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Legal and Ethical Considerations in Marketing, Product Safety, and Intellectual Property In this paper I am going to research 3-5 ethical issues relating to marketing and advertising, intellectual property, and regulation of product safety. I will argue for or against Direct-to-Consumer (DTC) marketing by drug companies. I will determine who regulates compounding pharmacies under the current regulatory scheme, what the Food and Drug Administration (FDA) could/should have done in this scenario, and whether the FDA should be granted more power over compounding pharmacies. I will decide whether PharmaCARE’s use of Colberian intellectual property would be in ethical accordance with (a) utilitarianism (b) deontology (c) virtue ethics (d) ethics of care (e) your own moral/ethical compass. I will analyze the way PharmaCARE uses U. S. law to protect its own intellectual property while co-opting intellectual property of Coleberia.

I will suggest at least 3 ways the company could compensate the people and nation of Colberia for the use of its intellectual property and the damage to its environment. I will compare PharmaCARE’s actions with those of at least 1 real-world company whose creativity in skirting legal technicalities led to ethical lapses and financial loss. I will determine the success PharmaCARE and WellCo shareholders would have in suits against the companies. I will determine whether or not PharmaCARE lives up to its brand. I will recommend at least 3 changes PharmaCARE can make to be more ethical going forward. There are many ethical issues relating to marketing and advertising, intellectual property, and regulation of product safety. Let’s look closely at a few and see how they have a common component that needs to be included for an organization to have strong ethical and legal relationships.

Ethical Issues Relating to Marketing and Advertising
Marketing is a social and managerial process by which individuals and groups obtain what they need and want through creating and exchanging products and values with others (Armstrong & Kotler, 2003). Advertising consists of paid notices from identified sponsors normally offered through communication media (Lane, King, & Russell, 2005). The ethical issues in which I researched for marketing and advertising are stereotyping, truth in advertising, and advertising tactics. The advertising industry operates within strict federal regulations and is monitored by the Federal Trade Commission. When it comes to marketing and advertising, marketing campaigns often cast particular groups in stereotypical roles, such as washing powder advertisements that show women as housewives preoccupied with their laundry. The stereotypical impression created by commercial marketing is that having an abundance of possessions will lead to fulfillment and happiness, however the opposing message is that the consumer will not be part of the happy group if he/she does not purchase the product.

The Federal Trade Commission Act set forth requirements for truth in advertising and created the FTC to enforce the provisions of the act (www. ftc. gov). The Bureau of Consumer Protection’s Business Bureau states that advertisements in the U. S. must by truthful, not deceptive and not unfair (www. ftc. gov). Deceitful statements can mislead consumers who act reasonably under normal circumstances and are likely to affect a consumers’ purchase decisions. The FTC defines unfair advertisements as those that are likely to cause substantial, unavoidable injury when using a product, unless the injury is outweighed by the provable benefits. Advertising tactics present additional ethical challenges. Advertisers have a range of less than ethical tools at their disposal.

These tools include subliminal advertising, emotional appeals, taking advantage of less educated individuals, spreading propaganda for political campaigns just to name a few. At the end of the day, consumers are more attracted to companies that do not use underhanded, manipulative tactics to gain their business (www. smallbusiness. chron. com). Advertising is the most prominent element of the marketing process (Armstrong & Kotler, 2003). Ethical Issues Relating to Intellectual Property

Intellectual property (IP) is the work product of the human mind (Halbert & Ingulli, 2012). Intellectual property is necessary to give one the right to protect and own his work with the arrival of the digital age it has become much harder to remain in control of a person’s intellectual property. Intellectual property can be easily and quickly copied (Halbert & Ingulli, 2012). Common types of intellectual property rights include copyright, trademarks, patents, industrial design rights, trade dress, and in some jurisdictions trade secrets. An ethical issue occurs when using images of people who are deceased or unable to give written permission for use. These are the obvious kinds of transgressions that could be made by an Indigenous researcher in undertaking Indigenous research work. Another ethical issue occurs with patents. Patents protect processes or products of processes which show genuine technical innovation. When the patent is lengthened it delays the entrance of less expensive generic drugs. As a result the branded drugs dominate the market and the cost is passed down to the consumer. Ethical Issues Relating to Regulation of Product Safety

The Food and Drug Administration (FDA) is responsible for establishing the Code of Federal Regulations which outlines the rules and regulations governing pharmaceuticals. Regulation of product safety majorly involves the consumers act which aims at providing quality and healthy products to customers. The most critical issues surrounding the regulation of product safety are environmental restrictions, product quality and safety, and marketing to children. The growth of imports to our nation is extremely rapid which will continue to increase steadily over the next decade. Product safety is an ethical obligation insofar as companies have a duty to provide consumers with whatever it is they pay for and products are assumed to be safe for ordinary use (www. ethicalrealism. wordpress. com). Every year millions of Americans require medical treatment from product-related accidents.

