

**Rebirth of Ethical Marketing in Pharmaceutical Industry - Levers for change**

*Dr. Ruth D'Souza*

The business world has witnessed an increasing spate of prominent corporate scandals in the last few years, which have led to the collapse of several large firms including global companies like Enron, World-Com, Arthur Andersen, Lehman brothers and Satyam. These corporations were involved in scandals that rocked the financial markets while decimating the lives and fortunes of millions of employee's, investors and innocent people and adversely affecting the global economy. The widespread scandals across industries, from banking to housing, from IT to pharmaceuticals have brought ethics and values to the forefront of the business world and global thought leaders have been emphasizing the need for principles and values in the manner in which corporations do business.

In the last few years, the pharmaceutical industry too has been making the headlines for unethical business practices affecting the lives of millions of innocent patients. Despite being a highly regulated industry because the potential risk to patients' lives and humankind is very high, unethical business practices have been on the rise. International courts have convicted and fined drug giants to the extent of billions of dollars for illegal marketing practices, promoting prescription drugs for uses not approved by the Food and Drug Administration (FDA), paying financial inducements to doctors to increase sales, false drug quality reporting and engaging in practices that pose grave danger to patients' health and lives.

Between 2008 and 2012 alone, giant global pharmaceutical corporations like GlaxoSmithKline, Pfizer, Johnson & Johnson, Astra Zeneca, Merck, Abbott, Eli Lilly and Allergan have paid about \$13 billion in fines to settle charges of misleading marketing, promising what drugs don't do, bribing doctors to get their drugs prescribed, sometimes causing fatal side-effects. Their target patients ranged from children to dementia afflicted senior citizens. However, their revenues from the sales of drugs for which they were proven to have engaged in violation far outweigh the penalties paid.

In view of the vital role of the pharmaceutical industry in society, it is imperative that pharmaceutical industry leaders find solutions to meet the challenges of capitalizing business opportunities while balancing public health and corporate profits. Values and ethics will have to play an important role in these solutions. The industry will need to pursue and promote a corporate culture of integrity founded on values based leadership where values and ethics are woven into day to day decision making; where the interests not only of stock holders, but also of all the stakeholders of the industry are considered.

### **Indian Context**

In India too, the problem has reached epic proportions with a vicious cycle of drug companies, doctors, chemists, clinical research organizations and sales forces being embroiled in unethical business practices. The pharmaceutical industry in India is characterized by intense competition wherein products of the original innovators compete with low priced generic copies. The drug discovery pipeline is dry with no new blockbuster drugs. These, together with the intense competition for share of the doctor's prescription and the pressure to show short-term profits in quarterly results, have shifted the focus of Pharma leadership to the goal of maximizing market share and bottom lines

Numerous studies have highlighted the ethical issues in pharmaceutical marketing to physicians, including the provision of gifts and sponsorship of educational and recreational activities as well as the lack of transparency of drug information. Many authors have concluded that pharmaceutical marketing activities pose serious problems, and medical professional organizations have elaborated guidelines on appropriate relationships between the pharmaceutical industry and physicians. Nevertheless, both pharmaceutical companies and medical professionals continue to give and accept gifts and engage in a variety of activities sponsored by drug companies.

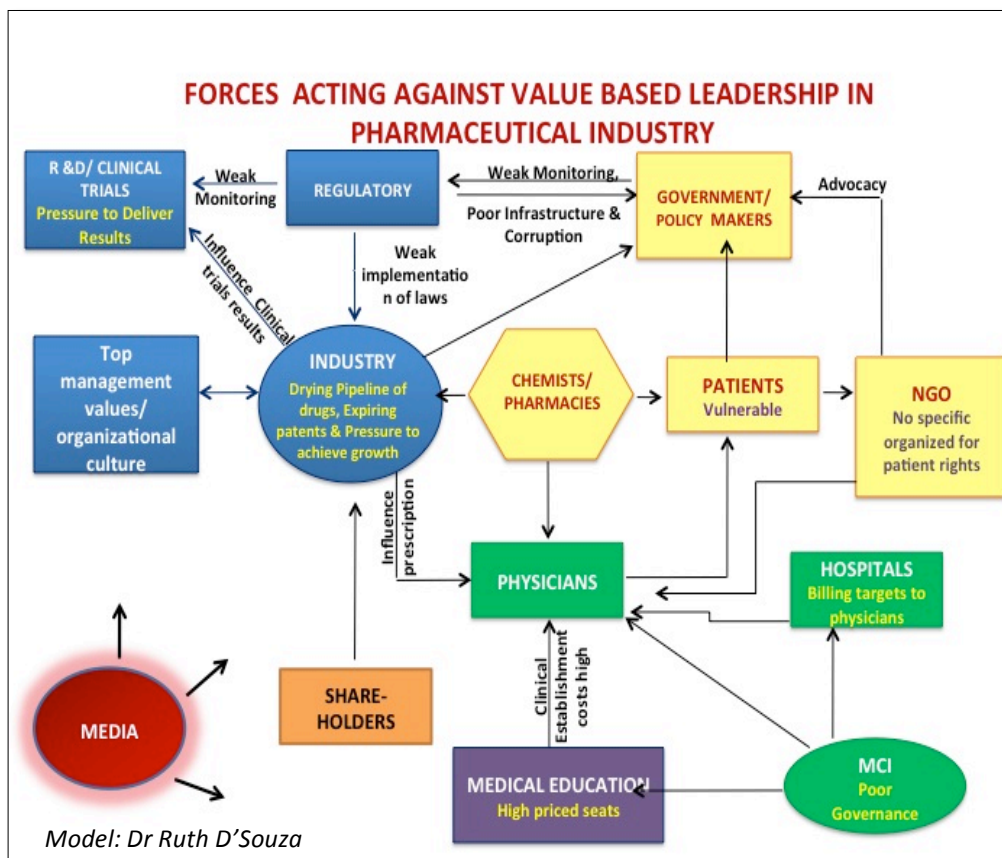
A recent survey conducted amongst top 50 pharma companies with 160 respondents from senior management and top management showed that there were wide spread ethical violation in a number of areas. Key among them were giving and receiving bribes (95%), unethical practices in marketing (91%), falsifying or incomplete information (75%), unethical practices relating to clinical trials (68%) among others. The survey also indicated that

