

# Ethics in the international marketing of pharmaceuticals

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*This Master's Thesis is carried out as a part of the education at the University of Agder and is therefore approved as a part of this education. However, this does not imply that the University answers for the methods that are used or the conclusions that are drawn.*

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## Abstract

The pharmaceutical industry offers valuable products that may positively affect the lives and well-being of people. The industry has been criticized for enormous profits, which some often link to unethical decisions. This paper will concern the international marketing of pharmaceutical products, and factors such as prices, patents, government and regulation, information asymmetry, as well as how cultural differences may lead to certain challenges. Corruption is a part of unethical acts, and it is an important phenomenon, as corrupt decisions may drastically affect the well-being and daily lives of millions of people around the world. Corruption will be defined, as well as corruption in the pharmaceutical sector, as the pharmaceutical sector is a vast, several hundred-billion dollar industry. Sadly, the counterfeit/substandard drug trade has risen to become a \$75 billion dollar industry as well, and it will be discussed what corporations and governments can do to ensure fair, ethical conduct of business, and how to ensure that the end-consumers get the real product. The purpose of this paper is to look deeper into the factors involved in international marketing, the ethics involved, how corruption may occur in the pharmaceutical industry – how to combat it, and what an international marketer must be aware of when navigating the landscape of the pharmaceutical sector.

Key words: Pharmaceutical sector, international marketing, ethics, inadequate institutions, patent laws, corruption.

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## 1.0 Introduction

*“It is clear that the pharmaceutical industry is not, by any stretch of the imagination, doing enough to ensure that the poor have access to adequate medical care.”*

- Paul Farmer, co-founder of Partners In Health and editor-in-chief of Health and Human Rights Journal

*“Advances in medicine and agriculture have saved vastly more lives than have been lost in all the wars in history.”*

- Carl Sagan, *The Demon-Haunted World* (1996), p.11.

The purpose of this paper is to discuss the ethical marketing of pharmaceuticals, and how corruption in the pharmaceutical sector may occur. Theories and articles concerning the ethical marketing of pharmaceuticals and corruption in the pharmaceutical industry will be analyzed, to get a better understanding of how pharmaceuticals are marketed. The phenomenon in question – ethics in the international marketing of pharmaceuticals is important, as drugs has helped numbers of people – beyond count – all around the world.

The standard of living has risen drastically in modern times, along with general health. The average lifespan of a human being has increased from 60 years to 75+ (at least in the developed world), due to progress in the medical field. The pharmaceutical sector offers a valuable service, but it has always been criticized; both when it comes to marketing practices, the conduct and corruption – but nevertheless, pharmaceuticals are very important products that may be the determinant in life-or-death situations for millions upon millions of people around the world.

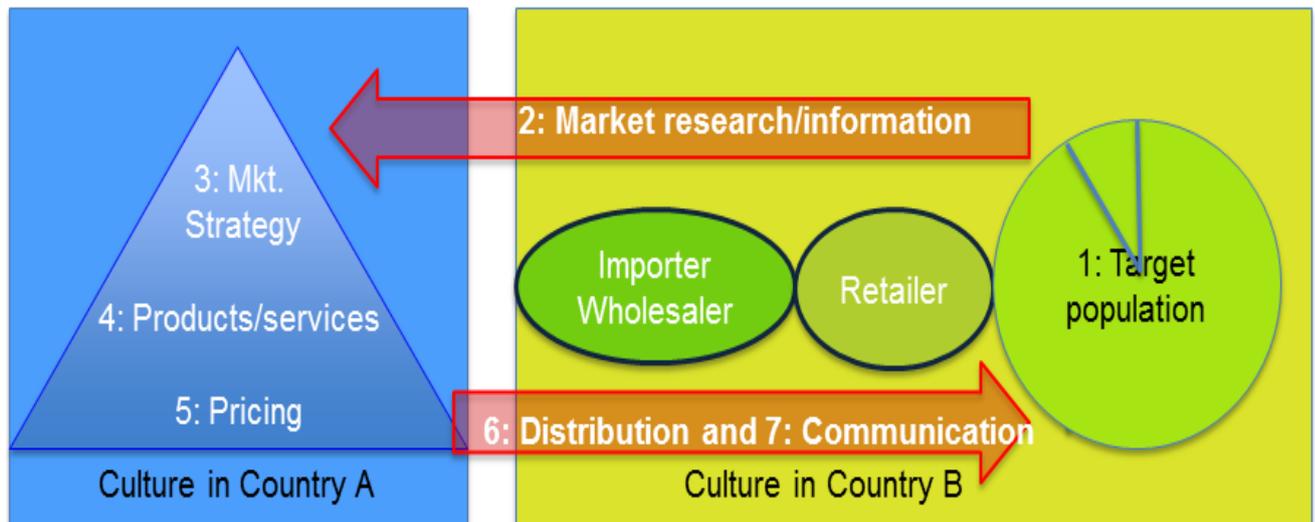
This paper will concern how pharmaceuticals are marketed, from producer to distributor, doctors/physicians, and to the end consumer/patients, and the influence the pharmaceutical companies has on the medical profession and the industry. Government regulation, legislature and institution, how the pharmaceutical products are being patented and priced – as well as the conflict of interest that may occur within the medical profession, and the information asymmetry that exists between the industry and the consumers (patients) will also be discussed.

By exploring the definitions of marketing, pricing, ethics, patent protection and corruption, both in general - and in the pharmaceutical sector, it will be discussed how to get an even better understanding of the pharmaceutical sector. The pharmaceutical industry is susceptible for corrupt practices, the paper will shed light on what an international marketer should be aware of, to ensure the product is being marketed and distributed in a sound, ethical fashion. The pharmaceutical sector is often portrayed as unethical, greedy and excessively profitable, which will also be discussed, to get a better understanding of the critic's, and the industry's point of view. The theories will be discussed

A significant portion of the paper will address corruption, as it is the ultimate form of unethical acts, and a framework for identifying corruption in the pharmaceutical industry will be presented. It is important to address the fact that corruption in the pharmaceutical sector has risen drastically in recent years, mostly due to substandard and counterfeit drugs flooding the market, as well as how pharmaceutical products are being marketed. The environment an international marketer has to navigate - when dealing with pharmaceuticals in the international marketing setting, will be assessed. As Transparency International puts it in a document on their website; *“The pharmaceutical system is susceptible to corruption for a variety of reasons. One of the most significant is the degree of government involvement in its regulation: studies from other sectors have found that the incidence of corruption is noticeably higher when the state retains a major involvement in the economy and its bureaucracy is pervasive. Without robust institutional checks, government regulators can make discretionary asymmetries exist between patient and physician”* (Cohen, 2006, in Transparency International).

# Theories & Discussion:

## 2.1 International marketing:



(Lecture #1 in International Marketing, Falkenberg, A., 2012)

Albaum & Duerr provides a simple definition of international marketing: “*international marketing is the marketing of goods, services, and information across political boundaries. Thus it includes the same elements as domestic marketing: planning, promoting, distributing, pricing, and support of the goods, services, and information to be provided to intermediate and ultimate consumers.*” (Albaum & Duerr, *International marketing and export management*, 2011, p.21) International marketing is typically more complex than domestic marketing because of the need to accommodate key differences between the environment in the “home” country’s domestic environment and the environment in the foreign market. The differences may include culture, consumer behavior, economic situation, market structures and the channels available, how business is conducted, and laws and regulations. These factors can render the company’s domestic approach ineffective (or even illegal) in the foreign market. The differences between the domestic and foreign market requires one to undertake a careful and well-planned approach when entering a foreign market or expanding internationally (Albaum & Duerr, 2011).

Marketing effectively in and to a foreign environment requires a clear understanding of each target market, the differences between them, and what accommodations must be done - fortunately there is information available on nearly every market in the world. The costs of acquiring this information, with regard to time and effort, can be expected to be far lower than the costs of making a mistake. There are facilitating organizations that can provide assistance in most aspects of marketing, though the effectiveness and costs may vary widely from country to country. Companies that provide assistance specifically for exporting and the legal and logistical aspects of importing are widely available – but in the end, it is the marketing manager’s responsibility to develop an effective approach to the target markets (Albaum & Duerr, 2011). *“It is also of great importance that top management be aware of all requirements so that adequate support can be provided. The business activities that must be carried out in marketing include the following:*

*- The analysis of markets and potential markets;*

*- The planning and development of products and services that consumers want clearly identified in a suitable package;*

*- The distribution of products through channels that provide the services or conveniences demanded by purchasers;*

*- The promotion of products and services - including advertising and personnel selling - to inform and educate consumers about those products and services, or persuade consumers to try new, improved, or different ways of satisfying their wants and needs;*

*- The setting of prices that reflect both a reasonable value (or utility) of products or services to the consumers, as well as a satisfactory profit or return on investment;*

*- The technical and non-technical support given to consumers - both before and after a sale is*

*made - to ensure their satisfaction, and thus pave the way for possible future sales that are necessary for company survival, growth, and perpetuation;*

*- The organizational structure, management, and remuneration of foreign employees.”*

(Albaum & Duerr, *International marketing and export management*, 2011, p.23-24)

One might say internationalization has three key points: a process, an end result, and/or a way of thinking. As a firm becomes more involved to serving markets outside of its home country, it becomes internationalized – this may be a planned process, or it may be the result from new opportunities and/or threats (Albaum & Duerr, 2011). *“For the international marketer, internationalization is most effective when developed as a carefully planned process for increasing penetration of international markets. In entering target markets, companies have traditionally begun with exporting, later developed a sales subsidiary abroad, and finally developed production facilities abroad. Licensing may be used as an initial entry strategy for some companies, and at later stages for others. Strategic alliances may be formed. Whatever the approaches used they should be carefully thought out, with advantages and disadvantages carefully analyzed, before implementation”* (Albaum & Duerr, *International marketing and export management*, 2011, p.24)

Albaum & Duerr also writes that the terms: international, multinational and global, are used frequently in international marketing. The three terms may seem to be rather similar, but it helpful to distinguish between them – as they represent differences in marketing strategy. International marketing may refer to the marketing that is done in foreign nations, and it can include exporting a single product to one country – to exporting a number of products to several countries. Multinational marketing used to be a term to describe companies who focused more on international marketing – and who treated the foreign markets as separate, creating strategies and products suited for each respective market. (Albaum & Duerr, 2011)

Levitt (1986) suggested that global corporations would treat the entire world, or a region, as a single entity. These corporations would sell their products in the same way all across the globe – and thus the term global marketing came into use. Levitt noted that the preferences of people around the world would become more similar, and argued that people would accept these products – if the price and quality was right (Albaum & Duerr, 2011) *“The economies of scale in producing and marketing a product in the same way worldwide would produce*

*substantially lower costs, and thus allow lower prices that would overcome remaining differences in tastes*” (Albaum & Duerr, *International marketing and export management*, 2011, p.25). Coca-Cola, Pepsi and McDonalds are great examples of global marketing. Coca-Cola is available nearly everywhere in the world, and there are few people who has never seen a Cola bottle or never heard about the product. McDonalds as well, where you can go into a McDonald’s restaurant located anywhere in the world – and still get the same standardized product (with the exception of Israel – where it has to be kosher, and India – where cows are considered holy). Pharmaceuticals on the other hand, are standardized products, and if you buy/get prescribed a certain brand name, you have several expectations – like Viagra or Paracetamol. Pharmaceutical products are more or less the same world-wide, but the methods of marketing differ from market to market. Some have restrictions on advertising/commercials for pharmaceuticals (like Norway) – whilst other nations, like the U.S. advertise openly for prescription drugs, encouraging consumers to buy the products.

The following part is an analysis of the previous theories, using the article *When in Rome ... Moral maturity and ethics for International Organizations* (2004), by Andreas Falkenberg.

Falkenberg writes: “*During the past 30 years, we have seen the emergence of very different views of the firm. From micro-economics and in finance we have seen the emergence of transaction cost economics and principal agent theory, both of which assume that man is opportunistic, selfish and not necessarily honest. We therefore need to create control systems (sticks) and incentive systems (carrots) which promote and protect the welfare of the owners or of society as a whole from opportunistic managers. The emerging area of corporate governance addresses these problems at the intersection between strategy and finance. This view assumes that individuals are selfish egoists and must be carefully controlled. The desirability of the carrots may have been stronger than the fear of the sticks in the cases of Enron, Parmalat and perhaps for some of the Russian oligarchs*” (Falkenberg, 2004, p.2).

When it comes to the *ethical egoist* view of ethics, one may think of Multinational Corporations (MNC’s) as they have been seen as economic powerhouses who are pursuing their own interests - with little regard for the happiness of people and the environment. “*This impression is consistent with a narrow view of the economic man’s self-interested behavior taught in many business schools*” (Falkenberg, 2004, p.2). According to transaction cost economics, man is opportunistic i.e. “*self-interested seeking with guile, to include calculated efforts to mislead, deceive, obfuscate and otherwise confuse*” (Williamson, 1994, p. 102 in

Falkenberg, 2004, p.2). The principal-agent model (PAM) also contains similar assumptions, where the agent is assumed to have no moral barriers against dishonest behavior, as well as effort aversion and deceitfulness (Bøhren, 1998; Jensen and Meckling, 1976 in Falkenberg, 2004). Another statement is that “*Business schools tend to recruit a disproportionately high number of self-interested students*” (Frank et al., 1993 in Falkenberg, 2004, p.3). “*The schools may reinforce this view and the students may conclude that if everyone thinks it is normal behavior to cheat and deceive, then people will cheat and deceive without feeling guilty*” (Noreeen, 1988 in Falkenberg, 2004, p.3). Managers learn that people they deal with inside or outside the firm should not be trusted, as they are expected to cheat if they can. This makes it indirectly OK to cheat – if you do not get caught – as the behavior is expected. Managers are also taught to work for their own benefit – and the owner’s, and these two benefits are often linked through incentive programs that are connected to the manager’s economic interests. Falkenberg also states: “*If it is legal, go ahead and do it, use cost/benefit analysis as a (moral) guide. Pay as little as possible and charge as much as possible. In Kohlberg’s scheme this would be a relative primitive version of the “sticks and carrots” view of moral development. It would be hard to argue that this view represents a set of desirable ethical guidelines for a firm; be it in the less- or more developed economies*”(Falkenberg, 2004, p.3). The modern version of the ethical egoist view is not quite the same as the ideas produced by the “fathers” of *utilitarianism* and economics - and how they looked upon markets and competition. John Stuart Mill described Utilitarianism as a way to produce as much good as possible, for all, at a macro level (Falkenberg, 2004).

“... *for that standard is not the agent’s own greatest happiness, but the greatest happiness altogether ... (happiness) secured to all mankind; and not for them only, but so far as the nature of things admits, to the whole sentient creation*” (John Stuart Mill, 1863 in Falkenberg, 2004, p.3).

John Stuart Mill and Adam Smith were rather skeptical to the pursuit of one’s own happiness without regarding the common good: “*Next to selfishness, the principle cause, which makes life unsatisfactory, is want of mental cultivation... As little is there an inherent necessity that any human being should be a selfish egoist, devoid of every feeling or care but those which center on his own miserable individuality*” (John Stuart Mill, 1863 in Falkenberg, 2004, p.3).

“*The interest of the dealers ... is always in some respects different from and even opposite to that of the public ... The proposal of any new law or regulation of commerce which comes*

*from this order ought always be listened to with great precaution, and ought never to be adopted till after having been long and carefully examined, not only with the most scrupulous, but with the most suspicious attention. It comes from an order of men whose interest is never exactly the same with that of the public, who have generally an interest to deceive and even to oppress the public, and who accordingly have, upon many occasion both deceived and oppressed it”* (Adam Smith, 1776 in Falkenberg, 2004, p.3).

These comments may still be relevant today and their statements have been confirmed numerous times, from the era of the robber barons (e.g. Lewis, 1951 in Falkenberg 2004) to the failures of Parmalat and Enron case (e.g. Watkins and Schwartz, 2003 in Falkenberg, 2004). If the morality of large firms were described by the selfish-egoist view, one should regard the MNC’s with suspicion (Falkenberg, 2004).

