CHAPTER 8

CONCLUSIONS, LIMITATIONS

AND AREAS OF FUTURE RESEARCH
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8.0.0.0 Ethics And The Pharmaceutical Industry

Values and ethics are at the heart of leadership. In the pharmaceutical industry, ethics and values in leadership are all the more critical because the industry is in the business of saving lives. Despite the pharmaceutical industry being highly regulated because the potential risk to patients’ lives and humankind is very high, unethical business practices have been increasing over the last three decades. Global drug giants like Pfizer, Eli Lilly, Merck, GlaxoSmithKline and Ranbaxy have been convicted in international courts and fined billions of dollars for violations ranging from bribing doctors, misleading marketing, manipulating clinical trials, suppressing information of side effects and launching irrational drugs. This has resulted in pharmaceutical companies’ being perceived as putting profits over patient’s health.

In a developing nation like India with its huge challenges on the healthcare front, the pharmaceutical business must fulfil the mandate of providing affordable healthcare for common diseases affecting large sections of the population. If business leaders focus merely on making profits, this mandate is not being fulfilled thereby increasing the disease burden of the nation and impacting the common man, leaving him with no access to medicines and affecting the quality of life of the most vulnerable – the poor.

There is a need to address the widespread ethical violations by advocating and promoting the need for values based leadership. While the Medical Council of India has issued a code of ethics for physicians’ and the Government of India has issued a code of ethics for the pharmaceutical industry mandating that physicians and companies need to shift to a more values based method of treating patients, drug discovery and marketing, the industry still needs to change their mindset and approach to comply with these initiatives. Corporate leadership teams will have to reorient themselves to display values based leadership. Since organisations have been successfully generating results through unethical means, there is a need to sensitize leaders and corporate teams to the principles of values based business. Leaders in
organisations will need to be trained to recognise ethical dilemmas, and make ethical decisions based on a value driven framework. There is a need for extensive re-orienting of mindset and re-skilling to enable them to be successful within the values based framework.

8.1.0.0 Critical Insights From Research

The data analysis of the research studies done in Part 1 – The Survey and Part 2- Qualitative in-depth interviews reveal the following key insights:

The research studies on values based leadership and the pharmaceutical industry reveals the following key insights:

- There is a definite crisis of values based leadership behavior in the pharmaceutical industry with widespread corruption at all levels. Pharmaceutical companies are now predominantly using unethical practices to generate business.

- The major reasons are intense competition, pressure to earn market share, weak implementation of laws, changing nature of values, lack of transparency and widespread corruption.

- 98% of the respondents felt that their organisations considered it important to do business in an ethical manner and over 90% are aware of unethical practices in operations.

- 66% of the respondents have encountered situations that have created ethical dilemmas for them; while 48% have experienced a conflict between their personal values and what was expected from them while dealing with ethical dilemmas.

- Most common ethical violations are unethical payments to doctors in lieu of prescriptions, regulatory violations, manipulation of clinical trial data, off label usage and incorrect drug information in drug promotion.
The major factors causing an individual to compromise with his/her values were focus on short-term results, rewarding results and not processes and furthering personal goals.

The experience of ethical dilemmas is across types of companies and levels of management.

Both multinational companies and national companies are indulging in unethical business practices although the MNC’s are more sophisticated in implementation.

There is definitely a great need to return to the fundamental purpose of saving lives and clean up the pharma regulatory and marketing system.

There is a general consensus that the values and mission statements of each company exist only on paper and are more of a corporate image building exercise.

96% of the respondents would like to be values based leaders.

93% of the respondents across types of companies and levels of management would like to develop their skills to become values based leaders.

It is possible to remain values based as demonstrated by the Caselets of companies who have maintained their values and yet achieved business goals. The common factor in all these cases is a clear strategy, a strong code that is communicated and implemented, the focus on training and retraining of employees on values and ethics and commitment of top management to conduct business ethically.

In order to bring about a positive transformation and enable the pharmaceutical industry to display values based leadership the following initiatives emerged from the research:
Strategy To Launch Institute For Values-Based Leadership Development

- **Leadership signalling and accountability**
  - Clarification by top management of what can be done and what cannot be done in an organization within an ethics framework. To management also needs to redefine parameters for “Success”, to create new norms for success and align organization with new norms.
  - Top management needs to demonstrate the values in action by ‘walking the talk’
  - Formulate an ethics policy framework for each organization and set up processes within the organization which can monitor compliance.

- **Leadership Training**
  - Impart training on values based leadership and ethical decision making for top management, senior management, leadership pipelines, doctors, and management students
  - Re-train and re-skill sales and marketing teams to market and sell products based on scientific rationale and not through gratification or unethical practices.
  - Expose leaders and stakeholders to leadership training where ethics and values are at the heart of the leadership program.
  - Conduct Values based leadership development programs where ethical dilemmas in day-to-day operations are discussed, approaches and skills to address these are built.
  - Need to create forums for CEO’s to debate the challenges of values based leadership and the pharmaceutical industry.
Strategy To Launch Institute For Values-Based Leadership Development

- **Sensitization programs and public awareness campaigns**
  - Continuous education to change mindset of all stakeholders of society.
  - Conduct sensitizing programs across industry and organizations on the long-term benefits of being ethical and the need to adhere to the code of ethics proposed by the government.

- **Governance**
  - Stronger governance and implementation of the Medical Council of India (MCI) code of ethics for physicians, the Pharmaceutical code of ethics for industry and the Income tax act.
  - Stricter implementation of existing laws using audits and inspections by regulatory authorities.
  - Fast track prosecutions of cases of companies suspected of violation and impose punishing penalties for those found guilt of subversion.

