SEARCY DENNEY SCAROLA BARNHART & SHIPLEY P.A.

OF COUNSEL

Of Counsel Special Edition: Vioxx... what you need to know

A quarterly report
to clients and attorneys.
VOLUME 05 ■ NUMBER 1

Greed Blinded Drug Makers

Patients suffered because Vioxx and Bextra makers ignored ample warnings and calls for more research

Ever since the much-advertised new generation of non-aspirin painkillers hit the market, government regulators, independent scientists and consumer watchdogs have warned of their potential ill-effects.

Included in this new class of nonsteroidal anti-inflammatory drugs (NSAIDs) were Vioxx and Bextra. Ignoring legitimate warnings, their own testing and pushing aside physicians' concerns and calls for more testing, the makers of these drugs, Merck and Pfizer, respectively, began to aggressively market their potentially fatal drugs directly to the public, spending hundreds of millions of dollars in the process.

The drug companies are now claiming to be good corporate citizens because they have voluntarily withdrawn the drugs from the market. The truth of the matter is that when faced with overwhelming evidence that they knew or should have known all along of these drugs disastrous side effects, these greedy pharmaceutical companies continued to pursue obscene profits at the expense of patient safety.

The big drug companies have now circled the wagons and are searching for ways to avoid being held accountable for their greed and dishonesty.

Patients who have suffered heart attacks, strokes and other tragic coronary side effects have begun to search for answers and explore legal action. We stand ready to support them in this difficult time with their efforts to find justice and guide them through what is sure to be a difficult process. We won't let these corporations hide behind false claims that they thought the drugs were safe. ■

We've built relationships with you, our clients and associates, for 30 years based on trust and honesty. We pledge to be as aggressive, diligent, hard-working and caring in handling cases involving COX-2 inhibitors.

Vioxx by the Numbers:

- **84 MILLION**
  people have used Vioxx since 1999
- **$2.5 BILLION**
  in sales for Vioxx last year alone
- **139,000**
  the approximate number of heart attacks one study links to Vioxx
- **1999**
  Vioxx gets FDA approval
- **2000**
  Merck's own study shows COX-2 (Vioxx, Bextra) inhibitors linked to heart problems
- **$100 MILLION**
  Merck's estimated annual advertising budget for Vioxx
- **4 Times**
  Factor by which Vioxx users were more likely to suffer a heart attack or stroke than patients prescribed a placebo

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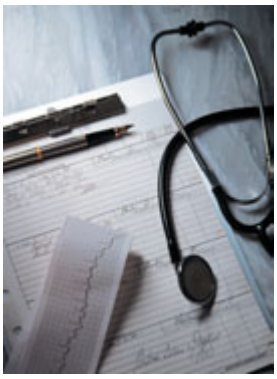
Arthritis Medicines and Cardiovascular Events - "House of Coxibs"

Journal of the American Medical Association
January 2005 (Excerpted)

Eric J. Topol, M.D.



From the outset, the coxib class of medicines (including Vioxx, Bextra, Celebrex and others) seemed destined for potential collapse. These drugs were mass-marketed from the moment they were commercially available in the new world of direct-to-consumer advertising, with unrealistic expectations about pain relief, marked gastrointestinal protection, and safety. Rather than a sufficient waiting period after approval to firmly establish safety in the large, representative "real world" population, the unbridled promotion exacerbated the public health problem. This is so poignantly clear for an indication such as arthritis, which is one of the most common conditions requiring medication. Furthermore, one has to question the wisdom of allowing direct-to-consumer advertising for lifestyle medications that have no capability of preserving life or preventing major events such as myocardial infarction or stroke. Here the paradox of actually promoting these events is all the more difficult to accept.

The combination of mass promotion of a medicine with an unknown and suspect safety profile cannot be tolerated in the future. An aggressive position going forward is necessary not only for ensuring the safety of prescription medicines but also to restore a solid foundation of public trust. ■

VIOXX TIMELINE:

Responding to mounting scientific evidence that its blockbuster drug Vioxx could induce fatal heart attacks and strokes, among other conditions, the Merck Co. on Sept. 30, 2004, withdrew its heavily marketed painkiller from the market. The following is a timeline of important dates related to Merck's handling of the Vioxx situation:

MAY 1999 The Food and Drug Administration approves Vioxx, a COX-2 inhibitor and non-steroidal anti-inflammatory drug (NSAID) for use in treating osteoarthritis, menstrual pain and other acute pain and inflammation — adults only.

JUNE 1999 Merck begins Vioxx sales.

OCTOBER 1999 Merck's first change to its drug information insert warns of possible adverse side-effects when Vioxx is used with the anti-coagulant Coumadin (warfarin).

NOVEMBER 2000 New England Journal of Medicine publishes Merck's VIGOR study comparing the gastrointestinal toxicity of COX-2 inhibitors with other non-steroidal painkillers. Study shows elevated risk for heart attack and stroke.

DECEMBER 2000 FDA admonishes Merck for misleading advertising related to Vioxx safety.

MAY 2001 Merck begins public relations campaign claiming Vioxx is safe based on its own research. The first press release in the series: *Merck Confirms Favorable Cardiovascular Safety Profile of Vioxx.*

AUGUST 2001 Journal of American Medical Association publishes, *The Risk of Cardiovascular Events Associated with Selective COX-2 Inhibitors.* "The available data raises a cautionary flag about the risk of cardiovascular events with COX-2 inhibitors. Further prospective trial evaluation may characterize and determine the magnitude of the risk."

SEPTEMBER 2001 FDA again warns Merck about misleading advertising claims related to Vioxx. "The implication that Vioxx's cardiovascular profile is superior to other NSAIDs is misleading; in fact, serious cardiovascular events were twice as frequent in the Vioxx group as in the Naproxen group in the VIGOR study."