Smith and Mill also pointed out the benefits of having *“markets and competition, the unrestricted mobility of resources to their most productive use (Smith) and that a test of ethics must imply that good outcomes have been created for the whole creation (Mill)”* (Falkenberg, 2004, p.3). Smith and Mill were not fond of people or organizations that disregarded the interest of the public – but – human rights were not regarded highly by utilitarians. Jeremy Bentham commented on human’s natural rights as *“nonsense upon stilts”* (cited in Almond, 1993 in Falkenberg, 2004, p.3). Ethical egoism and utilitarianism are both consequentialist perspectives that use cost/benefit calculations - however, classical utilitarianism is more about maximizing overall happiness over time and not the short term happiness of an individual or firm (Falkenberg, 2004)

*“From the behavioral disciplines in business schools like strategy, management and marketing literature, we have seen an increasing emphasis on the long term perspective regarding the relationships between individuals and firms, and the value of trust and commitment in such relationships”* (e.g. Arndt, 1979 in Falkenberg, 2004, p.4). This is represented by brand building, networking firms and relationship marketing. Opportunism, selfishness, and deceit are not beneficial to long-term relationships, trust, generosity and honesty. The view that man is more long-term oriented is more in line with John Stuart Mill’s view of utilitarianism maximizing the happiness for the whole sentient creation. Falkenberg also notes *“an organization depends on the trust of its stakeholders for long-term survival”* (Freeman, 1977 in Falkenberg, 2004, p.4). Stakeholders involved are owners, customers, suppliers, business-partners, governments, NGO’s, local communities, the public at large, and

last but not least, employees. *“The ethical failures that we have seen in the recent past have been due to excessive regards for the interests of the management at the expense of the interests of owners and other stakeholders. One cannot think of very many who would want to transact with people or organizations they could not trust”* (Falkenberg, 2004, p.4). Trust is *“the cement of society”* (Elster, 1989 in Falkenberg, 2004, p.4). *“Trust is the expectation that arises within a community of regular, honest and cooperative behavior, based on commonly shared norms on the part of other members of that community”* (Fukuyama, 1995, p.26 in Falkenberg, 2004, p.4). Trust can be viewed as common expectations in a culture - or adhering to conventions. Recruiting and holding on to investors, employees, suppliers and so forth would be rather difficult if there was a lack of trust. *“Without trust, transaction costs would skyrocket and our ability to transact efficiently would be seriously impaired thus result in a disintegration of our economy”* (Falkenberg, 2004, p.4). Firms often invest heavily in their own reputation and brand name to make sure they live up to the promises and expectations related to their reputation and brand name (Falkenberg, 2004)

If we did not trust the products we use every day, life would be intolerable – for us as consumers - and for the corporations. We trust our banks, the food we eat, the homes we live in, the cars we drive and our computers to do the jobs we expect of them. *“I may not have high expectations of what a given fast restaurant will serve, or how a computer program will perform – but as long as they produce what I expect – there is trust – or at least a degree of predictability. This may be called an enlightened view of self-interest”* (Falkenberg, 2004, p.4). It is “good” for a firm to have good and trusting relationships with its key stakeholders, and this may in the long-run also benefit the owners. Saying that the only Corporate Social Responsibility (CSR) that a firm has is to maximize profit for its owners may not be at odds with the way the stakeholders view the firm. Setting the rules of the game is up to civil society, to create the institutions that govern the actions of firms – and it is up to the business to maximize wealth within these rules. One can say that “ethics pays” in the long term - thus the challenge is to provide the sticks and carrots and governance mechanisms, which promote the long-term welfare for all (Falkenberg, 2004).

When entering a foreign nation with different norms, values and practices from the “home country”, corruption may occur. In regards to the pharmaceutical sector, one phenomenon which has occurred in recent years is the counterfeit drug trade. The counterfeit trade – or “fake drug” trade has skyrocketed over the last 10 years. The products are being marketed as substitutes or imitations of already known pharmaceuticals – often offering the “same”

product at a significantly lower price. In some cases, pharmacies/hospitals/physicians have ordered specific pharmaceutical products, and somewhere along the line of distribution, the real product has been replaced by a “bogus” product. This is a form of corruption, as the producer/imitator is literally offering garbage to the end customer, which may severely affect their health and well-being. Albaum & Duerr notes: *“Owners of trademarks must be on the continual lookout for imitation or even outright piracy of brands that are exported to foreign countries. This is the growing problem of counterfeit trade, which is the practice of attaching brand names or trademarks to “bogus” products or services, thereby deceiving customers into believing that they are purchasing the legitimate brand name or product of the owner of the trademark”* (Albaum & Duerr, *International marketing and export management*, 2011, p.635).

*“National governments are concerned with this problem, but it is difficult to resolve. To a large extent the exporter itself will have to “police” its foreign markets in order to detect counterfeiting of its products. Then government can step in. Some companies are starting to incorporate high-technology things in their products as a means of distinguishing the real from the fake”* (Albaum & Duerr, *International marketing and export management*, 2011, p.636).

## 2.2 Case example: Abbot Laboratories

The following case is an example of a real-life ethical issue in the marketing of pharmaceuticals, where the Abbott Laboratories (one of the “big” pharmaceutical companies) and the government of Thailand were in conflict over a patented drug being sold as a generic. The case is presented in “*Business Ethics: Concepts and cases*” by Velasquez, 2012, p. 152-154.

*“Many critics of free trade have argued that the international agreements and institutions that make free trade possible benefit global businesses, but harm the world’s poor and powerless. To understand these criticisms, consider, how Abbott Laboratories responded when Thailand’s government announced a new policy designed to provide its poorest people with a life-saving drug. On March 21, 2007, Abbott Laboratories, a U.S. drug manufacturer with annual revenues of \$26 billion and profits of \$4.5 billion, angrily announced it would now allow seven of its unique new drugs to be sold in Thailand, including the HIV/AIDS drug Aluviathat that, unlike similar drugs, did not have to be refrigerated in Thailand’s hot climate. Abbott was punishing Thailand who had decided to make a cheap version of Kaletra, a drug that Abbott had developed and to which it held the patent. The head of the AIDS Healthcare Foundation said: “I am horrified that Abbott would deprive poor people in need of lifesaving medications, particularly for those living with HIV/AIDS, in a country as hard-hit by the epidemic as Thailand”” (Velasquez, 2012, p.153-153).*

*“With about 600 000 of its people sick with HIV/AIDS and an average annual income of only \$ 2190 per person, Thailand was struggling to provide its HIV/AIDS patients with medications called “antiretrovirals”. Although HIV/AIDS is incurable, in 1996 scientists discovered that if HIV patients regularly took a combination of three “antiretroviral” drugs, the amount of the HIV virus in their bodies declined to where they could live healthy normal lives. But drug companies charged so much for the combination of antiretroviral drugs - \$10 000 to \$15 000 per year in year 2000 – that AIDS victims in poor developing countries could not afford them. In 2001, however, Cipla, an Indian drug Company, began to make “generic” versions of the antiretroviral drug combinations for as little as \$350 for a year’s supply and by 2007 its price was below \$100. A “generic” drug is a chemically equivalent copy of a brand-name drug, but the company that makes it does not own the patent to the drug. Large drug companies discover, develop, and test new brand name drugs at an*

*estimated cost of about \$800 million per drug. A company with a new drug can ask its government for a “patent” for the drug, and if granted, the patent recognizes that the drug formula is the property of the company and that it alone has a right to make that drug for a set number of years. The large U.S. and European drug companies held that without patents and respect for their property rights, they could not recover, and would have little incentive to pay, the huge costs needed to develop and test new drugs, and drug research would come to an end. The drug companies therefore objected to Cipla’s action, especially when Cipla started to sell the low-priced generic versions of their drugs to other poor countries”* (Velasquez, 2012, p.153).

Before 1994, patents in the U.S. gave only 17 year of protection for a new drug, - in the U.S. In the 90’s, the WTO was being formed, and drug companies in the U.S. started to lobby – targeting the government. The main purpose of the lobbying was to pressure the U.S. government to include patent laws in the WTO, and the drug companies made generous donations to politicians and government officials – who then in turn insisted that all members of the WTO had to adopt the strict patent and copyright laws that existed in the U.S. Poorer nations objected to this, but in 1995 when the WTO was “official”, the rules included TRIPS – Trade Related Aspects of Intellectual Property Rights – which was modeled on the U.S. patent and copyright laws, and required all member states to adopt them (Velasquez, 2012).

A non-WTO member country would have a difficult time to sell goods to WTO nations, so the majority of nations joined the WTO – even though they were against TRIPS. TRIPS ensured that a patent given to a company by a WTO member had to be respected by all member states for 20 years. India and Brazil, the least developed/poorest nations, did not have to comply with the TRIPS laws before 2006 – later extended another 10 years. Article 31 in TRIPS allowed an exception to the patent rules, where poorer nations did not need the authorization of the drug companies to make a patented drug – but only in case of circumstances of extreme urgency or national emergencies (Velasquez, 2012).

The WTO issued a ruling in 2001, stating that article 31 in TRIPS allowed a poor nation to give its own drug companies a “compulsory license” to make patented drugs, to protect the health of the people. If a poor country was not able to manufacture the drug themselves, they could import the patented drug from another poor country instead – given the other poor country also had a “compulsory license”. The WTO also stated that each nation had the right to determine “the grounds upon which such licenses are granted” (Velasquez, 2012, p. 154).

Going back to the case, Velasquez continues with: *“U.S. and European pharmaceutical companies had lobbied hard to defeat Article 31, but in the end enough WTO countries supported it and it had become an official WTO rule. The U.S. and European drug companies, however, vowed they would continue to oppose the rule and its use, especially by a company like Cipla that claimed TRIPS rule allowed it to make and sell cheap copies of their patented drugs. On January 25, 2007, Thailand announced that it was issuing a “compulsory license” to one of its own government-owned drug companies so it could make a generic version of Abbott’s Kaletra. Kaletra was one of a new group of expensive “second-line” antiretroviral drugs Abbott had developed and patented. When an AIDS victim began treatment, the antiretroviral drugs he or she received was called a “first-line” treatment and it was relatively cheap since companies like Cipla could provide cheap generic versions. Often, however, the patient’s HIV became resistant to the first-line drugs, and they stopped working. The patient then had to be given the newer antiretroviral drug combinations that were called a “second-line” of treatment that were expensive since only the large drug companies were making those. Thailand’s government estimated that about 80 000 of its AIDS victims now needed a “second-line” drug like Abbott’s Kaletra. However, it said, it could not afford even the “discounted” price of \$2200 Abbott insisted poor countries had to pay for a year’s supply of Kaletra”* (Velasquez, 2012, p.154).

*“Abbott Laboratories said that if Thailand started making a version of Kaletra, it would be taking Abbott’s property since the company held the patent and it had discovered, developed, and tested the drug using several hundred million dollars of its own money. Moreover, Abbott said, under its interpretation of TRIPS, Thailand had no right to ignore Abbott’s patent simply because it did not want to pay for the drug; reluctance to pay did not constitute an “emergency”. The head of Doctors Without Borders in Thailand said that of Abbott’s position: “For me, it’s just evil. It’s appalling... It reflects so badly on the multinational companies”*” (Velasquez, 2012, p.154).

Poorer nations often argue that the new free trade rules aids multinational companies, and are disadvantageous for poor countries. The poor countries say that large MNCs, like the big pharmaceutical companies have influenced the rules that controls international, and that they bend the rules into serving their own interests (Velasquez, 2012). Velasquez notes: *“In the name of free trade, the rich nations have forced the poor nations to accept rules that benefit the companies of the rich nations, while ignoring the welfare of the people of poor nations. Moreover, critics argue, new forms of property – such as patents on drugs – have been*

*developed that seem to actually conflict with free trade, since they restrict the free flow of the formulas and knowledge that constitute these new forms of “intellectual property”. These controversies over globalizations and free trade are but the latest episodes in a great and centuries-long moral debate: Should governments impose restrictions on business activities and economic exchanges, or should they leave business firms free to pursue their own interests within free markets, and allow them also to trade freely with members of other nations? Do governments align themselves with the interests of wealthy corporations, and if so, is it right for them to do so? One side argues that free markets and free trade are defective because they cannot deal with many of the problems business activities create, such as unfair competition, global pollution, unfair labor practices, sweatshops, discrimination, and disregard for the wellbeing of the poor. The other side argues that government restrictions on business are bad because they violate their property rights and right to freedom, lead to unfairness, and leave us all worse off” (Velasquez, 2012, p.154-155).*

One popular case when it comes to restricting government in the markets is the idea that humans have “natural rights” – and only a free market can protect these rights. Free markets are supposed to protect two natural things: the right to freedom and the right to private property (Velasquez, 2012). *“Free markets are supposed to preserve the right to freedom insofar as they enable each individual to voluntarily exchange goods with other free from the coercive power of government. They are supposed to preserve the right to private property insofar as each individual is free to decide what will be done with what he or she owns without inference from the government”* (Velasquez, 2012, p. 157).

John Locke (1632 – 1704), is considered the father of the idea that human beings have natural rights to liberty and natural rights to private property. Locke argued that without governments, human beings would live in “*a state of nature*” where each individual would be equal (politically) and would have no constraints apart from the laws of nature – “the moral principles that God gave to humanity and that each individual can discover by use of God-given reason“ (Velasquez, 2012, p.157). Locke describes a state of nature as:

*“A state of perfect freedom to order their actions and dispose of their possessions and persons as they think fit, within the bounds of the law of nature, without asking leave, or depending upon the will of any other man. A state also of equality, wherein all the power and jurisdiction is reciprocal, no one having more than another... without subordination or subjection to another...But...the state of nature has a law of nature to govern it, which obliges*

*everyone: and reason, which is that law, teaches all mankind, who will but consult it, that being all equal and independent, no one ought to harm another in his life, health, liberty, or possessions” (Locke in Velasquez, 2012, p. 157-158).*

Locke explains that the law of nature will “teach” that everyone has a right to liberty, and “no one can be put out of this natural estate and subjected to the political power of another without his own consent” (Locke in Velasquez, 2012, p. 158). The law of nature also tells us that we are the sole owners of our bodies, labor, the products of labor, and that these rights to ownership are natural, alas: “they are not invented or created by government nor are they the result of a government grant” (Velasquez, 2012, p. 158).

Velasquez analyzes the Abbott Laboratories case using Locke’s principles, and states: “Recall that Abbott withheld several lifesaving drugs from Thailand’s people when their government announced its intention to manufacture a drug that Abbott had patented. Abbott claimed that Thailand was “stealing” the company’s “intellectual property”. Regardless of what any government or other ruling body might say, Abbott insisted, it had created the formula for the drug and invested the money needed to develop it, and so it was Abbott’s property and no one else had a right to use it without Abbott’s authorization. Abbott’s position was based on the Lockean view that that private property is created by one’s labor and not by government. The right to property, like the right to liberty, are prior to, or more basic than, government’s authority and, as Locke insisted, government is created to protect these fundamental rights. The head of a pharmaceutical association that represented Abbott and other multinational drug companies said: “After the company does 10 years of research, and then suddenly the Thai government would like to impose a compulsory license, taking away the their property, their assets – this is not right.” Thailand’s government, on the other hand, issued a report in which it stated that it had “fully complied with all the national and international legal frameworks”, including TRIPS. It pointed out that the World Trade Organization had explicitly declared that to protect its citizen’s health, a country could issue a compulsory license and manufacture a drug without the authorization of the company that held the patent. Consequently, Thailand said, it was not wrong to manufacture the drug even though Abbott held the patent since the legal framework that created the patent and turned the drug formula into a form of “property”, explicitly allowed them to use the formula. Thailand’s view, then, was that property rights are created by government and its laws, a view that is decidedly un-Lockean” (Velasquez, 2012, p. 159-160).

*“Also unlike Locke, Thailand held that property rights are not absolute. Thailand said in its report that its decision was based on its “commitment to put the right to life above trade interests”. Property rights, then, are limited to “the right to life” because human life is more important than the international rules that protect “trade interests” by protecting property rights. The views of both Abbott Laboratories and Thailand, then, were shaped by their ideologies, i.e., by their views about which rights are most basic, about the purpose of government, and about the nature of private property” (Velasquez, 2012, p.160).*

This case is just one of many examples where drug companies have been in conflict with governments. Another example is GSK – GlaxoSmithKline, a British drug manufacturer that has been in several trials in the U.S. after several cases of dubious conduct, and sometimes outright illegal actions. The case of GlaxoSmithKline will be used later, as it is more relevant to unethical practices, such as marketing drugs for off-label usage.

### 3.0 Pricing, ethics and patents in the pharmaceutical industry:

The following is based on the works of Schlegelmilch, in the book *Marketing Ethics: An international Perspective* (1998)

*“A perennial ethical question for the pharmaceutical industry has been the aggressive pricing policies pursued by most large drug companies. Criticism has intensified in recent years over the high cost of new conventional ethical drugs and the steep rise in prices for many drugs already on the market. One result of this public clamor is that the pricing structure of this industry has once again come under intense scrutiny by government agencies, Congress, and the media.”* (Spinello, 1992 in Schlegelmilch, 1998, p.341) It is often claimed that the high prices - and the following high profits, are unethical and unreasonable, and that pharmaceutical companies could allegedly offer cheaper products without limiting R&D. *“It is quite difficult to assess, however, what constitutes an unethical price or an unreasonable profit. Where does one draw the line in the nebulous areas?”* (Spinello, 1992 in Schlegelmilch, 1998, p.341)

*“The major pharmaceutical companies strongly resist any form of regulation as a serious threat to the stability of their powerful industry. This industry has consistently put forward the same arguments for high prices - these focuses on the premise that premium prices are justified due to the excessive costs of developing new drugs”* (Spinello, 1992 in Schlegelmilch, 1998, p.343). This is based on the principle “high risk – high reward”. There are risks involved in the R&D when developing drugs – especially since only a few of these drugs make it through the expensive development process. *“Moreover, even if a drug is a commercial success, there is always the impending threat of product liability problems that earnings received from breakthrough drugs such as AZT (azidothymidine – an antiretroviral drug, used in the treatment of HIV/AIDS) are necessary to stimulate future research and compensate for many commercially unsuccessful drugs”*(Spinello, 1992 in Schlegelmilch, 1998, p.343). The pharmaceutical industry’s financial performance has been superior in recent years, and studies which compare the performance on a number of U.S. industries has shown that the pharmaceutical industry consistently top the charts when it comes to return on sales, return on assets and return on common equity (Schlegelmilch, 1998). *“For example, the drug industry currently boasts a return on sales of 20 per cent (1998). Also, its return on common equity of 31, 9 per cent compares quite favorably with the average return of 11, 7 per cent*

*and is the highest of all the industry groups tracked by Business Week (1991). These figures reveal that at least according to some criteria drug companies and their stockholders are receiving substantial returns for the risks they take” (Spinello, 1992 in Schlegelmilch, 1998).*

### 3.1 Ethical questions:

Spinello (1992 in Schlegelmilch, 1998) also notes that ethical or fair pricing is more significant when the product is such an essential and life-saving one such as pharmaceuticals, and not a luxury item. *“Few are concerned about the ethics of pricing a BMW or a waterfront condo in Florida. But the matter is quite different when dealing with vital commodities like food, medicine, clothing, housing and education. Each of these goods has a major impact on our basic well-being and our ability to achieve any genuine self-fulfillment”* (Spinello, 1992 in Schlegelmilch 1998).

