Ethical and Legal Issues in PharmaCARE Operations

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Introduction

In this paper, I am going to write a document memo featuring all the problems faced by the high-ranking partners of Pharma CARE. The three most important ethical issues will be discussed in the memo, which are related to advertising, marketing, and intellectual property, along with the regulation of product safety and an analysis of whether Pharma CARE violates any of the requirements in question. Here, I will discuss the pros and cons of direct-to-consumer marketing. Next, it will be determined which parties are answerable for the regulation of compounding pharmacies within the new regulatory system, all those actions that should be taken by these parties in this setup, and whether Pharma CARE should face any legal exposure. After that, an analysis will be made of which US law was used by Pharma CARE to secure its intellectual property, whether John claimed to be the real creator of AD23, and, if this is true, how Pharma CARE should compensate him. After all this, a summary of a recent example of theft related to intellectual property will be given, and its effects on the company's brand will be examined. By using that example, potential issues will be analyzed regarding John's wife's death and other similar complaints against Pharma CARE because of AD23. In the end, two important arguments will be specified that John can make to prove that he is the main whistle-blower and the type of protections he ought to be afforded.

Ethical Matters

According to the First Amendment of the US Constitution, freedom of voice is guaranteed in commercial speech. Unless it is considered obscene, offensive, or similar to provoking violent activities, the expression is secured by the marketplace of concepts and ideas (Halbert & Ingulli, 2012). In my opinion, the amendment was not violated by PharmaCARE, as it is the right of those people to have full information on all available products.

The information flow to consumers cannot be standardized or prohibited by state law because it gives rise to the supposition that their community is not sophisticated enough to recognize the advertising limitations (Halbert & Ingulli, 2012). According to Halbert & Ingulli (2012), the Federal Trade Commission Act of 1914 prohibits "illegal ways of competition & deceptive and unfair practices and acts," including misleading or false advertising. The FTC Act was violated by Pharma CARE when it

came to the safety of the product because misleading information was left out. Once Pharma CARE acknowledged that people were having heart attacks at a very alarming rate after receiving AD23, it should have stopped the sale of this product temporarily. But instead, it overlooked the information and continued filling the orders. This is against the FTC Act, as the company is suppressing consumer information. Consumer demand theory was also ethically dishonored by Pharma CARE.

One of the major and broad propositions of the theory is that “wants to originate in the consumer’s personality (Halbert & Ingulli, 2012).” “As the community is becoming more prosperous, there is an increased creation of want by the phenomenon through which that is fulfilled. This may function passively. Consumption increases by emulation or suggestion to produce wants. These are the producers who actively create wants through salesmanship or advertising (Halbert & Ingulli, 2012). When Pharma CARE started having fictitious patient names listed by the doctors and started advertising to clinics, physician offices, and hospitals, it satisfied a demand created by the company, and this fact was violated by not allowing compounding pharmacies to sell the drugs for general use in bulk.

Direct to Consumer

It is quite difficult for me to take a position on direct-to-consumer marketing. According to a survey conducted by the Food and Drug Administration in 2004, most physicians stated that one of the main reasons their dealings with patients and medical practices are affected is the viewing of direct-to-consumer advertisements. Direct-to-consumer marketing aids patients in getting more involved with healthcare and being more knowledgeable about the available ways of getting relief.

However, if we check the flip side, it can result in new demands from patients to take medication in excess that might not be 100% effective and can cause greater negative effects. This is the point where conflict arises. Although consumers are more involved in taking initiatives relating to their healthcare while paying attention to the pitches of marketing salesmen, the pitches usually leave out negative side effects. Consequently, consumers hear only the positive things about a medication and what that medicine can do, but they do not hear the specifics about how it might interact with another medicine or produce new side effects. As a result of such information, it becomes difficult for physicians to prescribe alternate treatment methods to patients.

Responsible Parties

The Food and Drug Administration, the Center for Drug Evaluation and Research, and the Consumer Product Safety Commission are parties that control and regulate compounding pharmacies. The Food and Drug Administration has the authority and is in charge of promoting and protecting public health by overseeing and monitoring food, prescription drugs, tobacco, and other new pharmaceutical drugs. In 1972, the Consumer Product Safety Commission was formed to protect customers from

unreasonable risks related to death due to unsafe products, illness, and injury (Halbert & Ingulli, 2012). The Center for Drug Evaluation and Research has the duty to make sure that the medicines available in the market to assist in improving individuals' health in the US are effective and safe.

CDER is an important part of the FDA, regulating over-the-counter drugs and prescription drugs. The above three organizations should take strict action against CompCARE and PharmaCARE. One of the main actions should be that big companies will not be permitted to start a wholly owned subsidiary branch of the company without being held accountable for its activities. It should be illegal to establish compounding pharmacies for the purpose of blatantly evading FDA inspection. Such companies should be considered answerable for their illegal activities just as if they were parent companies. This would result in the avoidance of too many injuries, backlash, and death. According to my perception, the re-creation of a drug to make it fit the requirements of specific patients is something that must be monitored severely. As these laws are impossible, I don't think that PharmaCARE should face any legal exposure relating to its actions.

