

# Ethical and Legal Issues in PharmaCARE Operations

Posted on March 27, 2018

## 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 regulation of the product's safety and analyzing whether Pharma CARE violates any of these problems in question. Here, I will argue directly with consumer marketing for the pros and cons. 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 analysis is made for which US law was used by Pharma CARE to secure their personal intellectual property & if it was claimed by John or not to be the real creator of AD23, & if it is true then how will the Pharma CARE compensate him? After all this, a summary of the 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 similar other complaints against Pharma CARE because of AD23. In the end, both important arguments will be specified that John can make to prove that he is the main whistle-blower and the type of securities he ought to be afforded.

## Ethical Matters

According to the First Amendment of the US Constitution, freedom of voice is guaranteed in commercial speech. Except 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's 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). 1914's The Act of Federal Trade, according to Halbert & Ingulli (2012), "illegal ways of competition & deceptive and unfair practices and acts," including misleading or false advertising. FTC was violated by Pharma CARE when it was related to the safety of the product because misleading information was left out. Once Pharma CARE acknowledged that people have heart attacks at a very alarming rate after receiving AD23, then they should stop the sale of this

product temporarily. But instead, they overlooked the information and continued filling the orders. This is against the FTC Act as they are 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). Pharma CARE when started having fictitious patient names listed by the doctors, and started advertising to clinics, physician offices, and hospitals they satisfied a demand created by them, and this fact was violated by not allowing compounding pharmacies to sell out the drugs for general use in bulk.

## Direct to Consumer

It is quite difficult for me to go for a stand when Direct-to-consumer marketing is in front of me. According to a survey conducted by the Drug and Food Administration in 2004, according to most physicians, one of the main reasons their dealings with patients and medical practices are affected is by viewing direct-to-consumer advertisements. Direct 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, then it can result in new wants of patients to take medication in access that might not be effective 100% 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, it usually leaves out negative side effects. Consequently, all consumers only listen to the good things of medication, and what that medicine can do, but don’t hear the specifics about how it might intermingle with another medicine or produce new ones. As a result of such information, it becomes difficult for physicians to prescribe alternate treatment methods to patients.

## Responsible Parties

Drug and Food Administration, The Center for Drug Evaluation and Research, and The Consumer Product Safety Commission parties controlled and organized compounding pharmacies. Drug and Food Administration has the authority and is in charge of promoting and protecting public health by overseeing and monitoring food, prescription, tobacco, and other new pharmaceutical drugs. In 1972, the Consumer Product Safety Commission was formulated to secure customers from unreasonable risk related to death due to unsafe products, illness, and injury (Halbert & Ingulli, 2012). Center for

Drug Evaluation and Research has the duty to make sure that the medicines accessible in the market to assist in improving individual's health in the US are effective and safe.

CDER is an important part of the FDA regulating over-the-counter drug sales and prescriptions. 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 taking themselves to be answerable for their activities. To evade the FDA inspection blatantly, it should be illegal to start compounding pharmacies. Such companies should be considered answerable for their illegal activities just like they were parent companies. This would result in the avoidance of too many injuries, backlash, and death. According to my perception, the drug's recreation 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 law area that deals with protecting the individual's rights who are producing their original works is known as intellectual property. It covers everything from novels to original plays marks of the company's identification with the invention. The basic motive behind laws of intellectual property is to inspire new inventions, artistic expressions, and technologies while encouraging economic growth. When security is given to individuals that all the creative work will be secured and 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 they wholly own; so, all products and findings belong to Pharma CARE. So now, whether John was working for himself and was contracted by Pharma CARE for his services then John would be eligible for compensation. According to the patent regulations trademark and copyright rules, John should be authorized for compensation.

## Current Example

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

## Issues:

## Whistleblower

According to the views of Herbert and Ingulli (specifically talking about the year 2012), blowing the whistle was a reported act by the employees of a firm about the unlawful or immoral acts of an employer. To understand the idea we must better know who is a whistleblower, so it is a person who feels that it is his duty or an obligation to blow a whistle when he feels like shedding light on some important actor during an 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 may also add a bad name, ill reputation, and dishonor to the company.

It may also break or lessen the trust, isolate and seclude them, and lead to termination. James Crowley, of the Chicago State University, an employee of the company was fired, the reason behind firing him was the refusal to reserve papers related to the University's president. This was asked of him as a request to keep, under the state's public records law. Crowley was also going through his whistle-blower case in which he earlier added that he was hit back for just reporting doubtful agreements to the Attorney General's office. The case Crowley filed was not a simple claim, but 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 for 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 defensible in reporting that the info was not fabricating 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 the unlawful and corrupt activity by state officials all over the state. The following law put forward an obligation upon all the employees to go through the training under the new law and that the employees were well aware of all the current information. In case the law is dishonored, there are both civil and criminal penalties for the one violating the law, but the law saves the whistleblowers who report the misconduct. Therefore, from the above case, one gets to know that if James has never had reported the correct information, in that case, he must have violated and disrespected the law and would have gone through risking his life for penalties and other possible criminal charges. Therefore, Mr. Crowley was bound to obey his duty to save 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 were led from drug addiction; some were more than adverse which cost the life of the addict, 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 the AD23 were used excessively, it would result horrifically, but the company seemed to do nothing astonishing. On the other hand, it was seen that there was a massive success in the business by excessive production commercially and the company stayed silent on the large-scale death rate resulting from the drug use by its consumers. There can be another view as well which can state that the act was not ethically wrong, but there had been something else as well, one might assume that the delay results from a detailed study of its side effects. The major issue raised here states that there is unethical and illegal conduct on the part of Pharma Care even in ensuring that the company is 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.**

The whistleblower’s protection points out the handling of a company or involving a government with a person responsible for reporting a dishonest or unlawful activity, showing discrimination towards one party of socioeconomic associations, which can be further checked and proved the fault of the accused (other) party. John could also have been called a whistle-blower if he ever asked for or made a request for his protection under his supervision, the executive director of HR and labor union, DFA, or another legal establishment. They are grateful to safeguard his confidentiality and non-retaliation. Since it is the fact that John knew much about the negative after-effects of the drug AD23, having this knowledge, one cannot assume that he knew that the following drug would result/ had resulted in the following numerous casualties. He had guidance about Pharma Care, and he got experience with its awareness of its corporate plans and the internal, central memo belonging to the company, which described that there are certainly potential issues with AD23. Therefore, John was not faulty and was liable to ask for protection and safety under the whistleblower laws (Workplace Fairness, n.d).

## References

Halbert, T., & Ingulli, E. (2012). Law and Ethics in the Business Environment (7th ed.). Mason, OH

U.S. Department of State. International Information Programs. Field, Thomas G. Jr. "What is Intellectual Property." Available from <http://usinfo.state.gov/products/pubs/intelprp/> August 2015

World Trade Commission. "Intellectual Property: Protection and Enforcement." Retrieved from [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/agrm7\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm)

U.S. Food and Drug. (2015). The Impact of Direct-to-Consumer Advertising. Retrieved from <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143562.htm>

AIPLA. (2017). What is IP Law? Retrieved from <http://www.aipla.org/about/iplaw/Pages/default.aspx>