Since these products are so important for the lives of human beings, the pricing – which leads to availability, must be considered. Several questions can be raised, such as: Should the free market decide the price of potentially life-saving products such as pharmaceuticals? Given the importance of these products in the lives of all human beings, one must consider how equitably they are priced since pricing will determine their general availability. Along these lines several key questions must be raised. Should free market, competitive forces determine the price of “essential” goods such as pharmaceuticals? If the market is willing to pay, is it wrong to charge high prices? Is it ethical to profit at the expense of suffering? And finally, what is the definition of reasonable profits? The pricing issue must be considered in the context of the pharmaceutical industry’s guidelines on return on assets, return on common equity, etc. (Schlegelmilch, 1998). *“On what authority are such targets chosen over other goals such as the widest possible distribution of some breakthrough pharmaceutical that can save lives or improve the quality of life? Pharmaceutical companies would undoubtedly content that this authority emanates from the expectations of shareholders and other key stakeholders such as members of the financial community. In addition, these targets are a result of careful strategic planning that focuses on long term goals”* (Spinello, 1992 in Schlegelmilch, 1998, p.344).

One important question occurs here: Should the needs of the poor and sick be taken into account – especially since the pharmaceutical products could mean life and death for them? *“As with many business decisions, there appear to be stark tradeoffs between superior financial performance versus humane empathy and fairness”* (Spinello, 1992 in Schlegelmilch, 1998, p.344). Should the “human cost” of the objectives of performance be considered? What role should justice and fairness take in pricing decisions?(Schlegelmilch, 1998) *“It is only by probing these difficult and complex questions that we can make progress*

*in establishing reasonable norms for the pricing of pharmaceuticals” (Spinello, 1992 in Schegelmilch, 1998, p.344).*

Falkenberg (2004) also offers a view on ethical maturity, using the theories of Kohlberg (1971). *“Kohlberg (1971) suggested six possible stages of ethical maturity. The two first stages are the pre-conventional stages. These can be described as a rather egoistic, or a “sticks and carrots” view of ethics. A child will typically try to avoid pain and seek pleasure. One may pay taxes because one fears the consequence of not paying, or one may speed between the speed traps. One may pay or receive bribes if the risk of discovery is low. A statement like “good ethics pays” may belong in this stage. It seems that much economic reasoning is based on this view. The following two stages are based on adhering to the conventions of one’s immediate group (stage three) or of society as a whole (stage four). It is important to do what the others are doing, follow fashion, get approval from ones immediate friends, ac as the local culture expects, do what the others do because “everybody is doing it...”. This could be called the ethics of the old boys club or the ethics of the group to which one belongs. If one follows local cultural conventions, then one is doing what most people consider to be right. The behavior meets with approval” (Falkenberg, 2004, p.18).*

*“In stages five and six, the post-conventional stages, one becomes more autonomous; deciding for oneself on a set of universal ethical principles to determine what is right. One may ignore the sticks and the carrots, and may even choose not to follow ethical principles because it is right to do so. Even if it is not customary to hire women into high level managerial jobs in Japan (by convention), and it may even be less profitable (cost/benefit) one may choose to do so anyway because it is wrong to keep this particular arena closed to women; it violates a basic ethical principle of equality. It will be argued that the pre-conventional “sticks and carrots view” is closely linked to much of what we teach in economics and finance in business schools. It is also similar to much of the reasoning used by firms. This kind of reasoning may require an expansive set of social controls, increase transaction costs and not be very efficient in promoting the greatest good for the greatest number. It will also be argues that conventional reasoning may be useful as moral guidance in jurisdictions with adequate background institutions. However, when in Rome, it may not be right to do what the Romans do if the local institutions allow feeding Christians to the lions. It will further be argued that both at home and abroad, one needs to make sure that economic*

*activities are beneficial and sustainable in the long term, which would require that one looks to sources of post-conventional ethics in order to know what is right and wrong” (Falkenberg, 2004, p.18).*

### 3.2 Free market vs. regulation:

*“Many would question the validity of basing drug prices on anything other than pure economic factors. Milton Friedman and his followers have argued persuasively that the only social responsibility of business is to increase profits. According to this “free market” philosophy, the responsible course of action is to charge whatever price the market will accept. This if the market will support an annual price of \$8000 a year for a drug such as AZT, that should be the end of the matter”* (Spinello, 1992 in Schlegelmilch, 1998, p.344-345). Schlegelmilch also notes that managers who do not price products to maximize profits are avoiding their duty to stockholders – and if the executives in the pharmaceutical industry were reluctant to raise prices due to a social objective, it would tax the shareholders (Schlegelmilch, 1998). *“When managers go beyond economic and financial data in their decisions they become political agents with a social agenda. This is regarded by Friedman as a pernicious state of affairs which will undermine the very foundations of our free society, “since managers lack the wisdom and ability to resolve complex social problems such as the equitable distribution of pharmaceutical products””* (Friedman, 1979: 90) (Spinello, 1992 in Schlegelmilch, 1998, p.345). This narrow view of CSR fails to realize that the decisions made by corporations can have a powerful impact on society. The decisions of large corporations *“inevitably involve social as well as economic consequences, inextricably intertwined”* (Mintzberg, 1989: 173 in Schlegelmilch, 1998, p.345). Firms become social agents whether it was intended or not, and it is hard to remain neutral on issues like these. It is a moral and social decision to determine prices – which will affect society. The corporations can choose to turn a blind eye or acknowledge the social consequences of their decisions – but by looking another way, when the damage is done, the public will protest (Schlegelmilch, 1998).

If a company chooses to take responsibility for the social actions they can inflict, they will have to treat the people affected as important “stakes” in their decision. *“The stakeholder model, which has become quite popular with many executives, allows corporations to link strategic decisions such as pricing with social and ethical concerns. By recognizing the legitimacy of its stakeholders such as consumers and employees, managers will better appreciate all the negative as well as positive consequences of their decisions”* (Spinello, 1992 in Schlegelmilch, 1998, p.345). *“Moreover, an honest stakeholder analysis will compel them to explore the financial and human implications of those decisions. This will enable corporations to become more responsible social agent, since explicit attention will be given to*

*the social dimension of their various strategic decisions” (Spinello, 1992 in Schlegelmilch, 1998, p.345)*

Schlegelmilch notes: *“Unfortunately, as outsiders to the operations of drug companies we are ill prepared to judge whether development costs for certain drugs are inflated or truly necessary. As a result, these corporations must be trusted to arrive at their own definition of a reasonable profit, given the level of legitimate costs involved in researching and developing the drug in question. But we can look to some case histories for meaningful examples that would serve as a guide to a more general definition. One of the most famous controversies over drug prices concerned the Hoffman-LaRoche Corporation as the United Kingdom in which the government’s Monopoly Commission alleged that Hoffman-LaRoche was charging excessive prices for Valium and Librium in order to subsidize its research and preserve its monopoly position. In the course of the prolonged deliberations between the British Government and the company, reasonable profits were defined as “profits no higher than is necessary to obtain the “desired” performance of the industry from the point of view of the economy as a whole” (Matthews et al., 1985). In general, then, under normal circumstances reasonable profits for a particular product should be consistent with the average returns if the rises and costs of development are inordinately and unavoidably high” (Spinello, 1992 in Schlegelmilch, 1998, p.350)*

Schlegelmilch also says: *“Thus, based on this Rawlsian ideal of justice, I propose the following thesis regarding ethical pricing for pharmaceutical companies: for those drugs which are truly essential the just corporation will aim to charge prices that will assure the widest possible distribution of these products consistent with a reasonable level of profitability. In other words, these companies will seek to minimize the deprivation of material benefits which are needed by all persons for their self-realization by imposing restraints on their egocentric interests in premium prices and excessive profits. Since only some pharmaceutical products can be considered as truly “essential”, it remains to be seen which of those products should be subject to the imperative of justice.” (Spinello, 1992 in Schlegelmilch, B., 1998, p. 350)*

### 3.3 Patents:

In 1984, the environment changed in the pharmaceutical sector, when the Drug Price Competition and Patent Term Restoration Act – also known as the “Hatch-Waxman Act” was passed.

The Hatch–Waxman shortened the approval process for generic drugs. *“To market a drug in the United States, a manufacturer must file a New Drug Application with the FDA, which includes data on safety and efficacy. Hatch–Waxman allows generics manufacturers to instead file an Abbreviated New Drug Application (ANDA), which relies on the safety and efficacy data submitted by the brand-name manufacturer. As part of its ANDA, a generics manufacturer must certify that its marketing of a drug does not infringe any lawful patent; if a relevant patent exists, the applicant asserts either that it's invalid or that it will not be infringed by the generic product — and in such a case must inform all patent holders of its claims. Patent holders then have the opportunity to sue the generics manufacturer for infringement”* (Hemphill, 2012, p.1682).

Sometimes, a patent holder who does not want to risk their market position nor participate in a lawsuit offers to pay the competitors to delay their marketing efforts of the competing product – *“until at least part of the patent period has elapsed”* (Hemphill, 2012, p.1682). This practice falls under the Sherman Antitrust Act – an act which restricts inter-company agreements that will unfairly interfere with competition. Paying a competitor to influence them to not enter the market is a violation of the Sherman Act – but the patents give the owners the exclusive right to market the specific patented product (Hemphill, 2012)

*“The first two courts that considered pay-for-delay agreements were dubious of their legality. In 2001 and 2003, respectively, the D.C. and Sixth Circuit Courts of Appeals considered an agreement by pharmaceutical company Hoechst consMarion Roussel (HMR) to pay generics manufacturer Andrx Pharmaceuticals \$40 million per year from the time Andrx's generic version of the calcium-channel blocker Cardizem (diltiazem) received FDA approval until Andrx began marketing its product or was found liable for patent infringement. Because another Hatch–Waxman provision gave Andrx (the first generics manufacturer to file an ANDA for diltiazem) a 180-day window of exclusivity from the time it received FDA approval, the agreement temporarily eliminated all HMR's competition. Both circuit courts viewed this*

*agreement as an illegitimate attempt to preserve monopolistic conditions” (Hemphill, 2012, p.1682).*

Subsequent courts had a different opinion, stating that a patent holder had the right to restrict competition in the market. *“According to rulings that the Eleventh, Second, and Federal Circuit Courts issued in 2003 to 2008, patent holders could make agreements with prospective competitors to get them to refrain from competing, because patents confer the right to stop competitors from marketing the products to which the patents apply” (Hemphill, 2012, p.1682).* This meant that the Sherman Act did not apply to the practice of “pay-for-delay” – as long as the delay paid for did not exceed the duration of the patent (Hemphill, 2012).

## 4.0 Conflict of interest and the influence of the pharmaceutical industry:

Kassirer (2005) notes, “*Without the willing engagement and active involvement of physicians*”, *the effects of many complicated conflicts between the medical profession and pharmaceutical industry would be diminished or eliminated*” (Kassirer, 2005 in Green, 2008, p.158.)

Thompson (1993) puts conflict of interest as “*a set of conditions in which professional judgment concerning primary interest (such as a patient’s welfare or the validity of research) tends to be influenced by a secondary interest (such as financial gain)*” (Thompson, 1993 in Green, 2008, p.159). “*The secondary interest does not pose a choice between competing values that characterize ethical dilemmas in medical decisions when each competing interest has a presumptive claim to priority (e.g. autonomy and paternalism if a patient requests termination of treatment). In contrast, only one of the interests and the goal is to ensure that the other interest (usually financial) does not dominate*” (Green, 2008, p.159).

A conflict usually depends on two factors: how likely it is that the secondary interest will affect professional judgment, and the harm this influence may cause. If a physician, intended or unintended, is involved in a conflict that goes against the standard of medical ethics, their behavior and conduct depends on: “*the degree to which their behavior detracts from the quality of health care and its cost, the integrity of research, and the profession’s integrity*” (Green, 2008, p.159). The pharmaceutical industry will now be assessed, by looking further into the relationship between the industry and physicians, medical institutions and governmental organizations – on a micro-level of the medical profession and a macro-level of society (Green, 2008)

#### 4.1 The impact on the medical profession:

**The impact of industry contact with trainees and practitioners:** Already in medical school, the members of the medical profession begins their relationship with the pharmaceutical industry, although the students often say that gifts do no influence – but research data does not support this view (Hodges, 1995 in Green, 2008). *“Reciprocity is central to persuasion that characterizes the interaction between pharmaceutical representatives (PRs) and physicians, as gifts foster a psychological indebtedness that consciously or unconsciously includes a sense of obligation in the recipient. And the omnipresence of PRs in academic medical centers (AMCs) has been demonstrated to have considerable impact on attitudes, knowledge and practices of physicians (e.g. prescribing patterns). Moreover, the degree of interaction between PRs and trainees correlates with the degree of contact with future practitioners, suggesting that a pattern, in process and content, is established during the nascent years of training”* (Green, 2008, p. 159)

**Education:** A large portion of the several billion dollars spent on continuing medical education (C.M.E) annually in the U.S. comes from pharmaceutical companies (Green, 2008). In Relman’s (2001) opinion, this is not an act of generosity or charity – but rather promotion of products and increasing profits (Green, 2008). *“An oft-quoted observation by one industry spokesman – “companies live through education” – supports this belief”* (Vergano, 2001 in Green, 2008)

*“The industry directly and indirectly funds a vast network of educational activities, primarily through medical education and communication companies (MECCs), for-profit organizations that produce CME programs and presentations for hospital rounds, and didactic materials for private practitioners. MECCs often prepare teaching slides and curriculum materials, ghost-write presentations for speakers, and subsidize trainees and practitioners to attend meetings”* (Green, 2008, p.159). Relman (2001) raises concern about the potential for bias – and a conflict of interest on the part of the pharmaceutical companies and the physicians hired by them (Green, 2008). This is supported by Kassirer (2005), who describes two situations of psychiatric education.” *He discusses an article that compares the efficacy of Celexa and Lexapro (produced by the same company), endorsing the latter as a superior medication. Of note is that Celexa was about to go off patent (and therefore become a less profitable product), the article was ghost-written, and the author, paid by the manufacturer as a*

*consultant, edited the journal in which it appeared. Kassirer also reports that physicians had accepted US \$1000 for signing their names to medical articles ghost-written by technical writers and submitted to neurology and psychiatry journals advocating off-label use of Neurontin. This particular example highlights a major reason that the industry sponsors educational activities” (Kassirer, 2005 in Green, 2008, p.159). In the U.S., it is illegal for companies to advertise medications for other uses than approved by the Federal Drug Administration (FDA) – now known as the Food and Drug Administration – but it is legal to use drugs off label (Green, 2008). “To bypass these regulations, companies recruit physicians to discuss off-label uses, essentially employing them for marketing purposes. The danger of this practice is highlighted by a situation concerning a second-generation antipsychotic (SGA) medication that was promoted for treating dementia in the elderly despite the fact that the medication carried a prominent FDA warning of increased death in the geriatric population” (Berenson, 2007 in Green, 2008).*

One of the fundamental responsibilities of the medical profession is to improve the skills and expertise of the members, and educational efforts that include scientific accuracy – or to promote a product, will disrupt this task (Green, 2008). Sharfstein (2006) observes that in the field of psychiatry, “*industry-sponsored educational activities have progressively transformed the bio psychological model into a “bio-bio-bio” model*” (Scharfstein, 2006 in Green, 2008, p. 159). “*Focus on pharmacological treatment in lieu of psychosocial interventions can also result in unwarranted diagnosis and, in turn, over-prescription of medications. This situation was illustrated by heightened consideration afforded attention-deficit disorder in the 1990s*” (Green, 2008, p.159). Halasz (2002) believes that the over-diagnosis of the disorder could be attributed to advertising efforts that: “*emphasized both its prevalence and the therapeutic benefits of stimulants*” (Halasz, 2002 in Green, 2008, p.159)

**Research:** “*Prior to the 1990s approximately 80% of clinical drug trials were conducted in AMCs under the direction of medical faculty with no potential for direct financial benefit from the work. Subsequently, a large amount of clinical research began shifting to non-academic settings, primarily practitioner’s offices, as pharmaceutical companies attempted to speed FDA approval by avoiding the slow-moving administrative research apparatus endemic to universities. Private practices enrolled patients in phase IV (so-called “post-marketing”) studies of existing medications, in order to investigate such issues as previously unknown side effects. Most phase IV testing is facilitated by contract research organizations (CROs), for-profit research entities that organize clinical trials and employ physicians to conduct them. In*

2001, over 100 CROs worldwide received an estimated US \$7 billion from pharmaceutical companies” (Relman, 2002 in Green, 2008, p.160). There are several ethical issues with this kind of research, “beginning with consideration as to whether its primary goal is scientific enquiry or marketing” (Green, 2008, p.160). Contact with practitioners may affect their prescribing patterns – and they are likely to be influenced, often by financial incentives, such as recruiting patients to participate as subject in research (Green, 2008). “Second, CROs analyze and interpret research data with minimal oversight from the medical profession. As a result they may report findings based only on a portion of the data, and leave some investigators uninformed about other aspects of a study. For example, the high incidence of obesity associated olanzapine was known to its manufacturer as early as 1999, but the company downplayed this health risk” (Berenson, 2006 in Green, 2008, p.160). Another example, where a clinical trial showed that the drug Paxil did not benefit adolescents in treatment, and the producer held back the results “in order to minimize any potential negative commercial impact” (Kondro, 2005 in Green, 2008, p.160). “Third, phase IV trials may compromise patient’s informed consent if they are not fully aware of physician’s financial compensation for conducting a study or of other available treatments (e.g. less expensive generic medications). Fourth, physicians participation in phase IV studies may compromise their integrity and, in turn, that of the profession, if their primary motivation is financial reward. Finally, phase IV studies may expose patients to higher risk than research conducted in academic settings” (Lo, Wolf and Berkeley, 2000 in Green, 2008, p.160).

