

Pharmacare company's study analysis essay sample

[Media](#), [Advertising](#)



1. Research three to five (3-5) ethical issues relating to marketing and advertising, intellectual property, and regulation of product safety and examine whether PharmaCare violated any of the issues in question. There is much ethical concern available which possibly relate to marketing and advertising intellectual property, and regulation of product safety. However, there are some common ethical concerns which must be included by any organization while framing these areas and with the focus of such concern organization can ensure an effective and legal ethical relationship. Marketing and Advertising:

Direct to consumer (DTC) advertising included a number of commercial advertisements which advertise through radio or television and few use to publish in newspapers as well as in magazines as long as also published on internet too. All have the same goals to make aware the customers about any prescribed drug, it's the sole purpose of any drug advertisement. However, FDA has made it compulsory for every Company. They have to list the side effects in every ad of which they are going to publish. This responsibility is where companies like DTC, need to collaborate with its clients and confirm before advertising any drug. This is so that the customers themselves will be guided to understand before using any drug.

Moreover, FDA expects that the prescribed drug maker should also provide the risk information in every promotion which must qualify as a product-claim advertisement. (Gab 2008) In the case of PharmaCare, where they didn't follow the rules and regulations of FDA, it must be considered ethically to maintain the customers trust. They had advertised a non-prescribed drug '

AD23' that could directly affect any customer and shouldn't be allowed to sale in market because it was a compounding drug which got reformulated without any prior approval through FDA, i. e. ethically wrong.

Intellectual property:

As we know, there are intellectual property laws which must be followed by any Company and/or by subsidiaries, i. e. no any subsidiary can break the rules of intellectual property. They can't share the secret trade off as well as monetary gain to others. Within the case, PharmaCare is the parent company of CompCare; thus it's PharmaCare's responsibility to protect its own brand name as it had started its own subsidiary (CompCare) where they had reformulated AD23 without taking any proper approvals from FDA or through other required regulatory bodies; therefore, it's an ethical issue because the intellectual property was used by the Company subsidiary.

(Davoren 2012)

Regulation of product safety:

Manufacturing companies have liability once their product leaves for sale into a market. They have to ensure that legislation is governed byproduct's safety. The main ethical concern is that they have to ensure that the company has been providing only those products which have been tested for safety. The product safety engineers are expected to examine and test products to various standards and make sure that they have received the approval certification. This certification provides that the respective products are free of any harmful effects. (Gabb 2008) Within the case, CompCare got

the information that continuously increased consumption of medicine AD23 which increased the rate of heart attack. Even after knowing the harmful impact the Company ignored the reality and had started taking bulk orders and earned more profit with one single product sale. Hence, there was an ethical issue related to the product's harming effects of which they ignored the risk factor to gain the high rewards as well as an increase in the profit margins. (Davoren 2012).

2. Argue for or against Direct-to-Consumer (DTC) marketing by drug companies. Provide support for your response. In the pharmaceutical business, DTC marketing refers as an advertising practice where medical products and services are advertised to the consumers rather than passing it through the main distribution channels like; through physicians, retailers and hospitals. These ads are used to create both positive as well as negative impact. (Davoren 2012) I think it can be a misleading activity because customers usually don't have sufficient and technical knowledge on how to judge the medical product and its actual benefits. Thus, they were misleading by the overstated advantages of the products which were mentioned in its direct to customer advertisements.

Although, there are certain laws like; Federal Food, Drug and Cosmetic Act, which expect that distributors should properly disclose the detailed information about the product and its risk factor to the consumer. The fine print ads usually don't reveal any real facts about the product. In turn, this can create a negative impact. This shows that the experts of this area, who have the actual knowledge about the products benefits and its real producer

of consumption, can get missed out in direct to consumer marketing. (Gabb 2008) For attracting the consumers, companies are coming up with ads of products which make promises like; easy weight loss, regained youth etc. Celebrities and actors are involved in these ads to increase the level of consumption.

