CHAPTER III
CORPORATE SOCIAL RESPONSIBILITY OF THE PHARMACEUTICAL INDUSTRIES: WITH SPECIAL REFERENCE TO THE THALIDOMIDE TRAGEDY.

‘Earth provides enough to satisfy every man’s need, but not every man’s greed’
– M.K. Gandhi

“He who ignore the past is condemned to repeat it, He who anticipate the future can safeguard the present”

As in the previous chapter, the role of Chemical Corporation to integrate CSR efforts is analyzed and how can chemical industries mitigate mass torts like of Bhopal Gas Tragedy. In this chapter researcher will analyze role of Pharmaceutical Corporation and there CSR efforts to mitigate mass torts as happened in the thalidomide tragedy.

3. CORPORATE SOCIAL RESPONSIBILITY: AN OVERVIEW

The Conventional rule of market says that the prime objective of Business is to do Business; i.e. profit maximisation at any cost. Before the last decade the world of business flourished around the globe with only a single responsibility on their shoulder- “responsibility” to make money and increase shareholder value. In other words, corporate financial responsibility has been the sole bottom line driving force. However, with the break of the next decade the companies started flirting with a new concept, a movement defining broader corporate responsibilities– for the environment, for domestic communities, for working conditions, and for ethical practices–has gathered momentum and taken hold. This new driving force is known as corporate social responsibility (CSR).

As described by Zynia L. Rionda, CSR is the “triple bottom line”—the totality of the corporation’s financial, social, and environmental performance in conducting its business.\(^\text{110}\)

The term CSR has not been defined in a proper manner covering all its dimensions however there have been several sincere attempts for the same. Few defined it as ‘An obligation, beyond that required by the law and economics, for a firm to pursue long term goals that are good for society’; others called it a mode to attain equilibrium between the

economic profit and societal obligations\textsuperscript{111}. The term "corporate social responsibility" came into existence in the late 1960s and early 1970s when several multinational corporations coined the term 'stakeholder', pointing those on whom an organization's conduct have an impact. One of the greatest challenges that man-kind actually faces is to ensure sustainable, just and balanced development. CSR in its wider scope proves to be an effective tool for the purpose\textsuperscript{112}.

CSR, is stretched in four dimensions- Economic, Legal, Ethical and voluntary/philanthropic. The economic obligations pin points to the target of profit maximization\textsuperscript{113}. The legal responsibility means complying to the demarcation of societal rights and avoiding societal wrong. The Third and the fourth dimensions are fundamentally overlapping. They include promotion of human welfare and acting in a manner which is fair and just.

Corporate social responsibility not only benefits the society but also benefits the firm. It can be seen as a long term investment. Complying with the facet of CSR, a company gathers a good reputation and enhances its intangible assets such as goodwill. This further gives them positive press coverage and enhances their recruitment cycle as well. It further knits an effective bond between the local authorities and the firm owners which directly helps in functioning such as distribution, promotion of goods etc.\textsuperscript{114}. CSR improves the internal work environment too. According to Maslow's Theory, Motivation to do good is one of the sine quo non in the business cycle. CSR serves the purpose rightfully. Therefore CSR should be perceived not only as tool for social benefit but as a long term investment that pays off without the involvement of risk\textsuperscript{115}.

3.1 PHARMACEUTICAL INDUSTRIES AND CSR

Any existing company as a matter of fact, is widely seen to be involved in activities which aim not only on profit maximization but things that contribute to the welfare of the society

\textsuperscript{111} Friedman, Milton (1970-09-13). "The Social Responsibility of Business is to Increase its Profits". The New York Times Magazine
\textsuperscript{112} Catalyst Consortium (2002). "What is Corporate Social Responsibility?"
in whole\textsuperscript{116}. Plethora of activities such as blood donation camps, hygiene awareness programmes, imparting knowledge about draconian disease such as cancer and AIDS etc have been undertaken by such firms\textsuperscript{117}. Pharmaceutical Industries are no different. They have successfully adapted to the need of hour. Understanding their obligation towards the society several big names such as Cipla have actually started working for the people of third estate\textsuperscript{118}. There was a time when ethics had to take the back seat, however we cannot deny the fact that it has taken the driver’s seat again. Now firm never looks for profit at the stake of humanity\textsuperscript{119}.

