PharmaCARE Production of AD23

Name

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Introduction

PharmaCARE is one of the world's most successful pharmaceutical companies, enjoying a reputation as a caring, ethical and well-run company that produces high-quality products that save millions of lives and enhance the quality of life for millions of others. In this paper ethical issues in marketing and advertising, intellectual property, and regulation of product safety are discussed in relation to AD23, a drug developed by PharmaCARE to be sold under its subsidiary, CompCARE. Further, arguments for and against Direct-to-Consumer (DTC) marketing by drug companies are discussed. There are several controversial issues in the pharmaceutical industry such as human health considerations and intellectual property theft that are under review.

Ethical Issues Relating to Marketing and Advertising

Ethics in this sense refer to the certain standards and rules of conduct that are recognized in a certain profession. Several ethical issues that are related to the advertising, marketing and the regulation of product safety can be raised. One of these issues is stereotyping. Advertising companies frequently cast specific social groups in cliché roles, for example, washing powder adverts that show ladies as housewives distracted with their clothing, or fix-it advertising that usually depict only men as being able with tools. Moreover, the advertising company may create the impression that acquiring a lot of their products will prompt satisfaction and bliss in the buyer consequently positing that the buyer will not be included in the happy prosperous group should he or she choose not to buy the item being advertised by the company. Stereotyping thus is ethically wrong since it tries to appeal to the more vulnerable nature of people to try and coerce them into buying goods and services. CompCARE however does not breach this ethical issue in any apparent manner.

Another issue that arises is the use of subliminal messages in the advertisement of certain products. Subliminal messaging refers to the use of relatively undetectable messages within the advertising material with the hope of manipulating the consumers' thoughts towards purchasing a commodity being purchased. Use of subliminal messages is ethically wrong since it uses manipulation to coerce buyers instead of giving the buyer a chance to make a conscious decision on whether or not to make the purchase. CompCARE does not in any apparent way use subliminal messaging in its advertisement.

The use of truth in the advertising is another ethical issue. Ethical advertising requires that messages relayed by advertisements should be truthful and not deceptive. Deceptive messages are not only unethical, but inhumane, especially if the goods involved can pose a health hazard to the consumers. It thus goes against the mantras of public safety. CompCARE shows unethical behaviour by not clearly stating the side effects of their product, AD23. In addition to that CompCARE colludes with doctors to create a fictitious list of patients in order to propagate the unsafe drug, AD23.

The laws of United States of America provide the utility to lay a claim on property that is original such as new inventions. CompCARE could have taken advantage of the provision and patent the new drug and trademark the name AD23. In doing so, the law would have provided exclusive rights to the manufacture, distribution and sale of AD23 for a certain period of time. The government thusly would have recognized CompCARE as the owner of the intellectual property, AD23. Moreover, the company, CompCARE, may have indicated in its policies that any research that will carried out under the company's premises and funding will be the property of the company and that all inventions will be the property of the company. However, John can still claim the copyright of the intellectual property.

Arguments in Support of Direct-to-Consumer Marketing

Informs, educates, and engages patients. DTC teaches patients and permits them to assume responsibility of their health. In the United States, it is thought that advising consumers will profit the drive for health insurance reform. Consumers can likewise profit from having entry to numerous data sources about medications and other treatment alternatives as opposed to depending exclusively on medical care providers.

Encourages patients to contact a clinician. A typical claim is that DTC encourages patients to consult a medical care provider to look for restorative advice. A 2004 FDA consumer study found that introduction to DTC prompted 27% of Americans to make a meeting with their specialist to discuss a condition they had not formerly discussed (NCPC, 2014) .Another study found that the little print in a medication advertisement was unequivocally connected with patients reaching their social insurance providers. The impact of DTCPA in expanding patient contact with medical care providers could likewise be beneficial by promoting dialog about lifestyle changes that enhance patients' wellbeing, whether or not a medication is recommended.

Promotes patient dialogue with health care providers. Most medicinal services experts appear to concur that DTC is advantageous in light of the fact that it promotes dialog with patients. In the 2004 FDA study, 53% of doctors said DTC prompted better discussion with patients and 73% accepted that consumer medication publicizing helped patients ask more insightful questions. Additionally, in a review of 221 American oncology medical caretaker professionals, 63% of participants felt that DTC promoted dialog with patients (Abel, Penson, & Joffe, 2006). DTC might additionally benefit patients promoting heightened awareness and recognition of adverse reactions, which additionally may prompt an

examination with a medical provider. Research indicates that DTC increases the probability that a patient would start a dialog with a doctor to ask for an advertised medication.