CROs have also had another effect on academic-based research (Green, 2008). “Because of the pharmaceutical industry’s decreasing dependence on academe for professional expertise, the prestige of scientific publication that may contribute to market success and as a conduit for recruiting research subjects, its financial support of academic research has steadily declined. Although AMCs remain non-profit entities, they have become increasingly entrepreneurial in an effort to regain research dollars. For example, in 1986, 46% of private firms in the life sciences supported academic research; by 1996, 92% did so” (Blumenthal, 1986, 1996 in Green, 2008, p.160).

“By 1999, 68% of academic institutions in the US and Canada held equity in businesses that sponsored research performed by their faculty. During this same period, financial ties between individual faculty members and the pharmaceutical industry proliferated. These observations suggest a new revenue model of “medical entrepreneurialism” that blurs the line between academic and commercial values” (Blumenthal, 1986, 1996, Bekelman, 2003 in

Green, 2008, p.160). Relman and Angell (2002) note that since the incentives of the marketplace has meddled with academic medicine, *“the public can no longer be confident that the testing of new drugs is unbiased”* (Relman and Angell, 2002 in Green, 2008, p.160). *“For example, an association exists between industry sponsorship and pro-industry research findings”* (Bekelman, 2003 in Green, 2008, p.160). Perlis *et al.* (2005) studied the sources of funding for clinical trials that were published in 4 major psychiatric journal in 2001 – 2003, and found that *“the prevalence of author’s conflict of interest was associated with a greater likelihood of reporting a drug to be superior to placebo”* (Perlis *et al.*, 2005 in Green, 2008, p.160). Findings like these are often attributed to the design of the study and how the data is reported (Green, 2008). Melander *et al.* (2003) studied the findings of industry-sponsored studies of serotonin reuptake inhibitors submitted to the drug regulatory agency in Sweden in order to get marketing approval for the treatment of depression (Green, 2008). They concluded that: *“selective reporting “was the major cause for bias in overall estimates based on published data” and that lacking access to all studies, positive as well as negative, “any attempt to recommend a specific drug is likely to be based on biased evidence””* (Melander *et al.*, 2003 in Green, 2008, p.160)

The pharmaceutical manufacturer’s role in research can be summarized by Bodenheimer (2000). He concludes that the research done in the commercial sector is *“heavily tipped toward industry interests, since for-profit, CROs... contracting with industry in a competitive market, will fail if they offend their funding sources”* (Bodenheimer, 2000 in Green, 2008, p.160), and *“academic-industry drug trials have been tainted by the profit incentive”* (Bodenheimer, 2000 in Green, 2008, p.160), but also *“contain the potential for balance between the commercial interests of industry and the scientific goals of investigators”* (Bodenheimer, 2000 in Green, 2008, p.160).

## 4.2 The impact of the pharmaceutical industry on society:

*“Pluralist societies attempt to balance the needs and independence of individuals against a variety of greater goods (e.g. protecting the environment). Pluralism is characterized by the dynamic interaction of public and private interest groups, each of which requires financial support to pursue its goals”* (Green, 2008, p.161). The pharmaceutical industry has vast resources they can use to influence politics in their favor – and by doing so, influencing society (Green, 2008). The pharmaceutical industry has been criticized in recent years due to the amount of money the industry earns, and the resources they possess. *“It is sobering to comprehend the extent of these resources. Since the early 1980’s, it has been the most profitable industry in the US (falling to third place in 2003). According to Fortune magazine, in 2001 the 10 American drug companies in the Fortune 500 list ranked far above all other American industries in average net return as a percentage of sales – 18, 5% as compared to a median return of 3,3% for all other industries. A Congressional Budget Office (CBO) report concurs that the industry’s profits exceed the average for all US industries, but disputes the degree to which they do so. Nevertheless, in 2002 the combined profits for the 10 drug companies in the Fortune 500 (US \$35, 9 billion) were more than the profits for all the other 490 businesses combined (US \$33, 7 billion) – figures that have been particular relevance to psychiatry. In 2003, Americans spent US \$200 billion a year on prescription drugs; three of the 10 most popular medications in sales were the psychoactive agents Zyprexa (fifth, US \$ 3, 2 billion), Zoloft (eight, US \$2, 9 billion), and Neurontin (tenth, US \$2, 4 billion)”* (Green, 2008, p.161).

The cost of medications – and in turn *earnings* – are justified by the pharmaceutical industry on the basis of the costs of R&D. Pharmaceutical companies justify the cost of medications – and by inference their earnings – largely on the bases of expenditures for research and development. *“A recent, widely circulated study estimates that it takes 12 years to develop a new drug at and approximate cost of US \$800 million”* (DiMasi *et. al.*,2003 in Green, 2008, p. 161). Green challenges the study with these three statements: *“First, the actual expenditure is half the amount, as the calculation includes the “opportunity costs” of interests or earnings not realized from those monies invested in research and development”* (Green, 2008, p.161).

*“Second, the US \$800 million figure is based on development of a sample of new molecular entities (NMEs) by large pharmaceutical firms. However, most new non-NME drugs have*

*substantially lower research and development costs because they are incremental improvements of already existing products. And, as the CBO report notes, non-NMEs constitute about two-thirds of the drugs approved by the FDA accounting for “only about one-third of the industry’s R&D spending” making their average direct cost “about one-fourth that of an NME” (Green, 2008, p. 161).*

*“Third, some argue that the industry claims expenses for research that is actually performed by others. For example, in 1998 “15% of scientific articles cited for patent applications for clinical medicine came from industry research, 54% from academic centers, and 13% from government and the rest from various public and nonprofit institutions”. Finally, as noted by Public Citizen, the Washington-based consumer interest group, research and development costs are deductible from a company’s tax base. It therefore argues that the costs of development should be reduced by the amount of corporate taxes avoided, and calculates that the net out-of-pocket, after-tax costs for research and development would be less than US \$100 million for each drug approved between 1994 and 2000” (Green, 2008, p.161).*

**Drug pricing:** Taking the previous statements into regard, one might say that the actual costs of research and development might be unclear in some cases. But the costs that the pharmaceutical industry claims will affect the price of the drugs *“in a way that still raises ethical questions about fairness”* (Green, 2008, p.161). The lion’s share of FDA approved drugs are non-NME, and, *“as the CBO notes, the higher prices charged for those “that are merely extensions of current product lines may not be commensurate with the additional value that those drugs provide”* (CBO, 2006 in Green, 2008, p.161). After the 2005 CATIE study (Clinical Antipsychotic Trials of Intervention Effectiveness), the *New York Times* gave a similar opinion, noting how the US had wasted *“billions of dollars on heavily marketed drugs that have never proven themselves in head-to-head competition against cheaper competitors”* (Carey, 2006 in Green, 2008, p.161). Green notes that health care resource allocation is an additional issue: *“By expending precious funds on higher-priced medications, state programs (e.g. Medicaid) are forced to limit other services. In that same vein, drug pricing has a broad effect on society because the cost of pharmaceuticals is a rapidly growing fraction of a US \$1.4 trillion health budget in the US, now 15-16% of gross domestic product”* (Green, 2008, p.161).

The pricing policies for medications will also have an effect on the individual members of society: *“If based in a libertarian model, those with resources can purchase needed*

*medications while those lacking funds are considered victims of ill fortune but not unfairness. A utilitarian model for drug pricing relies on greater utilization of generic medications which increases the numbers of individuals who can afford medications. Many managed health care and pharmacy benefit plans employ this model. Finally, a fair equality of opportunity model, formulated by the philosopher John Rawls, relies on resource distribution that attempts to ensure that all citizens have an equal chance for achieving their desired goals. This can take the form of social policies that subsidize pharmaceutical benefits of those most in need. The US employs an admixture of these policies, though the predominant model is libertarian (paralleling the US model of health care insurance) despite skepticism about how ethical the distinction is between that which is “unfortunate” and “unfair”” (Green, 2008, p.161).*

**Political activities:** Relman and Angell (2002) propose that the pharmaceutical business is “critically dependent on governmental help... as its lifeblood is government-granted monopolies – in the form of patents and FDA-approved exclusive marketing rights” (Relman & Angell, 2002 in Green, 2008, p.162). The pharmaceutical industry has done extremely well in the US since 1980; which coincides with legislation that “has transformed the relationship between industry and academe, which some believe reflects the effectiveness of successful influence pedaling” (Green, 2008, p.162). Two U.S. Senators support this view – Bernie Sanders (Independent-Vermont) declared that the pharmaceutical industry “has hundreds of victories to its credit and zero defeats in the United States Congress”, and Richard Durbin (Democrat-Illinois) stated that PhRMA (The Industry’s Washington-based trade association) “has a death grip on Congress” (Pear, 2003 in Green, 2008, p.162). The Bayh-Dole and Stevenson-Wydler acts of 1980, which led to a flourishing commercial relationship between the academe and industry, was undoubtedly made possible via lobbying (Green, 2008). “The former permitted universities and small business to patent discoveries supported by tax-sponsored research of the National Institutes of Health (NIH), grant exclusive licenses of those products to pharmaceutical companies, and charge royalties for their use. The biotechnology industry subsequently joined forces with academe and all profited from intramural research conducted on the campus of the NIH” (Green, 2008, p.162). In 1986, this was amended by the Federal Technology Transfer Act - which required “federal laboratories to actively seek opportunities to transfer technology to industry, universities and state and local governments” (Green, 2008, p.162).

The industry’s financial success was continued by subsequent U.S. legislations, for example the 1992 Prescription Drug User Fee Act which “funneled significant monies to the FDA from

*pharmaceutical companies that paid a fee of US \$310 000 in order to speed the agency's review process of each new products. These user fees soon accounted for 50% of the agency's budget in 2002. By 2004 they totaled US \$260 million, and in 2006 represented US \$400 million of the agency's US \$1.9 billion budget" (Green, 2008, p.162). "Some view these developments as making the FDA financially dependent on the industry it is supposed to regulate, particularly since these monies were not used to monitor the safety of already manufactured drugs" (Green, 2008, p.162). In 2006, the Institute of Medicine blamed the FDA in a report for "being too interested in the rapid approval of drugs at the expense of ensuring their safety, and issued several recommendations about the overall review process. The primary goal was to bring the strengths of the pre-approval process to a post-approval process in order to ensure ongoing attention to a medication's risk and benefits" (Institute of Medicine, 2006 in Green, 2008, p.162).*

The Medicare Bill of 2003 also acknowledged the pharmaceutical industry's influence which, in terms of *"dollars, the numbers of people affected, and the political stakes involved"* (Altman, 2004 in Green, 2008, p.162), the Medicare Bill has been described as *"the most important piece of health care legislation in the US since Medicare and Medicaid were originally passed in 1965"* (Green, 2008, p.162). Senior citizens have two options for coverage; and their benefits can only come from private health plans, which raise concerns that one piece of legislation will not have any effect on controlling drug costs in the long run (Green, 2008). *"Next, the federal government is prohibited from negotiation prices with pharmaceutical companies – in sharp contrast to the government's ability to do so in the Veterans Administration system which has demonstrably lowered pharmaceutical costs"* (Green, 2008, p.162). The legislation also contains the hotly debated "donut hole"- which refers to the lack of coverage between US \$2251 and US \$5100. *"Congressional lawmakers may have allowed the provision in order to provide at least some aid to seniors with both low and high drug costs. However, it results in sicker patients with higher drug costs paying more for their drugs"* (Green, 2008, p.162). As noted in the discussion of R&D costs, the US tax policies have also favored the pharmaceutical industry. *"Between 1993 and 1996, drug companies were taxed at a rate of 16.2% compared to an average tax rate of 27.3% for all other major industries"*. (Angell, 2004 in Green, 2008, p.162)

**Marketing:** *"According to the US Securities and Exchange Commission (SEC), in 2001 the major pharmaceutical companies spent 35% of their revenues on "marketing and administration", the largest single item in their budgets. That year the industry reportedly*

*spent US \$19.1 billion for marketing: US \$2.7 billion on direct-to-consumer (DTC) advertising, US \$5.5 billion for detailing representatives to physicians' offices (plus US \$10.5 billion for free samples to clinicians) and US \$380 million for advertising in medical journals*" (Angell, 2004 in Green, 2008, p.162). Green also notes that more than one-third of the workforce was dedicated to marketing, exceeding those in manufacturing R&D. Mintzes *et al.* (2003) argues that direct-to-consumer advertising accounts for only 15% of the money spent on drug promotion. *"Nevertheless, it has been effective due to selective demographic targeting and thoughtful decisions about which products to promote (e.g. drugs are often advertised in response to competitors). One study concluded that if DTC "opens a conversation between patients and physicians that conversation is highly likely to end with a prescription, often despite physician ambivalence about treatment choice"*" (Mintzes *et al.*, 2003 in Green, 2008, p.162). The money spent to finance PRs and dispense free samples suggests that marketing efforts are primarily focused on individual physicians (Green, 2008). *"Approximately 88 000 sales representatives in the US visit doctors in hospitals and their offices, at an average cost of US \$8 000-US \$13 000 per physician"* (Relman & Angell, 2002, Wazana, 2000 in Green, 2008, p.162). Many argue that the line between marketing and industry-sponsored education is so thin that it is nearly invisible (Green, 2008). *"A General Accounting Office report indicates that the cost of activities such as CME meetings and travel subsidies to attend them, consulting fees, speakers' fees and unrestricted educational grants are excluded from the industry's US \$19.1 billion marketing budget which, Angell claims, brings the actual figure to US \$54 billion"* (Angell, 2004 in Green, 2008, p.163).

Green notes that *"the effectiveness of focusing marketing on physicians is demonstrable"* (Green, 2008, p.163). PR contact (as noted above) with trainees and physicians is likely to influence the thinking and behavior regarding the prescription of drugs. The results of the CATIE study is still being digested – and has shown that SGAs (Second-Generation Antipsychotics) generate US\$10 billion dollars annually, and has captured 90% of the U.S. market (Green, 2008). Green points to the principal investigator of the CATIE study, who observed that *"the SGA are not the great breakthrough in therapeutics they were once thought to be; rather, they represent an incremental advance at best"* (Lieberman, 2006 in Green, 2008, p.163). The CATIE principal investigator also attributed the preference for SGAs to *"an overly expectant community of clinicians and patients eager to believe in the power of new medications"* (Vedantam, 2006 in Green, 2008, p.163) as well as *"enhanced perception of their effectiveness in the absence of empirical information"* (Vedantam, 2006 in Green, 2008,

p.163). The CUtLASS (Cost Utility of the Latest Antipsychotic drugs in Schizophrenia Study) study's principal investigator observed that *““certainly one issue” in their widespread use was that “pharmaceutical companies did a great job in selling their products””* (Vedantam, 2006 in Green, 2008, p.163). Green also considers a second benefit of focusing marketing on physicians: facilitating off-label use of medications. *“Constraint against advertising for such purposes can be bypassed by recruiting physicians to write and/or speak about these matters, then have PRs spread that information to trainees and physicians. A testimony to the effectiveness of this strategy was Neurontin’s earnings of US \$2.4 billion in 2003”* (Green, 2008, p.163).