Healthcare companies are an apple of discord as an outcome of rising healthcare prices and amplification in healthcare fraudulent cases. Recent era has also seen crimes such as collecting money from the government under some nonexistent healthcare policy. Thus, as aforementioned, there is a common public perception that pharma and healthcare companies profit immensely and most of the times through high prices/charges and unethical practices by some. Therefore enhancement of their goodwill and strengthening their brand’s image becomes a sine quo non. CSR as earlier discussed is an effective tool to regain the image the companies initially enjoyed. It is a good way of not only contributing to the society in whole but also enhancing the business by escalating firm’s goodwill.

Pharmaceutical Industries, in particular have benefitted a lot by adoption of CSR, they have seen factors such as enhancement in brand loyalty, increased ability to attract not only the customers but investors and financial analysts. Going according to the statistical data 83 per cent of the people will trust a company more if it is socially responsible. Further, it is also proved that a firm which is more socially active retains maximum number of employees, according to a survey by Monster Track, 90 per cent of young professionals would prefer to work for an environmentally friendly employer this empirical data substantiates the aforementioned assertion\textsuperscript{120}.

\textsuperscript{118} Allouche, J. (2006), Corporate Social Responsibilities, Concepts, Accountability and Reporting, Palgrave Macmillan, Hampshire
\textsuperscript{119} Idowu, S. O. & Filho, W. L. (2009), Global Practices of Corporate Social Responsibility, Springer, Heidelberg
\textsuperscript{120} Becht, Marco, Patrick Bolton, Ailsa Röell, "Corporate Governance and Control" (October 2002; updated August 2004).
Pharmaceutical industries can use their expertise and technology to initiate a war against the diseases. They can address the critical needs of the poor people in terms of health care and appropriate need. The day they start striving not for only profit maximization, and start contributing towards social welfare all the threads of criticism that has been weaved for them would be null and void.

3.1.1 CSR IN INDIA

The learned prime minister of India Dr. Manmohan Singh very aptly in his address at the CII Annual General Meeting in May 2007 said that CSR is not an imported western notion but a part of our cultural heritage. Indeed a remarkable comment. In a report, it was claimed that CSR in India can be traced under four distinct tabs. The very first one was motivated by charity and philanthropy. The origin of CSR can be traced since the roots of Ancient India, Vaishyas who used to provide relief at the time of desertification, drought, famine, etc. Modernisation and British rule didn’t uproot rather took this conventional concept to a new altitude. Soon after, Business Tycoons (Those from the family of Tata, Birlas, Bajaj) took over the charge of Indian Market. They were guided by the principles of philanthropy. They believed in charity; inclusive of giving sporadic donation to educational institutions or health centres. The Second term of CSR expanded during India’s struggle for freedom. Governed by the explicit code of social reform, CSR took a completely new shape. The notion of trusteeship encouraged businesses to setup trusts for schools, colleges, and other institutes of higher learning.

121 Available at http://www.cii.in/About_Us.aspx?enc=n9fJzmNKJnsoOQCyKqUmaQ== The Confederation of Indian Industry (CII) works to create and sustain an environment conducive to the growth of industry in India, partnering industry and government alike through advisory and consultative processes.

CII is a non-government, not-for-profit, industry led and industry managed organisation, playing a proactive role in India's development process. Founded over 117 years ago, it is India's premier business association, with a direct membership of over 7100 organisations from the private as well as public sectors, including SMEs and MNCs, and an indirect membership of over 90,000 companies from around 250 national and regional sectoral associations.

CII catalyses change by working closely with government on policy issues, enhancing efficiency, competitiveness and expanding business opportunities for industry through a range of specialised services and global linkages. It also provides a platform for sectoral consensus building and networking. Major emphasis is laid on projecting a positive image of business, assisting industry to identify and execute corporate citizenship programmes. Partnerships with over 120 NGOs across the country carry forward our initiatives in integrated and inclusive development, which include health, education, livelihood, diversity management, skill development and water, to name a few.

The CII Theme for 2012-13, ‘Reviving Economic Growth: Reforms and Governance,’ accords top priority to restoring the growth trajectory of the nation, while building Global Competitiveness, Inclusivity and Sustainability. Towards this, CII advocacy will focus on structural reforms, both at the Centre and in the States, and effective governance, while taking efforts and initiatives in Affirmative Action, Skill Development, and International Engagement to the next level.

