COMPOUND Y[1]

Early in 2018 after several years of work and considerable investment in research and development, researchers at the Venn Pharmaceutical Company (VPC) had completed blind tests using Compound Y on laboratory rats previously induced to develop vestibular schwannomas, malignant primary brain tumours – the usual treatment for which included traditional and stereotactic surgery, radiation therapy, and chemotherapy; all rather uninspiring. In every instance, following a three week regime of intravenous Compound Y the inflicted rats made a full recovery. VPC also conducted tests on human tissue samples and had obtained a Health Canada Clinical Trial Authorization. The company was now in phase 2 of its clinical trial process where "Compound Y Therapy" was being administered to 150 patients with the disease and showing the same amazing results, catalyzing VPC into seeking a waiver from phase 3 of the clinical trial process and seeking an immediate New Drug Submission Review in order to fast track Compound Y becoming a Schedule 1 Drug and available to the public. Fast tracking the approval however was not looking promising as Health Canada officials were adamant that the full phased clinical trials be completed before the new drug submission review would occur. This, they said, was the procedure and in the public's interest. VPC argued that the residual risk involved was more than offset by the potential health benefits. VPC management was also concerned about having their intellectual property "scooped" before they could recover the significant investment in the drug's development. Health Canada also advised VPC that recovering the costs would be a longer-term matter as, even if the drug was eventually approved as a Schedule 1, its costs to the public would be regulated by the Patent Medicine Prices Review Board, and this would involve additional time.

VPC's phase 2 clinical trials progressed without negative incident until May 2009, when one patient died. The autopsy confirmed the cause of death was heart failure, caused by hardening of the arteries. A second patient died of heart failure in June 2009 attributed to the same cause. In both cases, there was no history of heart disease in either family. By August 2009, eight more patients had died from heart failure and in each case death was attributed to arterial constriction caused by the build-up of plaque. Heath Canada moved quickly to revoke Venn's clinical trial authorization, pending additional and robust scientific analysis that would rule out a relationship between rapid plaque formation and Compound Y. Despite the government's action, many patients inflicted with vestibular schwannomas wanted to continue with the clinical trials indicating they would be quite willing to assume the risk. VPC argued that it could use an existing approved treatment to reduce plaque formation that would more than mitigate the risks to patients in the clinical trials. The government argued that this would not

[1] Delcorde, David H J: The Art of Business & Management Case Analysis, Kendall Hunt 2019

be prudent since the cause and effect relationship had not been scientifically established and that the effect of using the plaque reducing medication with the Compound Y was unknown.

Around the time of the interruption of clinical trials, Venn received news from its public relations research department that a Japanese company, Angin-san Corporation was starting human trials with a drug that was very similar to Compound Y. Venn raised the matter with the federal government, arguing that its clinical trials should not only be allowed to proceed but the government should also waive phase 3 of the clinical trial process, as originally requested by Venn. VPC argued that according to the government's own literature, regulation "*is intended to promote a fair and competitive market economy*" and clearly this delay on the part of the government is compromising VPC's ability to compete. If Japan can bring a similar treatment to the public before Venn, then VPC would lose millions of dollars invested in research and development.

The government argued back that social regulation as it relates to the health and safety of its citizens is more important than any economic argument VPC could offer and that it must protect the public interest and make decisions based on hard evidence. Until the evidence could be provided by VPC it had no intention of authorizing a continuation of phase 2 clinical trials and under no conditions would phase 3 of the clinical trials be waived. The government noted that VPC would have access to the courts if it thought Angin-san Corporation was infringing on its intellectual property rights.

Questions:

1. Who are the "key" stakeholders in this matter, and what are their "stakes"?
2. In your view, is the government correct in its position on this issue? Justify your response.
3. How does this case demonstrate arguments for and against government regulation of business?
4. Suppose VPC decided to lobby the federal government on this matter. In your view, what would be the best approach?