**Legal activities:** *“The pharmaceutical industry also affects society by mobilizing its vast financial resources in the legal arena, including reaching financial settlements with plaintiffs. Eli Lilly recently agreed to pay US \$500 million to settle 18 000 lawsuits from people who claimed they developed diabetes or other diseases taking Zyprexa. In conjunction with earlier settlements, the company paid a total of US \$ 1.2 billion to 28 500 people”* (Rosack, 2007 in Green, 2008, p.153).

*“GlaxoSmithKline agreed to pay US \$14 million to 49 states to settle allegations that it blocked generic versions of Paxil from being made, causing the states to pay higher prices. Pennsylvania had settled a previous suit primarily concerned with purchases by Medicaid. The company also paid US \$70 million to settle a series of civil lawsuits for claims that it inflated wholesale prices of several of its medicines as far back as the early 1990s”* (Washington Post, 2006, New York Times, 2006 in Green, 2008, p.163). Author notes: In 2012, GlaxoSmithKline was subject of a settlement resulting in a US\$146 million fine to New York State (WNYC, July 2012), and US\$3 billion as a fine - the largest in the U.S. history of healthcare fraud settlements. The BBC report on the case: *“The drug giant is to plead guilty to promoting two drugs for unapproved uses and failing to report safety data about a diabetes drug to the FDA. GSK, one of the world’s largest healthcare and pharmaceuticals companies, admitted to promoting antidepressants Paxil and Wellbutrin for unapproved uses, including treatment of children and adolescents...The illegal practice is known as off-label marketing...The company also conceded charges that it held back data and made unsupported safety claims over its diabetes drug Avandia... In addition, GSK has been found guilty of paying kickbacks to doctors”* (BBC, July 2012). As Green puts it: *“The amount of money spent by the industry to pursue legal activities is extraordinary, but companies seem willing to accept these expenditures given the countervailing profits”* (Green, 2008, p.163).

The Hatch-Waxman Act (Drug Price Competition and Patent Term Restoration Act) of 1984 is an example that illustrates that not all legislation favors individual companies. The Act *“attempted to serve the dual purpose of stimulating production of generic medications while providing some additional protection for brand-name drugs. The intended balance of the Hatch-Waxman Act has to some degree been undercut by a series of legal manoeuvres employed by the pharmaceutical industry to exploit the second goal of the legislation. Brand name companies have been able to delay distribution of a generic drug for 30 months by suing its manufacturer on the basis of patent infringement, even though such suits were for uses of the drug that were different from its original patent as defined by the criteria of “usefulness, novelty and non-obviousness” by the US Patent and Trademark Office”* (Green, 2008, p.163).

On the basis of the previous discussion regarding the influence of the pharmaceutical industry, Green offers a reflection on morality: *“Morality is concerned with right ideas and principles of human conduct. Medical ethics examines the role of values in clinicians’ relationships with patients, families and colleagues – psychiatric ethics pursues the same goal with issues specific to mental health care – in an attempt to ensure morally correct treatment. Ethical deliberation and decision-making is justified by different moral theories that incorporate an amalgam of rights, consequences, obligations virtues and other parameters. For example, the decision to terminate medical treatment may be justified by the principle of respect for autonomy (e.g. honoring patients’ wishes) or a utilitarian calculus of whether continued treatment conveys more harm than benefit. Theoretical justification in medical ethics can become extremely complex. For example, allocating resources on a utilitarian basis, characteristic of managed health care, may conflict with the Kantian belief that physicians have a duty to provide treatment to all. Moreover, ethical dilemmas can arise even when adhering to a single theory, such as trying to meet absolute, but conflicting obligations of Kantianism. Consequently, a methodology for ethical decision-making is required in order to reconcile the demands and directives of different theories, as well as any contradictions arising within a single theory. Hundert (1987) offers one such methodology, proposing a schema for balancing competing ethical values – a “reflective equilibrium” that evolves from clinicians’ ongoing experience. Bloch and Green (2006) suggest another framework that emphasizes the place of care ethics, given the importance that the approach affords the role of emotions in moral decision-making”* (Green, 2008, p.163-164).

Green concludes that the medical profession should: *“devote more energy informing students and trained physicians about the ethical pitfalls inherent in commercial collaborations, which already occurs in some medical schools. The profession should also reform medical and continuing medical education, primarily by invigorating instruction in pharmacology and the critical review of research design and analysis”* (Green, 2008, p.164) He also notes that the pharmaceutical industry should not be involved in educational activities, no acts of gift-giving, ban PRs from participating/being present in medical school training, as well as abolishing *“drug-sponsored symposia at professional meetings; and prohibiting participation in speakers bureaus”* (Green, 2008, p.164). He also suggests barring physicians from research where they (the physicians) might have financial interests, but also states that companies should feel free to contribute financial support to centralized institutions that are independent from the industry.

On government, Green notes: *“the US is the only developed nation that does not regulate drug pricing, which at the very least is unreasonable, and more likely unfair, given the millions of Americans unable to purchase needed prescription medications”* (Green, 2008, p.164). He also mentions that the Bayh-Dole Act permit the government to take control of drug pricing under certain circumstances *“one of which is generally interpreted to involve establishing reasonable costs to consumers, and those powers should be exercised when required”* (Green, 2008, p.164). According to Green, the FDA is in need of reform, in order to limit the potential of conflicts of interest.

Green ends the article saying that the public needs to be responsible to inform themselves about the pharmaceutical industry – for desired changes, and the influence the industry has on the medical profession. *“This would involve the lobbying members of Congress by individuals and interest groups (e.g. to amend provisions of the Medicare Bill of 2003), and require patients to be more proactive by regularly engaging physicians in discussion about the rationale for specific pharmacological treatments”* (Green, 2008, p.164).

## 5.0 Information asymmetry and ethical issues in cross-cultural marketing.

### 5.1 Information asymmetry:

*“Economic theory distinguishes between three types of goods, according to the nature and timing of information that consumers can obtain about their quality. The quality of “search goods” can be ascertained before purchase, whereas for “experience goods”, quality can only be learned through use. The quality of the third category “credence goods” cannot be evaluated through normal means. Assessing credence goods’ value requires additional costly information. Repair of durable machines or human beings are the classic examples because most consumers are highly unfamiliar with their intricacies and peculiarities” (Katz, 2008, p.12-13). According to Katz, the line between experience goods and credence goods may not always be clear, especially is perceived through usage over the lapse of longer time. Most goods are in possession of several attributes: some of the attributes are known before the purchase, some after purchase, and some attributes are never discovered (Katz, 2008). “For example, a potential buyer of canned tuna can know before the purchase that she buys a canned product, and can know after purchase that the content of the can indeed looks and tasted like tuna. However, she may find it more costly to verify that it is indeed tuna (and not some imitation). She will find it prohibitively costly to verify whether eating this particular tuna is safe (e.g. not contaminated), or verify other attributes that some consumers may deem important such as whether the product contains genetically modified organisms, whether it was derived from organic farming, the age and working conditions of the labor force, the environmental impact of the production process, compliance with animal welfare standards, nutritional properties, or the geographical origin of the product” (Katz, 2008, p.13).*

When it comes to drugs, Katz states they can be characterized as credence good – in regard to the most important attributes: efficacy and safety. Customers can easily assess how effective drugs are for common symptoms – especially when used frequently. Looking away from placebos, most consumers suffering from headaches can instantly assess the efficacy of for example a painkiller. And similarly, most men who suffer from erectile dysfunction can easily assess the effectiveness of drugs like Viagra. For drug users who on the other hand, who do not experience the expected effects immediately, assessing a drug can be rather difficult (Katz, 2008). As Peter Temin (*Taking your medicine: Drug regulation in the United States*,

1980) highlights; the concept of effectiveness is a vague one, as it is not solely linked to the drug's ability to treat a condition – but may also be dependent on other characteristics such as: how the drug is administered (oral, injectable, topical), and the required dosage. It is even more difficult for consumers to know and evaluate the long-term effects of the drug, eventual complications, or how the drug may react to other substances. Even if the consumers are well-endowed and want to combine different drugs - it may be ineffective - even lethal. The consumers cannot simply try every drug and cure until the “optimal” is reached. No matter how dramatic the effects of a drug on an individual - the effect of drugs are likely to vary from person to person, and meaningful information on the quality of drugs can only be obtained by inspecting large samples and applying statistical methods (Katz, 2008). *“Not only is this type of epidemiological research beyond the reach of the consumers, it is also beyond the reach of most practicing physicians. Therefore, if sellers (drug companies) have better information about the efficacy and safety of their products, severe asymmetry of information about the quality of drugs (their efficacy and safety) may occur. And when the information held by sellers and buyers is asymmetric the market may fail, as George Akerlof (The market for “Lemons” – Quality, Uncertainty and Market Mechanism, 1970) showed in his famous “lemons market” paper”* (Katz, 2008, p.14).

Akerlof (1970) describes how the interaction between quality heterogeneity and asymmetrical information regarding the quality of products may cause markets to disappear, despite sellers of high-quality products willing to sell at lower prices than what the buyers would buy. Akerlof's model shows that the buyer's inability to discover the quality of a product creates information asymmetry – which then creates the incentive for sellers of low-quality products to sell their goods as higher-quality (Katz, 2008). *“The buyer, however, takes this incentive into consideration, and discounts all sellers' quality claims, so that for any given price only the average utility will be considered. As a result, sellers who offer higher-than-average quality will be driven out of the market. Unless credible guarantees of the quality of the good exist, this mechanism, in which the low-quality products drive out the high-quality, repeats itself until a no-trade equilibrium is reached”* (Katz, 2008, p.15). Akerlof presented his model using the used car market, and also mentioned other examples, such as the elderly having a reduced degree of availability of privately supplied health insurance, employers' being reluctant to hire from minority groups, or undeveloped countries having a scarcity of formal credit markets (Katz, 2008). *“Nineteenth century drug markets, and perhaps contemporary dietary supplement markets, could easily supplement this list”* (Katz, 2008, p.15). In Akerlof's

stylized model, the market disappears – but we rarely see markets disappearing together in real life (Katz, 2008). *“They may also shrink as the frequency of transactions decrease in comparison to what would occur if the available information were perfect, or if “anti-lemon devices”, mechanisms to credibly assure the quality of products, were available”* (Katz, 2008, p.15). Akerlof’s theory and the prediction that the market disappears is not in conflict with the fact that a market for quack medicines did exist in the nineteenth century. If quack medicines are low in costs – both in production and sale, and that it does not require any large investment in R&D – this seems like a viable assumption. Such a market can sustain on modest sales and low prices. This market can exist as long as there are enough people who are willing to purchase such medicines. *“Therefore, it is not the market for quack medicines that disappears under Akerlof’s theory, but rather the market for quality medicines which disappears, or more precisely, fails to emerge. Therefore, while a small subset of consumers may deserve paternalistic regulation to protect them from their own ignorance, the more important effect of such regulation is actually on those consumers and sellers who would not otherwise be in the market”* (Katz, 2008, p.16).

Government intervention designed to increase the consumers information availability operates against the self-interest of the sellers. The consumers would love it, but the producers would hate it. In the Akerlovia case, the *“honest sellers of high quality credence goods are interested in providing enough accurate information to consumers, yet they cannot credibly do so. Given consumers’ inability to distinguish between honest sellers and dishonest ones, sellers face the problem of persuading consumers that the information provided by them is indeed sufficient and accurate. Rather than causing consumers to wastefully expend money on ineffective drugs, this failure to signal quality results in under-expenditure on drugs, which in turn, may lead to under-investment. In the Akerlovia scenario, honest sellers and consumers alike would welcome measures that would allow them to credibly signal their quality. Such measures may include regulatory ones”* (Katz, 2008, p.16).

Regarding goods such as pharmaceuticals, Katz writes: *“Without mechanisms capable of credibly assuring the quality of drugs, drug markets would perform sub-optimally. They may turn into lemons markets. Anti-lemon devices this enable both drug consumers and drug producers to increase the available gains from trade. Consumers’ trust in the safety and efficacy of drugs means more money for drug companies. It increases the value consumers ascribe to new drugs and translates into and increase in the expected returns for investment in new drugs. Now, if regulatory review of new drugs provides such assurances, it may*

*actually supplement patents in creating incentives to innovate, not detract from such incentives. The justification for patent term extension is thus turned on its head. Instead of decreasing the expected profits secured by drug patents, regulatory review boosts them. Instead of diminishing the incentives to innovate, regulatory review strengthens them. Instead of a burden, one can recognize regulatory review of new drugs as a valuable pro-innovation service the government provides. In fact, re-conceptualizing drug regulation as a service rendered to the drug industry may even justify shortening patent terms for new drugs. A potential argument could be that if the government provides this service through tax revenues, the public may justifiably insist on demanding earlier competitive supply of new drugs, The quid pro quo argument (“you penalize us by demanding prior approval of new drugs and therefore should compensate us”) can be used to promote just the opposite result (“we subsidize you by assuring the quality of your products and therefore we should get in return lower drug prices earlier”). Yet any such polarized views about the relationship between patents, drug regulation, and innovation would be misleading” (Katz, 2008, p.17).*

Katz follows up on patents by writing that even if regulatory review of drugs will generally benefit the industry, it can only be up to a certain limit. *“If it took nineteen years for approval of a new drug, it is less likely that one remaining year of EPL would yield enough profit to make the investment worthwhile”* (Katz, 2008, p.17). Regulatory review will only benefit the industry if a FDA approved drug sold under patent, for a short time, will generate higher profits than a non-approved drug that is sold under patent for the full term. Since the optimal patent term is unknown, it is still likely that patents should be extended - despite the positive effects of regulation. Even though there are benefits of regulatory approval, it does not mean that the regulatory framework is optimal – and cannot be improved. Improvements like reducing development costs may increase the incentives brought by patents and regulatory review, and may bring newer drugs to the market earlier. *“Lastly, ultimately determining whether regulation is a burden or a benefit requires considering how effective alternative measures for quality assurance can be. In particular, it requires determining whether public regulation inhibits, substitutes, or complements effective market-based, anti-lemon devices”* (Katz, 2008, p.18).

## 5.2 Ethical issues in cross-cultural marketing:

The following theory is from Doole & Lowe's book *International Marketing Strategy* (2008), pages 95-96: Cultural sensitivity is often at the heart of the ethical dilemmas that managers face when operating in international markets. There are few, if any, moral absolutes, and a few actions for which no one can provide reasonable justification. Almost every action can be justified on the basis that it is acceptable in one particular culture. In thinking about ethics managers need to be aware that simply defining what is ethical by the standards, values and actions from their own culture may be insufficient in satisfying all the stakeholders of a multinational enterprise. What is often seen as an acceptable business practice in one culture can be seen as ethically questionable in another (Doole & Lowe, 2008).

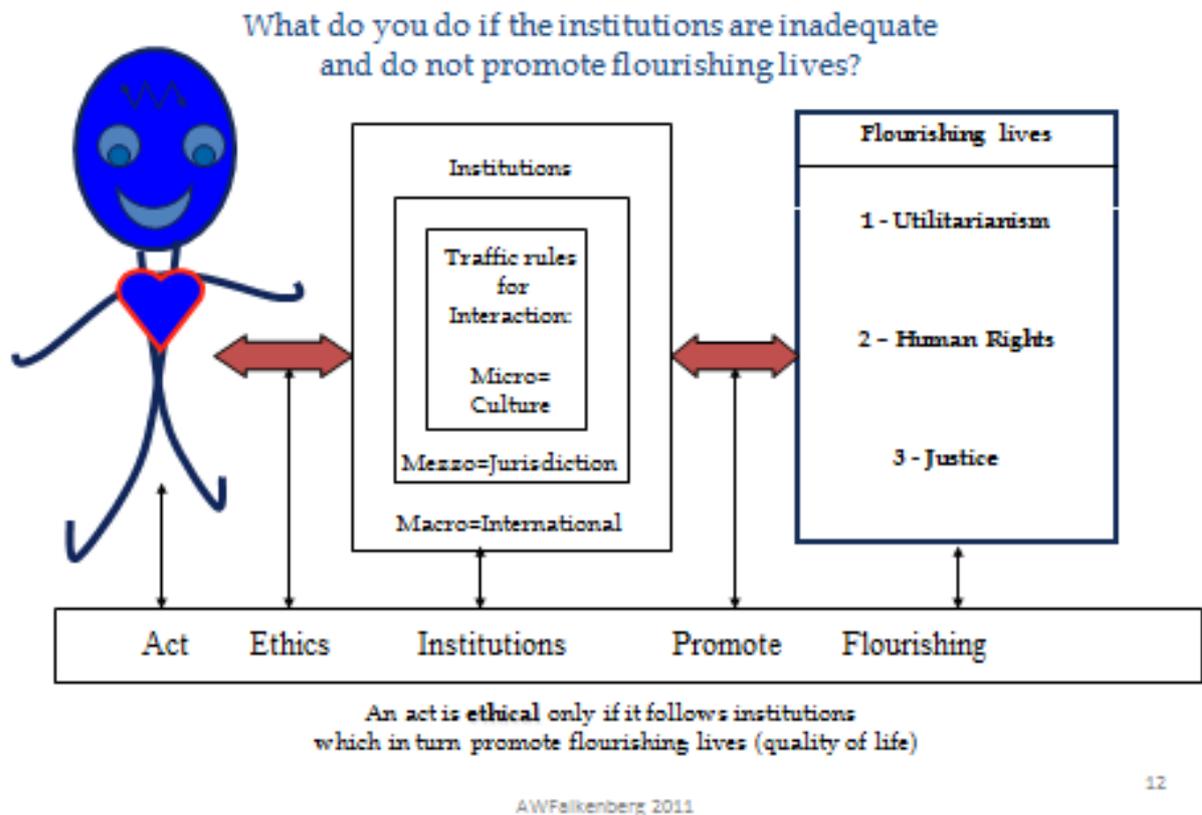
The ethical challenges facing international marketing managers are many. In recent years such issues as environmental abuse, the use of child labor, poor working conditions and the low levels of pay in Third World factories have received particular attention. Western consumers choosing brands look for reassurance that the product has been produced in what they see as a socially responsible manner. Many sportswear brands such as Nike, Levi and Gap have suffered adverse publicity when it has been made known that child labor has been used to produce their products (Doole & Lowe, 2008).

