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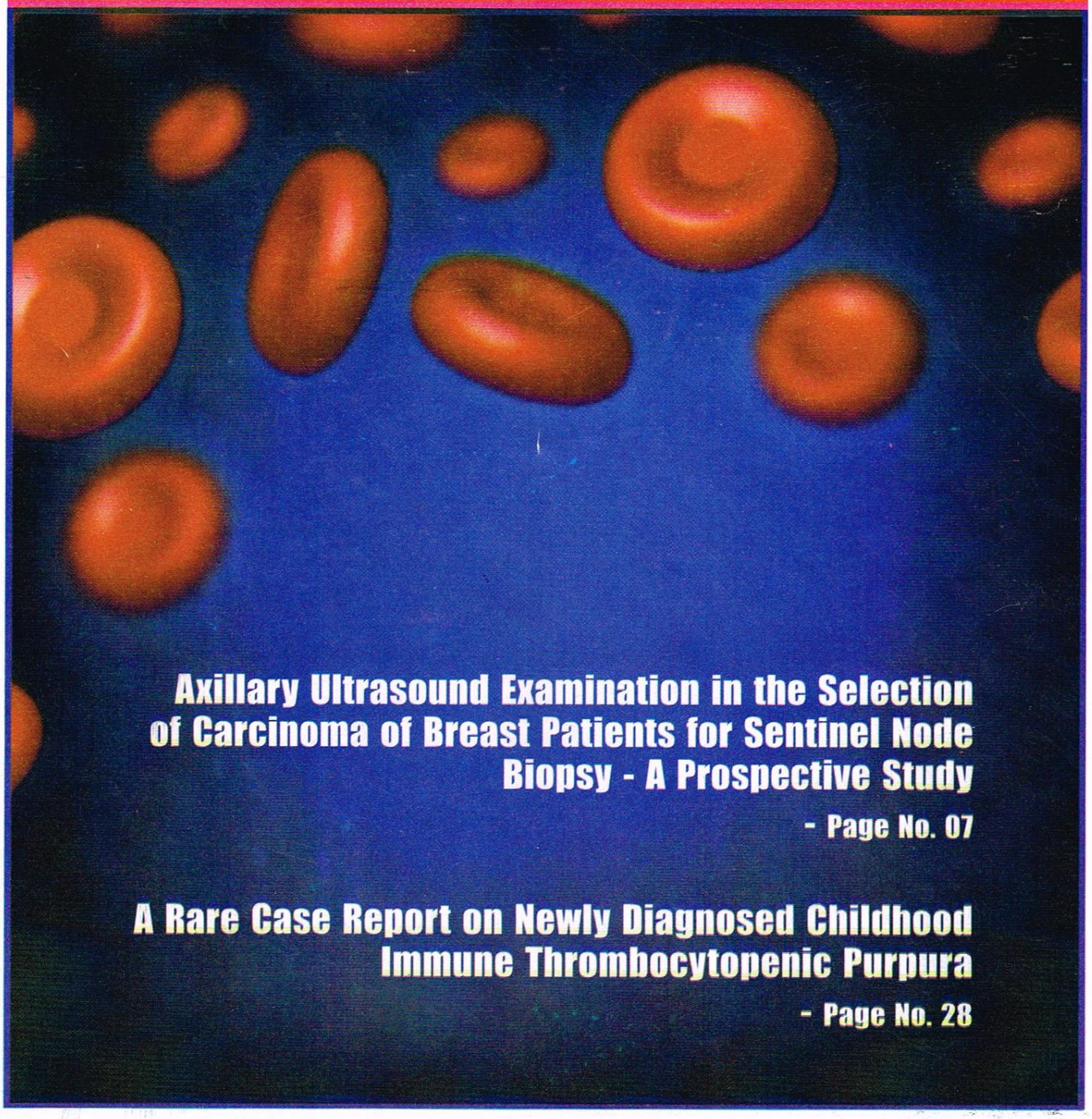

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Nutraceuticals and Pharmaceuticals

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Background

With the increasing diseases burden all over the world, there is an increase in the consumption of medicines. There is a movement from developed nations to the emerging ones. Globally, the US and Japan are the most developed markets for nutraceuticals, due to the consumer acceptability achieved in these regions. India, China and Brazil are developing nations which show huge potential for the nutraceuticals market, India and China have emerged as a key sourcing destination for natural ingredients[1].