Consumers get easily attracted towards those ads and they start consuming the product even without reading the complete prescription. DTC advertising of medicines on the basis of prescription is only authorized in US and New Zealand because other countries are still not considering spending millions every year in this crucial area. For Example; Pfizer DTC advertising of anti-cholesterol drug, Lipitor has created controversy of inventing an artificial heart and even Robert Jarvik, creator of that heart, was not a licensed medical doctor. The World Health Organization did a detailed investigation of the ad and it was a misleading act.

3. Determine the parties responsible for regulating compounding pharmacies under the current regulatory scheme, the actions that either these parties or the FDA could / should have taken in this scenario, and whether PharmaCare could face legal exposure surrounding its practices. Support your response. Compounding pharmacies is defined as the practice in which a licensed pharmacist uses to mix or alter the ingredients of any particular drug. This is done so that he/she can modify and create the medicine as per the requirement and need of an individual patient. All pharmaceutical manufacturing companies are regulated by The Federal Food and Drug Association (FDA). Apart from this, state is considered as the primary

regulator of the pharmacies which includes the drug stores, store pharmacy counters, large chains and specialty pharmacies.

Every state has its own laws and regulations in which a pharmacy company has granted with extra and explicit authority to compound and mix the pharmaceutical ingredients to form a patient-ready product where they are authorized to do this only if they have prescriptions written by doctors, Staff Writer (2012, January 18). As we know, PharmaCare wholly owned subsidiary of CompCare, realized the scope of more profits margin. Keeping this in mind, they started the direct to customer advertising and selling AD23 in bulk orders to the medical stores and hospitals. They were not allowed to do this because the medicine AD23 was reformulated as a compounding drug without taking any prior approval from the authorized communities. With consideration of such circumstances the FDA would have collected the sample of the drug AD23 and it should have been examined and collected under a compounding pharmacy.

FDA is also having the complete authority where they can examine the records of prescriptions and other operational records like; product quality test, results of stability testing and various other important records. Such inspections are required to perform on timely basis to ensure that the company is not exceeding the traditional bounds of compounding and it is also implementing the federal standards to minimize the public health threats. Yes, PharmaCare has to face the legal exposure for surrounding its practices because its subsidiary CompCare has sold the medicine AD23 directly to the customers on the basis of fictitious facts, to a list of patients

they had taken from the doctors. It is an inoffensive act for which company has to undertake detailed legal investigations even law is also authorized to take the action against those doctors who has forwarded these fake list of patients to the company.

4. Analyze the manner in which PharmaCare used U. S. law to protect its own intellectual property and if John has any claim to being the true “ inventor” of AD23. Suggest at least three (3) ways the company could compensate John for the use of his intellectual property. The PharmaCare followed United States (U. S.) laws to protect its own intellectual property. This was an U. S. based company and it had opened its subsidiary by the name of CompCare where it has formulated the new drug so that it can sell that drug to all individuals and various pharmacies outlets on the basis of required prescription. Once FDA researched and they discovered that PharmaCare pharmacist are reformulating the drug AD23 to maximize its effects, CompCare will get protected by patenting the new drug under the FDA and U. S. patent and U. S. Federal Trademark laws. (“ STATE REGULATION OF COMPOUNDING PHARMACIES”)

Out of the three ways in which PharmaCare can compensate the John are, 1) Through financial incentives because it was the John and his team who had reformulated the medicine so he can be compensated in monetary terms because he is the member of the inventor team of AD23. 2) The company can provide facilities and environment to John where he can foster his creativity. He should get the cost and risk of securing the IP. CompCare can sign a contract with John where it can promise the payment of life time

royalty. 3) CompCare is the subsidiary company of PharmaCare and the share prices of company are booming and it has reached at the new heights of \$300 per share, so John can be offered good amount of shares so that he can become a stakeholder of the company and can enjoy the long term benefits. Since, John has lost the life of his wife so company should take care of the situation by providing him the financial as well as emotional security.

Summarize at least one (1) current example (within the past two [2] years) of intellectual property theft, and examine the effect on that company's brand. Intellectual property is defined as the innovation, an exclusive name, symbol, new method or logo used by the company to create its unique identity. These Intellectual properties are protected by patents, trademarks and copyrights under the state and federal laws. Stealing these intellectual properties is considered as a crime and the organization and/or an individual who did this theft has to bear harsh levels of punishment. South Korean giant, Samsung is blamed by Apple for stealing its intellectual property rights. Apple says that Samsung has copied its hot selling product iPhone features and illegally fixed the prices so that they can attract large number of customers and become the dominate player of the market.