**8.2.0.0 Strategic Intent Of Institute For Values Based Leadership Development**

**8.2.1.0 Strategic Intent Statement**

Revive values based leadership in the pharmaceutical industry by launching a leadership development training institute which will equip, empower and enable individuals and organizations to display values based leadership.

**8.2.2.0 Concept of Leadership Development Institute**

To launch an institute for values-based leadership development in the pharmaceutical and healthcare industry in India, aimed at sensitizing, equipping, empowering and enabling individuals and organizations with the tools, knowledge, attitudes and skills needed to display values based leadership.
The institute will operate like a professional corporate training institute. The target audience as will consist of corporates, NGO’s Government and policy makers of the pharmaceutical and healthcare industry.

8.2.3.0 Validation Of The Strategic Intent And Concept

The concept and strategic intent of the institute has been validated in Part 3 of the study by testing the concept on 100 business leaders. The validation study shows that the concept of the institute was widely accepted as being unique, useful and would contribute to create an awareness of values based leadership while promoting the need for corporate integrity. While respondents want to use and recommend the services of such an institute for their own organizations, they are not sure whether pharmaceutical companies will engage the services of such an institute. This only goes to prove that unethical practices are so deeply rooted in the industry that respondents are sceptical whether there will be a change. This finding also validates the theory that industry needs values based leadership and there is a definite role for such an institute to catalyze change.

8.3.1.0 Launch Strategy Of Institute For Values – Based Leadership

8.3.1.1 Name of the institute

The Leadership Institute for Values and Ethics (LIVE)

8.3.1.2 Positioning

The Leadership Institute for Values and Ethics (LIVE) is the only leadership institute which equips, encourages, enables, and empowers organizations to LIVE up to higher standards and deliver outstanding performance.

8.3.1.3 Mission

To influence, revive and strengthen values based leadership in the pharmaceutical and healthcare industry by building values-based leaders who, in "doing the right thing," deliver outstanding and sustainable business results.
8.3.1.4 Vision

The Leadership Institute for Values and Ethics (LIVE) will be a platform for research, dialogue, sensitization, training, and support for values based leadership, beginning with the pharmaceutical industry and progressing to all stakeholders of the healthcare industry.

8.3.1.5 Strategy

1. Use the levers of change to work against the barriers to values based leadership and launch and establish the institute. Levers include the recent government initiatives to improve governance, the global demand for quality and compliance, pressure on companies to sell ethically thereby creating the need to retrain employees, need to improve the reputation and corporate image of pharmaceutical companies and pressure on doctors for ethical behavior.

2. Mainstream the issue of lack of values based leadership in the pharmaceutical industry through research, publications and speaking assignments so that there is an increased awareness and sensitization of all stakeholders.

3. Address the critical success factors of credibility of the institute by appointing a board of management with strong credentials, and business development by leveraging the networks in the pharma industry to generate revenue. Resource faculty should have strong credentials and should be drawn from cross industries, leading management institutes and practitioners.

4. Price the service offerings affordably, promote aggressively, hire infrastructure, work with a lean core team of people, and break even by year 3 of launch.
8.3.1.6 Objectives

Short term: (Year 1 – 3)

- To launch the Leadership Institute for Values and Ethics
- To establish the credibility of the institute through research and publications
- To mainstream the issue of values and ethics in pharmaceutical business and create an urgency for change
- To achieve break even in year 3

Long term: (Year 4-8)

- To establish the Leadership Institute for Values and Ethics (LIVE) as an influencing voice for values-based leadership among industry, government, media, physician’s, patients and civil society by promoting, equipping for and advocating change.
- To expand the activities of the institute to all areas of healthcare and achieve sustainable profitability.

8.3.1.7 Product/Service offerings

The Leadership Institute of Values and Ethics will have three revenue streams, which will promote values based leadership in the pharmaceutical industry. These include Training and Development, Consulting and Research and Publications. The scope of the institute will be to focus on values based leadership, business values and ethics, sales and marketing re-skilling, corporate accountability and governance and CEO and stakeholder forums.

The institute will offer the following services:

**Training and development**

1. Values based leadership
2. Values based leadership and business ethics
3. Customized in company workshops for sales and marketing re-skilling
4. CEO briefings
5. Seminars and events

**Consulting**

1. Defining ethics policy and business process
2. Compliance audits (Sales and marketing, Regulatory, Clinical trials, business process)
3. Ethics certification programs for implementing industry code of ethics
4. Reorienting rewards systems to integrate short term and long term results
5. Developing values based culture-interventions for change.

**Research and Publications**

1. Most ethical companies annual survey
2. Research on topical issues like quality issues, clinical trials, marketing cases
3. Publication of the research through print, web based media and use of the research as a business development tool and customer engagement tool

**8.4.1.0 Limitations Of The Study**

- The study is restricted to the pharmaceutical industry in India.
- Since, the sample size considered is representative of the universe but is not the complete universe, the study is a part study.
- Values based leadership has been considered as one component of ensuring business ethics. There could be other components to ensure compliance to business ethics.
- Being a very sensitive and personal area, respondents were reluctant and to some extent resistant to share information. Many of the respondents of Part 1, Part 2 and Part 3 of the study have requested that their identity be kept confidential.
Respondents of the qualitative depth interviews did not give permission to video or audio record the interviews. However they permitted the researcher to take detailed notes.

The study has a geographical limitation of being limited to the major cities in India.

8.5.1.0 Areas Of Future Research

The potential areas for future research are:

1. To explore how parameters other than values based leadership could ensure compliance to business ethics.

2. The study could be expanded to other industries.

3. The study could be expanded to other geographies.

4. Another study could explore the repercussions of leadership decisions which are not values based and assess the extent of damage that has been caused to the stakeholders of business and society.