With 63 offices including 10 Centres of Excellence in India, and 7 overseas offices in Australia, China, France, Singapore, South Africa, UK, and USA, as well as institutional partnerships with 223 counterpart organisations in 90 countries, CII serves as a reference point for Indian industry and the international business community.

Third phase begun when India opened its economy for the foreign market, with the emergence of PSUs there was an urge felt to shift focus from self-regulation to strict legal regulation. The PSU’s were established with the intention of appropriate distribution of wealth to the needy. However, this had its own limitations. With the growth of private sector, development of socio-economic hand became indispensable. There was a slight shift again and the concept of CSR entered its fourth zone, where there was an interface between philanthropic and business approach. CSR now became a sine qua non, of the internal policies of the firms and business houses. From the crudest form of CSR which was based on philanthropy to the most refined form that is governed by the social conscience, Indian market has undergone a great change and the phase of changes is still not stagnant. What we see in India currently is its refined form.

3.2 CASE STUDIES

3.2.1 CIPLA: Can ethics be traced in the era of profit maximization?

The sole reason why the case study of CIPLA in this thesis begins with the question-‘can ethics be traced in the era of profit maximization?’ is because it is a fact that CIPLA is one of the companies that has maintained its stand on the social grounds as well.

Following are the pointers that were followed by CIPLA and which has helped it retain this goodwill in the global domain:

a) The CIPLA Palliative Care and Training Centre in Pune continue to offer selfless care to cancer patients. Till date, the Centre has successfully provided comfort and

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125 “Cipla’s Receives Approval for Generic HIV Drug Tenofovir – Medication News”. Internationaldrugmart.com. 2010-02-11
126 According to the National Cancer Registry Programme of the Indian Council of Medical Research, there are: -2 to 2.5 million cancer patients in the country at any given time

• Less than half percent have access to palliative care treatment
• Seven hundred thousand to nine hundred thousand new cancer cases are detected every year
• 70 percent of the cancer patients in India require palliative care as a majority of the cases are diagnosed at an advanced stage, resulting in poor survival and high mortality.

There is a desperate need to broaden awareness about palliative care and extend its reach. For the first time ever, palliative care became a part of medical education in 2012, with the M.D. (Palliative Medicine) course at Tata Memorial Centre. There is a desperate need to sensitize and educate medical personnel at all levels.

We have been making concerted efforts to not only care for patients but also to spread the knowledge by informing and training professionals and others in palliative care.
solace to more than 6000 patients. Their prime objective is extension of aid to maximum number of patients who need constant care and support. They have even provided chemotherapy and have focussed on several curative techniques at reasonable price that suit the pockets of every individual.

b) The Company has actively promoted education and has contributed in community welfare through its charitable trusts.

c) Environment protection has also been one of the priorities of the company, the company continues to maintain a modern, and well organised effluent treatment plant and treat every drop of discharge with great care. The objective behind this is not to end the pollution completely (which certainly cannot be done if perceived on pragmatic floor), but to minimize the risk to nullity.

d) Conservation of energy, reduction of wastage and consumption optimization is also a part of paradigm followed by CIPLA.

As a result of these steps, CIPLA has not only established a strong hold on the market but has also developed an emotional connection with the consumers and the employees. They have not only proved to be a mammoth when it comes to profit maximisation but also when moral and ethical grounds are taken in consideration.

3.2.2 Roche. An excellent platform to show gratitude towards the society Though CIPLA has done a lot in this regard, however it is not the only one in this regard. Roche