Data additionally demonstrate that patients who discuss about a physician recommended pharmaceutical with their specialist after seeing DTC frequently get an alternate proposal or treatment. According to a 2006 review led by prevention Magazine, of the patients who had a discourse with their specialists after seeing DTC, 77% reported that their specialists proposed wellbeing and lifestyle changes rather; 55% said they were endorsed a generic prescription; and 51% said their specialist proposed non-prescription treatment, such as the over-the-counter medicines (Antone, 2009).

Encourages patient compliance. The medical literature consistently indicate that small, but statistically significant, improvements in adherence happen among patients due to DTC advertisements. This increased consistence is believed to be because of medication ads serving as a reminder about patient's health conditions and prescriptions. . DTC is also thought to reinforce physician recommendations and make patients more likely to follow treatment instructions.

Arguments Opposing Direct-to-Consumer Marketing

Misinforms patients. In spite of the fact that DTC publicizing may educate patients, it additionally can deceive them. A common objection is that DTC discards vital information (Frosch, 2007). For instance, in one study, 82% of DTC ads made some verifiable cases and rational arguments for utilization of the promoted medication; nonetheless, just 26% of the ads depicted danger elements or reason for the condition, and just 25% mentioned prevalence. DTC likewise has a tendency to propose that wellbeing change originates from a medication, maybe in combination with healthy exercises, yet never from conduct alteration alone.

Overemphasizes drug benefits. Adversaries to DTC caution that ads for medications overemphasize potential benefits. In backing of this perspective, content expository studies have found that most DTC ads emphasize drug benefits over risks (Grande, DI, DM, & Kravitz, 2010). A 2007 study in the *Journal of Health Communication* likewise found that the normal DTC TV plug commits more of an opportunity to profits than to risks (Shaw, 2008).

Doctors likewise report that most patients who start a request for a new drug understand the benefits much better than they comprehend its risks. Studies have found that when a case shows a medication as being exceptionally solid, buyers don't attempt to process whatever remains of the data inside the message. Information about risks is normally introduced in frequently overlooked more diminutive print or as a component of a vast, undifferentiated block of text or audio. Also, ads regularly demonstrate a mismatch between visual imagery and verbal messages when risk information is presented. For instance, a person may be seen enjoying a stroll in a recreation centre while the narrator lists serious side effects (Grande, DI, DM, & Kravitz, 2010). Research has demonstrated that when visual and verbal messages are conflicting, visual messages have a tendency to prevail, which can bring about lacking transforming of verbally presented risk information.

Promotes new drugs before safety profiles are fully known. New medications have been connected with previously unknown serious adverse occasions after they have been in traduced to the market and a substantial amount of use has occurred. This is especially valid for "first-in class" drugs (Schuchman, 2007). Clinical trials needed for FDA approval are ordinarily not intended to discover uncommon adverse effects, and current routines for post marketing surveillance regularly fail to interface unfavourable events that have a high rate of background predominance with the use of a specific drug. Drugs that are relied upon to be "blockbuster" sellers are also most vigorously advertised early in the item's

life cycle, which can present a public health risk the drug's security profile is not completely known at that point.

Manufactures disease and encourages drug over-utilization. DTC has been criticized as helping the "medicalization" of common conditions, cosmetic issues, or trivial ailments, bringing about an overmedicated society. For this reason, a few observers have even alluded to DTC as a risk to public health. One frequently referred to example is DTC ads for ED drugs, which appear to target men who may be experiencing normal variations in sexual performance. Studies show that just 10% of American men experience an aggregate inability to attain an erection. Therefore, numerous requests for ED medications appear to be for intermittent issues, which might really be "normal." Similarly, DTC drug ads have also been criticized for redefining menopause as a hormone-deficiency ailment rather than a typical midlife experience (NCPC, 2014).

Strains relationships with health care providers. DTC is frequently condemned for its potential effect on the patient–clinician relationship (Abel, Penson, & Joffe, 2006). Drug ads can have an impact in diminishing a patient's trust in their health medical provider's clinical decisions. Additionally, clinicians might end up being challenged with increased work and disappointment when a patient inquiries their clinical authority with a bit of "evidence" obtained from an advertisement or Web site.

Pharmaceutical Regulatory Bodies

Under the current regulatory scheme, there are a number of parties responsible for regulating compounding pharmacies, which include the FDA and ICH. These bodies had a role to play in PharmaCARE's CompCARE venture to sell AD23.

The FDA should have taken action in this case to ensure that AD23 supply was regulated and that the drug met the standards according to their policy to protect the public

health by assuring the safety, effectiveness and security of human drugs. Failure by the organization to regulate DTC contributed to this problem by permitting a variety of approaches to risk communication that confuse consumers and reduce their understanding of drug-associated risks. FDA regulations also don't address the use of qualifying language in DTC, thereby allowing the use of non-qualifying language with respect to side effects therefore misdirecting and open to various translations in light of the use of words, such as "mild," "usually," "short time," "if," and "may" (NCPC, 2014).