APRIL 2002 FDA tells Merck to include precautions on its labeling alerting consumers to heightened cardiovascular risks.

SEPTEMBER 2004 Merck recalls Vioxx amid rising controversy.

OCTOBER 2004 New England Journal of Medicine *Perspective* article written by early Vioxx critic Dr. Eric J. Topol estimates that "there may be tens of thousands of patients who have had major adverse events attributable to rofecoxib (Vioxx) ... Sadly, it is clear to me that Merck's commercial interest in rofecoxib sales exceeded its concern about the drug's potential cardiovascular toxicity."

Vioxx/Bextra Legal Issues

The legal issues surrounding Vioxx, Bextra and the other nonsteroidal anti-inflammatory drugs (NSAIDs) being recalled from the market are complex. With tens of thousands of people potentially injured by their use of these drugs, there has been talk of special courts, class action or mass tort suits, multi-state and multi-party suits. Determining just how to proceed with a particular case depends on the victim's specific set of circumstances and how that relates to the emerging legal landscape. Some suits may be better handled separately as individual claims while others may be better suited for inclusion in a class or multi-tort action.

Searcy Denney Scarola Barnhart and Shipley has extensive experience in each of these areas and is prepared to help clients determine which avenue is best for them. Having represented literally thousands of clients in medical malpractice and product liability cases, our firm has the know-how and resources to pursue cases that can take years to settle. We have successfully pursued claims for victims of negligent health care providers and hospitals, L. tryptophan toxicity, defective breast implants and deficient medical laser devices.

The drug manufacturers will have seemingly endless resources to fight legitimate claims. And, make no mistake, they will fight legitimate claims. One industry analyst, Richard Evans of Sanford C. Bernstein and Co. recently estimated that Merck may spend upwards of $12 billion on its defense and in settlements. Other industry analysts predict that Merck's liability lies somewhere between $4 billion and $18 billion.

Experience when it counts most

Few firms have the experience necessary to successfully represent clients who have fallen victim to the negligence of a health care provider or willful deceit of a major corporation. What's more, few firms have the capital necessary to effectively investigate and prosecute what are invariably arduous and very expensive cases.

"The purpose of the law is to prevent the strong from always having their way."
– Ovid

Through our work with clients and our legal associates around the state and nation, we have become a nationally recognized trial law firm, committed to protecting and vindicating the rights of people injured through negligence, deceit and abuse of power. We have tried cases in nearly every courtroom in the state since 1978. And in that time, we have also represented clients in courtrooms throughout the country at the state and federal level. Many times the results we have achieved together have broken new legal ground and obtained unprecedented results. Over the past 15 years alone, we have recovered more than $1 billion in settlements and verdicts for our clients and their loved ones. These verdicts and settlements have often been among the highest in Florida and the nation.

And while we cannot possibly promise outcomes to cases not yet even filed, we can promise to bring to these cases the same work ethic, resources and commitment for which we have become known. ■

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Vioxx Dangers Were Well Known

Drug company's reluctance to act may have cost thousands their lives.

An unmistakable impression has emerged since Merck first pulled Vioxx from the market Sept. 30 2004. It appears company execs were well aware of the drug's potential to induce heart attack, strokes and other fatal reactions. The scientific community had already raised numerous red flags about Vioxx, calling for a greatly expanded research scope. Regulators, though aware of potential problems, were reluctant to press Merck to do further research or compel the company to recall the drug. The following are excerpts from several of the most important articles and programs on the subject.

New England Journal of Medicine Eric J. Topol, M.D.

Failing the Public Health - Rofecoxib, Merck, and the FDA

October 21, 2004 (Excerpted)

Neither of the two major forces in this five-and-a-half-year affair — neither Merck nor the FDA — fulfilled its responsibilities to the public. The pivotal trial for rofecoxib involved 8,076 patients with rheumatoid arthritis and demonstrated that this coxib had lower gastrointestinal toxicity than Naproxen. Even though the drug was approved in 1999 on the basis of data submitted to the FDA, the data were not submitted to a peer-reviewed journal until the following year and did not appear in print until November 23, 2000, one-and-a-half years after commercial approval had been granted.

CBS News 60 Minutes Ed Bradley Reporting

Prescription For Trouble November 14, 2004 (Excerpted)

(CBS) When the pharmaceutical giant Merck pulled its blockbuster pain medication Vioxx off the market in late September, it became the largest prescription drug recall in history.

The company says it took immediate action after a new study showed that Vioxx doubled the risk of heart attacks and strokes in some patients.

However, according to internal Merck documents *60 Minutes* has seen, and interviews with outside scientists, Merck had concerns that Vioxx could possibly cause cardiovascular risks long before it was pulled off the market.

New York Times Sunday Edition

Despite Warnings, Drug Giant Took Long Path to Vioxx Recall November 14, 2004 (Excerpted)

This article was reported and written 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 multi-billion dollar drug Vioxx, made a fateful decision.

The company's top research and marketing executives met that month to consider whether to develop a study to directly test a disturbing possibility: that Vioxx, a painkiller, might pose a heart risk. Two months earlier, results from a clinical trial conducted for other reasons had suggested such concerns.

But the executives rejected pursuing a study focused on Vioxx's cardiovascular risks. According to company documents, the scientists wondered if such a study, which might require as many as 50,000 patients, was even possible. Merck's marketers, meanwhile, apparently feared it could send the wrong signal about the company's confidence in Vioxx, which already faced fierce competition from a rival drug, Celebrex.

VIOXX & BEXTRA LINKED TO HEART ATTACKS AND STROKES
Find out what you can do to fight back.