127 AIDS Healthcare Foundation’s official release on Cipla’s pricing in India, August 8, 2007

128 Roche - Committed to a better future - At Roche, our mission is to create exceptional added value in healthcare. We strongly believe that this is the best way to offer significant benefits to society. But we also want to do more. While only a financially successful company can take an active role in addressing environmental and social issues, we have also long recognised that business success depends on behaving in an environmentally and socially responsible way. Our group has a long history of corporate philanthropy and social involvement, and this ‘little-known’ side of the Roche story is a focus of this Website. In countries around the world we are working every day to enhance the quality of people's lives through support for community projects, charitable contributions and a raft of collaborations and partnerships with non-profit organisations. As we see it, these are all part of good business practice. Good corporate citizenship at Roche is a multifaceted process of commitment and action in areas ranging from humanitarian aid, health promotion and education to environmental stewardship and support for the arts. As a healthcare Company, Roche has special skills to contribute. Our BlueSky Global Initiatives in Caring are an example of how we are helping to combat HIV/AIDS in countries around the world, especially in the least developed nations. And there are many other areas where Roche is lending a much-needed helping hand. For years now our Task Force SIGHT AND LIFE has been actively involved in the fight against vitamin A deficiency and its devastating complications among children in Africa, Asia and Latin America. Of course, this Website can provide no more than a selective glimpse of the wide range of activities reflecting our commitment to communities around the globe. Underpinning all these activities is the belief that every contribution is important in making our world a better place to live in. We will continue to foster hope by working for a brighter future.
is a neck breaking competitor of CIPLA. Following are the paradigms that were adopted by Roche that gave the title of company with Big Heart:

- **Community Based Rehabilitation (CBR):** It is an initiation by ROCHE. This CBR project extended to 7 community based rehabilitation centres provides Occupational Therapist to children suffering with any sort of deformity- mental or physical, developmental or emotional disabled. Owing to this fact, they received a token of appreciation on Feb, 2010 from the Ministry of Women, Family and Community Development\(^\text{129}\).

- **News Straits Times School Sponsorship Programme:** Since 2006, the company has participated in the School Sponsorship Program initiated by a leading local English daily – News Straits Times and has become the first in its genre (Pharma industry) to take up such an action. Roche has exhibited phenomenal level of Humanity as a result of their handwork in the field of education; the fluency of spoken and written English especially in rural and semi-urban areas has improved by leaps and bounds.

- **Roche Bi-Annual Blood Donation Drives:** The triumphant organization of the Blood Donation Drives over the years has resulted in not only close collaboration with the Blood Bank but also clearly demonstrates that Roche (Malaysia) is a company with a big heart as mentioned in the initial paragraphs.\(^\text{130}\)

- **Support for marketing gimmicks from handicapped Centers:** The Company encourages marketing departments in all business units, as part of their promotion activities, to maintain close contact with handicapped Centers that can produce useful gimmicks and souvenirs for our customers. Besides providing support to such handicapped Centers, the gimmicks are appreciated by our customers and help to establish Roche as a responsible corporate citizen\(^\text{131}\).

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\(^{130}\) Supra fn 16
3.3 PHARMACEUTICAL INDUSTRIES IN INDIA

In India there are various factors that influence the form and functioning of the pharmaceutical industries. Some of factors are

- Political
- Economical
- Technological and
- Legal

3.3.1 Political Factor –
A very important factor that influences the pharmaceutical industry in India is India’s accession with World Trade Organisation (WTO). The pharmaceutical industries started developing the generic versions of patented drugs is long as they altered the production process under the existing Patent laws in India. India being the member country to WTO, government started taking major steps to comply with Trips. All the pharmaceutical companies were granted the exclusive market rights (EMR) for drugs patented and marketed in any member country to WTO. This decision of the government have helped the pharmaceutical industries to develop their market in India.

The Indian Patent (Amed) Act 2005 started giving protection to patented products for minimum of 20 years; also following the provisions of Trips Agreement the pharmaceutical industries in India stated booming.

3.3.2 Economic Aspect
The change in the government took place in 1980,s when the then finance minister Dr. Manmohan Singh has instigated many reforms to culminate in the complete liberalization in India. The Indian pharmaceutical Industries stated booming with such healthy step taken by the then government. The Indian pharmaceutical industries stated gaining the recognition for its manufacturing capabilities in the world market. It also helped in the growth for countries GDP.

3.3.3 Technological
Use of Technology in Pharmaceutical industry has developed bioinformatics in India. At the same time many industries also started building alliance with foreign partners for generating growth for the software companies.
3.3.4 Legal factor

Indian constitution provides various provisions related to life and health care. If we talk about some of the provisions like Article 21 which guarantees right to life to all citizens, Article 47 deals with raising public health standards and Article 39 talks about Right to good health for the population. There was also some amendment made in the patent Act in 2005 to rectify the shortcoming in certain area.