The nutraceutical market broadly consists of two major segments - Food supplements and vitamins and Mineral supplements, the former constituting over 60 percent of the market and the rest 40 percent comes from the latter. Among vitamins and mineral supplements have continued to be marketed and distributed like prescription drugs in India, as the general awareness level are still low. Food supplements on the other hand, are marketed and distributed more like FMCGs, a reason why they are also clubbed as fast moving healthcare goods by various pharma companies. Nutraceuticals market penetration is more in urban population as compared to rural India as the demands for protein supplements is increasing among the urban youth due to rising desire towards maintaining fitness and building a strong physique.

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The nutraceuticals industry in India is one of the rapid growing markets in the Asia-Pacific region. Factors like rising awareness about health and fitness, ageing population, changing lifestyle are fostering this growth. The industry is anticipated to grow at around 20 per cent over the period to reach USD 6.1 billion by 2019-2020 as the reports suggest[2]. The emerging nations are experiencing a change in the demographics wherein the incidence of lifestyle diseases is on the rise. The young population is keen on adopting preventive measures and means to stay healthy and fit. Moreover, the trend indicates that the market is shifting from curative ways of treatment to preemptive and preventive ways. Both preemptive and preventive methods of treatment depend largely on nutraceutical. Inspite of the rising market, The Indian consumer's awareness about conventional nutraceutical ingredients such as omega-3 fatty acids or lutein is severely limited, and nutraceutical manufacturers need to take up the cause and spread awareness about their products to the Indian masses[3]. The FSSAI has recently drafted new guidelines regulating the manufacture and sale of nutraceuticals[4].

Large global food companies, which are always on lookout for ways to diversify their product line and still turn a profit, have set up functional food or nutraceutical divisions. Pharmaceutical companies are now adopting the nutraceutical and the recent trend is convergence of food manufacturing companies with pharmaceuticals to implement the research necessary for drug discovery, the move into the less expensive and time consuming nutraceutical research process. It is thus becoming a logical progression for many food companies to enter into the nutraceutical market.

A perfect example of a curative method would be microbes. Microbiome that live in the human body protect their host in lieu of food and shelter; Thus being a vital part of the host's wellbeing. A disruption in the microbes in the body can lead to serious health conditions ranging from obesity to diabetes, through heart disease, asthma and such lifestyle diseases. In pharma, these microbes are treated only when they are disturbed. Pharmaceuticals have a system centric approach wherein the affected body system such as the cardiovascular system, gastrointestinal system is treated separately. Similarly, nutraceuticals have a nutrition based approach where the balance of the microbiome is always maintained in the body. Nutraceutical does not alter microbial balance (which is required for in balance health) within body like drugs can alter. If either of the system is used separate from the other then the patient's recovery and resistance may not be as quick and effective. When a patient centric approach is adopted then both pharmaceuticals and nutraceuticals would work hand in hand. So, they would not only carry out their individual functions but also aid each other for the quick recovery of the patient, instead of competing with each other[1].

Recently, there is a global disenchantment with drug industry for various reasons ranging from

chemophobia to the industry doctor nexus. However, this general lamenting on pharma performance is not always justified. Unlike drugs, nutra industry has grown from naturals and nutritionals. Drug industry is focused on diseases, whereas nutra emphasises on wellness, health and longevity. The latter are major ingredients in the very definition of Ayurveda and traditional Chinese medicine. Obviously, safety is paramount when a large healthy population ingests any product for an extended period[1].

Basic difference between Pharmaceutical and nutraceutical is pharma is curative and another is preventive. In United States, pharmaceutical (drugs) are regulated by food and drug administration (US-FDA) whereas in India drugs are approved by DCGI (drug controller government of India) which is regulated through CDSCO (Central drug standards and control organization). Difference is mainly in regulation of nutraceuticals that it does not have any regulation authority even in USA and India. That is the biggest lucrative factor in favour of nutraceutical companies for faster production.

Although there is only one check point regarding quality control by FSSAI (food safety and standards authority of India) before coming any nutraceutical product, FSSAI does not have authority to disapprove nutraceutical products. According to law there is no prerequisite of conducting clinical trials before nutraceutical approval in Indian market if it does not claim any health related benefit. So there is big gap in establishment of safety and efficacy data for nutraceuticals. Incorporation of clinical trial with pharma drugs takes 8 to 9 years for bringing new molecule in the market; in addition pharma companies have to spend tremendous amount of money. In comparison of that nutraceutical companies have to spend little amount of money for production in a short time span. Even matter of fact, nutraceutical companies also makes umpteenth profit in comparison of drug companies.

