

Why am I mad at Merck over Vioxx?

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**Why am I mad at Merck over Vioxx?**

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

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What is disturbing to me, is that given years of evidence that there was a risk of stroke and heart attack from Vioxx, Merck did NOT set out to study the cardiac impact -- rather only when it had an opportunity to add a new market for the drug did they do a study which accidentally caused Merck to acknowledge publicly what it already knew privately. This study, and only by "accident" turned out to the public what the public should have known and Merck already did know sooner...

In May 1999 the Food and Drug Administration (FDA) approved Vioxx. The original safety database included approximately 5,000 patients on Vioxx and did not show an increased risk of heart attack, stroke, blood clots, or sudden death. One year later in June 2000, Merck submitted a safety study called VIGOR (Vioxx Gastrointestinal Outcomes Research) to the FDA that found an increased risk of Vioxx heart attacks and strokes in patients taking Vioxx compared to patients taking naproxen. After reviewing the VIGOR study results and other available data from controlled clinical trials, the FDA consulted with its Arthritis Advisory Committee in February 2001 regarding the clinical interpretation of this new questionable Vioxx-related information.

Perhaps, back in Feb of 2001, it was "questionable," but the "question" about the lack of safety for Vioxx was squarely put forth to Merck, and Merck had a moral obligation, not to mention a financial obligation to its shareholders, to look further into this -- THEN. They did not.

Why not?

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Why did it take 22 months (June 2000 to Feb 2001) to alert the medical community and its patients about life threatening risks for Vioxx induced chest pain, heart attacks, blood clots, stroke, and sudden death?

... I would argue, and yes, this is me with my attorney hat on and you are the jury, that there were \$2.5 Billion reasons each year that they did not look further at the heart attack issue for years.

On September 17, 2001 (and, to Merck's good fortune, lost in the news of the terrorist attacks of 9/11),

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the FDA issued an 8–page warning letter to Merck concerning its false and misleading promotional campaign. The FDA found:

"You have engaged in a promotional campaign that minimizes the potentially serious cardiovascular findings that were observed in the VIOXX Gastrointestinal Outcomes Research (VIGOR) study, and thus, misrepresents the safety profile for VIOXX. Specifically, your promotional campaign discounts the fact that the VIGOR study patients on VIOXX were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients on the comparator nonsteroidal anti–inflammatory drug (NSAID), Naprosyn (naproxen)."

So, finally, in April 2002, after "foot dragging" (you'd call it due diligence or appropriate caution) an FDA that is stacked with folks coming in and out of the Pharma industry, in release T02–18 (4/11/2002) required Merck to label the drug as a cardiac risk.

"FDA has approved a supplemental application for the use of Vioxx (rofecoxib) for rheumatoid arthritis adding the indication to the previously approved indications for osteoarthritis and pain. FDA has also approved new label text and precautions that are based on the results of the Vioxx Gastrointestinal Outcomes Research (VIGOR). The VIGOR study, a prospective, randomized, double–blind, one year study, evaluated approximately 4000 patients on Vioxx 50 mg a day (twice the highest approved dose for chronic use) and approximately 4000 patients on the standard dose of naproxen (1000 mg a day), a non–steroidal anti–inflammatory drug (NSAID). Patients who were under treatment with low dose aspirin for heart attack prevention were excluded from the study.... An additional finding in the study, however, was that there was a higher cumulative rate of serious cardiovascular thromboembolic adverse events (such as heart attacks, angina pectoris, and peripheral vascular events) in the Vioxx group (1.8%) compared to the naproxen group (0.6%). Data from two smaller studies comparing placebo and Vioxx 25 mg daily did not show a difference in the rate of serious cardiovascular thromboembolic adverse events. The relationship of the cardiovascular findings in the VIGOR study to use of Vioxx is not known. After carefully reviewing the results of the VIGOR Study, FDA agreed with the Arthritis Advisory Committee recommendations of February 8, 2001 that the label for Vioxx should include the gastrointestinal and cardiovascular information. The committee advised that the NSAID–class warning regarding GI adverse events should be modified, but not removed from the VIOXX label. This warning advises patients and their doctors about the risks of GI ulcers, bleeding, and perforation. "

That is an increase over over 1 in 100 people who take the drug having a heart attack because of it. Pretty statistically significant. It means that we both probably know someone who this happened to. OK, now fast forward to the more recent study. Only when they saw gold in their pockets, selling Vioxx into the cancer prevention market, did Merck do the study. Only this time the study turned out to confirm what they already "suspected" in June 2000, but failed to actually study it. At the very least, they should have done further study three years ago for the specific problem that they subsequently confirmed in the more recent study.

This attitude simply ignored the mounting evidence that VIOXX was, indeed, the killer it had always been suspected of being. This is all the more obvious when one considers the following facts:

Kaiser Permanente, the largest HMO in the United States, found the incidence of sudden cardiac death to be three times greater for VIOXX than Celebrex among its patients.

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Cigna Health Care regarded VIOXX as a "non-preferred medication" for its policy holders.

Aetna, Inc., the third largest health insurer in the United States, announced that VIOXX was the subject of an ongoing study and recommended "alternative drugs" be prescribed in its place.

Every study ever conducted with respect to VIOXX between 1999 and 2004 showed an increased risk of heart attack.

Several medical research organizations consider the entire COX-2 class of drugs to have an increased cardiac-related risk (although it appears that Celebrex may have a lower risk in this area).

A study done at Vanderbilt University, and published in *The Lancet* on October 5, 2002, noted that patients taking 50mg. of VIOXX for more than 5 days demonstrated a 70% greater likelihood of developing coronary heart disease (CHD).