majority of respondents have in the course of discharging their duties have encountered the following types of ethical violations which is unethical marketing methods (33%) doctors asking for bribes (22%), wrong information to customers (15%), poor product quality (11%), pressure from top management to achieve results (11%), manipulation of clinical trials (14%).

A developing nation like India faces enormous challenges on the healthcare front and affordable healthcare is critical for the billion plus population where the patient is the payer for his health care needs. In this context, 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 profit the disease burden of the nation will increase with its corresponding human and economic implications.

**Forces Acting Against Values-Based Leadership**

The crisis of values-based leadership stems from multiple factors operating in the Indian pharmaceutical environment. These forces work are depicted in the following model:



### 1. Physicians and medical practice

Due to the shortage of government medical colleges, aspiring doctors have to pay huge capitation fees to get seats in private medical colleges, which they have to recover from their practice. Since a physician's education is of a longer duration, a doctor starts earning much later than than peers from other disciplines. Moreover, it takes time to establish a physician's reputation in the chosen area. In this context, physicians are often enticed by pharmaceutical companies' incentives in their quest to quickly recover the investment of time and money. Meanwhile, due to the proliferation of hospitals, there is stiff competition for business and in the pursuit of profits; physicians are given revenue targets that they meet through hospitalization of patients. The Medical Council of India, the regulator of medical education, has itself been caught up in allegations of corruption with indiscriminate issuing of licenses to private medical colleges in exchange of huge bribes.

### 2. Governance

In terms of regulation and governance, the Food and Drug Administration (FDA) is understaffed to regulate the numerous companies and retail outlets all over India<sup>1, 2</sup>. This, compounded with the widespread corruption ensures that the monitoring mechanisms are weak.

### 3. Patients are vulnerable

In India, the physician is treated like 'God' and since there is no system of accurate patient records. Thus, in case the patient decides to switch doctors the treatment protocol is lost leaving the patients dependent on the doctor and hence vulnerable. Considering the above, patients are reluctant to fight for their rights. Moreover, unlike the western world, there is a

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<sup>1</sup> Report of the 44th Meeting Of The Drugs Consultative Committee Held On 20th July, 2012,

<http://www.cdscsco.nic.in/dtab%20dcc%20ind/Reports%20of%20DCC/Report%20of%2044th%20DCC%20Meeting%20%2020.07.2012%20.pdf>

<sup>2</sup> R.A. Mashelkar, (2003), Report of the Expert Committee on a Comprehensive Examination of Drug Regulatory Issues, including the Problem of Spurious Drugs in India

<http://cdscsco.nic.in/html/Final%20Report%20mashelkar.pdf>

dearth of Non Government organizations (NGO's) who are involved in fighting for patients' rights.

#### **4. Pharmaceutical Industry - pressure to deliver profits**

Pharmaceutical companies are influenced by shareholders who demand profits. They are however constrained by the drying pipeline of new products, the stiff competition among generic players and the pressure to deliver growth. The Research and Development (R&D) departments of pharmaceutical companies face productivity challenges. The pressure to launch new molecules often results in clinical research being influenced with subsequent fatal consequences for patients as evident for instance in the cases of Merck and Vioxx and GSK and Avandia. Although companies have a code of ethics, they often lack processes to implement the code and have very little or no provision for training on ethics, internal ethics committees, an ombudsman and whistle blower policies.

#### **Six levers for change**

If pharmaceutical companies decide to reorient their business operations to the fundamental purpose of saving lives and of making profits based on the principles of business ethics and values based leadership, it will entail weaving values and ethics into day to day leadership decision making while considering the interests not only of stock holders but also of all industry stakeholders. Thus, pharmaceutical companies need to review their working and reformulate their culture where corporate integrity is vital and unethical behaviour is neither condoned nor rewarded.

