Vioxx decisions – were they ethical? essay sample

Sociology, Ethics

In the late 1990s, a pharmaceutical company called Merck was a leader in this industry. The pharmaceutical industry required millions of dollars and great amounts of time to be invested in research and development. From 1995 to 2001, Merck was successful in releasing 13 major drugs into the market. One of these drugs was one that would treat rheumatoid arthritis. The drug, Vioxx, acquired the approval of the Food and Drug Administration (FDA) in May 2009 (Cavusgil, 2007). Vioxx became one of the top five selling drugs in the market in the next five years. However, Merck pulled the drug from the market on September 30, 2004 due to increased observations of cardiac arrest and stroke in many consumers. Merck faced an ethical dilemma when it found increased observations of cardiovascular problems in patients. However, it took many years for the company to pull its top selling drugs from the market. The ethical issue, the interested parties and solutions will be addressed in the following paragraphs (Brooks & Dunn, 2012). Ethical Dilemma

As in many industries, the pharmaceutical industry has great competition. Vioxx was competing successfully with Pfizer’s products, Celebrex and Bextra. However, Merck’s product was especially thriving because, unlike Celebrex and Bextra, Vioxx did not contain naproxen. This ingredient is harmful to the gastrointestinal system (Cavusgil, 2007). By 2003, Vioxx gained revenue for Merck that reached $2. 5 billion per year and was available in 80 countries (Brooks & Dunn, 2012). The company filled 105 million prescriptions that accounted for 20 million consumers since its release in 1999. Within those four years, Vioxx was one of the top five drugs for Merck in terms of profits. Since March 2000 Merck had obtained

increasing evidence of adverse side effects, and yet, allowed the drug to remain in the market until the latter part of 2004. Studies in 2000 showed an increased risk of cardiovascular disease when compared to existing arthritis drug. The statistics said that the group taking Vioxx was four times more likely to develop cardiovascular conditions than the group who was taking a drug that contained naproxen.

The company found that these studies were inconclusive, so Merck did not attempt to pull their top selling product from the market (Cavusgil, 2007). It is also important to note that Merck had spent $161 million to advertise the drug. Nonetheless, the FDA forced Merck to revise Vioxx labels to warn about cardiovascular risks when taking the drug (Vlad, Sallot, & Reber, 2006). In addition, the company did not continue conduct studies that directly tested the risks of cardiovascular disease in patients. The executives' reasoning behind this was that it would be unethical to conduct these trials because they would be giving placebos to one group and Vioxx to a group with risk of developing cardiovascular problems. Instead, Merck executives decided to monitor clinical trials that were testing for other reasons (Cavusgil, 2007). Until September 2004, the executives made the ruling to remove the drug from the market.

The decision was made because, during that month, the health risks associated with Vioxx became apparent. There was evidence in the studies done that suggested that Vioxx caused increased risks of heart attack and stroke in consumers of the drug (Cavusgil, 2007). At first, Merck was commended for pulling Vioxx from the market; however, the actions of the

company’s executives soon came to light. E-mails were revealed that showed evidence that the executives knew since 2000 about the potential health risks their drug posed. During the scandal, it was not just Merck’s actions that were questioned. The FDA’s acts were also criticized because they did not do what the public would have expected. Research that was being conducted for Vioxx was not completed. It could be due to the fact that the pharmaceutical industry funds much of the FDA’s. Due to Merck’s inability to respond more quickly to the evidence found in 2000, many stakeholders suffered as a result activities (Vioxx, the impolosion of Merck, 2004). Stakeholders and Interested Parties

As in all ethics cases, more than one party is affected by the unethical decisions made by a company. The affected range from the patients taking the medication to the shareholders and even the FDA. Before Merck had decided to pull Vioxx off the market, the stakeholders that were particularly affected were the patients who were prescribed the drug. In May 2003, a study found a 20% higher risk of heart attack, stroke, and congestive heart failure in patients taking Vioxx. By September 2004, the trial that percentage increased to 120%. The committee conducting the study observed that 45 of the 1, 287 patients taking the drug experienced cardiovascular problems. The product was pulled from the market by the end of September; however, the damage was done. Vioxx had been on the market for about four and a half years (Cavusgil, 2007).

During these four and a half years that Vioxx had been on the market, Merck set itself up for litigation problems. Therefore, the company is another

stakeholder that was affected by its own actions. Those affected include executives, doctors employed by Merck, and ordinary employees of the company. Merck published many of the studies it had conducted on Vioxx and its safety on the cardiovascular system. This action gave lawyers and patients all of the information needed to sue the company. In addition, pulling the product from the market alerted patients about potential damage when taking Vioxx. It led to 28, 000 filings of personal injury lawsuits (Wolsing, 2008). Merck's decision to postpone any trials may have been due to the executives' concerns regarding the shareholders of Merck. The drug had been generating profits in the billions of dollars, so discontinuing the product would bring a definite drop in profits. The executives would also have to explain to the shareholders that they needed to discontinue producing Vioxx and still had millions of dollars worth of R&D costs it needed to pay.

As a result of Merck's actions, shareholders were also affected because they were unaware of the adverse effects Vioxx was having on patients. Once discovered, the product would have to be pulled, and Merck's sales would decrease significantly since Vioxx was a top seller. In effect, stock price would likely fall as well with a drop in profits (Cavusgil, 2007). In addition, the FDA was also affected by the actions of Merck. Even though the FDA did force Merck to provide patients with a label that warned against the risks of cardiovascular problems, it has been criticized for not being stricter when approving medications. As a governmental agency, they have been entrusted with ensuring the safety and efficiency of new drugs. The safety of the public should be the first concern when approving medications (Cavusgil,

2007). Another group affected is the general public. Within the public are consumers and potential consumers of the drug. This group was not only affected by the actions of Merck, but also by those of the Food and Drug Administration. The public expects the FDA to conduct significant trials on the pharmaceutical industry. The FDA should not consider the pharmaceutical industry as a customer because it funds many of its ventures. Their first duty should be to the public and not to the industry they are entrusted to regulate. (Vioxx, the impolosion of Merck, 2004).

Alternatives

Throughout the years that Vioxx was available in the market, Merck had many alternatives to change their course.