

Big Pharma: In Whose Best Interest?



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The recent recall of the anti-inflammatory drug Vioxx was a defining moment in the history of modern medicine. It has convincingly and dramatically driven home the point that for pharmaceuticals, maximizing profits takes priority over public interest. Furthermore, it highlights the failure of the regulatory system to protect the public.

Somewhere along the course of developments in medical treatments and technology, the priorities of the “big pharma” and their consumers they are marketing to seem to have diverged.

From January 1st, 1994 to April 30, 2004, 2.3% of all new molecular entities approved by the FDA were recalled due to an intrinsic property of the drug that caused harmful side effects (FDA, 2004). While this figure may appear to be small, adverse side effects of over-the-counter and prescription drugs are responsible for the death of 100,000 Americans and severe injury of another 2.1 million every year, not including illness due to drug abuse or prescribing errors (CNN, 1998). Severe drug-induced reactions have been ranked sixth among the leading causes of death in the United States (CNN, 1998). A definite idea of whom a drug is suitable for, as well as its potential side effects, should be determined before consumers begin to use it. From a patient’s perspective, this makes the most sense. However, it would appear as though the big pharma is not taking this as seriously as patients are. This article will consider three cases that demonstrate the need for greater accountability in the drug industry.

The effect that a severe lack of information can have in terms of the safety and effectiveness of drugs first became evident with the Thalidomide tragedy. Thalidomide was a drug that was first put onto the market in 1957 as a treatment for morning sickness in pregnant women (Thalidomide Victims Association of Canada, 2003). Unfortunately, its beneficial effects were outweighed by negative effects. The drug not only inhibited proper growth of the fetus leading to devastating birth defects such as blindness, deafness, cleft palate, disfigurement, and phocomelia in thousands of children around the world, but it was also responsible for the deaths of a staggering number of babies (Thalidomide Victims Association of Canada, 2003). One would assume

that after such a tragedy, government drug regulations would be amended to prevent the reoccurrence of such events. However, decades after the Thalidomide tragedy, people continue to be the victims of insufficient research and data on the part of the big pharma. Two prime examples of this are the recall of the anti-inflammatory drug Vioxx and the relationship between antidepressants and suicide in adolescents and children.

The FDA approved Vioxx (also known as rofecoxib) in 1999 (Beller, 2005). Vioxx is a non-steroidal anti-inflammatory drug (NSAID) also known as a COX-2 inhibitor, prescribed as a painkiller primarily for arthritis. In the five years it was on the market, more than 80 million patients were prescribed Vioxx and its annual sales were over \$2.5 billion (CBC News Online, 2004; Beller, 2005). Vioxx’s popularity soared because many patients suffered from serious gastrointestinal bleeding from traditional NSAIDs such as aspirin (CBC News Online, 2004). Researchers claimed that the drug reduced the likelihood of stomach ulcers and internal bleeding (CBC News Online, 2004).

Vioxx was recalled in September 2004 because of the findings in a study done by the FDA, which showed that it increased the risk of myocardial infarction (Beller, 2005). Researchers analyzed data from 1.4 million patients in California who had been taking Vioxx and other similar COX-2 inhibitors from 1999 to September 2004 (Olive, 2005). Of the 1.4 million, 8,143 patients were found to be suffering coronary heart disease, of whom 1,508 suffered sudden cardiac deaths (Olive, 2005). When compared with other COX-2 inhibitors, researchers found that Vioxx posed a 34% higher risk of heart disease of which many cases would prove to be fatal (Olive, 2005). According to the lead researcher of the study, Dr. David Graham, “An estimated 88,000 – 140,000 excess cases of serious coronary heart disease probably occurred in the U.S.A. over the market life of rofecoxib (Vioxx)” (Olive, 2005).

