LITERATURE REVIEW

Regson, B., Cartlidge, A. & Bond, J. et al (1991). The promotion of interdisciplinary approaches in the delivery of health, welfare and educational services has long been regarded by planners and practitioners as a worthy end to pursue, in the hope that it would have a positive impact upon the quality of services that the public receives.

Bennett (1994). It is to be realized that, as elsewhere in the world, the private sector in India too has been shown to maximize profits; fail to address public health goals; lack integration with government health services; draw professionals from the public sector instead of supplementing it; and in this unregulated environment provide inappropriate or poor quality care.

De Smet, P.A et al (1995). The quantum of Ayurvedic and Homoeopathic medicines used / procured in both public and private health sectors is huge. There has been wide ranging concern about spurious, counterfeit and sub standard drugs. Both pharmaceutical firms and Retail marketer’s trends found exploitation of traditional knowledge and organic farming concerned herbal products even adulteration and facts which were misrepresented on the finished product for marketing.

Foster S et al (1996). The formulations of the drugs must satisfy strict quality control standards to ensure conformity. These medications regularly contain virtually uniform quantities and ratios of substances which were rarely established.

Bernhofe, Opie et al (1997). Inter professional relationships continue to be characterised by conflict rather than co-operation and are frequently distorted by mutual suspicion, hostility and disparities between the way that a particular profession views itself.
Kraft, K. (1999). The WHO Regional Office for the Western Pacific invited a group of experts to develop criteria and general principles to guide research work on evaluating herbal medicines. This group recognized the importance of herbal medicines to the health of many people throughout the world, stating: ‘A few herbal medicines have withstood scientific testing, but others are used simply for traditional reasons to protect, restore, or improve health. Most herbal medicines still need to be studied scientifically, although the experience obtained from their traditional use over the years should not be ignored. As there is not enough evidence produced by common scientific approaches to answer questions of safety and efficacy about most of the herbal medicines now in use.

Ellis, Randall, Alam, et al (2000). Health Insurance can be broadly defined as a financial mechanism that exists to provide protection to individual and households from expenses incurred as a result of unexpected illness or injury. Under this mechanism, the insurer agrees to compensate or guarantee the insured person against loss by specified contingent event and provide financial coverage for which the insured party pays a premium.

Benatar SRI (2000). Daily encounters with poverty and indignities often force the healthy and the sick to be “willing” participants for the trials. According to the ICMR’s guidelines, “… payments should not be so large or the medical services so extensive as to make prospective participants consent readily to enroll in research against their better judgment, which would then be treated as undue inducement”. However, the reality is often more grim. This is why stricter regulation and enforcement is absolutely necessary to prevent our hospitals from morphing into human laboratories.

Agarwal, S., Desai, S., Holcomb, M. and Oberoi, A.et al (2001). Indian Pharmaceutical industry is in life saving process which is evolved by various marketing strategies. In theory as well as in practice marketing strategies can be combined in number of ways. Optimization is to be achieved by trying out several
alternative combinations. The marketing mix elements are substitutable by one another to a certain extent, in which intermediaries have got prime importance in making medicines readily available in market. Resources can be taken from one element and assigned to another, to achieve balance as per the marketing objectives of Industrial pharmaceutical Industry.

Mahal A, Singh J, Afridi F, Lamba V, Gumber A.et al (2001). The growth of private healthcare sector has been largely seen as a boon, however it adds to ever-increasing social dichotomy. The dominance of the private sector not only denies access to poorer sections of society, but also skews the balance towards urban-biased, tertiary level health services with profitability overriding equality, and rationality of care often taking a back seat. The increasing cost of healthcare that is paid by ‘out of pocket’ payments is making healthcare unaffordable for a growing number of people. The number of people who could not seek medical care because of lack of money has increased significantly between 1986 and 1995.

Butler, (2002). Patent protection of innovative pharmaceutical products is restricted to 10–12 years after the molecule registration. Companies have therefore limited window of opportunity to make their business from the product before it is destroyed by arrival of its generic copies. Therefore producers strive to shorten the time from molecule registration to market entrance. Historically, the R&D process has taken around 10–12 years, today, the objective is to launch to market in an average of just 7 years.

Tyler VE et al (2003). Any conventional medication can have side effects. These side effects are described and reported after drug trials and research studies have been conducted. Side effects are further reported and evaluated after the marketing of the medication. Information about drug components, drug interactions, usage in pregnancy, while in breastfeeding, for pediatric patients, and dosing limits are outlined and made available in standard references for doctors treating patients.
**Rao Sujatha et al (2004)** While taking health insurance, the customer often misconceived on the limits, sub-limits or restrictions that may come handy on the claims that you make based on age, disease or hospital when you opt for portability.

**Nundy S, Gulhati CM, Desai K, et al (2005)** In the complicated process of drug development, approximately 30% of the costs is incurred in actual drug development while the remaining 70% are incurred in clinical testing. In contrast to the drug discovery process, the clinical development process is heavily dependent on the human element; hence regions of the world with cost competitive human resources are an attractive alternative with nearly one billion people as potential patients and a large number of highly skilled investigators, India clearly falls into this category.

**Josef Bednarik, et al (2005)** As soon as the product is available physicians seem to develop their opinion and their prescribing habits mainly on their own clinical experience. Information from producer as well as from independent sources seem to be less influential while impact of colleagues’ opinion slightly increases. It is important that physicians test products in their clinical practice based on recommendations given by producer. In today’s business environment some unethical marketing is also involved to promote drugs which are categories as ‘Forwarding Class’ drugs from US FDA. Government should take strict action against promoter of these drugs.