3.4 HISTORY OF PHARMACEUTICAL INDUSTRIES IN INDIA

After independence in 1947 the government of India was keen to protect the industry for the welfare of their citizen at large. Special emphasis towards the health care sector. Government of India does not want to depend upon the foreign MNC’s hence they nationalized at the important industrial sector in India Including pharmaceutical Industries. The policies of the government of India were not so favorable to attract the foreign MNC’s in India. The existing pharmaceutical industry in India started taking advantage of the same. It was after 1970, Government of India started entry for small scale units in the capital intensive industry.

In 1961, The Government of India introduced Drug Price Control order\textsuperscript{132} (DPCO) (Reference Annexure C) to put prices of 347 drugs under control to discourage foreign pharmaceutical MNC’s. Hence the pharmaceutical industry was in the major government protection. DPCO revises a Drug under control from 347 to 143 in 1979 and 74 in 1995.

The government encouraged Research and Development in Pharmaceutical Industries. To promote Research and Development in Pharmaceutical Industries the government of India started giving reducing to interest rates and removal of custom surcharge in some lifesaving drugs.

\textsuperscript{132} Available at \url{http://www.goa.gov.in/pdf/DrugsOrder1995.pdf}  Drug is considered as one of the essential commodity under Essential Commodities Act, 1955. Therefore, Government of India have issued an order under the above name which lays down the procedure for fixing the prices of the drugs. Under the said Order, each and every retail price is required to be displayed on the label of the container of the formulation and no person can charge exceeding the price printed on the label. With a view to securing compliance of the order, State Government have authorized the officers of the Directorate to look after the enforcement of the Order. Consumer has to check the price charged vis-à-vis the price given on the label when the drug is being purchased. If the price charged is more, then accordingly consumer may complain to the Directorate by writing.
3.5 THALIDOMIDE TRAGEDY: THE SAGA OF MISFORTUNES

Background

Thalidomide is a sedative drug introduced in the late 1950s that was used to treat morning sickness. It was sold from 1957 until 1961, when it was withdrawn after being found to be a cause of birth defects.\(^{133}\)

On November 18, 1961, four years after thalidomide entered the market, Widukind Lenz, a German physician and geneticist, indicated that thalidomide was associated with severe teratogenic malformations. He had observed more than 50 malformed infants whose mothers had taken the drug during pregnancy. In December 1961, independent confirmation came from William McBride, an Australian obstetrician, who questioned whether thalidomide was responsible for teratogenic malformations.\(^{134}\) The findings of these 2 investigators soon were confirmed by numerous physicians worldwide. As a result, by the end of 1961, thalidomide was taken off the market in most countries. Although the manufacturers of thalidomide initially contested these findings, the drug quickly was proved to be a powerful teratogen; nearly 10,000 infants were affected worldwide.

In the United States, the drug was never approved for marketing, thus averting a major tragedy. Thalidomide initially was denied Food and Drug Administration (FDA) approval by Dr Frances Kelsey, who reviewed the new drug application and had concerns about the lack of safety data. Dr. Kelsey was instrumental in preventing the drug from being marketed in the United States.

Once the teratogenic properties of the drug were known, the application for FDA approval was withdrawn. Dr Kelsey subsequently received the President’s Award for

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\(^{133}\) Available at [http://www.leiomyosarcoma.info/chemo67thal.htm](http://www.leiomyosarcoma.info/chemo67thal.htm) browsed on 10 March 2012 at 10.00 PM.

\(^{134}\) Available at [http://www.thalidomide.ca/history-of-thalidomide/](http://www.thalidomide.ca/history-of-thalidomide/) browsed on 10 March 2012 at 10.45 PM

\(^{135}\) FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation.

FDA is also responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health. FDA also has responsibility for regulating the manufacturing, marketing and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

Finally, FDA plays a significant role in the Nation’s counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.
Distinguished Federal Civilian Service from President John F. Kennedy. The thalidomide tragedy led to major reorganization of the FDA; the agency became responsible for approving drug safety and efficacy with the passage of the Kefauver-Harris amendments by Congress in 1962\textsuperscript{136}.