The most frightening part of this whole incident is that both the development of coronary heart disease, as well as the death of so many people could have been prevented. Not only did Merck, the pharmaceutical company responsible for the production of Vioxx, spend adequate time testing the effects of the drug before having it approved by the FDA, but they also ignored the results of many trials demonstrating Vioxx’s devastating side-effects. A study published in the *New England Journal of Medicine* in 2000 showed that Vioxx appeared to increase the risk of heart disease when compared with another painkiller, Naproxyn (CBC Health and Science News, 2004). Merck responded by saying that there was nothing wrong with Vioxx, but rather, it was Naproxyn

that was having a cardioprotective effect. (CBC Health and Science News, 2004). Rather than looking further into the matter, Merck merely dismissed researchers' findings, thus endangering the lives of millions. Furthermore, another study was published in the *Journal of the American Medical Association* in August 2001 that showed a correlation between the use of Vioxx and heart attacks (CBC Health and Science News, 2004). What was the response of the FDA and Health Canada? Merely to have the label on Vioxx bottles changed to indicate that the drug posed a risk for heart attacks (CBC Health and Science News, 2004). By November 2004, the University of Bern in Switzerland had compiled 29 different studies linking Vioxx to an increased risk of heart attacks, published during the five years Vioxx was on the market (CBC Health and Science News, 2004).

Moreover, the negligence of limited research done by the big pharma on the effects of Selective Serotonin Reuptake Inhibitors (SSRIs) on pediatric depression patients has also led to devastating results. Before the discovery of SSRIs, physicians relied on tricyclic antidepressants to treat depression (Garland, 2004). As tricyclic antidepressants were both ineffective and potentially toxic, physicians were open to research suggesting the effectiveness and better tolerance of SSRIs in patients being treated for depression, developed in the late 1990s (Garland, 2004). However, as several large randomized controlled trials of the eight most popular antidepressants came to an end in 2003, both physicians and researchers received devastating news (Garland, 2004). First paroxetine (Paxil) was contraindicated in Canada, the United States and the United Kingdom as a treatment for Major Mood Disorder (MMD) in patients under the age of 18 (Garland, 2004). Studies done with the drug had found it not only to be ineffective in the treatment of MMD, but that it was linked with twice the rate of aggression and suicide when compared with the placebo (Garland, 2004). Furthermore, three trials involving venlafaxine, another SSRI, found this drug to be ineffective in treating MMD as well, and once again associated with double the rate of suicide and anger when compared with the placebo (Garland, 2004). The startling results from these studies finally led the FDA to issue a public health advisory pertaining to all antidepressant medications being used to treat pediatric patients because of their ineffectiveness and relation to suicidal ideation and attempts (Garland, 2004). Another study testing the effects of sertraline on approximately 400 patients found that 69% of patients showed an improvement when on the medication versus 59% in the placebo group (Garland, 2004). Only one in every ten patients experienced some improvement in their condition yet this drug was being prescribed at the time to treat pediatric depression (Garland, 2004).

These are just three key instances where big pharma has neglected its utmost duty – providing effective treatments



Canadian Broadcasting Corporation. (2005, January 25). Study linking Vioxx to heart problems finally published. Retrieved March 21, 2005 from the World Wide Web: www.cbc.ca

that improve the quality of life of patients. Public-health institutions will continue to experience an erosion of trust as long as devastating side effects keep arising from drugs that have not been thoroughly tested. In the long-term, a failure to act constructively when signals of risk become evident will lead to significant public skepticism about what the priorities of the big pharma really are, and whom they are really interested in representing. More importantly, trusting patients will continue to suffer due to negligence on the part of the big pharma.

At this point, the important thing to determine is what can be changed to improve this situation and to prevent future tragedies from occurring. First of all, Health Canada and the FDA must more effectively protect the public interest by developing and enforcing stricter policies with the health of the consumer as the primary focus for clinical trials of a drug. Serious side effects of drugs often remain unknown until they have been widely prescribed. Therefore, clinical trials must be much more extensive and thorough to ensure that the health of patients will not be put at risk. When concerns about side effects arise, big pharma must immediately begin research to determine what is actually occurring, as it is their obligation to the public. Physicians also have an important role in protecting the public interest by ensuring that they lobby big pharma whenever they have any concerns about the effect a drug is having on a patient.

Finally, and most importantly, the priorities of everyone involved in the health care system, including the pharmaceuticals, patients and physicians must be discussed and re-examined. The primary focus of healthcare must be on the people it serves. The health and well-being of patients must always come first and every effort must be taken to prevent putting these principles into jeopardy. If everyone involved is working toward the same goal, achieving it becomes that much easier. **M**