The Vioxx Scandal Explained

Vioxx, also known as Rofecoxib, is a painkiller that was prescribed to treat arthritis, migraine and other pain conditions. It was released to the public in 1999 and withdrawn from the public in 2004 due to public health concerns, but what exactly were those public health concerns and should such a drug have been approved at all?

In November 1998 Merck, a pharmaceutical and global health care company, asked the FDA to approve the painkiller drug Vioxx, having tested the drug on 5,400 subjects in eight different studies themselves. But it was after Merck published their VIGOR study with over 8,000 subjects that the FDA approved Vioxx. This study was successful because it compared the occurrence of GI problems as a side effect with Vioxx and Naproxen. Vioxx caused fewer ulcers and gastrointestinal bleeding than Naproxen as proven in their study. Vioxx is then seemlying a better painkiller drug than Naproxen as proven in their study and the FDA then approves Vioxx.

But being the sole researchers for their new product that they wished to sell proved to have a conflict of interest. They ignored the other dangerous side effects of Vioxx: heart attacks and strokes. In 2000 The New England Journal of Medicine published an article titled" Expression of Concern". They had found the data in the VIGOR study and found Vioxx's risks of heart attacks , strokes and other cardiovascular problems to be much higher compared to painkiller Naproxen.

First table of data shown in "Expression of Concern" shows these ratios of risks: 17 to 4 is the number of heart attacks of study group subjects taking Vioxx versus taking Naproxen. This is the risk findings of the VIGOR study that does not include three heart attacks that were in the VIGOR study data,

but were not submitted to the Journal. These heart attacks were made public in the updated data released by the FDA from a memorandum dated July 5 2000 that was obtained by subpoena in the Vioxx litigation , and was than made available to the Journal.This puts the ratio of risk at 5 times higher than Naproxen. At least two of the three authors knew about the three heart attacks at least 4 1/2 months before publication of their VIGOR study according to the memorandum as well.

Yet they did nothing. The number of heart attacks caused by taking Vioxx were clearly dangerously higher then from taking Naproxen and yet Merck sought approval for it's drug Vioxx anyway. The exact number of patients who took Vioxx and suffered a heart attack is not entirely clear but according to Dr.David Graham, Associate director of The FDA Office of Drug Safety, the FDA's failure to recall Vioxx from the market could led to as many as 60,000 deaths from heart attacks and stroke.

Carol Earnest was the first of tens of thousands who sued Merck over damages they claimed was caused by the drug Vioxx. Carol's husband Robert Ernest, took Vioxx to treat the pain in his hands and less than eight months later he died of a heart attack in his sleep. Not understanding the cause of her husband's tragic death, Carol researched until she concluded that Vioxx was the cause of his death. She was awarded 253 million dollars after suing Merck but later had that award reduced and then overturned by a court of appeals that found insufficient evidence that Vioxx was the cause of Robert's death.

How were other similar lawsuits handled? In 2007 Merck settled the rest of the lawsuits of the Vioxx cases for 4.85 billion dollars. Merck then had to settle Department of Justice criminal charges for 950 million dollars in 2011. Merck then settled a class action lawsuit by investor's lawsuits for 830 million dollars in 2016. By settling these lawsuits they avoided having to dispute any more lawsuits brought against

them and avoided actually taking responsibility for the charges brought against them.

After the Vioxx scandal, there was great public outcry for reform in the FDA's ability to regulate and restrict the release of new pharmaceutical drugs to the market. The FDAA then passed the Amendments Acts of 2007, to better manage drug safety and past market surveillance, as well as transparency towards the public.

Some critiques have made on the lack of change in transparency in this Act by The New England Journal of Medicine and others, but the underlying problem remains. The FDA views Big Pharma as it's client it must cater to, not properly regulate.According to a FDA User fees PDF, in fiscal year 2022, user fees represented 46% of the FDA's total budget of 6.2 billion dollars. Dr David Graham stated on CBS news among other concerns that "If you're a scientist, and you raise a safety question, almost all of the time, almost 100 percent of the time, pressure gets brought on you to change your opinion". This makes sense as so much of the FDA's funding comes from Big Pharma. The FDA doesn't want to disappoint it's client if it can possibly avoid it.

The Vioxx scandal is a clear and tragic example of Big Pharma's corruption as well as the FDA's indifference to Big Pharma's corruption. The corrupted structure of the FDA's relationship with Big Pharma remains the same. Nothing has changed to protect the public from another Vioxx and so there is no protection at all, from Big Pharma or the FDA from any new dangerous pharmaceutical drugs.

Sources

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