Introduction

Venn Pharmaceutical Company (VPC) has put a large amount of work and considerable investment into their research and development and completed a blind study on its new drug, Compound Y. The research done into the safety and stability of Compound Y have proven that while Compound Y may appear safe in rats and tissue samples, there may be a link between Compound Y and an increase in heart failure. This case study will examine the government's role in blocking Compound Y's release and Compound Y's desire to compete in the global market, specifically against the Japanese corporation Angin-san.

The Canadian Government and in specific Health Canadas' decision was in the best interest of the general public and their decisions were simply enforcing the law that all pharmaceutical companies in Canada are required to abide by. The government of Canada was correct by revoking permissions from VPC due to the fatalities observed in the clinical studies. Had this drug been allowed to skip phase 3 of the clinical trials, there would be a potentially deadly drug being taken by unsuspecting Canadians. Even with the promise VPC had made to distribute Compound Y with existing approved medicine that would prevent heart plaque build up, the risk to the lives of the patients would be too high.

This case shows a valid case of government regulation by Health Canada blocking however, arguments can be made for the case against government regulation. The government blocking of the testing of this drug may have made way for a competing drug from another country to be released to the market first. This anti-competitive decision by the Canadian government may lead to massive losses for VPC which is a Canadian company. The Canadian government should be interested in promoting growth to Canadian companies and should have worked with VPC to assist them in getting Compound Y to market as soon as possible.

In order to assist with the release of their drug, VPC could attempt to lobby the Canadian government, allowing them to continue with their trials. While there are many approaches to lobbying the government, face to face or consultations would be the best approach to getting a result in a short amount of time. Face to face meetings would be highly effective as long as meetings could be set up with the right people. Easier than this would for VPC to participate in consultations. If VPC could be present at the consultation meetings, they could sway many opinions and put pressure on Health Canada to allow trials to continue.

This study will go in depth to the topic related to government regulation and the government's effect on stakeholders in this situation. This paper will examine these points using the analytical methods learned in class.

Background

Compound Y is a pharmaceutical drug being developed by a Canadian Corporation VPC. This drug is meant to help treat vestibular schwannomas, a malignant brain tumor and form of schwannoma, found in the vestibulocochlear nerve. Vestibular schwannoma effects can appear at any age but are most common in people between 30 and 60 years old, affecting approximately 1 in every 100,000 people. Despite being categorized as a brain tumor, vestibular schwannoma has a high survival rate, however it can still be life threatening if not treated. This is where the importance of Compound Y comes in, potentially saving thousands of lives by curing patients of this form of brain cancer.

The method used to test this drug's effectiveness was initially rat testing and human tissue samples after approval and acquisition of samples. This methodology is common for testing the effectiveness and safety of new medication before performing human testing, however, a more common form of medical testing is by using Mice or Syrian Hamsters, specifically for cancer, due to their higher numbers and more rapid reproduction rates. Human tissues can be used for testing of new medication with permission of Health Canada in the form of a Cells, Tissues and Organs Registration. After testing has been successful, a company can apply for a Clinical Trial Authorization. This will allow the company to test their new drugs on

live patients. A clinical trial in Canada consists of three (3) phases. Phase 1 is the phase where the drug will be tested on humans, typically a group of healthy adults. If phase 1 is successful the drug can then move into phase 2 testing, this is where the drug is tested on a slightly larger group of people who are patients who have the condition that the drug claims to be effective towards. Assuming phase 3 has been successful, the drug then moves to the final phase, phase 3. This phase is where the group of participants grows to hundreds, possibly thousands, and span multiple countries. Once a drug has passed all clinical trial phases, it can be scheduled, patented, and released. This process is partly controlled by the Patented Medicine Prices Review Board (PMPRP) and partly controlled by Health Canada. The PMPRP is an independant, semi-judicial agency responsible for issuing and maintaining the patents related to drugs and medical compounds in Canada. The PMPRP also regulates how much a company can charge for their drugs, this decision is legally binding according to Bill C-22.