Thalidomide was the production by German pharmaceutical company called Grunenthal. Thalidomide was developed in 1954, as the effect of the drug was vast. It was sold in the number of countries across the world from 1957 until 1961. When it was found that the drug results into birth defect then it was withdrawn from the market. No one can predict that, what is the number of victims of such drug, but the estimate range from ten thousand to twenty thousand. But later on once again it was introduced after being prescribed again in a number of countries, but its use is altogether contravention.

3.5.1 CONSEQUENCES OF THALIDOMIDE TRAGEDY

For the formation of limbs, thalidomide binds to and inactivates the protein cereblon, such inactivation leads to a tetagenic effect on fetal development and due to such kind of a tetagenic effects it leads to :-

- Absence of the auricles with deafness
- Defects of the femur and tibia
- Malformation of the heart, the bowel, the uterus and the gallbladder.
- Defects of the muscles of the eye and of the face
- Malformation of the arms
- Thalidomide slows down the cytokines and blocks angiogenesis causing insufficiency and oxygen delivery to the developing organ and limbs.
- Taking only one 100 mg tablet early in pregnancy, when limbs buds and organs.

Use of thalidomide during pregnancy may cause malformation in different children differently, in some registered cases, the ears are missing, and there is also deafness and paralysis of the muscles of the eyes and the face. In some cases the thumbs are abnormal with three joints possibly.

\textsuperscript{136}Available at http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/R13279703082005.pdf browsed on 11 March 2012 at 01 AM.
If thalidomide has been taken during the pregnancy period the consequence may be severe. It is also seen that out of 40% of thalidomide victim died within the period of one year from the birth.

It is also seen that between 1950 – 60 more than ten thousand children in 46 countries were born with deformities. Major tragedy was in Germany were 5000 German’s were victim of thalidomide and has about 2800 are still alive.

3.5.2 LEGAL DIMENSIONS

It was in May 27, 1968 a criminal suit was filed against seven men of chemie grunenthal by the public prosecutor. The issues in the case was about the sale of a drug which caused an acceptable degree of bodily harm without conducting proper test on it, and also failed to react on generating information on side effects in due course of time.

The court decides to pay the compensation of DM 100 Million to the children with malformation due to thalidomide. There was no sentence or acquittal. The court also confirmed that thalidomide was a tetrogenic and stressed that it was more important to change the whole system by restricting the sale of drugs.

3.5.3 CHANGE IN THE PERCEPTION OF CSR AND THALIDOMIDE TRAGEDY

Changing social expectations are nothing but a strong denotation of how aware the consumers all around India have become. The case of Thalidomide tragedy was no different. Thalidomide Tragedy also demands Corporate Social Responsibility. In India, the focus of CSR was mainly on Charity. Whether or not companies had a penchant for CSR, they addressed the issue of medical as they regarded factory monitoring as a potential legal liability.

But with the Thalidomide Tragedy, came an increased risk of observance of CSR on the legal angle, and this forced many organisations into greater compliance. Corporate social responsibility must be compatible with the bottom line. Bad public relations hurt profits; good public relations help profits. The pharmaceutical industry is, in some important respects, not like ‘Coca Cola’; it is more like the defense industry. World-wide health threats are as much a matter of national defense as terrorist threats. The industry should not react to AIDS as if it were like arthritis or sexual dysfunction, and it should not simply placate special interest groups; AIDS is a serious epidemic; but like the defense
industry, it should demand and get a profit from the government for its efforts in responding to such national threats. The defense industry is not asked to subsidize counter-terrorism; the pharmaceutical industry (which saves lives) should not be asked to subsidize dealing with epidemics. The pharmaceutical Industry should and must take a leadership role in the healthcare debate. Promote sound public policy that will save the most lives and improve the most lives in the long run\textsuperscript{137}.

3.5.4 CRITIQUE ON THE REINTRODUCTION OF THALIDOMIDE IN THE MARKET

On November 18, 1961, four years after thalidomide entered the market, Widukind Lenz, a German physician and geneticist, indicated that thalidomide was associated with severe teratogenic malformations\textsuperscript{138}. He had observed more than 50 malformed infants whose mothers had taken the drug during pregnancy. In December 1961, independent confirmation came from William McBride, an Australian obstetrician, who questioned whether thalidomide was responsible for teratogenic malformations\textsuperscript{139}. The findings of these 2 investigators soon were confirmed by numerous physicians worldwide. As a result, by the end of 1961, thalidomide was taken off the market in most countries. Although the manufacturers of thalidomide initially contested these findings, the drug quickly was proved to be a powerful teratogen; nearly 10,000 infants were affected worldwide\textsuperscript{140}.