Direct-to-Consumer marketing refers to promoting a product or service straight from the seller to the consumer, without intermediary advertising such as television commercials, radio ads, or public displays. This form of marketing can be particularly effective for small- and medium-size businesses with little brand recognition and moderate advertising budgets (www. smallbusinesschron. com). Direct-to-Consumer (DTC) has grown rapidly during the past several decades and is now the most prominent type of health communication that the public encounters. When it comes to advertising prescription drugs on radio and television and in magazines, doctors say that, for the most part, the ads have both positive and negative effects on their patients and practices (www. fda. gov). There are both advantages and disadvantages of DTC. Direct marketing methods track customer responses, allowing for marketing effectiveness to be monitored to ensure a strong return on investment. Advances in technology have made the development of lead lists and the tracking of customer responses easier. Targeted lead lists ensure that time and money are not wasted on uninterested consumers.

Direct marketing may be offensive to some consumers and can result in a backlash or boycott of your product or service, or even create a negative public image. In recent years national “ do not call” lists have been established that restrict telemarketers from phoning particular consumers, and “ no soliciting” signs are frequently put up in commercial buildings and on the doors of retail stores (www. smallbusiness. chron. com). In my opinion it seems as though the DTC can be biased. In order for us to determine who regulates compounding pharmacies, we must first know what it is. Compounding pharmacies are a long-standing less frequently discussed element in the complex matrix of prescription drug manufacturing, distribution and patient use. The term refers to any physical pharmacy that is licensed to mix or “ compound” chemical ingredients into a finished medication ready to use by an individual patient, based on a prescription ordered by a physician or other legally authorized prescriber (www. ncsl. org.).

Every state has laws and regulations guiding pharmacy standards and requirements, addressing issues such as required licenses for each facility and for the credentialed pharmacists and other employees who work there. Consumers and health professionals rely on the drug approval process to ensure that drugs are safe and effective and made in accordance with Federal quality standards (www. fda. gov). The FDA should have firms register with them as an outsourcing facility under section 503B and be regulated and inspected by the FDA according to a risk-based schedule. Organization should have been inspected by the FDA, they didn’t denote the facility as outsourcing; they used an existing office park and did a renovation. In the case of PharmaCARE and CompCARE, the company did not reformulate a drug to meet the individual needs of patients. However, the company reformulated a drug and sold it to the masses without clinical trials that would have been required to obtain FDA approval. CompCARE was created solely as a front for PharmaCARE.

The bogus list of patients’ names provided to CompCARE by doctors was used to cover up PharmaCARE’s and CompCARE’s unethical practices. There should be more power granted to the FDA over compounding pharmacies preventing these types of gaps in their oversight of compound drug manufacturing across the country. Decide whether PharmaCARE’s use of Colberian intellectual property would be ethical in accordance with: a. Utilitarianism The basic idea of utilitarianism is to behave in a way which results in more good than bad consequences, preferably with the most good possible. Utilitarianism relies upon some theory of intrinsic value: something is held to be good in itself, apart from further consequences, and all other values are believed to derive their worth from their relation to this intrinsic good as a means to an end (www. utilitarianism. com).

Utilitarianism is similar to what’s known as cost-benefit analysis, except that the latter is principally concerned with monetary costs and benefits, while the former is concerned with all goods and bad and in regard to all stakeholders. Based on the PharmaCARE scenario, utilitarian’s would not consider the company’s use of Colberian intellectual property as ethical because the act does not help the Colberians. b. Deontology Deontology is the theory or study of moral obligation (www. merriamwebster. com). The process used by PharmaCare and Colberia did not follow deontology because the company and its management staff were aware of the side effects of the drugs being made and the numerous deaths that were caused. They did nothing to stop its production. c. Virtue ethics Virtue ethics directs our attention to what human beings are capable of being, on how to cultivate the habits of good character that will naturally lead them to their fullest potential (Halbert & Ingulli, 2012).