Currently, there does not exist a cure for vestibular schwannoma, there are only methods of treatment. Often, treatment is not necessary, by observing the tumor and tracking its growth, doctors can decide if a tumor will need to be acted upon or not. If it is determined that a tumor has to be treated there are two main options for treatment, surgery or radiation. The most common of the two is surgery, at the most abstract level, the goal of surgery is to remove the tumor while protecting the functioning nerves that the tumor was acting upon. Complications due to surgery may arise and can range from mild complications such as hearing loss or nerve

damage all the way to paralysis and even death due to infringement on the spinal cord. While radiation is a viable treatment method, not enough work has been done to study it and there is not enough information about the extended effectiveness of this treatment method.

Key Stakeholders

This case has 7 key stakeholders which all have a different profit or loss to make in regards to the successful clinical trial of Compound Y. These stakeholders fit to the three sides of the boulding triangle, with Health Canada and the Canadian Government representing the state, VPC and Angin-san representing the corporation, and the Canadian and general population representing civil society. All three of these groups have unique best interests and goals with respect to the clinical trials.

In this case, the primary corporation that is represented is VPC, who has the largest stake in seeing that this drug successfully passes its clinical trials. If Compound Y fails to pass they will lose their entire investment and their investment in time on the research and development. If Compound Y passes, they stand to be the only medical cure for vestibular schwannoma which would put them in a position to establish them as a stable and profitable company.

Health Canada on the opposing hand has a stake in ensuring that all laws related to public health and safety are upheld. Their concern is not with profits or loss but with the well being of the general public. They want to allow all safe drugs to enter the market and block all unsafe products from getting into the hands of a sick and vulnerable population. Similarly, the Canadian Government wants to balance the safety of the Canadian public and the success of Canadian corporations. This can be a hard balance to reach especially when a foreign company is threatening a Canadian companies profits.

The Japanese Company Angin-san has a stake in their own product, that they wish to beat VPC to market with. Similarly to VPC, they have most likely conducted research and development to create their drug and have a large sum of money to make off it's success. If they manage to beat VPC to the market, it is likely they will gain a higher market share and make greater initial profits off of their drug.

The Canadian public has a stake in the drug as they want a safe and inexpensive drug on the market that cures the issues that affect them, in this case vestibular schwannoma. The trial patients in the studies and those affected by vestibular schwannoma also have a stake in this drug's release as they want access to a safe and reliable drug to treat and hopefully cure the disease they have. This release is a matter of life and death for patients diagnosed with this condition.

Government Decision

The government's decision to revoke VPC's permission to conduct clinical trials may lead to a great loss in a Canadian companies profits. The decision to delay the release of Compound Y will also delay those affected by this disease from getting treatment that may save their lives. Despite the negative consequences of this decision by Health Canada, it is in regards to their stake in the public's well being and the well being of the remaining patients in the trial. Due to the unstable nature of this drug, it can be said that we can not know how many people would contract heart problems and due in the future if Compound Y had been released at its current state. More testing and modification must be done to the formula of Compound Y before clinical trials should resume and the drug should be allowed to move onto phase 3 and it's eventual release.

VPC has argued that they should be able to continue their clinical trials of Compound Y with a seperate, tested drug, to take care of the heart plaque buildup. However, since the two drugs have not been tested together, there is no guarantee that the drugs will work together. This issue has occurred previous in clinical trials and continuing the trials only resulted in further deaths.

The government isn't the only stakeholder that should view this decision as the proper one. According to corporate social responsibility, VPC should not only be concerned with the profits it makes but its relation to civil society and the value of human life. VPC should hold itself accountable to its customers and stakeholders by withdrawing themselves and fixing their product instead of releasing an unproven fix in the form of a bundle of drugs to mitigate symptoms.

Government Regulation

Approach to Lobbying

Conclusion