Intellectual Property

The area of law that deals with protecting the rights of individuals who produce original works is known as intellectual property. It covers everything from novels and original plays to marks of a company's identification and inventions. The basic motive behind intellectual property laws is to inspire new inventions, artistic expressions, and technologies while encouraging economic growth. When individuals are assured that their creative work will be secured and that they will benefit from their labor, they continue producing things that will develop the latest technology, create jobs, craft more beauty in the world surrounding us, and make processes well organized. PharmaCARE used US law to defend its intellectual property since PharmaCARE is known as the parent company, and John worked under the company that it wholly owns; therefore, all products and findings belong to Pharma CARE. If John was working for himself and was contracted by Pharma CARE for his services, then John would be eligible for compensation. According to patent regulations, trademark rules, and copyright rules, John should be authorized for compensation.

Current Example

According to Versata, Ford received a patent in 2014 on software developed internally based on technology that was licensed to Ford and is known as Automotive Configuration Manager. This software by Versata was able to identify incompatible parts in various vehicle configurations, which would assist vehicle manufacturers in reducing recalls and other similar concerns.

Issues:

Whistleblower

According to the views of Halbert and Ingulli (specifically talking about the year 2012), blowing the whistle was the act of employees reporting unlawful or immoral acts of an employer. To understand the idea, we must know who a whistleblower is. A whistleblower is a person who feels that it is his duty or obligation to blow the whistle when he believes it is necessary to shed light on an important act or event. Such a situation is mainly unlawful, immoral, and corrupt at the place of work; it may also affect the status of the company or add a bad name, ill repute, and dishonor to the company.

It may also break or lessen trust, isolate and seclude employees, and lead to termination. James Crowley, an employee of Chicago State University, was fired because he refused to preserve papers related to the University's president. He was asked to keep these papers under the state's public records law. Crowley was also pursuing his whistle-blower case, in which he earlier added that he was retaliated against for reporting doubtful agreements to the Attorney General's office. The case Crowley filed was not a simple claim; it was a claim targeting not only the University but also the President, Wayne Watson, and seven other company trustees. At the time when Watson was selected as Chicago State president, James Crowley was working on reporting information to public records, and neither of them was on the same page in responding to these requests.

The inconsistency and disturbance gathered around Watson's start at the beginning of his career at the University. If Crowley had ever reported that Watson had started on the first of August, Watson would never have been entitled to the pension that he received from his previous job at City Colleges of Chicago. This could be termed a dilemma since the law demands at least sixty days to transfer state jobs.

Justification

James was believed to be justified in reporting that the information involved fabricated documents. In 2003, there was a special action taken by Governor Rod Blagojevich; he played a great role in introducing the Employees Ethics Act. The major purpose behind designing such an act was to stop unlawful and corrupt activities by state officials all over the state. The law required all employees to go through training under the new law so that the employees were well aware of all the current information. If the law is violated, there are both civil and criminal penalties for the person violating the law, but the law protects whistleblowers who report misconduct. Therefore, from the above case, one learns that if James had never reported the correct information, he might have violated and disrespected the law and risked penalties and other possible criminal charges. Therefore, Mr. Crowley was bound to obey his duty to protect himself and the company he served.

Sarbanes-Oxley Act

The Sarbanes-Oxley Act “stops any public company from being unjust to any one of the employees who had under the law given detailed information or has otherwise assisted well in an ongoing investigation of the behavior in which the employee “sensibly believes” establishes a desecration of the centralized sanctuaries law.”

Many harmful effects resulted from drug addiction; some were severe enough to cost the lives of addicts, and many customers died as a result of overdosing on the drug. One such example was that of John’s wife. The thought was that the company already expected the same danger and had the knowledge that if AD23 was used excessively, it would have horrific results, but the company seemed to do nothing about it. On the other hand, it was seen that there was massive success in the business through excessive commercial production, and the company stayed silent on the large-scale death rate resulting from the drug’s use by its consumers. There can be another view as well that can state that the act was not ethically wrong. One might assume that the delay resulted from a detailed study of its side effects. The major issue raised here is whether there was unethical and illegal conduct on the part of Pharma Care, even in ensuring that the company was doing its best for the security of its employees and customers.

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.

Whistleblower protection concerns the treatment by a company or government of a person responsible for reporting dishonest or unlawful activity or discrimination toward one party in socioeconomic associations, which can then be investigated and used to prove the fault of the accused party. John could also have been called a whistle-blower if he ever asked for or made a request for his protection under his supervisor, the executive director of HR and labor union, DFA, or another legal establishment. They are required to safeguard his confidentiality and protect him from retaliation. Since John knew much about the negative after-effects of the drug AD23, one cannot assume from this knowledge alone that he knew that the drug would result in or had resulted in numerous casualties. He had knowledge about Pharma Care, and he gained experience with its corporate plans and the internal memo belonging to the company, which described that there were certainly potential issues with AD23. Therefore, John was not at fault and was entitled to ask for protection and safety under the whistleblower laws (Workplace Fairness, n.d).

References

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