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**Timeline of Merck's failure to act on removing Vioxx from the market**

**By Michael Monheit, Esquire, Monheit Law, PC**

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Based on an article by THE NEW YORK TIMES, by Alex Berenson, Gardiner Harris, Barry Meier and Andrew Pollack, "In May 2000, executives at Merck, the pharmaceutical giant under siege for its handling of the multibillion-dollar drug Vioxx, made a fateful decision."

The article shows the following timeline of Merck failures to recall Vioxx:

1998: Vioxx put on the market amid controversy over the safety of Cox-2 drugs.

January 1999: A study of 8,100 rheumatoid arthritis patients begun in January 1999.

February 2001: FDA members expressed concerns about the heart risks of Vioxx and doctors on FDA panel argued that the drug's possible harm to the heart was a real problem. FDA panel felt that more studies should be done.

March 2000: Clinical trial suggested heart risk concerns. In the study, called Vigor, patients were treated with either Vioxx or naproxen, an older pain reliever. While Vioxx reduced the risk of internal bleeding, it also appeared to raise the incidence of heart problems. Five times as many patients taking Vioxx had heart attacks as those taking naproxen.

March 2000: Company executives were told about the preliminary results from the Vigor trials that showed increased cardiovascular risk and were "open to the possibility that Vioxx was at fault."

April 2000: Merck plays down the heart risk findings, with no basis that has ever been defined by Merck as to why it ignored the findings.

Spring 2000: Merck researchers reviewed safety data from a study of Vioxx and was unable to find that Vioxx posed a risk. "But Merck never ran a clinical trial seeking to scientifically establish the heart-protecting properties of naproxen or to quantify how powerful an effect might be. In recent interviews, company officials said they did not believe there was a reason to conduct such tests because the critical issue was not proving naproxen's benefits but determining if Vioxx posed a risk."

May 2000: Merck marketing executives considered whether to directly test Vioxx for heart risk.

May 2000: Merck's policy-making group met to discuss ways to defend Vioxx against competing drug makers' accusations that it posed cardiac risks. A cardiovascular risk study was considered.

May 2000: Merck's marketing executives opposed further cardiac study.

## Timeline of Merck's failure to act on removing Vioxx from the market

June 2000: Merck executives rejected pursuing a study focused on Vioxx's cardiovascular risks. Study would require as many as 50,000 patients. Merck worried that this study would hurt its marketing. Marketing of Vioxx was the primary concern for Merck.

Many scientists (from the academic community, not from Merck) repeatedly asked Merck to perform studies of the cardiovascular risks from Vioxx.

For the following years, Merck took the position that "Vioxx was safe unless proved otherwise."

During this time, "researchers fiercely debated how the question should be pursued, and some even now question whether the drug needed to be withdrawn."

2001: "Dr. Deepak L. Bhatt, a cardiologist at the Cleveland Clinic, proposed to Merck a study of Vioxx in patients with severe chest pain. Merck declined, saying the patients proposed for the study did not reflect typical Vioxx users."

September 2001: FDA sent Merck a warning letter stating that Merck's promotional campaign for Vioxx "minimizes the potentially serious cardiovascular findings" in Vigor.

September 2001: Merck required by the FDA to send letters to physicians across the country "to correct false or misleading impressions and information."

2001: Merck achieves \$2.5 billion dollars of sales of Vioxx.

2001: Study critical of Vioxx appears in The Journal of the American Medical Association. Data from several clinical trials of Vioxx showed that Vioxx may increase the risk of heart attack and stroke, and that the danger from Vioxx appeared higher than other Cox-2 drugs.

October 2002: Study by an epidemiologist at Vanderbilt University, found that high doses of Vioxx caused significantly more heart attacks and strokes than similar patients who were not taking high doses.

2002: Elucida Research examined Vioxx and found that Vioxx damaged the lipids and caused an increase in blood clots.

Late 2002: Merck faces initial lawsuits from individuals suffering from strokes and heart attacks

April 2004: Harvard Medical School found that Vioxx raised the risk of heart attacks relative to Celebrex.

June 2004: Researcher showed that Vioxx increased the risk of hypertension.

August 2004: Epidemiological study F.D.A. researcher based on Kaiser Permanente health care system data showed an increase cardiovascular risk for Vioxx. Study showed increased the risk of heart disease 3.7 times

September 2004: Merck withdraws Vioxx from the market.

October 2004: Thousands of people come forward with claims that their heart attacks and strokes had been caused by Merck's Vioxx.

October 2004: "Dr. David Graham, estimates Vioxx had been associated with more than 27,000 heart attacks or deaths linked to cardiac problems."

November 2004: SEC announces an investigation into Merck's misrepresentations to its investors.

November 2004: Congress announces hearings into Merck's failures and the failures of the FDA to regulate Merck.

November 2004: The Justice Department launches investigations into what Merck knew and whether there was corporate/criminal malfeasance.

Merck now claims that it took "prompt and decisive action" once it knew Vioxx was dangerous.

This original of this article can be found at:

## **The New Drug Recall Lawyers**

**By Richard Martin**

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Given the monstrous size and profitability of drug companies, some plaintiff lawyers are considering focusing more of their practice on drug litigation. In fact, shortly after Merck's announcement of the Vioxx recall, some large plaintiff firms started aggressive media campaigns aimed at bringing in prescription drug injury victims. The media blitz has been non stop. Billboards, TV, web marketing, radio, and direct mail are just some of the marketing vehicles that attorneys have used to try and find new cases for them to work on. Many plaintiff law firms are no longer focusing on chasing run of the mill car accidents. Some of them have gone so far as to reposition themselves as "drug recall lawyers," seeing that the future of their practice may be shaped by the initial outcome of these new pharmaceutical cases.

When Merck chose to withdraw Vioxx, the CEO stated that a voluntary recall was the responsible course of action. Prior to pulling Vioxx from the market, Merck was spending \$500 Million per year on advertising Vioxx. Vioxx is classified as a non-steroidal anti-inflammatory drug, or NSAID. However, Vioxx belongs to a new family of NSAIDs called "COX-2 inhibitors." There are not many COX-2 inhibitors on the market in the US: Bextra and Celebrex may be the only other two.

Both the number of potential Vioxx plaintiffs and award amounts of the lawsuits are projected to be extremely large. The investment bank S.G. Cowan recently estimated that eventually more than 600,000 plaintiffs could file suit in the Vioxx case. Furthermore, some investment banks think that plaintiffs may file for more than \$10Billion in damages in years to come. Even the national TV networks have covered the Vioxx withdrawal. A November 2004 story on the Vioxx withdrawal appeared on CBS News' 60 Minutes. The CBS story implied that the US Justice Department is conducting an investigation and the Securities and Exchange Commission is looking into Merck's conduct. Given the media coverage of the Vioxx withdrawal and the number of people who were prescribed Vioxx, there may be many new "Drug Recall Firms" founded in years to come.

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