# Good legal and ethical considerations in marketing, product safety, and intellect...

Business, Company

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## Ethics Violations of PharmaCARE

When viewing the behavior of PharmaCARE in marketing and selling its drug AD23, there are a number of ethical issues that the company is brazenly violating. The first and most brazen violation of marketing ethics was creating a subsidiary (CompCARE) to do the marketing for AD23 in order to circumvent the regulation of the FDA. This is a clear violation of the ethical need to comply with government regulation, which businesses are expected to do. By creating CompCARE and shuffling off the product to them, creating a hasty renovation and shifting of resources, the goal was to prevent the FDA from being able to properly regulate the product (since, technically, the product was no longer PharmaCARE's, but CompCARE's). By marketing AD23's new formulation as the same drug, the company has performed

pharmacy compounding, which prevents the FDA from being able to re-regulate and inspect the product (since it is hiding under the guise of a new product).

The second ethics violation occurred by the use of unethical and dubious business practices to sell AD23 directly to hospitals, private physicians and clinics, despite that being illegal. The encouraging of CompCARE to have doctors create lists false patient names in order to provide a pretext for ‘ selling’ the drugs to hospitals for general use is a deceptive practice that circumvents FDA regulations to knowingly violate the laws regarding selling of wholesale compounded pharmaceuticals.

The third ethics violation occurred with the company’s willingness to continue to market AD23 despite the increased risk of heart attack that was seemingly occurring. Product liability is a concept in which manufacturers are held accountable for the injuries caused by these products, particularly if they are aware of the product’s dangers. Specifically, PharmaCARE is guilty of failure-to-warn, which is when companies place warnings on their unsafe products to inform consumers of the risk (Henderson Jr., and Twerski, 1990). To fail to do so is an egregious ethical breach on the part of PharmaCARE, and puts lives in danger as well. This makes them liable for resulting injuries and deaths that might result from these hazards, making PharmaCARE’s complete ignorance of these blatant trends regarding AD23 particularly unethical.

## Direct-to-Consumer Marketing

One of the biggest problems related to AD23's sale by PharmaCARE is the unethical nature of direct-to-consumer (DTC) marketing, which they used to exaggerate, obfuscate, and lie about the effects of the drug on its customers. Drug companies in general do engage in DTC marketing to a wide extent in some nations, including the United States of America, and so the practice of DTC is not strictly illegal in this instance. However, the extent to which companies can influence prescription of their products to patients based on the demands of the consumer makes the practice somewhat ethically dubious.

DTC advertising can take many forms, including the ' help-seeking ad,' which just involves informing a consumer about a medical condition and asks them to talk to a physician; the ' reminder ad,' which gives the name of the product in question; and the ' product claim ad,' which tells the consumer about the alleged benefits of the product – this is the most common form of DTC advertising (Ventola, 2011). Since the FDA relaxed DTC broadcast regulations in 1997, DTC ads became much more prevalent, and also made the existing FDA regulations difficult to enforce. This is due to a number of factors, including increased regulatory red tape, the small percentage of staff compared to drug ads, and the low funding of the FDA (Ventola, 2011). This creates problems in enforcing FDA regulations, which makes it more enticing for companies to violate these rules on a regular basis.

The difficulty inherent to DTC, and AD23 in this case, comes from pharmaceutical companies using clever marketing tactics (attractive ads, bold medical claims, etc.) to convince consumers that AD23 is right for them.

For instance, if PharmaCARE ran an ad claiming that AD23 would help them fight off the effects of Alzheimer's, that might convince them to ask for it from their doctor. To that end, prescription of AD23 would increase at a higher rate than other, possibly more effective drugs that are not marketed as heavily. As a result, a possibly inferior and dangerous product is more frequently prescribed simply due to marketing exposure and consumers' familiarity with it. This danger inherent to DTC marketing, in addition to the inability of the FDA to properly regulate it, makes it a somewhat ethically dubious practice to endorse.

