**Assignment 4: Legal and Ethical Considerations in Marketing, Product Safety, and Intellectual Property**

You are a new associate at the law firm of Dewey, Chetum, and Howe. John, a former researcher at PharmaCARE, comes to your office. He has concerns about PharmaCARE’s use of AD23, one of the company’s top-selling diabetes drugs. Two (2) years ago, after PharmaCARE’s research indicated that AD23 might also slow the progression of Alzheimer’s disease, John and his team of pharmacists began reformulating the drug to maximize that effect. In order to avoid the Food and Drug Administration’s (FDA) scrutiny, PharmaCARE established a wholly-owned subsidiary, CompCARE, to operate as a compounding pharmacy to sell the new formulation to individuals on a prescription basis. CompCARE established itself in a suburban office park near its parent’s headquarters. To conserve money and time, CompCARE did a quick, low-cost renovation.

CompCARE benefited from PharmaCARE’s reputation, databases, networks, and sales and marketing expertise, and within six (6) months had the medical community buzzing about AD23. Demand soared, particularly among Medicare, Medicaid, and Veterans Affairs patients. Seeing the opportunity to realize even more profit, CompCARE began advertising AD23 directly to consumers and marketing the drug directly to hospitals, clinics, and physician offices, even though compounding pharmacies are not permitted to sell drugs in bulk for general use. To circumvent this technicality, CompCARE encouraged doctors to fax lists of fictitious patient names to CompCARE. PharmaCARE sold CompCARE to WellCo, a large drugstore chain, just weeks before AD23 was publicly linked to over 200 cardiac deaths.

As CompCARE and its new parent company enjoyed record profits and PharmaCARE’s stock price approached $300 per share, reports started surfacing that people who received AD23 seemed to be suffering heart attacks at an alarming rate. The company ignored this data and continued filling large orders and paying huge bonuses to all the executives and managers, including John, whose wife recently died from a heart attack after using AD23.

John has come to you with an internal company memo describing the potential problems with AD23, and information describing the company’s willingness “roll the dice” and continue to market the drug.

Your senior partner has asked you to write a memo outlining the following issues for review by the senior partners.

In preparation for this assignment, use the Internet to research examples of intellectual property theft that occurred within the past two (2) years.

Write a ten (10) page paper in which you:

1. Research three to five (3-5) ethical issues relating to marketing and advertising, intellectual property, and regulation of product safety and examine whether PharmaCARE violated any of the issues in question.
2. Argue for or against Direct-to-Consumer (DTC) marketing by drug companies. Provide support for your response.
3. Determine the parties responsible for regulating compounding pharmacies under the current regulatory scheme, the actions that either these parties or the FDA could / should have taken in this scenario, and whether PharmaCARE could face legal exposure surrounding its practices. Support your response.
4. Analyze the manner in which PharmaCARE used U.S. law to protect its own intellectual property and if John has any claim to being the true “inventor” of AD23. Suggest at least three (3) ways the company could compensate John for the use of his intellectual property.
5. Summarize at least one (1) current example (within the past two [2] years) of intellectual property theft, and examine the effect on that company’s brand.
6. Analyze the potential issue surrounding the death of John’s wife and other potential litigants against PharmaCARE as a result of AD23.
7. Specify both the major arguments that John can make to claim that he is a whistleblower and the type of protections that he should be afforded. Justify your response.
8. Use at least (5) quality resources in this assignment. **Note**: Wikipedia is not an acceptable reference and proprietary Websites do not qualify as academic resources.

Your assignment must follow these formatting requirements:

* Be typed, double spaced, using Times New Roman font (size 12), with one-inch margins on all sides; citations and references must follow APA or school-specific format. Check with your professor for any additional instructions.
* Include a cover page containing the title of the assignment, the student’s name, the professor’s name, the course title, and the date. The cover page and the reference page are not included in the required assignment page length. .