**Petryna A. et al (2006)** Being a research intensive industry, the average R&D sales ratio is 18% as compared to the manufacturing industry of 4% in US (pharmaceutical researchers and manufactures of America 2003). Therefore, more emphasis is being laid on multicentre clinical trials to get the US FDA regulatory
approval at a faster pace. Moreover, this act helps in avoiding the loss to the companies due to the early patent expiration of the blockbuster drugs

Srinivasan S (2007). India was not the preferred destination for major global pharmaceutical companies, even though some of them were conducting clinical trials here. In the last 10 years however, there has been a steep rise in the global demand for world class clinical trial management capacity and productivity. With the average R&D expenditure growing at more than 15% per year, biopharmaceutical majors worldwide are realizing that the time-consuming and expensive affair of drug discovery and development can be done easier and better in India, given its rich technical resource pool, them relative ease and attractive economics of recruiting large number of patients and the sheer diversity inherent in the country’s genetic texture

Lisa A. Sanchez et al (2008). Today’s cost-sensitive healthcare environment has created a competitive and challenging workplace for clinicians. Competition for diminishing resources has necessitated that the appraisal of healthcare goods and services extends beyond evaluations of safety and efficacy and considers the economic impact of these goods and services on the cost of healthcare. A challenge for healthcare professionals is to provide quality patient care while assuring an efficient use of resources

George Pulikuthiyil, Sunil Kumar, et al (2008). Major Pharmacy companies to look at alternative destinations for sourcing patients for their global studies. Exploration on these lines guides pharmaceutical industry to take interest in the countries like Latin America Eastern Europe and Asia. Amongst Asian countries, India stands out prominently due to its huge treatment-native patient’s population, English speaking doctors and a large pharmaceutical presence that has dominated the world market due to cheap generics.
Christine M. Thorp (2008). Health care professionals can be ideally placed to spot adverse drug reactions and to play an important role in the long-term monitoring of commonly prescribed drugs. As professionals, they should be able to advise patients or know when to refer them to other experts in the health care team.

Annas, George J et al (2009). Certainly the economic advantages of conducting trials in India cannot be denied. Cost savings in clinical trials could be substantial, resulting from a combination of the different factors. Depending on the number of patients and investigators, and the amount of analytical work completed in India, most sponsors will enjoy a 30–50% cost advantage over a similar trial in the US or Europe.

Shayne Cox Gad et al (2009). It is interesting to note, that the greatest cost savings come on the clinical side of the equation. Central laboratory services or other analytical services provided in India do not enjoy the same deep discounts, as the cost of liquid chromatography and mass spectrometry equipment is the same worldwide. Only the cost of the labor to operate them is less expensive. Although the cost of labor is less, it is mandatory to make investments in training and support systems to ensure data quality. Generally a sponsor will realize a 10–20% discount on analytical services.

R.Kavitha et al (2012). In the past, the hospitals were considered almshouses. They were set up as charity institutions specially for the poor and weaker sections of the society. But now healthcare industry has restructured its service delivery system in order to survive in an unforgiving environment resulting from maturation of the industry, reduced funding and increased competition.
Irfan Khan Pathan, Suresh Nuthaki, Baburao Chandu, et al. (2012). In order to coordinate the ever increasing interest from international and domestic sponsors a Clinical Research Secretariat, Scientific Review Committee, and Ethics Committee have been established.

Hafeez Ullah Khan, Rai Muhammad Sarfraz et al. (2013). About 35% of the population of the doctors stand them in culprits that are promoting the unethical practices and are playing with the lives of the innocent public. Here doctors have the authority to prescribe and there are no evaluation services of the product for price, toxicity, duplicity etc. by Pharmacists as per rules of the ministry of health of Pakistan.

P. Vasavi, Kpl. Sravanthi et al. (2013). Health insurance is like a knife. In the surgeon’s hand it can save the patient, while in the hands of the quack, it can kill. Health insurance is going to develop rapidly in future.

Poortinga et al. (2013). Western Europe look east to outsource research and clinical trial activities, countries such as India will gain proficiency and expertise, assisting its move from generic and specialty contract manufacturing to innovative drug discovery and development in its own right, setting the stage for increased global competition. Proven the success in outsourcing. Large patient poor. Educated health care team. Hospitals with super-specialist equipments. Cost reduction etc.

Geetanjali M et al. (2013). The Indian pharmaceutical industry is growing at an annual rate of 11% while the clinical research industry is growing an annual rate of whopping 84%.
**Divya Christopher, Miss Arishma et al (2013)** Alternative methods are devised for the creation of generic drugs that are sold in large numbers so that they have similar impact like the blockbuster drug(s) in terms of profit generation.

**Bertram G. Katzung, et al (2013).** Adverse drug reactions are claimed to be the fourth leading cause of death, higher than pulmonary disease, AIDS, accidents, and automobile deaths. The FDA has further estimated that 300,000 preventable adverse events occur in hospitals, many as a result of confusing medical information. Some adverse reactions, such as overdose, excessive effects, and drug interactions, may occur in anyone. Adverse reactions occurring only in susceptible patients include intolerance, idiosyncrasy (frequently genetic in origin), and allergy (usually immunologically mediated). During the IND and clinical phase 1–3 trials and before FDA approval, all adverse events (serious, life-threatening, disabling, reasonably drug-related, or unexpected) must be reported. So FDA began publishing quarterly a list of drugs being investigated for potential safety risks. The ability to predict and avoid adverse drug reactions and optimize a drug's therapeutic index are an increasing focus of pharmacogenetic and personalized medicine.

**Ramaiah Itumalla, Acharyulu et al (2012)** Indian government prudent on globalization, but later part, it was found hampered the condition of domestic industries, some who were merged with foreign firms, (Increasing direct and indirect domination by transnational corporations and wealthy individuals over states). We can’t avoid the truth; most of them were closed down, which were unemployed masses.