulated to satisfy particular dietary requirements that exist because of a particular physical or physiological condition or specific diseases and disorders and which are presented as such, wherein the composition of ordinary foods of comparable nature, if such ordinary food exist, and may contain

1. minerals, vitamins and proteins or metals or their compounds and amino acids or enzymes;
2. other dietary substances, plants or botanicals;
3. substances from animal origin, etc.
and shall be labeled either as Food Supplement/Nutraceutical/Functional Foods or Food for special dietary uses, as the case may be, and can be formulated in the form of powders, granules, tablets, capsules and other dosage forms except parenterals
Important Regulatory Considerations

1. Follow international best practices and Codex;
2. Type and quantity of permitted ingredients and nutrients (including botanicals);
3. Importance of validated GMPs (no contaminants, hormones, steroids or precursors);
4. Scientific basis for establishing permitted health claims;
5. Consistent with Codex standards for food supplements, use scientific risk assessment (not RDA multiples) to set upper limits of vitamins and minerals;
6. Consider combining pre-market notification of products entering commerce and post-marketing surveillance;
7. Ensure sufficient label information with any required cautionary wording (e.g., contra-indications); and
8. Supplements are formulated to promote maintenance of health (they are not drugs, do not cure or treat disease, and are not formulated to replace a healthy balanced diet
Important Regulatory Considerations

8. Follow international categorization best practices;
9. Such products must differ significantly from comparable foods if such foods exist;
10. Formulae based on sound medical/nutritional principles;
11. Manufacturers to substantiate the products shall safe and effective when used as recommended based on current scientific data;
International Approach to Nomenclature

Supplements
  Dietary Supplements – name used by US, Canada,
  Food Supplement – name used by Codex, EU, UK, SAM
  Nutritional Supplement – Australia, Malaysia
Foods for Special Nutritional /Dietary purposes
  FSDU – Codex, US
  PARNUTS – EU (being eliminated)
  Special purpose foods – FSANZ, Malaysia
  Foods for Special Dietary Use – Japan (medical foods)
Foods for Special Medical Purpose
  Dietary foods for special medical purpose – Codex, EU
  Medical Foods - US
How can an increase in intake of certain ingredients help not just the individuals but a nation as a whole?

Case Study: The Lewin Studies from the US.
Study Purpose

• To provide the Dietary Supplement Education Alliance™ (DSEA) and its affiliated members with a detailed analysis of the health benefits and cost effects of selected dietary supplements

  – Review scientific literature for health benefits
  – Extract findings from peer reviewed articles and apply to a health cost framework
  – Monetize costs and savings of dietary supplement use
  – Determine if use of supplements is cost-effective
Why Was the Lewin Group Chosen?

• Nationally recognized for expertise and influence
  – Top 10 health care consulting firm
  – 35 years in health care consulting

• Multi-disciplinary staff of 100 consulting professionals
  – Health Care Management
  – Human Services Policy
  – Community Health
  – Health Care Finance
Dietary Supplements Selected for this Study

- Calcium with Vitamin D
- Omega-3 Fatty Acids
- Lutein with Zeaxanthin
- Folic Acid
Conceptual Framework for the Study

- **Effect on Biological Markers**
  - Does the supplement produce a physiological effect as shown by a change in biological markers?

- **Clinical Effects from Change in Biological Markers**
  - Does the physiological effect create a change in health status?

- **Cost Effect from Reduced Health Care Utilization**
  - Is the change in health status associated with a decrease in health care expenditures?
Study Methods — Cost Estimation

• Cost
  – Size of the at-risk population
  – Cost of supplement
  – Take up rate (e.g., product utilization)

• Benefit
  – Number of users achieving therapeutic effect
  – Reduction in health service utilization

• Net Savings
  – Net Savings = Benefits less Costs
Key Study Findings

- Existing evidence-based research indicates positive health effects:
  - Calcium and vitamin D reduce bone loss and/or osteoporosis, especially among post-menopausal women
  - Folic acid reduces the occurrence of neural tube defects (NTDs) if women consume the supplement before they become pregnant, and continue to do so in the early stages of pregnancy
  - Omega-3 fatty acids reduce the relative risk of coronary heart disease (CHD)
  - Lutein with zeaxanthin reduce the risk of age-related macular degeneration (AMD)
Key Study Findings