ICH also had a role to play insuring safe manufacturing and handling of the drug and also reviewing it before it was introduced to the market. Furthermore, the body had a responsibility to ensure that the consumers had good information on the use of the drug. Finally, the body was responsible to enforce and launch a corrective measure in the event of complaints from customers who used AD23. If ICH considered using its policies against PhamaCARE's production and sale of the drug, the company would be held legally viable for sale of un-standardized drug. The basis of accusation would be on the various heart attack cases reported and also the assessment that would be done by the body.

How PharmaCARE used the law to protect its intellectual property

CompCARE can compensate john for his contribution to the creation and improvement of the drug, AD23, in several ways. Compensation can be made to john through monetary and non-monetary forms. When done via monetary form, it can be through royalties. A royalty is a utilization based instalment made by one party (the company) to an alternate (John) for the right for the continuous utilization of the intellectual property (AD23). The royalties will be regularly concurred upon as a rate of net incomes inferred from the utilization of AD23 for every unit sold of the drug; however there are different rates of remuneration from the company's income that both parties can agree to (FSC, 2012). Another

way of monetary compensation is a lump sum of money paid to john by the company, followed by subsequent regular loyalties that are paid upon a lower rate. The last monetary compensation is one lump sum of money paid to john by the company with no subsequent royalties (FSC, 2012).

Intellectual Property Theft: Case Example

Since the approval of Stribild about two years ago, there has been several cases of the drug counterfeit reported in many African countries such as Kenya. The drug is commonly used in the treatment of HIV infection (NCPC, 2014). This Identity Infringement has greatly damaged the brand name resulting to adverse effects to the manufacturer, Gilead Sciences, which include loss of customer loyalty, which has in turn led to the decrease in incentives to innovate and fall in revenue.

Litigants against PharmaCARE

The company, PharmaCARE, faces the risk of a lawsuit for the death of one of its workers wife. In addition to that, the company faces lawsuits charging them with distributing fatal prescription drugs. The company is to be charged for the deaths of over 200 patients. The company also faces litigation for intentionally hiding from the scrutiny of the Food and Drugs Administration (FDA). The company opened a subsidiary company that they named CompCARE, that appeared to be separately owned and whose work was to operate like a pharmacy for compounding and selling of the new drug to patients through prescriptions by medical practitioners (Loevy, 2005).

Additionally, contrary to laws on pharmaceutical drugs that state that compounding pharmacies do not have the permission to sell prescription drugs or any other drugs for general use in bulk. CompCARE also face litigation for direct advertising the drug to their consumers and the direct marketing of the drug to clinics, hospitals and physicians.

PharmaCARE also face charges of colluding with medical practitioners in faking a patients list so as to increase the number of orders of AD23 TO BE supplied to the health units. In addition to that, other charges may include duping and tarnishing the name of the company they sold CompCARE to CompCARE was sold to WellCo, a few weeks before AD23 became involved in a public scandal involving the deaths of more than two hundred patients as a result of consumption of the drugs (Loevy, 2005). The company also bribes its employees, including john, with big bonuses, so as to continue with filling the orders of AD23. That is another crime that the company faces litigation over.

Justification of Whistle-blower Claim

John can make argument that he is merely a whistle-blower in the litigation of PharmaCARE. One argument would be that since John as an individual, out of his own good will, sees that the general public interest overrides the needs of PharmaCARE and decides to expose the company as being degenerate, the court should view him as a whistle-blower and prosecute the company instead (Loevy, 2005). John could also say that as a researcher, he was in no position of authority to redirect the company's illicit sale of potentially harmful drugs and the best step he was in a position to take was to call the authorities on the company (Loevy, 2005). In accord to his whistle blowing, john is entitled to immunity from any type of sanction, when the company is being prosecuted. He is also entitled to protection from the company's administrator's reactions by letting him remain anonymous. This protection is justified since he helped the state to uphold the law and it is possible that the company might retaliate on him for exposing their actions.

Conclusion

The company practices unethical advertising strategies like stereotyping, use of subliminal messages and deception. Laws exist to protect ones rights to his intellectual property. Royalty is compensation made in exchange for rights to one's intellectual property. For selling potentially fatal medication, PharmaCARE faces several of litigants among them John, the whistle-blower. The whistle blower may thus get protection from the law if the company is charged in court. The use of Direct-to-Consumer marketing in the pharmaceutical industry has a number of advantages, which include **i**nforming, educating, and engaging patients; **e**ncouraging and promoting patient dialogue with physicians and encouraging patient compliance. Some of the demerits of DTC include misinforming patients, overemphasizing drug benefits, promoting new drugs before the consumers have any knowledge on them and straining relationships with healthcare providers. FDA and ICH are some of the bodies that control the pharmaceutical industry.

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