Apple iPhones are copied by Samsung and today, it has become a leading player of the global market. (Tobak 2014, Jun 18). A court case is already placed and legal battle is going on. Samsung is contributing near 17 % towards the Korea's GDP so the country keeps on following the copy culture without taking into consideration under the basic rules of ethic and integrity. Samsung is having a long track record where its engineers had

copied the methodology without giving any second thought about the patent rights which they had violated. (Tobak 2014, Jun 18)

6. Analyze the potential issue surrounding the death of John's wife and other potential litigants against PharmaCare as a result of AD23. After a successful launch of medicine AD23, PharmaCare team realized that this drug can slow down the impact of Alzheimer's disease. In order to increase the sales volume and for maximizing the profit margins the company decided to reformulate the drug without taking approval from FDA (Food and Drug Administration). To avoid any kind of scrutiny PharmaCare opened its subsidiary CompCare where all this illegal work was carried out. However, the central law demands that all the drugs should be approved by FDA to ensure the safety and effectiveness of the drugs. During the approval process manufacturers have to present the complete process of producing the drug, which is always reviewed by FDA.

It also checks the labelling to insure that healthcare professional are having the information and they understand the risk factor attached with that particular drug product. (" STATE REGULATION OF COMPOUNDING PHARMACIES") There is a belief that, Company which is marketing its products without taking approval from FDA, is not meeting the expectations of basic standards of safety, quality and labelling. The major fault, which was done by the company, had manufactured the product without approval. This resulted into a death of John's wife and various other innocent people because they had consumed the medicine AD23 without prescription of the

doctor. They all had faith in the strong brand image of the PharmaCare products.

7. Specify both the major arguments that John can make to claim that he is a whistle blower and the type of protections that he should be afforded. Justify your response. John has decided to become a legal witness against the company, although he was also enjoying the huge amount of bonus and incentives. He was receiving the big profit margins of the company. But with the consumption of the medicine AD23 one of the hottest selling products of PharmaCare, his wife died of a heart attack. It was an emotional loss which John has suffered in his life, had made him realized that he should take a step forward and protect the lives of various other customers. (“Unapproved Prescription Drugs: Drugs Marketed in the United States That Do Not Have Required FDA Approval”) The initiative by John can be considered as a whistle blowing act and he can be given protection against his employer under various programs formed by the Occupational Safety and Health Administration (OSHA) and the Securities and Exchange Commission (SEC) for the disclosure as he has done in front of a legal agency against the wrong doing happened in his own organization.

The whistle blowing act provides protection to the employee from the discrimination he has to suffer from his employer during the phase of investigation. If at any point of time employee feels that he has being discriminated against for exercising his rights he can freely file a complaint and the agency can take strict action against the company. In such situations even the government is not allowed to take any action or threaten

the employee who has become the witness because that employee has disclosed the information that is having sustainable and specific danger for the public safety and health. John will be provided the complete protection by the law firm of Dewey, Chetum, and Howe thus he should give details that is threatening the public health without fear of reactions. He will be having all the rights to freely communicate with the public body for their investigation.

If John feels comfortable he can even allowed to assemble at public places to discuss the matter openly. He will be given the protection by the firm to freely disclose the illegal activities that are threatening the public health and safety without any fear of reactions. In the duration of investigation John can enjoy all the terms and conditions of his employment, like his other team members. He can access all his personal, medical and the other relevant files related to his work as and when required, “ Unapproved Prescription Drugs: Drugs Marketed in the United States That Do Not Have Required FDA Approval”.

John is also having certain obligations towards the society in which he lives. It is expected that he should disclose all the violated activities carried out by PharmaCare without any kind of fear. John could have even shared the matter with his supervisor so that he could have taken the matter further instead of hiding it. In this particular situation since John has directly approached the law firm of Dewey, Chetum, and Howe, they are required to perform investigation at serious mode and take an immediate disciplinary action against the company.

References

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