• Calcium with Vitamin D

There is considerable evidence supporting, through the daily intake, 1,200 mg of calcium with Vitamin D:

• The association of reduced bone loss and reduced fractures, with the best evidence supporting a reduction in hip fractures
• A reduction not only in the cost of the hospitalization to repair the hip, but also the post-acute stay for some proportion of patients in a skilled nursing facility
• Cost offsets result from the potential avoidance of approximately 138,000 hospitalizations for hip fractures, as well as avoided skilled nursing facility stays for some proportion of patients.
• The five-year estimated net cost effect associated with avoidable hospitalization for hip fracture is approximately $13.2 billion.
Key Study Findings

• Omega-3 Fatty Acids
  
  – The estimate of the potential five-year (2006-2010) savings in health care expenditures resulting from a reduction in the occurrence of coronary heart disease (CHD) among the over age-65 population through daily intake of approximately 1800 mg of omega-3 is $3.1 billion.

  – Approximately 384,303 hospitalizations and associated physician fees due to CHD could be avoided.
Key Study Findings

- **Lutein with Zeaxanthin**
  
  - The estimate of the five-year (2006-2010) potential net savings from avoided transitions to dependency associated with a reduction in the relative risk of age-related macular degeneration (AMD) through daily intake of 6–10 mg of lutein with zeaxanthin is **$2.5 billion**.

  - Across the five year period, approximately 130,959 individuals could avoid the transition to dependence either in the community or a nursing facility that would accompany a loss of central vision resulting from advanced AMD.
Key Study Findings

• Folic Acid

  – Of the approximately 42 million American women who are of childbearing age and not taking folic acid, if just 10.5 million began taking 400 mcg. of folic acid on a daily basis periconceptionally, 600 babies would be born without NTDs, saving as much as $319,200,000 in the first year as a result.

  – Over five years, taking into account the cost of the supplement, $1.3 billion could potentially be saved.
Conclusions

The rapid expansion of the US population age 60 and older has a number of significant economic implications. The people in this group, about 18 percent of the US population, account for about 30 percent of all health care expenditures.

The four supplements result in estimated cost savings of over $20.1 billion in US health care expenditures over a five year period.

The US Congress and government officials are beginning to realize the benefits that supplementation has on the health of citizens and cost savings to the national health care system.

These cost savings do not take into account the “human factor” that prevention has on the millions of individuals and their families that would benefit from taking just these four supplements.

Imagine the worldwide benefits!
Expanding the studies

The US Council for Responsible Nutrition has commissioned Frost and Sullivan to evaluate the potential healthcare savings due to increased use of omega 3 fatty acids, CoQ10, B-vitamins, fibre, soy, sterols and stanols, calcium, vitamin D, magnesium and chromium piccolinate.

Work underway on healthcare cost savings studies in Japan and Russia, and potentially in the European Union and China to build a broader global picture.

Why not India?
Politicization of Nutrition: The risks

We have to ensure that the politicization of nutrition allows consumers to access such products with the information that they need to make the right choices.

Codex is key. As the only global framework in the food area, it has a huge role and responsibility to ensure fair and free trade and keep the food and nutrition sectors based on solid ground where consumers can have full confidence in the food they eat and companies know they can invest in innovation with the prospect of a sound return.
What are the challenges? Anti-Innovative Regulation in EU

Anti-innovation impact of Claims Regulation. Result may be to drive companies to invest more outside Europe, particularly in India.
What went wrong in Europe?

Regulation failed:

To propose adequate model for the assessment of claims other than vitamins and minerals (Qualified claims required)

○ Certain categories may disappear  
  e.g. Joint maintenance, Probiotics

To stimulate investments in nutrition

○ No clear guidance for the substantiation of health claims
  Lack of satisfactory approach for the protection of proprietary data

To tackle public health concerns through nutrition

○ Obesity: >1/3 of EU citizens are overweight (25<BMI<29.9) and one in ten is obese (BMI>30)  
  Poor diet and lack of exercise are among the leading causes of avoidable deaths in Europe, with obesity making up as much as 8% of healthcare costs

○ Healthy ageing: The number of people aged 65+ is projected to rise by nearly 50% in the next 20 years
Responsibility on industry and scientific bodies to take actions to strengthen health policies, identify health priorities reduce healthcare costs in an appropriate manner.

If we have the right regulatory climate, we then need more investment in data collection, research, innovation and education.