## Regulation of Compounding Pharmacies

When regulating the compounding of pharmacies, two organizations are chiefly responsible – the Food and Drug Administration (FDA) and the state board of pharmacy. Different states have different laws and governing principles regarding compounding pharmacists, and so the regulation of this particular issue may vary by state. According to the Drug Quality and Security Act of 2013 (DQSA), the FDA is chiefly responsible for handling issues of noncompliance with current good manufacturing practices (CGMP). Technically, the CompCARE facility could technically qualify as an ' outsourcing facility,' which can potentially qualify for exemption from requirements for FDA approval, but they must still comply with CGMP requirements (FDA, 2014).

In the case of PharmaCARE's ethical breaches, the FDA and/or the state boards of pharmacy should engage in inspections of these compounding pharmacies and take enforcement actions to ensure public health. The heart

attack phenomenon related to A23 should be sufficient cause for the FDA to perform for-cause inspections at each of CompCARE's facilities to determine whether or not the formula is the same as what was previously approved by the FDA. The FDA should force a recall of AD23 in all instances, and PharmaCARE and CompCARE's licensing and ability to sell the drug should be removed posthaste.

The company should also face legal exposure regarding its practices. The government should be able to sue the company for violation of these regulations and laws relating to failure-to-warn, compounding pharmacy, and more, levying fines and/or prison time for the managers and executives in charge of these decisions. By doing so, the FDA and other regulatory bodies can help make PharmaCARE and CompCARE an example of what happens to organizations that commit such unethical, hazardous business practices in pharmaceuticals.

## Intellectual Property Law and AD23

PharmaCARE's use and distribution of AD23 may not necessarily fall under a violation of intellectual property law, as it is not exactly established who created AD23 in the first place (simply that John was among the team of pharmacists who reformulated the drug to maximize the potential restorative effect on Alzheimer's). Furthermore, if John created AD23 while under the employment of PharmaCARE, it is entirely possible that anything he creates or develops in the scope of his employment is the property of PharmaCARE (Howell, 2012). As a result, it is extremely unlikely that he would truly have a case against the company for the rights to his product.

That being said, there are three ways in which PharmaCARE could provide John with compensation if he made a case that AD23 was ‘ his’ drug. First, he could be compensated with a lump sum settlement that was decided by private meetings, effectively buying him off with a mutually agreed-upon amount of money. This would provide John with appropriate pay commensurate to the importance and success the product has provided to PharmaCARE, and allow him to somewhat reconcile the lost royalties for the creation of the drug.

Secondly, John could be let in on a percentage of the profits of the sale of AD23, both to date and in perpetuity, allowing him to continually profit off the drug provided its sale continues. If the drug is truly his, and he has expectation to royalties and a percentage of the profits to the sale of the drug, it is possible for him to make a claim with the company that he is deserving of a percentage of the profits from PharmaCARE’s sale of the drug.

Third, John can be compensated by having his involvement be publicly announced via press release or other official announcement from PharmaCARE itself, indicating their admittance of John’s responsibility for creating the property. While this is not financial compensation, this would restore John’s credit as the creator (or partial creator) of the drug. Though the names of pharmaceutical developers are not typically placed on the label of the product itself, this would be a way to publicly announce PharmaCARE’s admittance that John helped to develop and create AD23, thus cementing his credit for the creation of the product.

## Recent Issues with Intellectual Property Theft

Intellectual property theft is a significant issue, even today, and can have devastating effects on a company's brand. For example, networking company Cisco Systems has recently accused Arista Networks, a rival company that was started by a former employee of Cisco, of stealing platforms and code from them in order to more evenly compete with the company. According to Cisco, this was done to avoid the needed investment of funds and time that are usually required to develop products. Among the products that have been allegedly stolen from Cisco include " Zero-Touch Provisioning" and " Virtual Port Channels," among other network facing elements (Parker, 2014). Other instances of intellectual property theft include the outright stealing of material from their user manuals, which was copied and pasted from Cisco's documents onto those of Arista, including the same grammar errors.

The effect of this intellectual property theft on Cisco has not been insignificant . By existing as a significant company in the networking market, but without having to do the same amount of work that Cisco had to in order to develop these products, Arista was able to take shortcuts in their work and thus have more profit for themselves, thanks to lower overhead. By doing this, they present an illegitimate threat to Cisco, as they present themselves as a rival in the market without needing to build an infrastructure. Cisco's brand is consequently hurt by this, as their profits will naturally not be as high due to the greater amount of work they had to do to develop the technologies and documentation in question.