Consumers globally are becoming better informed through better education and faster and more effective communications. Increasingly, therefore, they are able to question the actions of multinational enterprises. For their part, whilst the largest multinationals are extending their influence within the global markets, they are becoming more vulnerable to criticism. Over the past few years quality and service have improved considerably, but now firms are increasingly expected to ensure that their behavior is ethical and in the interests of the global community which makes up their market. However, international marketing executives operating across cultures will find themselves facing moral and ethical dilemmas on a daily basis on a wide range of issues. Some of those currently receiving particular attention are bribery and corruption, counterfeiting and piracy (Doole & Lowe, 2008).

When entering a foreign nation, the cultural differences need to be addressed. In several third-world countries, child labor is quite common, as families may not have the money for schooling, and they might rely on the extra income from the children to make ends meet. The

international marketer must be fully aware of the culture(s) in the foreign nation, and how they might collide with the culture in the home-country. The differences, ranging from norms and values, to business procedures must be addressed, to avoid any unnecessary scandals, such as the Telenor in Bangladesh scenario (Falkenberg and Falkenberg, 2009).

## 6.0 Inadequate institutions: Mezzo, macro and micro levels.



(Falkenberg, A. Lecture #10 in Culture & Ethics, Fall 2011)

Institutions at three levels: (Falkenberg, A. 2007)

Macro: The international level

Mezzo: The national governance level

Micro: The local cultural level

When marketing internationally, the “condition” of the target markets (or even the home country’s) institutions are vital, in order to avoid any acts that are considered unethical. The focus will now shift from the practices and actions of the pharmaceutical industry to perhaps *the* most unethical act: corruption.

On inadequate institutions, Falkenberg and Falkenberg (2009) notes: *“The exchanges or transactions in multinational value creation networks are governed by different sets of institutions, that is, (1) laws, (2) regulations, (3) norms, and (4) values that constitute framework behavior for a country (North, 1990). Macro institutions are those that affect international transactions. Mezzo institutions are jurisdiction specific at the national level for each country and are related to the governance of the country. Micro institutions are the traffic rules of behavior emanating from the culture itself. For some countries it may be necessary to revise North’s 1990 definition; for example, the formal institutions in a country are based on (1) laws and (2) regulations that may prohibit certain practices (corruption, child labor, and unsafe work practices). However, the more informal institutions based on local (3) norms and (4) values practiced at the mezzo level may tolerate and perhaps accept these practices. In other counties the mezzo institutions may favor the ruling elites and be contrary to the local cultural values. These countries are often plagued by limited economic freedom, monopolies, corruption, and inadequate legal systems”* (Falkenberg and Falkenberg, 2009, p.356).

*“If an act, that follows the traffic rules of behavior stipulated in an institution which, in turn, promote flourishing, then the act can be seen as ethical. Or; good consequences are a result of acts that follow benign institutions. Bad consequences are a result of acts that follow inadequate institutions, and should generally be avoided”* (Falkenberg, Macromarketing Conference, 2007).

As explained by Andreas Falkenberg in the Culture & Ethics and International Marketing lectures here at UiA, the value creation networks are governed by 4 sets of institutions: Laws, regulations, norms, and values. As mentioned in the theoretical framework, if there are any loopholes or lack of governance/monitoring in the laws and regulations, corruption may (or: is likely to) occur. The norms and values of course play a big part, as in certain parts of the world; corruption has become the rule, and not the exception. When speaking of norms and values, one would think that everyone knows what is right – and what is wrong, but as I mentioned; in certain societies, corruption had become almost a tradition – a “natural” element when conducting business. If the job has low pay, with little or no transparency, the desire for personal gain may prove too strong for “dirty” employees/officials.

Macro institutions are different though; as countries may be well aware of the corrupt practices in other nations, and will actively avoid any involvement in corruption – as international firms has to take care of their reputation and integrity.

Mezzo institutions: In countries that has been synonymous with the term corruption, the jurisdiction may be flawed, or even in favor of corruption. A prime example: Indonesia - ranked as the most corrupt nation on earth, with a history where the rulers have been “Official Moguls” (Johnston, 2005), corruption is present in every facet of daily life and business.

When it comes to micro institutions, a quote from one of the many conversations and lectures with Andreas Falkenberg: *“the traffic rules of behavior emanating from the culture itself”* - notably poorer nations, where the incentives of participating in corrupt practices are more rewarding than staying “pure” – will see a larger extent of corruption. A culture where loyalty to your family, tribe, or clan comes before loyalty to the state – or even the general population - combined with inadequate institutions, leaves opportunities for unethical practices and corruption.

“Corruption is a big problem in many countries with inadequate institutions. Organizations that trade with corrupt governments must sometimes “help” kleptocrats steal from the treasury” (Falkenberg, 2012).

In a country, where corruption is present in any of the institutions, in the author’s opinion – the institutions can be classified as inadequate.

The article *“When in Rome... Moral Maturity and Ethics for International Economic Organizations”* by Falkenberg (2004) address inadequate institutions, and Falkenberg states: *“Modern and well developed markets do not operate according to the “law of the jungle” with guile opportunism and deceit. They function within a set of “traffic rules” or institutions, which have evolved over time. Institutions are humanly devised constraints that shape human interaction (North, 1990). Institutions include the legal and regulatory framework in a jurisdiction as well as the norms, values, customs and patterns of behavior present in a particular place at a given time”* (Falkenberg, 2004, p.20). In a democratic country, the country’s cultural values are reflected in the institutions – and one might say that Kohlberg’s conventions (presented earlier) are represented by the institutions (Falkenberg, 2004). *“The will of the people is reflected in the institutions through a democratic process”* (Falkenberg, 2004, p.20) - meaning different cultures will have different institutions, for example

institutions in Norway, Mexico and Thailand. International companies will therefore meet differences in foreign markets. In the West, institutions are generally in place to make sure that companies/organizations will not act in a harmful way, violate rights, the environment, or being unjust. The firms are expected to promote the interests of society, in addition to their own (Falkenberg, 2004). *“The institutions are like traffic rules that are internalized in the members of a culture in a common set of do’s and don’ts (Hofstede, 1984)”* (Falkenberg, 2004, p.21). In the past, firms and individuals sometimes focused entirely on their own economic gain, with great consequences for the parties involved. Adam Smith was in his time a great critic of the “dealers”. Resulting from the conduct and decisions of economic organizations, “movements” were formed – for example the labor movement, the environmental protection movement, the female rights movement, the abolitionist movement, the civil rights movement and so on (Falkenberg, 2004). As Falkenberg puts it: *“Each of these movements has had some success in changing the way we think about our right and wrong. They have influenced our cultural values; our conventional thinking and the institutions that govern what economic organizations can and cannot do. Often, these “movements” have been voluntary non-governmental organizations (NGO’s), inclusive groups (Olsen, 1965), deriving their influence from their large following. Over time, the advocacy of these groups has resulted new norms and values within a culture and eventually in new laws and regulations governing our conduct. We have seen developments in civil rights for different groups, safer products, better pollution standards etc. The NGO’s have also helped shape our sense of fairness and what constitutes good business practice. Our feelings of rights and wrong have changed and we have a different built-in moral compass today that our forefathers had a hundred years ago. Conventions have changed”* (Falkenberg, 2004, p.21)

Cultures in the West have developed quite similar institutions that regulate economic activities. If you want to compete in European Union or the United States, you will have to follow resembling rules and regulations concerning the firms’ relationship to: the workforce, customers, competition, the environment, gender equality, minorities, the environment, the society etc. (Falkenberg, 2004). *“As long as a firm competes within the limits set by these institutions, it may by and large, look out for its own interests; its own costs and benefits in a utilitarian manner. This is not to say that all the institutions are just, or that following them constitutes ethical acts (Falkenberg, 1996). It used to be considered appropriate not to grant women access to certain arenas, notably in education and certain kinds of employment. Institutions are slowly evolving – and it is hoped that is it in a direction which will produce a*

*better world for the whole “sentient creation” as John Stuart Mill expressed it. In other words, following current institutions/conventions does not ensure ethical behavior. Firms that adhere to the minimum of the legal requirement only, may be considered marginally ethical at best. It may be legal to sell pornography, gambling services, alcohol, and tobacco or to stimulate their demand, but it may not be the hallmark of the ethical firm” (Falkenberg, 2004, p.21).*

Compared to the home country, the institutions in emerging and developing countries are often quite different. One might say that the institutions in the developed world are a little “tighter” – alas a little better to protect the people and the environment from abuse.

Falkenberg explains the institutions in emerging and developing countries may be influenced by:

- *“The legal and regulatory framework may be incomplete and fail to adequately protect people and the environment from harmful practices”.*
- *“There could be cultural differences which may permit practices which are in clear violation of basic human rights, such as differential treatment based on political beliefs, religion, nationality, race, ethnicity or gender. This of course is still a problem in developed countries”.*
- *“One cannot always assume that there is a democratic government in place – thus the institutions may not be grounded in the local culture, but designed to serve those with political and economic power”.*
- *“The social conditions may be such that one can ill afford to cover basic needs in the areas of education, health care and nutrition for the children”.*
- *“Concern for basic survival may override concerns for the environment, safe products and the like”.*
- *“Corrupt officials and judges may disrupt the proper functioning of markets, competition, property rights and due process of law”.*
- *“Poor countries may have to agree to unreasonable terms when seeking to attract much needed foreign skills, technology and investment. Many countries are much smaller in economic terms than the major multinationals and must often negotiate with other locations for MNC investments” (Falkenberg, 2004, p.21).*

Based on the statements above, one might say that when it comes to a framework for economic organizations, developing economies may lack *“adequate background institutions”*

(DeGeorge, 1993 in Falkenberg, 2004, p.22). This might lead to some ethical dilemmas for multinational companies, as it may be possible to act unethically since there might be no laws or regulations against it. The local cultural values/conventions may also not be in conflict with what we regard as unethical acts. Violating laws or regulations may not lead to any consequences for the company, due to failure/lack of enforcement of the authorities (Falkenberg, 2004).

Falkenberg describes the scenario where a company enters a foreign market with inadequate institutions as follows: *“If a firm were to take full advantage of the local conditions in an opportunistic, selfish and egoistical manner, costs could be reduced substantially; revenues could be increased, this positively affecting the bottom line. It may be possible to hire employees at or below subsistence wages. It may be possible to hire and exploit young children or expose employees to hazardous working conditions. It may be possible to deplete natural resources, extinguish species, release toxic wastes to the water or to the air, ignore unions, bribe public officials, pay no taxes, produce and sell dangerous products, or engage in illegitimate discrimination. And it may be possible to work with government officials and obtain rights to natural resources, which would normally belong to the people of the country. An opportunistic ethical egoist may engage in these kinds of activities if the chances of getting caught are next to nil. However, it is not a comforting thought that some of our material welfare may be resting on exploitive practices in LCD’s”* (Falkenberg, 2004, p.22).

Both utilitarianism and ethical egoism are in favor of employing cost benefit analyses and to use an expected value calculation as a tool when making decisions. Does crime pay – and what are the benefits? What are the odds of getting caught – and what will it cost to be exposed? Calculations like these are sometimes used for the interests of the firms – not for society. Cost benefit analysis and value calculation may serve a great purpose when searching for efficiency – but not a good idea when it comes to *ethics* (Falkenberg, 2004). Falkenberg presents the reasoning of an opportunist as follows: *“I will do something bad if the probability by with a wrongful act, times the benefits of the act, is greater than the probability being caught, times the cost of punishment”* (Falkenberg, 2004, p.22). The Ford Pinto prone to bursting into flames in left turn rear end collisions, and when deciding not to install a protective device, Ford uses a calculation similar to Falkenberg’s opportunist:  $(\# \text{ of accidents})(\text{cost per accident}) < (\text{cost of a part})(\# \text{ of vehicles sold})$  (Shaw and Barry, 1992 in Falkenberg, 2004, p.22). *“The application of this kind of calculus met with public outrage and it was clear that it was unacceptable by convention in the American culture. Hopefully,*

*managers have learned from cases like this one – but we still see a lot of “business decision” made with insufficient regard to affected parties. Ethical egoists may apply the cost/benefit analysis on a national or international level (greatest good for the greatest number); the ethical egoists usually focus on what is good for the individual or the organization without much regard for others” (Falkenberg, 2004, p.22).*

## 7.0 Government, political and legal forces:

In the book *International marketing and export management* by Doole & Lowe (2011, p. 218 – 222), the role of government is defined as: As an environmental force affecting international/export marketing, government *intervenes* in a single country's (and the world) economy by being a participator, planner, controller, or stimulator. Such intervention activities can be categorized into the following three groups:

- Those that *promote* (i.e. encourage or facilitate) international/export marketing transactions.
- Those that *impede* such transactions.
- Those that *compete* with or replace international/export marketing transactions by private business firms.

These basic types of intervention exist to some extent at all levels of government, but with varying emphases. At the supranational level, the actions taken are primarily those whose effect is to encourage and facilitate international marketing relationships, especially exports. Illustrations include the many agreements and conventions that are made between countries, such as international commodity agreements, and bilateral agreements. (Albaum & Duerr, 2011)

Protection of intellectual property is of concern to most governments, and there are patent and copyright laws “on the books”. Looking at the process of obtaining a patent, standards for what is new, or even how to describe something new, vary widely, and the process involves a mass of paperwork. What is really lacking is a single global standard, something that will be necessary if globalization is really to take hold. Progress was made for such a standard in June 2000 when 43 countries signed – and 64 others were expected to sign – a new world patent-law treaty under the auspices of the United Nations’ World Intellectual Property Organization (WIPO). The treaty, known as the Madrid Protocol, became effective in late 2003. Members of the Protocol include Australia, Japan, Korea, Singapore, the United States and most European countries. A trademark owner files a simple application with the home country, a “basic” registration, and can designate extension of the registration to other member countries. The most significant impact – in addition to standardizing forms, etc. – is the requirement that authorities of member states accept nationally any patent filed according to an international standard known as PCT, or Patent Co-operation Treaty. This is a step towards

filing a single patent according to a global standard. The United States and the European Union have developed innovative trade initiatives to enhance the protection of international property rights and allow managers to better deal with anti-counterfeiting tactics. These initiatives, which target both organized pirates and consumers, are discussed by Chaudhry (2006). Individual companies also have a responsibility to protect their intellectual property by following sound practices regarding registration. For example, in some countries, intellectual property rights are granted to the first registration of a trademark; China is one such a country. In other countries, such as the United States, protection is given to the first use. One industry in which counterfeiting occurs regularly is the pharmaceutical industry. In addition to pursuing legal redress from counterfeiters by courts Pfizer has used another approach – civil suits to recoup money lost to counterfeiters and more (Bennett, 2010 in Albaum & Duerr, 2011).

In addition to regulating trade, government also regulates other business activities, although not to the extent some would like. Major concerns include the environment, labor rights, human rights, intellectual property, tax policy, antitrust, and corruption. Corruption of officials is of concern to many throughout the world. Corruption can affect the international marketer in many ways, both positive and negative. Countries are using many measures to fight corruption with the intent of control, reduction, and ultimately elimination. A role model of how to handle the problem is Hong Kong's Independent Commission Against Corruption (ICAC), which has been very effective in Hong Kong. A region where corruption has a long history is Southeast Asia, except Hong Kong. While there have been encouraging signs of effective counter-corruption measures, there is still much to be done. This situation stems in part from a lack of laws, personnel, and money to fight corruption. But the resource in shortest supply is political will to tackle the problem (The Economist, 2004b in Albaum & Duerr, 2011).

Katz (2008) notes: *“If the assumption that without regulation or other forms of quality assurance the market will become a market for lemons is true, then rather than a burden, regulatory review of new drugs may actually be an effective mechanism for assuring the quality of drugs, on that drug companies would have had to establish themselves in order to avoid the “lemons” problem (e.g. by establishing their own certifying body)”* (Katz, 2008, p.11-12).