Fetal malformations due to thalidomide occur when the drug is ingested by a pregnant woman between days 35 and 49 after the last menstrual period. A single pill is sufficient to produce teratogenic effects. Fetal malformations include absence of ears and arms, deafness, phocomelia, defects in the face and palate, and malformations of the gastrointestinal system. Approximately 40% of affected infants die within their first year of life.

Today, individuals affected by the thalidomide tragedy have reached adulthood and have adapted to their severe physical challenges. Several organizations for these affected individuals exist, including the Thalidomide Victims Association of Canada.

\textsuperscript{137} Available at http://www.bmpllp.com/files/CorporateSocialResponsibility.pdf browsed on 10 February 2012 at 02.00 am.
\textsuperscript{138}Lenz W. Thalidomide and congenital abnormalities [letter].\textit{Lancet}. 1962;1:45.
\textsuperscript{139}McBride WG. Thalidomide and congenital abnormalities [letter].\textit{Lancet}. 1961;2:1358.
\textsuperscript{140} Available at http://farmacists.blogspot.in/2009/05/rebirth-of-thalidomide.html browsed on 8 March 2012 at 3.30 pm
After the 1960's tragedy and thalidomide being taken out of use, not all the drug was destroyed. A few years later, the story took a surprising turn by means of an Israeli doctor. In 1965 the doctor was treating leprosy patients. One in particular had developed a bacterial infection coupled with inflammation. After stumbling across some thalidomide, remembering it was a sedative, the doctor administered it in the hope it would help the patient sleep and ease his pain141.

This is not the only situation in which Thalidomide has proved effective. Since it reduces growth of blood vessels, it has been tested on cancer patients, as tumours require new blood vessels. It has been used to treat weight loss associated with AIDS/HIV and on Chron's disease patients. It has also been studied for its potential property of stopping HIV progression. But what about the victims, as the effect of the tragedy is still alarming and is a big question on re-introduction of Thalidomide.

3.6 CSR: AN OBLIGATION OR MANDATE

Expectation

Various sectors and industries take up different types of CSR activities. The pharmaceutical sector, if we take an example, is one such industry. All the major players like Pfizer, Roche, Cipla etc. have their own CSR policies. They range from patient assistance programs to medicine safety education to climate change to mass production of life saving drugs. Pharmaceutical companies vigorously spend millions of dollars in developing new medicines to combat draconian diseases like HIV/AIDS and thus maintain an edge over other competitors. At the same time when it comes to making new medicines available to the most unprivileged class of society, they shrug off their responsibility. This calls for specific measures to compel pharmaceutical giants to work in the interest of society.

Right to health is a crucial element of human life and therefore the pharmaceutical sector stands on a different footing in comparison to other industries. It has higher and immediate bearing on human life. Therefore, specific enforcement of CSR norms in pharmaceutical industry becomes all the more important.

141 Available at [http://www.chm.bris.ac.uk/motm/thalidomide/return.html](http://www.chm.bris.ac.uk/motm/thalidomide/return.html) browsed on March 07, 2012 at 10.00 PM.
3.6.1 RANBAXY CASE

Recently EU antitrust regulators have imposed fines totaling 146 million euros on nine global drug makers, including Ranbaxy, for blocking the supply of cheaper versions of Danish Company Lundbeck’s antidepressant drug citalopram. In 2002, Lundbeck had entered into agreements with Ranbaxy and other companies to delay the entry of cheaper generic version of its blockbusters citalopram. The punishment follows the 2009 report by the European commission on the pharmaceutical sector which says “pay for delay”. “Agreements of this type directly harm patients and national health systems, which are already under tight budgetary constraints,” EU competition commissioner Joaquin Almunia said in a statement, adding, “The Commission will not tolerate such anticompetitive practices.” The European Commission, which acts as competition regulator across the 27-member European Union imposed a 21.4 million euro fine on Germany’s Merck KGaA, and another 7.77 million euros on it jointly with former subsidiary Generics UK, which is now owned by US generic drugmaker Mylan.