Intellectual property theft such as this poses a significant threat to the

equalizing nature of business, and therefore must be tightly regulated. By legislating and prosecuting cases like this, it is possible for companies who did the ground floor work and spent money on the infrastructure of these products to benefit from the brand recognition and market power they deserve, without being undercut by other companies who actively steal ideas in lieu of doing their own ground work and infrastructure. The recent investigation of cases like this indicates that intellectual property theft is still a significant issue in today’s economy.

## Litigation of PharmaCARE for Wrongful Death

Beyond the issue of intellectual property, however, is the much more immediate and devastating consequences of the death of patients, including John’s wife, due to the distribution of AD23. Despite the evidence that AD23 is a clear hazard and link to increased rates of heart attack, PharmaCARE has chosen not only to keep the product on the market, but not provide any warning or notification of this risk to its customers. Executives and managers are even being rewarded for this cover-up with bonuses and promotions, rather than providing punitive measures and changing leadership in the light of these failures.

As previously mentioned, the failure of companies to adhere to the duty to warn places the onus on PharmaCARE to warn users of the potential for heart attack risk when they use AD23. By failing to supply appropriate instructions, they are not adequately informing the consumer of the risks of their product, the company itself is performing an egregious ethical breach, in violation of Section 502(f) of the Federal Food, Drug & Cosmetic Act which allows the

FDA to outlaw drugs unless their labeling contains “ such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application as are necessary for the protection of users" (1992). Given the relatively clear-cut nature of this rule, John and other spouses and guardians of patients may have cause to file wrongful death lawsuits against PharmaCARE for failure to warn, even after finding out about the risk.

## Whistleblowing and PharmaCARE

John’s efforts to get the word out about AD23’s effects and true origins can easily qualify as whistle-blowing. According to Faunce and Jefferys (2007), whistleblowers can be defined as people who choose to expose misconduct or injustice perpetrated by an organization – usually these individuals are members of said organizations. John’s actions are totally justified, given the egregious and unethical behavior that PharmaCARE is engaging in – between ignoring health concerns to intellectual property theft, to performing cheap tricks with subsidiaries to avoid FDA regulation and compounding pharmacies. John’s motivations for releasing the memos are numerous – first and foremost, he wishes to reveal that he was responsible and should be credited for the creation of AD23, despite PharmaCARE’s reluctance to do so. Next, he wishes to inform the FDA of the unethical practices the management and executives are engaging in to avoid FDA regulation, such as the motivations behind setting up CompCARE, the use of false names to allow for wholesale distribution of AD23 for general use, and the refusal to

acknowledge and failure to warn patients of the risk of heart attack related to AD23.

Based on his arguments, John has a clear claim to whistleblower protections under the Sarbanes-Oxley Act of 2002. Whistleblowers are allowed through the Act to be protected from retaliation with legal action, which can include both imprisonment and steep fines (Sarbanes-Oxley Act, 2002). While John no longer works for PharmaCARE, being a ‘ former’ researcher, there is no risk involved in the retaliation of losing his job; however, he would be protected from litigation through the Act, as well as any other harmful action taken against him based on Section 1170 of the Act. Whistleblowers are reasonably granted many protections under the law, and so John himself must be given protection from retaliation by PharmaCARE for the release of their personal documents.

## Conclusion

The situation involving PharmaCARE and its handling of AD23 is horrifying, unethical and life-threatening, resulting in a number of ethical breaches involving intellectual property theft, unethical marketing of products, and circumventing of federal regulation. The FDA and state boards of pharmacy should immediately act on John’s information, protecting him from retaliation as a whistleblower and stopping the continued distribution of AD23 pending FDA approval and further research into the medical issues it creates. Greater oversight and regulation of these companies can prevent such issues as the theft of John’s intellectual property and, possibly, the death of his wife and

many others thanks to improperly tested, unethically marketed pharmaceuticals and other products.

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