It is possible that the governments are most suited to undertake this role, as they act as a disinterested third party. Governments can impose sanctions for attempts of cheating, and enforce compliance with the approval process. Rather than hindering innovation, regulating the approval of new drugs may actually act as a service that increases the expected returns from innovation (Katz, 2008). *“Drug regulation provides the quality assurance necessary to persuade consumers to purchase drugs, and patents provide the mechanism for recouping the investment necessary for developing both the drug and information regarding their quality. Moreover, even if drug regulation increases the cost of innovation, it increases the cost of all new drugs so it “simultaneously discourages creative destruction through between-patent competition... [thus providing] an improved patent by keeping out low-quality innovators that could have competed with high-quality innovators” (Lichtenberg & Philipson, 2002). However, the cost of regulation is not equal for all drugs. Testing and approving the new drug whose safety and efficacy are apparent will be less costly than testing and approving a new drug that is less effective and causes more side effects and complications, Therefore, drug regulation’s discouraging effect affects low quality drugs more than it affects high quality drugs, which then face less intense competition in the market place”.* (Katz, 2008, p.12)

The following is translated from Andreas Falkenbergs’ *Kulturverdier, etikk og økonomi* (2012), pages 244-249:

Corruption is often related to politicians and the public sector, which have the power to decide how the resources in a society should be used. In everyday life, the politicians are busy with elections and re-elections. To achieve this, you have to gather as many voters as possible, often through expensive campaigns. Money and support can be achieved by prioritizing certain interest-groups both politically and economically: energy-companies, the health sector, the education sector, the transport sector, farmers, unions, lawyers, the elderly, the media, political youth-organizations, the cultural sector, publishers, newspapers, religions and spirituality, cooperation’s, the tourist industry, sports or artists.

These priorities can come in different forms. They could be nice tax-laws for different groups, customs and surcharges to protect industries from international competition, bidding preferences, allocation of resources directly to specific groups, legislation that prioritize specific groups etc. If democratically elected politicians promise to allocate more resources to their voters than they are willing to demand in taxes, the democracy will gradually decline.

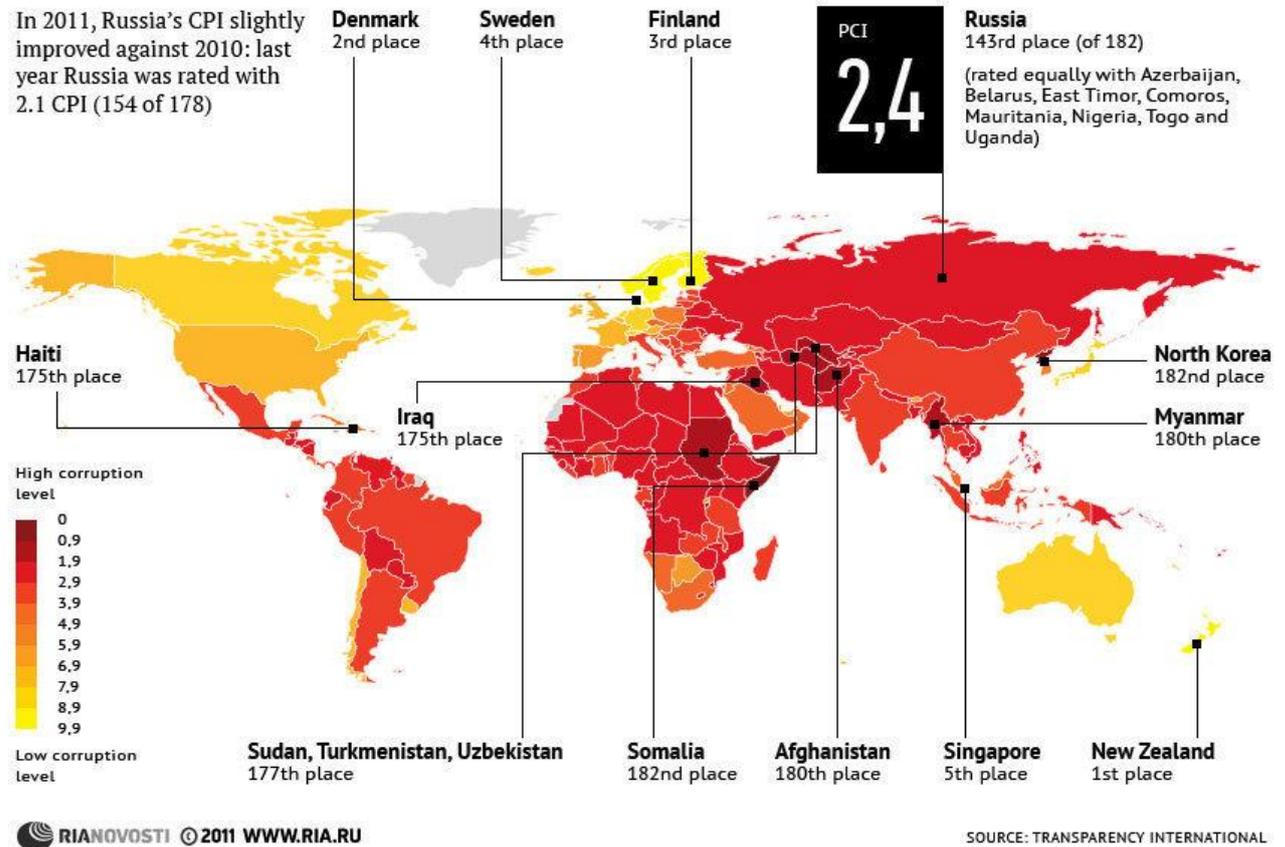
Rogue politicians in certain countries have discovered that they can bribe their voters with the voters own money. This is the case in Greece, where the present (and future) citizens have exacerbated their lives through political opportunism, with the help of international banks. The crisis hit Greece, but should also equally hit the banks that have lent money to the Greek politicians. (Falkenberg, 2012, p.244-249).

## 8.0 Corruption:

# 2011 Corruption Perceptions Index

The Corruption Perceptions Index (CPI) measures the perceived level of corruption in the public sector. A larger number corresponds to the lower corruption level in the country

In 2011, Russia's CPI slightly improved against 2010: last year Russia was rated with 2.1 CPI (154 of 178)



(The 2011 Corruption Perceptions Index (CPI), by Transparency International.

<http://en.rian.ru/infographics/20111202/169219288.html>)

According to Michael Johnston, corruption can be described as:

*“Corruption involves the abuse of a trust, generally one involving public power, for private benefit which often, but by no means always, comes in the form of money. Implicit in that notion is the ideas that while wealth and power have accepted sources and uses, limits also apply. But in rapidly changing societies it is not always clear what those limits are, and the term “corruption” may be applied broadly (Hao and Johnston, 2002). Even in more settled societies its meaning is open to dispute, manipulation, and change” (Johnston, 2005, p.11)*

*“I define corruption as the abuse of public roles or resources for private benefit, but emphasize that “abuse”, “public”, “private”, and even “benefit” are matters of contention in many societies and of varying degrees of ambiguity in most. If our goal were to categorize specific actions as corrupt those complications would be a serious difficulty; indeed they are reasons for the inconclusive nature of the definitions debate. But at a systematic level, particularly where the problem is severe, such contention or ambiguity can be useful indicators of difficulties or change at the level of participation and institutions” (Johnston, 2005, p.12)*

Another definition from Mühlbacher, Leis and Dahringer (2006) is:

*“The word corruption comes from the Latin verb “rumpere”, meaning “to break”. What is broken in the case of corruption is a moral or social norm of behavior, or, more often, administrative rules. To be broken, administrative rules must be precisely formulated and transparent. A second element of the term corruption is that the administrator breaking the rules receives a favor in return for him/herself, the family, friends, his/her clan or party, or another social group. In addition, this favor in return must be seen as a direct “quid pro quo” (this for that) for a special act of breaking a rule. This simple description of corruption shows that there are many sources of problems with “corrupt practice” in different cultural environments” (Tanzi, 1995 in Mühlbacher, Leis and Dahringer, 2006, p.197).*

Doole & Lowe (2008) covers bribery and corruption briefly on page 96-98 in *International Marketing Strategy*. An integral part of conducting business internationally is the practice of gift-giving. However, in many Western countries such practice is seen as bribery/corruption and is tightly regulated and controlled. Business gift-giving – or bribery, depending on your point of view – if improperly executed, could stop sensitive negotiations and ruin new and potential business relationships. German and Swiss executives tend to feel uncomfortable accepting gifts, which they view as bribes, as they will not want to be seen as being under obligation to the other party. However, business gift-giving in many cultures is an important part of persuasion. In cultures where a business gift is expected but not given, it is an insult to the host. In China it would be virtually impossible to gain any local government approval without offering financial inducements. (Doole & Lowe, 2008, p.96)

Cultures that view bribery as an unacceptable business practice tend to fall into the high context category. In such a culture the communication style is more implicit, non-verbal and more reliant on hidden cues in the context of personal relationships. In Japan, for example, a

highly developed and affluent society, gift-giving practices are widespread in the business culture. Refusing to participate in gift-giving in such cultures can cause bad feeling and misunderstandings between business clients. In high context cultures, financial inducements are often seen as important steps in bringing a person into the inner circle of a business relationship or to strengthen the relationship between a buyer and seller. By contrast, people in low context cultures rely on explicit contracts, communication is more formal and explicit and negotiations based on a more legalistic orientation. Laws applying to bribery tend to be very well laid out. In some cultures, all business gifts will be viewed as illegal bribes; on the other hand, other cultures view gifts, pay-offs, and even bribes merely as a cost of business. Bribery and corruption are part of the commercial traditions of many parts of Asia, Africa and the Middle East. Transparency International, a global counter-corruption watchdog, ranks Indonesia as the most corrupt country, followed closely by Vietnam. They estimate in Vietnam that 20% of infrastructure spending finds its way into the pockets of corrupt officials. (Doole & Lowe, 2008, p.96-98)

In the book *The many faces of corruption*, Campos & Pradhan (2007), offer some perspectives on corruption in the pharmaceutical industry, and the following is from pages 31 - 32.

The pharmaceutical system is susceptible to fraud and corruption for a variety of reasons. First, the sale of pharmaceutical products is lucrative, the more so because the final customers (patients and their families) are more vulnerable to opportunism than they are in many other product markets, mainly because of asymmetric information. Pharmaceutical suppliers (drug manufacturers, importers, wholesalers, prescribers, and pharmacists) are profit maximizers and will choose to behave in ways that maximize their interests. There is nothing wrong with profit maximization so long as behavior does not go beyond legal norms and, in the health sector, professional ethical norms. The illegal sale of counterfeit, substandard, unregistered, and stolen drugs is particularly attractive where the opportunity for arbitrage exists. In 2002, for example, preferentially priced HIV drugs produced by GlaxoSmithKline that were destined for poor patients in Africa were intercepted and illegally resold in Europe at a substantial markup by a Dutch wholesaler. (Cohen, Mrazek & Hawkins in Campos & Pradhan, 2007, p.32)

In the transitional economies of Eastern Europe, to give one regional example, the rapid deregulation and privatization of the pharmaceutical sector, combined with an often unstable economic and political environment, not only created opportunities to engage in corruption

but also became a survival strategy for many when salaries of government and health sector workers declined sharply in real terms in the early transition years. In Albania, corrupt actions included private financial interests determining the drugs to be procured for the public health system, bidders giving kickbacks or bribes to gain access to confidential information, and use of direct procurement instead of competitive bidding without sound justification (Vian, 2003). In recent years, Albania has made significant strides in eliminating corruption from public procurement of hospital drugs by introducing a transparent, international tendering system that has significantly lowered the price of the average purchase contract for a given drug (World Bank, 2006). However, a history of weak drug quality controls has caused consumers to equate cheap prices with bad quality, and so the low-cost generic drugs often go unused. (Cohen, Mrazek & Hawkins in Campos & Pradhan, 2007, p.32)

The pharmaceutical sector is also susceptible to fraud and corruption because it is subject to a significant degree of government regulation. If appropriate checks are not in place, individual government officials might control several core decision points in the pharmaceutical supply chain and may have discretion in making regulatory decisions. Government intervention is justified in the pharmaceutical sector given the imperfect nature of the market and the need to improve the efficiency of resource allocation. Also, regulation is rationalized on the grounds of protecting human life and public health by ensuring that only safe and efficacious medicines are made available in the market. However, the trade-off is that the incidence of corruption may be higher because the state retains a major role in the sector and its bureaucracy is pervasive (Marshall, 2011). Without transparency and an accountability framework, state regulation in the pharmaceutical sector can be subject to regulatory capture, permit individual deviance from norms, and be open to corruption in general. (Cohen, Mrazek & Hawkins in Campos & Pradhan, 2007, p.32)

## 8.1 Framework for identifying corruption:

The framework for identifying corruption is presented in *The many faces of corruption* by Campos & Pradhan (2007) on pages 33 – 34.

The pharmaceutical system is technically complex. It is made up of several core decision points, ranging from manufacture to service delivery, each of which must be recognized and understood so that corruption cannot thrive out of ignorance. (Cohen, Cercone & Macaya, 2002). By understanding the multiple decision points along the pharmaceutical value chain, decision makers can determine where and how corruption can occur and implement effective anticorruption strategies to improve transparency and accountability. If best practices are known, inefficiencies and incompetence are easier to identify and address. This in turn creates a pharmaceutical sector that is less vulnerable to the risks of corruption. (Cohen, Mrazek & Hawkins in Campos & Pradhan, 2007, p.33)

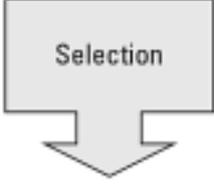
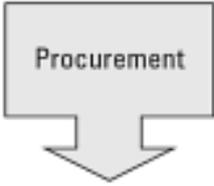
The framework is built on the rationale put forward by Klitgaard:  $M$  (monopoly) +  $D$  (discretion) –  $A$  (accountability) –  $T$  (transparency) =  $C$  (corruption). This corruption framework can assist decision makers in identifying circumstances that allow monopoly and discretion and situations where limited accountability and transparency could contribute to the risk of corruption. Policy makers can use the framework to diagnose potential risk points for corruption and to develop anticorruption strategies that address specific, identified risks. While the nuts and bolts of a pharmaceutical system are similar from country to country, the vulnerable decision points may differ and may even vary within different levels within the same country. Each core decision point needs to function well so that the system as a whole offers safe, efficacious, and cost-effective medicines. If only one decision point is vulnerable to corruption, the integrity of the entire supply chain is at risk, which means that the population's access to essential medicines could be compromised. If a particular decision point is corrupted, the impact on health outcomes may also vary, depending on the institutional organization of the system and the depth of the corruption. (Cohen, Mrazek & Hawkins in Campos & Pradhan, 2007, p.33 - 34)

Klitgaard (2000) identifies three main phases in combating corruption. The first phase involves consciousness-raising and includes educating decision makers and the public about corruption and its deleterious effects. The second phase involves adding system analysis to consciousness-raising to determine where pharmaceutical systems are vulnerable to

corruption. The third phase involves determining what strategies are necessary to prevent corruption from happening in the first place. (Cohen, Mrazek & Hawkins in Campos & Pradhan, 2007, p.34)

Using the Klitgaard equation  $M$  (monopoly) +  $D$  (discretion) –  $A$  (accountability) –  $T$  (transparency) =  $C$  (corruption), (Cohen, Mrazek & Hawkins in Campos & Pradhan, *The many faces of corruption*, 2007) can be a helpful tool to assess a foreign market for the possibility of corruption, and if corruption is detected, use the three phases mentioned above.

**9.0 Anatomy of corruption: Five (Six) core decision points:**

| <i>Decision point</i>   | <i>Processes</i>  |
|---|---|
|  <p>Manufacturing</p>                | <ul style="list-style-type: none"> <li>• Adherence to GMPs<sup>a</sup></li> <li>• Quality management</li> <li>• Packaging and labeling active pharmaceutical ingredients</li> <li>• Master, batch, and laboratory control records</li> <li>• Production and in-process controls</li> <li>• Certificates of analysis</li> <li>• Validation</li> <li>• Tracking complaints and recalls</li> </ul> |
|  <p>Registration</p>                 | <ul style="list-style-type: none"> <li>• Full registration or abbreviated drug applications</li> <li>• Safety and efficacy</li> <li>• Labeling</li> <li>• Marketing</li> <li>• Indications</li> <li>• Pharmacovigilance and warnings</li> <li>• Batch testing</li> <li>• Reevaluation of older drugs</li> </ul>   |
|  <p>Selection</p>                  | <ul style="list-style-type: none"> <li>• Determine budget</li> <li>• Assess morbidity profile</li> <li>• Determine drug needs to fit morbidity profile</li> <li>• Cost-benefit analysis of drugs</li> <li>• Consistency with WHO (and other evidence-based) criteria</li> <li>• Pricing and reimbursement decisions</li> </ul>  |
|  <p>Procurement</p>                | <ul style="list-style-type: none"> <li>• Determine model of supply/distribution</li> <li>• Reconcile needs and resources</li> <li>• Develop criteria for tender</li> <li>• Issue tender</li> <li>• Evaluate bids</li> <li>• Award supplier</li> <li>• Determine contract terms</li> <li>• Monitor order</li> <li>• Make payment</li> <li>• Quality assurance</li> </ul>                         |
|  <p>Prescribing and Dispensing</p> | <ul style="list-style-type: none"> <li>• Consulting with health professionals</li> <li>• Inpatient and outpatient care</li> <li>• Dispensing of pharmaceuticals</li> <li>• Adverse drug reaction monitoring</li> <li>• Patient compliance with prescription</li> </ul>  |

The model above is from Campos & Pradhan (2007) *The many faces of corruption*, p.35.