Despite requests from the American Heart Association, the National Stroke Association, and the

Arthritis Foundation that Merck conduct additional safety studies, Merck claimed that VIOXX was safe and that it did not plan to conduct any such study.

An early 2004 study, which was actually funded by Merck, disclosed that VIOXX posed a risk of heart attack and stroke which was three times greater than that of other COX-2 pain relievers. Shamefully, when this finding was made, Merck had the name of its scientist removed from the list of authors on the study.

Now, back to the FDA and how bad an actor Merck really is... On September 8, 2004, the FDA actually approved the use of VIOXX in the treatment of infants as young as 2 with rheumatoid arthritis. To say that this request by Merck was anything less than an unconscionable display of corporate greed is an understatement.

Next, Merck's greed was its own undoing. Although Merck is attempting to make the best out of a very bad situation by making it appear as if its voluntary withdrawal of VIOXX was motivated by concern for the public, the evidence does not support that position. There is little doubt that the removal of VIOXX from the market was anything but a purely financial consideration on the part of Merck which stands to lose \$700 to \$750 million in the fourth quarter of 2004 alone. The lawsuits are piling up and some will be proceeding to trial shortly. And Merck is not acting out of an interest in public safety, but only to protect shareholder value. Consider this before concluding that Merck was thinking about safety and not dollars:

The study (APPROVe trial) which led to Merck's decision to voluntarily withdraw VIOXX from the market was really aimed at gaining FDA approval for VIOXX as a treatment for preventing the recurrence of colon polyps. (APPROVe stands for Adenomatous Polyp Prevention on VIOXX which clearly shows the study had nothing to do with safety and everything to do with gaining approval from the FDA for even wider use of VIOXX). In Merck's open letter to "VIOXX Patients," which has appeared in newspapers across the country, Merck claims that the study was "a clinical trial to better understand

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the safety profile of VIOXX." It was no such thing. In fact, had the 3-year study not been halted abruptly on September 24 by the Data Safety Monitoring Board for safety reasons, VIOXX would still be on the market.

Merck has already developed a new COX-2 pain reliever called ARCOXIA which is presently being marketed in 47 countries and for which Merck expected FDA approval in the near future. While ARCOXIA is not yet a billion dollar drug and must gain approval in 33 more countries to equal the worldwide market enjoyed by VIOXX, it is clear that VIOXX was well on the way to being replaced when it was pulled from the market. Clearly, safety was, at best, a distant second when it came to a reason for Merck's voluntary withdrawal of VIOXX.

Finally, even though VIOXX was finally exposed for what it was; a dangerous drug, Merck stated in its press release that the drug was being withdrawn despite Merck's belief that "it would have been possible to continue to market VIOXX with labeling that would incorporate these new data..." Bull. Merck would still have kept VIOXX on the market had it not met with the FDA on September 28 and been forced to confront the disastrous results of its own study.

So this is 3+ years ago that Merck had reason to know, let alone reason to explore this issue. They chose not to. Again, you know why I think that they made that choice. And having seen this before, in addition to this clear failure of Merck to study this earlier, the adverse reports that Merck received in between will, I believe, spell out more than a simple mistake, but at least the inference of an intent to

simply make money at the expense of patient safety.

### **What was done about the inadequate Vioxx warnings?**

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For years leading up to its withdraw, the FDA had taken steps to force Merck and Pharmacia, the makers of these drugs, to disclose the risks associated with their products. Changes in medication labels have been made, along with orders to cease misleading advertising practices.

Doctors finally began to speak out and to inform their patients about the actual benefits, cost, and problems of Vioxx and Celebrex.

Class action suits were filed against Merck, the maker of Vioxx. The lawsuits are pending.

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The warnings on Vioxx were late to come and the drug should have been pulled sooner.

Finally, on September 30, 2004, Merck got the message and pulled Vioxx from the shelves, and issued a Vioxx warning — patients should stop taking the Vioxx and return the unused pills. The Vioxx warning came as a result of a study that showed the drug doubled the risk of heart attack and stroke. At the

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same time, it sounded an Vioxx warning alarm for the millions of people who took Vioxx.

The FDA should force companies like Merck to issue warnings on Vioxx sooner  
The Food and Drug Administration needs to push drug companies harder to do long-term safety studies of drugs on the market once concerns develop so that a better Vioxx warning would have been developed before so many people were harmed.

Without the FDA pushing for these studies to develop better warning the public about the dangers of drugs like Vioxx, according to the University of Pennsylvania bioethicist Arthur Caplan the problem is like "we're relying on the fox to tell us about what's wrong inside the chicken coop."

On its own, Merck issued only a luke warm Vioxx warning.

In some cases, experts say, such warnings on Vioxx's official labeling aren't sufficient. Since 2002, Merck's Vioxx warning mentioned increased cardiac risks based on results of its own post-approval study, but disputed its own findings and the drug remained on the market despite the Vioxx warning. Merck undertook the latest study because less-rigorous experiments indicated Vioxx could prevent recurrence of potentially cancerous colon polyps, said company spokesman Tony Plohoros.

Dr. Alastair Wood, professor of pharmacology and associate dean at Vanderbilt University School of Medicine, said it should not have taken so long for the heart risks to come to light. Had they come to light sooner, proper Vioxx warnings would have been issued.

People were hurt by the inadequate Vioxx warnings

"A helluva lot of people got the drug between 2000 and 2004, and a very quick, very cheap study would have determined that risk" had the FDA taken a tougher stance after the first sign of trouble, Wood said. If better studies were performed, Vioxx warnings would have been more stringent — or the drug would not have been on the market at all.

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