The case of PharmaCARE, it is obvious that the corporation had information that the Colberians had the rights for their intellectual property. d. Ethics of care Ethics of Care is widely applied to a number of moral issues and ethical fields, including caring for animals and the environment, bioethics, and more recently public policy. Ethics of care would consider PharmaCARE’s use of Colberian intellectual property as unethical because the Colberians do not benefit from the exchange of information. e. Your own moral/ethical compass PharmaCare had a moral and ethical duty to do what was right and in my opinion that did not happen. Their lies and misleading strategies hurt those that needed them. The way in which PharmaCARE uses U. S. law to protect its own intellectual property while co-opting intellectual property in Colberia is the lack of jurisdiction by the FDA over the manufacturing of pharmaceutical drugs. It makes it much easier for PharmaCARE.

A significant factor that PharmaCARE has taken advantage of is the fact that intellectual property laws in the US the fact that the transparent and predictable legal systems which are applicable in the solving of disputes. The protection laws failed to protect the workers at Colberia and the consumers that were hurt or killed due to a bad drug. Intellectual property is a pharmaceutical company’s most valuable resource. It can protect the company and help with the success of the company. Colberia is a developing nation that aided PharmaCare in manufacturing an affordable drug and PharmaCare exploited the intellectual property laws. The first way in which PharmaCARE can compensate the people and nation of Colberia for the use of its intellectual property and the damage to its environment is to increase the pay of the workers. An increase means that the workers will be able to get more of the things they need to take care of their families.

Another way PharmaCARE can compensate the people of Colberia is to provide a living headquarters with running water and electricity. As well as medical benefits to aid in the wear and tear of their health from walking five miles at a time while carrying baskets that at times weigh up to 50 pounds. Wal-Mart is committed to providing unbeatable prices, quality products, and easy shopping for its customers all with a smile. In 2008, Wal-Mart paid nearly $640 million to settle 63 lawsuits filed against the company in 42 states for cheating hourly workers by forcing them to work through breaks and not paying them for overtime (www. walmart. com). This came months after the company agreed to settle a $54. 3 million wage and hour class action lawsuit in Minnesota. A judge found Wal-Mart guilty of violating wage and hour laws more than 2 million times. Wal-Mart failed to pay employees according to the requirements of federal labor laws. Just like PharmaCARE, Wal-Mart portrays an outward image of caring, however, the employees told a different story.

PharmaCARE and WellCo shareholders would have little ground to stand on if employees file a suit against the company for not maintaining the air quality according to OSHA standards. The companies and shareholders would be held liable. The employees brought the situation to their attention in an attempt to have the problem solved before their illness progressed and before filing the suit. If the Colberians file a law suit against the company because they were not compensated for intellectual property rights, the companies and shareholders were given the information freely by the healers. PharmaCARE has a reputation as being caring, ethical and a well-run company that produces high-quality products that saves lives. PharmaCARE clearly does not live up to its brand. At first it had a good reputation, consumer database and sales/marketing expertise. This made its products sales high and the company was able to enjoy more profits. It is later discovered that these products were dangerous causing many deaths as a result of heart attacks.

A caring, ethical and well-run company that produces high-quality products that saves lives would compensate the healers for their intellectual property rights and would appropriately pay the indigenous workers. Living up to its brand would require them to do an extensive research and inspection on its products to ensure that it is safe for the consumption of the human beings as well as having corporate social responsibility. The first change PharmaCARE could implement is setting formal policies and regulations, expectations, values and norms, and offer incentives to guide the behaviors of all employees.

This includes implementing a strong whistleblower policy that encourages employees to report fraud and wrongdoing. PharmaCARE needs to place a more significant focus on consumer safety. A business cannot exist without its customers. Decisions made by stakeholders affect more than just the company’s employees and investors. Another change PharmaCARE can make is to pay the indigenous workers of Colberia a fair salary and compensate the healers for their intellectual property. Without this change, PharmaCARE is sending the message that the people of Colberia are not part of the team, but are only commodities to be used up and discarded.

References

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