## 6 LEVERS FOR CHANGE



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### 1. Lever 1: Recent Government Initiatives To Increase Governance.

#### Initiative 1: Industry Code Of Ethics

The increasing exposés from the media has put the pharmaceutical industry's ethical violations, regulatory failures and corruption in the spotlight. The government of India has taken a stricter view of the situation and has taken steps towards increasing governance. Till 2012, the industry had a self-defined, voluntary code of ethics, which was not implemented, and violations had no negative consequences for companies. From January 1<sup>st</sup> 2015, the Department of Pharmaceuticals has brought in a code of ethics<sup>3</sup> governing the conduct of pharmaceutical companies which defines what is acceptable business behaviour.. This code is initially meant for voluntary implementation by the industry for a period of six months, during which the government intends to observe the degree of implementation of the code. Subsequently the government intends to make it mandatory with penalties for violation. Every Managing

<sup>3</sup> Department of Pharmaceuticals, Code of Marketing Practice for Indian Pharmaceutical Industry <http://pharmaceuticals.gov.in/uniformcode.pdf>

Director has to give an undertaking in writing that his organisation has complied to the code of ethics. This is welcome move and will go a long way in helping companies to change the way that they do business.

### **Initiative 2: Income Tax department**

The Income Tax (IT) department has also prevented companies from accounting for expenditure on doctors, sponsorship and certain promotional activities as expenses, which means that companies have to pay tax on such expenditure. The Income Tax department has also begun querying physicians' and cross verifying their passports with their bank statements to assess whether the physician himself/herself has paid for international travel expenses or whether some company has sponsored them.

These two initiatives to increase governance with strict penalties for non-compliance and greater monitoring will be a strong lever for change.

## **2. Lever 2: Global demand for quality products**

While India can capture the generic market and the world, we have seen many cases in the recent past on the USFDA banning the import of generic drugs from India over quality concerns. They have also banned facilities which did not comply with norms. Some of the issues which need to be addressed and which have been highlighted as the basis of these bans are fudging of date, hiding or providing inaccurate information or inadequate staff training to comply with Good Manufacturing Practices (GMPs). Indian manufacturers will have to ensure transparency in data and comply with international standards of manufacturing any order to regain the trust of the global markets.

## **3. Lever 3: Need to improve the reputation and corporate image of pharmaceutical companies**

We live in a digital world where reputation of 20 years are destroyed in 5 minutes.

The pharma industry has a major problem with its reputation as has been proven over and over again through numerous surveys. The overall perception is that the industry is more interested in profits than in patients' health. The government perceives that the industry makes huge profits and is constantly forcing companies to reduce prices

through the Drug Price Control Order (DPCO) or the National Pharmaceutical Pricing Authority (NPPA).

Hence, a comprehensive image restoration has to be done for all the stakeholders of the pharma industry like Government, Patients, Global companies, Media, Hospitals and Physicians.

#### **4. Lever 4: Pressure on doctors for ethical behavior**

There is increasing pressure on physicians to adopt ethical behavior in all aspects of their practice. The physician – pharmaceutical company nexus has been constantly in the news globally as well as in India.

In response to all these pressures, the Medical Council of India has issued a set of guidelines for doctors to encourage ethical behavior, violation of which can entail the physician losing his license to practice. As recently as December 2014, over 320 doctors under Medical Council of India were under the lens for bribery charges

Continued pressure on physicians from media, patients and the tax authorities will compel doctors to consider change.

#### **5. Lever 5: People: Organisational and top management changes:**

The mind set of top management needs to be changed from focusing on stock holders and quarterly profits to needs of all stakeholders. Decisions need to be taken in line with corporate values and the mission and vision documents of companies need to be lived out starting with the top. Mechanisms for governance and compliance need to be put in place. People within the organisation need to undergo continuous training and reskilling to be able to do business ethically.

Thus, the key to transformation is not only governance, but also a deeper sensitization and change in mind-sets of all stakeholders, a focus on developing values based leaders who have the courage and the confidence to stand for their values, make ethical decisions and influence the world around them. The changed environment will slowly but surely force companies to shift to ethical marketing and compel them to re-skill their teams to be ready to sell in a changed environment.



### 6. Lever 6: Empowering patients

Finally patients need to be empowered and their rights need to be protected. Counter balancing mechanisms which hold industry and government agencies accountable need to work in tandem in order to provide quality healthcare at affordable prices. Patients and civil society need to be more informed and vigilant and need to push government to hold violators accountable.

#### **Conclusion**

Pharmaceutical companies have a very critical role to play in public health. As they attempt to balance their duty towards the vast health needs of the public with their business and profitability goals, it is increasingly clear that the need for change is urgent. With the introduction of new code of ethics, and the integrated action of all the levers together hopefully, we will see the rebirth of ethical pharma marketing. Martin Luther King Junior said “The time is always right to do the right thing”. It is now time to restore the ethical reputation of pharma industry.