Ranbaxy may appeal against the EU order. The company is disappointed with the decision by the European Commission to rule its patent settlement agreement with Lundbeck, covering the molecule Citalopram, anti-competitive, and intends to appeal the decision to the General Court of the European Union. These events took place over 10 years ago, and the company considers that the commission has misunderstood the facts, and misapplied the law. It believes it has strong grounds of appeal.

In 2002, after Lundbeck’s basic patent for the citalopram molecule had expired, it only held a number of related process patents which provided a more limited protection. Producers of generic versions of citalopram therefore had the possibility to enter the market. But instead of competing, generic companies agreed with Lundbeck not to enter the market in return for substantial payments, and other inducements amounting to tens of millions of euros.

The agreements gave Lundbeck the certainty that generics producers would stay out of the market for duration of the agreements, without giving the generic producers any guarantee of market entry thereafter.

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143 Ibid
3.7 WHAT CAN BE DONE

Many social proposals undertaken by business do not pay their own way in an economic sense; therefore, someone must pay for them. Ultimately, society pays for all costs, although it may seem that a corporation is paying the bill. Some people believe that social benefits are costless, but socially responsible businesses will try to recover all of their cost in some way. For example, stock holders may receive lower dividends; employees may be paid less; or consumers may pay higher prices. If the public knew that it must eventually pay these costs, and if it knew how high the true costs were, it might not be so insistent that companies act in socially responsible way. The same might be true of government regulations intended to produce socially desirable business behavior. By driving up business costs, these regulations probably increase prices and lower productivity, in addition to making the nation’s tax bill higher.

3.8 CONCLUSION AND RECOMMENDATIONS

CSR should be viewed as a process and not as a destination. Although CSR has grown at a rapid pace over the last few decades, it still faces a lot of challenges in proper implementation. Some commercial organisations still believe that CSR would deviate their attention from economic activities but many companies have experiences that it doesn’t lessen the profits; rather, it increases the long-term profits of a company by brand and image building of a company enhancing its most valuable asset i.e. “Goodwill”.

Recommendations suggested are as follows

- To mandate CSR through legislative enactments (as in Indonesia) from the government’s side.
- To rationalize and harmonize the economic, compliance, ethical, and sustainability dimensions of corporate responsibility and sustainability in the context of stakeholder requirements.
- Integrating eco-design and other sustainability requirements into product and service offerings.
- To manage the sustainability performance, optimization process to continually increase stakeholder satisfaction.
- To promote and encourage whistleblowers to ensure a check on business operations.
- To manage non-financial risk, particularly to brand, reputation, performance and instability as an integral part of corporate sustainability management.
- To promote and regularize welfare practices for the greater good of the society.
- To control the perils of uncontrolled development, satisfy the needs of the present generation and at the same time ensuring that the resources for future generations are not jeopardized.

What is needed is a joint effort by the government and civil society i.e. People, NGO’s, NPO’s etc to make CSR a success. The need is regarding awareness and encouragement of corporate sustainability and corporate philanthropy from NGO’s and civil society to ensure that business operations are sustainable. It is expected from business houses to realize that money and profit is the primary but not the ultimate aim of a business rather it is service and welfare of the society.

Recommendations with Special Reference to Pharmaceutical Industries

CSR is an essential element of Corporate Governance in today’s world. No industry is expected to show altruistic behavior and forgo its commercial objectives. But, implementing CSR measures is an equally important and vital part of the functioning of every corporate entity. The pharmaceutical sector is no exception and like any other industry it would also try to maximize its profit. However, as pointed out earlier pharmaceutical industry stands on a different footing altogether and its activities are capable of causing severe consequences if not directed towards the common good of society. A rigid patent regime would make the situation even worse. In light of this it becomes essential that we recognize the importance of compulsory licensing.

Compulsory licensing under Article 31\textsuperscript{144} of Trips

\textsuperscript{144} Article 31 Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;
(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making
After determining the various examples and case studies about pharmaceutical Industries observing CSR practices for the welfare of the people at large. In the following chapter the researcher has given role and legal position of Nuclear corporations in case of Nuclear disaster and how can, nuclear corporations can mitigate disaster through CSR efforts.

a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
(d) such use shall be non-exclusive;
(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;
(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:
(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and
(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.