Because of these factors so many pharma industries now a day are inclined to produce and market more nutraceuticals rather than pharma drugs. These unjustifiable laws and regulations market so many irrational nutraceutical combinations which do not treat condition and does not play any role in improving patient's condition. Examples like there is a well-known and highly marketed product FDC named metformin and vitamin B12 for diabetic neuropathy which is a long term complication in case of type 2 diabetes mellitus. There is good reason to make and improve patient's condition with this combination but there are so many other combinations having amino acids and other vitamins also available in the market in addition of these two ingredients which safety and efficacy have not been established. Other important example is Vitamin E. There is a documentary proof of effectiveness of vitamin E in a dose of 200 mg RDA which is a very good antioxidant available in the market. But in this era so many different dose strengths of vitamin E (400 mg) also available which is really a very high in dose as compared to the recommended daily allowance. This much dose can even generate free radicals which even further damage to cell and worsen the patients' condition. Another good example in CVS disorders, omega 3 fatty acids plays a vital role in lowering cholesterol but adding this with other amino acids and vitamins make this combination irrational because safety and efficacy of this is not established. Another very important example of marketing irrational combinations is of vitamin B12 preparations with variable dose strengths. Only 1500 mcg dose strength of RDA is rational in combination, rest combinations with different strengths are irrational.

Pharmaceuticals spend millions of dollars for research and paperwork for a new therapeutic claim of an established drug all to satisfy Food and Drugs Administration requirements. Food and Drugs Administration requirements for health supplements are not at all stringent apart from barring them from making any false health claims about their product and adding a disclaimer

The nutraceutical industry is not far behind offering stiff competition to pharmaceutical counterparts. But Indian government should implement few laws and regulation and to control irrational production and make nutraceutical market towards more rationality. DCGI has to take few steps for betterment of patients and their health.

Although, there is a growing market for nutraceuticals worldwide, there are regulatory concerns for the safety and efficacy for the products. This situation is not different than what existed and is currently going on for the pharmaceuticals. The origin of drugs by and large from herbal sources, as the history reveals, cannot be undermined. With the increase in new clinical applications nutraceuticals are likely to fall within the novel foods and ingredients regulations but their purity, dosage requirements and clinical consequences exceed those of most health foods. Further, the fact the effects obtained from nutraceuticals are due to complex mixtures or due to one or more individual substrates

are making the situation more complex. Thus, nutraceuticals will play an important role in future disease management. However, their success will be governed by control of purity, safety and efficacy without inhibiting innovation. The application of pharmaceutical standards, standardization of formulations, dosage forms and production controls are likely to be a challenge and present a threat that could paralyze the industry[5]. It is imperative that every individual has access to responsible nutrition, and for this both the pharma and nutra sectors must work in tandem to convey credible information to the consumers about their products and avoid marketing gimmicks that endorse false claims. Moreover, the nutraceutical sector must support each product with infallible scientific evidence. The newly introduced regulatory norms have paved way for this[1].

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Gestational diabetes mellitus (GDM), defined as glucose intolerance first recognized in pregnancy, is 'the front end' of the diabetes epidemic that commenced in the mid to late 20th century, and continues to grow.

A 'vicious cycle' of maternal obesity and / or antenatal hyperglycaemia leads to abnormal glucose and insulin metabolism in the offspring, which in turn creates mothers with hyperglycaemia in pregnancy.

The Pathophysiology of GDM is likely to be heterogenous.

The final event in the path to GDM is an insufficient ability to increase insulin secretion enough to overcome the growing insulin resistance associated with the pregnancy. Strategies for prevention therefore focus on approaches that reduce insulin demand, as there are few approaches to date that can increase insulin secretory capacity. The heterogeneity of GDM is reflected in the diagnostic groups that become evident clinically. This includes women with pre-existing levels of hyperglycaemia that probably preceded the pregnancy [e.g. (overt) diabetes in pregnancy, monogenic diabetes, elevated first trimester fasting glucose, women with reduced and / or falling insulin secretory capacity (e.g. developing type 1 diabetes), women with significant insulin resistance from early pregnancy (e.g. those with polycystic ovarian syndrome, over-weight or obese women, some ethnic groups) and women with a combination of reasons (e.g. those with a family history of diabetes or previous GDM). In some women, the reasons for developing GDM are unclear.

Diabetes, obesity and metabolism

Esophageal Physiology Relevant to GERD

- Inappropriate relaxation of the lower esophageal sphincter is the most frequent mechanism for gastroesophageal reflux to occur.
- Presence of a hiatus hernia increases the frequency of inappropriate lower esophageal sphincter relaxation, and reduces resting pressure of the lower esophageal sphincter, thereby promoting reflux.
- Reduced esophageal motor function allows prolonged contact of the refluxed acid with the esophageal mucosa.