The following theories and discussion are presented by Campos & Pradhan in *The many faces of corruption* (2007) from pages 33 – 53. In the following theory and analysis, there an additional sixth point not shown in the model: Distribution - and it is presented before Prescribing and Dispensing.

Manufacturing: Manufacturing of pharmaceutical products requires adherence to standards of good manufacturing practice (GMP) to ensure “that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization” (WHO, 2003). GMP is a term defined in the quality assurance to be followed by drug manufacturers to help ensure that the products meet the required quality. Unless these established standards are followed throughout the manufacturing process – including handling of raw materials, storage, and packaging and labeling – there are risks to quality of drugs produced. Where such standards are not clearly defined or are weak or poorly enforced, there is a higher risk that counterfeit or substandard drugs may be in circulation.

Counterfeit or fake drugs are defined as drugs that are deliberately made to look like the original product, and they thus violate trademark or patents. Drug counterfeiting is a growing market globally. The Center for Medicine in the Public Interest forecast that the global market for counterfeit medicines will grow more than 90 % by 2010 to reach annual sales of \$75 billion (Pitts, 2005). Substandard or counterfeit medicines can result in poor health outcomes, and in the worst case scenario, death. One of the most tragic examples occurred in Haiti in 1995, where 89 people died when they consumed paracetamol cough syrup prepared with diethylene glycol, a toxic chemical used in antifreeze. (Cohen, Mrazek & Hawkins in Campos & Pradhan, *The many faces of corruption*, 2007)

Registration (and market authorization): Drug registration and market authorization were originally introduced to protect patients from drug catastrophes like the thalidomide tragedy of the 1950’s, when inadequate safety testing of the drug resulted in severe malformities in children born to women who had taken this drug during their pregnancies. The process of market authorization is generally undertaken by a national drug agency, responsible for the evaluation of a drug’s safety, its efficacy against a specific disease, its possible side effects, and, in the case of a generic, its bioequivalence or bioavailability.

Drug regulatory agencies are also often responsible for setting and enforcing standards relating to the manufacture, storage, and distribution of pharmaceutical products; licensing of pharmacists, pharmacies, and wholesalers; defining labeling, marketing, usage, warning, and

prescription requirements: and providing post-market surveillance. Examples of potential vulnerabilities at the registration decision point include the following: the law defining drug registration may be weak, vulnerable, or flawed; suppliers may pay government officials to register their drugs without the requisite information; government officials may deliberately delay the registration of a pharmaceutical product to favor market conditions for another supplier; or officials may deliberately slow down registration procedures to solicit payment from a supplier. (Cohen, Mrazek & Hawkins in Campos & Pradhan, *The many faces of corruption*, 2007)

Selection: For publicly funded drugs, the primary government task in drug selection is to ensure that the most cost-effective and appropriate drugs for a population's health needs are chosen with a fair and transparent manner through the use of impartial expert committees. WHO's essential drug list (EDL) is a helpful framework for most developing countries because it establishes priority medicines and lists the most common diseases together with effective and affordable drugs. However, if the selection process is not institutionally sound, even if the EDL is followed, corruption can still occur because manufacturers have a strong interest in getting their products listed. If institutions are weak and individuals have incentives to engage in corrupt activities, the selection process can be replete with kickbacks and payoffs so that drugs on a national drug list are not necessarily those that are appropriate and cost effective. (Cohen, Mrazek & Hawkins in Campos & Pradhan, *The many faces of corruption*, 2007)

Procurement: The goal of procurement is to acquire the right quantity of quality drugs at the most cost-effective price. Government functions in this decision point include inventory management, aggregate purchasing, public bidding contests, technical analysis of offers, the proper allocation of resources, payments, receipt of drugs purchased, and quality control checks. Procurement is often poorly documented and processed, which makes it an easy target for corruption. (Cohen, Mrazek & Hawkins in Campos & Pradhan, *The many faces of corruption*, 2007)

Distribution: Whether it is done by a government agency or by a private company that has been contracted by the government, the public distribution system needs to ensure the timely and safe delivery of appropriate quantities of drugs to health facilities and pharmacies where supplies are needed. Distribution and storage costs and make up a significant amount of the

retail price of a drug, especially when drugs are distributed to remote locations or where a lack of competition leads to inappropriate markups by wholesalers and retailers.

Poor storage conditions can lead to losses through both the diversion (corruption) and the expiration of drugs (inefficiency). A well-designed and well-managed distribution and storage system aims to maintain a constant supply of drugs, keep them in good condition throughout the distribution process, minimize drug losses due to spoilage and expiry, rationalize drug storage points, and use available transportation resources as efficiently as possible. (Cohen, Mrazek & Hawkins in Campos & Pradhan, *The many faces of corruption*, 2007)

Drug prescribing and dispensing: The main concern with drugs prescribing and dispensing is that the patient may not always receive the most appropriate drug for a given condition because the prescription decision can be driven by other factors, in particular, a self-interested profit motivation. In any developing countries, it is common for a pharmacist or an unqualified drug seller to dispense drugs without a prescription. In such situations, the pharmacist takes on a critical role in drug choice and can be directly motivated to dispense the most expensive drug to earn a higher margin rather than select the most appropriate product for a patient. This inherent conflict of interest is one reason for separating the prescribing and dispensing functions. The task for a government if the prescription system is weak is to establish a regulatory environment that promotes appropriate drug choice and dispensing practices and cost-effective care. (Cohen, Mrazek & Hawkins in Campos & Pradhan, *The many faces of corruption*, 2007)

The following analysis/discussion is developed using the theories from Campos & Pradhan in *The many faces of corruption* (2007) from pages 33 – 53.

Manufacturing: The multinational pharmaceutical industry is particularly concerned about ensuring the integrity of its supply chain and mitigating reputation risks by preventing infiltration of counterfeit drugs. While bar coding and scanning have been popular methods for the past 20 years, leading drug makers are rapidly embracing more sophisticated technologies such as radio frequency identification (RFID) tags and electronic product codes (EPCs). The advantage of these newer technologies over bar code systems is that the older system requires personnel to “read” the codes, while the newer systems are automated to read and store the information in ways that can easily be retrieved. In the case of RFID, this information can be easily read and retrieved from anywhere throughout a network that can extend across countries, enabling manufacturers to track and monitor their products (including storage conditions) more easily. Further, with this system a wholesaler, retailer, or even customs official, for example, could potentially read the RFID tag to check the electronic pedigree of a product and hence verify its legitimacy and integrity. To further discourage counterfeiting and the production of substandard drugs, those manufacturers found to be noncompliant with standards should be named, penalized, and shamed, with their violations publicly announced. Compliant manufacturers should also be recognized and have their names posted on the drug agency Web sites, for example, to help health professionals and patients more easily recognize the manufacturers that are achieving quality. (Cohen, Mrazek & Hawkins in Campos & Pradhan, *The many faces of corruption*, 2007)

Registration (and market authorization): Various strategies can be used to lower the risk of corruption in the drug registration process. For example, to minimize the risk of individual discretion, procedures should be applied uniformly and all criteria made available to the public. The regulatory authority must operate impartially and justify its decisions clearly and openly. To facilitate this, all regulatory employees should be screened for any potential conflict of interest that could bias any decision making. Information on the drug registration process, its criteria, and results should be published regularly and disseminated in local newspapers and on the Internet. Disclosing the Web site lists of all applications for registration and of all registered drugs (with dates) increases transparency. Overhauling the drug quality control requires a multipronged approach pushed forward by strong political leadership. Drug quality control requires not only a transparent drug agency but also ongoing market surveillance. To ensure the integrity of the drug supply, a market surveillance strategy

should include mechanisms for monitoring the drug supply, such as random batch testing and reporting streams to ensure feedback from health professionals and users to responsible authorities when problems are identified. (Cohen, Mrazek & Hawkins in Campos & Pradhan, *The many faces of corruption*, 2007)

Selection: There are several strategies for curbing the risk of corruption in the selection process. Explicit criteria must be defined ahead of time by an expert committee and publicized so that stakeholders have clear knowledge about what criteria are being applied in the drug selection process. Members of the expert committees should be publicly identified, and their credentials and the terms of reference for membership on the committee posted publicly. As long as the methods used are uniform, publicly available, and based on objective criteria, and the process is as transparent and objective as possible, corruption can be curbed. Suggested strategies include public dissemination of written procedures for pricing; establishment of specific criteria and terms of reference committees, which should include disclosure of any potential conflict of interest; the monitoring and dissemination of prices; and creation of a formal appeals committee to hear pricing disputes. Making pricing decisions publicly available over the Internet has also helped to add transparency. Assessing the vulnerability of this process is vital to identifying a strategy to strengthen the process. Best practices in transparency and mitigating corruption in pharmaceutical pricing can be taken from a number of industrial countries that have learned from their own incidences of corruption to identify less vulnerable processes. (Cohen, Mrazek & Hawkins in Campos & Pradhan, *The many faces of corruption*, 2007)

Procurement: The best protection against corruption is generally international competitive procurement because it maximizes competition and minimizes opportunities for personal discretion in the selection of suppliers. Competitive procurement requires an open bidding process and clear criteria for the selection and processing of winning bids. The procurement process must include continuous monitoring, including reviews from the inspector general's office or similar internal and external audit institutions for the public sector (USAID, 1999). Reports must also be easily available for public scrutiny. (Cohen, Mrazek & Hawkins in Campos & Pradhan, *The many faces of corruption*, 2007)

Distribution: Some countries have introduced codes of Good Distribution Practice that standardize requirements for distribution personnel, documentation, premises, and equipment. If good practices are not in place for this decision point, direct losses can be caused by

breaches in the process, including incorrect transport and storage conditions, unnecessary stocks, expired stocks, and theft of drug suppliers. Opportunities for the diversion and theft of goods are present in all stages of the storage and distribution system. Shipments can be plundered by sea – or airport workers or systematic crime syndicates may steal large quantities from customs warehouses, airport fields, and elsewhere. During transportation, drugs may be sold by drivers at markets along the way, or large quantities may be diverted to the black market. Politicians and local leaders may divert supplies to their supporters or patronage networks, and health facility staff may resell subsidized drugs or steal drugs for use in their own private practices or private use. (Cohen, Mrazek & Hawkins in Campos & Pradhan, *The many faces of corruption*, 2007)

#### Drug prescribing and dispensing:

A problem area in many countries is the potential for corruption when drug companies seek to influence physicians' drug prescription practices. The influence of the industry on physician prescribing behavior is a concern globally, but it can be particularly influential in developing countries, where physicians are typically not well paid well and standards of legal or professional ethical behavior are less well established or enforced. A recent WHO report on drug promotion noted that in the United States, almost \$21 billion was spent on drugs promotion in 2002. The same report emphasizes that the pharmaceutical industry is often the only source of drug information for health care providers in developing countries (Norris and others 2005).

Prescription fraud is a common form of medical claims fraud in public and private health insurance systems and can involve doctors, pharmacists, and patients. Prescription forms need to be treated with the same type of security features as blank checks, and systems put in place to detect, investigate, and prosecute fraud to countervail this problem. Some countries have introduced electronic systems for tracking prescriptions and dispensed drugs by patient, doctor and pharmacist and use data analysis to identify risks of claims of fraud.

Strategies to reduce corruption in this decision point could include ensuring that patients receive drugs only with the appropriate prescription. That will be challenging, however, so long as patients face a financial disincentive of having to pay for both the cost of the physician visit to receive the prescription and then the cost of the drug. Even where insurance systems are meant to cover both physician visits and drug costs, in areas where pharmacy salaries are low, additional informal payments are often charged on “free” drugs to

supplement the pharmacist's income. Pharmacies and pharmacists should be subject to appropriate licensing and inspections and breaches should be sanctioned. Typically, these aspects of pharmacies are self-enforced through associations of pharmacists. Corruption can occur in this decision point if codes of conduct either do not exist or are ineffectively enforced. However, ensuring their enforcement is challenging, particularly for the private retail drug market in developing countries. (Enemark, Alban, and Velasquez, 2004).

(Cohen, Mrazek & Hawkins in Campos & Pradhan, *The many faces of corruption*, 2007)

## 10.0 Conclusions

When marketing to foreign markets, the differences between the “home” country and the foreign countries may lead to challenges for the international marketer. The pharmaceutical sector suffers from a bad reputation, even though the intentions of the services and products offered are good - and can potentially mean the difference between life and death. The fact that the industry is extremely profitable fuels the accusations of “excess, or “unreasonable” profits – which the industry defends by stating the fact that the research and development costs of a single drug – which might never even make it to the market – is in the range of 800 million dollars. Although criticized, patent protection gives a pharmaceutical company only 17 years of exclusive rights to sell the drug, and when a drug goes generic, the profitability decreases. That leaves the pharmaceutical companies with reasonably short time to earn back the enormous costs of R&D, which in turn requires them to set high prices. On the other hand, the cases of unethical conduct, like promoting drugs for off-label usage, or the practice of doing something unethical (and more profitable than doing it the “right” way) and paying the fine/penalties (which will still leave them with more profits than doing it “right”) is harder to defend.

The information asymmetry that exists between the industry and the end-consumers is decreasing, most notably in the more developed parts of the world where information technology is getting more and more available to all members of society, and the end-consumers can evaluate their options before consulting a doctor/physician. The public and the government have a responsibility to educate themselves, as transparency is a widespread norm these days. The author notes that both the public and governments should restrict the involvement of influence groups, as well as reducing the influence the pharmaceutical industry has on the medical profession, as Green (2008) noted with centralizing all monetary funds and let institutions separated from the industry be in charge of distributing monetary support for research and development.

It would be rather bold to state that a country where corruption is present has a “corrupt culture”. The pharmaceutical sector is vulnerable to corruption, and being an international marketer in this sector may be a challenging task. In certain areas of the world, corruption has become a “natural” part when doing business, but may still be in conflict with the norms, values and traditions. Even here in Norway, we have experienced a series of corruption

scandals being uncovered. Corruption in the pharmaceutical sector is very complex, and may occur on nearly all stages, from manufacturing to distribution and dispensing. There are pitfalls everywhere, and the author feels that the vulnerabilities discussed are just a part of the pharmaceutical sector's problems. It seems that flawed jurisdiction and laws, loop holes and a lack of government initiative (and/or *will*); along with inadequate institutions and incomplete procedures/standards when dealing with pharmaceuticals are the drivers behind corrupt practices in the pharmaceutical sector.

In the authors' opinion, one solution might be through technology and the cooperation with governments (as long as they are not corrupt!), along with raising awareness and being proactive. International marketing is a wide term, and corruption is sadly a part of it. When working in different cultures, with "different ways of doing things", problems may occur – which is normal when cultures "clash". Countries with large gaps between the rich and poor may have a high degree of opportunism, which may lead to underpaid pharmacists, physicians, doctors, government officials – and marketers seeing a potential for exploiting their position for their own private gain – on the expense of the lives and health of the end consumers/customers.

When writing this paper, the subject felt enormous – but this paper has hopefully covered at least the basics of the issues concerning ethics in the pharmaceutical industry, and ultimately, corruption. The subject is a very important one – which encourages to further studies, in the authors' case: looking further into patent laws and patents in other industries.

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### Models & Internet Links:

BBC: <http://www.bbc.co.uk/news/world-us-canada-18673220>

Model Page 6: Falkenberg, A. Spring 2012, Lecture #1 in International Marketing, UiA.

Model Page 48: Falkenberg, A. Fall 2011, Lecture #10 in Culture & Ethics, UiA.

Model Page 58: The Corruption Perceptions Index 2011:

<http://en.rian.ru/infographics/20111202/169219288.html>)

Model Page 65: Campos, J.E. & Pradhan, S. (2007), *The many faces of corruption: Tracking the vulnerabilities at sector level*, World Bank Publications

Transparency International (quote in introduction):

[http://www.bu.edu/actforhealth/actforhealth04/Part1\\_5\\_corruptioninpharmasector.pdf](http://www.bu.edu/actforhealth/actforhealth04/Part1_5_corruptioninpharmasector.pdf)

WNYC: <http://www.wnyc.org/articles/wnyc-news/2012/jul/02/drug-giant-pays-record-setting-fine/>

Alternative Link:

[http://www.bu.edu/actforhealth/actforhealth04/Part1\\_5\\_corruptioninpharmasector.pdf](http://www.bu.edu/actforhealth/actforhealth04/Part1_5_corruptioninpharmasector.pdf)