

"What the people want is very simple. They want an America as good as its promise." – Barbara Jordan

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This newsletter is published for the exclusive use and benefit of Vioxx injury claimants represented by Hill Toriseva & Williams; Hill Peterson Carper Bee & Deitzler; Clark Perdue Arnold & Scott; and Michael Martin & Associates. Questions concerning editorial content should be addressed to:

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Lawmaker says Merck censored Vioxx safety concerns

A promotional card that Merck's sales force used to tout the safety profile of Vioxx to doctors was "inaccurate and misleading" and did not reflect just-released findings from a major clinical study that linked the drug to increased cardiovascular risks, according to a prominent House Democrat.

"Instead of informing doctors about the risks of Vioxx, Merck told its representatives to continue to rely on the highly questionable

"Cardiovascular Card," Waxman said during a recent committee hearing on the role of the FDA and drug makers in ensuring the safety of drugs like Vioxx.

Waxman based his conclusions on an analysis of thousands of pages of documents obtained from Merck, including the Cardiovascular Card. The tri-fold pamphlet stated patients taking Vioxx were 11 times less likely to die and eight times less likely to die from heart attacks and

strokes than patients taking standard anti-inflammatory drugs. The data presented in the card appears to have little or no scientific validity, and did not contain data from the VIGOR study, Waxman said. "Instead, the card presented pooled data from clinical trials conducted prior to the drug's approval in osteoarthritis patients," he noted.

More on the CV card in story at top of page 2

Risk of heart attack or stroke starts early

When Vioxx went off the market in September 2004, because of an increased risk of heart attacks and strokes, Merck claimed that the risk does not exist until a person is on the drug for 18 months or longer. Experts dispute this.

Lee Simon, M.D., a rheumatologist at Harvard University, says that there is a clear and significant increased risk of heart attack in the first 30 days after starting on Vioxx, compared to Celebrex, shown in data taken by Solomon *et al.* from Pennsylvania and New

Jersey Medicare databases and published in the American Heart Association journal, *Circulation*. Dr. Simon also says that Merck's VIGOR study from 2000 shows a statistically significant increase in risk at about 80 days.

Wayne Ray, Ph.D., Director of Pharmacoepidemiology at Vanderbilt University, points out that the increased risk shows in several studies of less than 18 months duration.

John Markis, M.D., a Harvard University cardiologist, says that the risk is present, at least in

theory, as soon as a person reaches a steady level of the drug, which takes about four days.

Dr. Markis indicates that 18 months marks the point in Merck's "APPROVe" study when the risk was deemed to have become "statistically significant" but "clearly people in the study had these events before 18 months."

He adds that in his opinion the 18-month period is not relevant in assessing whether Vioxx contributed to causing a cardiovascular event.

Merck announces resignation of chief and names replacement

Merck announced on May 5, 2005, that Raymond Gilmartin is stepping down effective immediately from the top leadership spot at the drug maker, which has been under pressure since recalling Vioxx last fall.

Merck named Richard Clark as president and chief executive officer in Gilmartin's place. Clark is currently the president of Merck's manufacturing division.

Gilmartin had been president of Merck since 1994. Lawyers representing Vioxx claimants charge that Gilmartin fostered a culture of profits over safety at Merck that contributed to the Vioxx debacle.



Gilmartin

Tolling agreement expected soon

Ongoing negotiations with Merck's lawyers are expected to result in an agreement available to our clients that would stop the statute of limitations from running on their claims without being required to file a lawsuit in court.

Such an agreement is called a statute of limitations tolling agreement. Both sides benefit from the cost savings these agreements provide.

A client whose claim is put on a tolling agreement will not be disadvantaged by it. Our case development process will be the same in cases on tolling agreements as it is for cases filed in court.



How Merck stacked the deck against doctors

Four years ago, as evidence mounted that Vioxx causes heart attacks, the company ordered its sales force not to discuss the subject with doctors, but instead to paint a reassuring picture of minimal risks, according to documents made public in May 2005.

A Merck company bulletin from 2001 ordered the sales force to steer clear of discussing a scientific meeting convened by the Food and Drug Administration to evaluate Vioxx safety. "DO NOT INITIATE DISCUSSIONS," it said in a prominent warning.

Other internal documents refer to doctors as "obstacles" to be overcome in promoting Vioxx sales.

Merck's aggressive marketing campaign was astoundingly successful. The overwhelming majority of the 100 million Vioxx prescriptions dispensed in the United States were written after concerns had surfaced about heart risks. Vioxx reached \$2 billion in annual sales faster than any previous Merck drug.

A key to the campaign was a pamphlet the company issued in April 2000 to its salespeople, dubbed the Cardiovascular Card or CV Card. It was meant to ease doctors' concerns after a Merck-funded clinical trial — called the VIGOR study — produced what turned out to be the first solid indications that Vioxx increases the risk of heart attack and stroke.

The VIGOR study found a fivefold increase heart

attacks and strokes for Vioxx patients when compared to patients taking naproxen, the active ingredient in Aleve. But the CV Card failed to mention those findings. Instead, it combined data from several older studies to suggest that Vioxx patients were eight times less likely to die than people taking other painkillers.

In early 2001, an FDA advisory committee recommended that doctors be informed about Vioxx's cardiovascular risks.

But Merck's sales force was instructed to avoid such discussions. Sales representatives were told not to bring up the subject. If doctors asked about the VIGOR trial, sales representatives were supposed to encourage them to submit the questions in writing to the company's medical services department.

Merck received and answered about 123,000 such queries. But the company responses merely referred back to the outdated information mirrored in the CV Card.

The sales force received detailed coaching on everything from how to shake hands with doctors (firmly, not painfully, and for three seconds) to table manners when taking physicians to lunch (eat bread in small pieces).

Merck used sophisticated databases to learn the prescribing patterns of individual doctors and set targets for selling its products to them. Sales representatives earned bonuses for increasing Merck's share of a doctor's prescriptions.

How is my case coming along?

There are two ways, and only two ways, your Vioxx claim can result in money being paid to you: (1) a settlement, where Merck agrees to pay you an agreed amount in exchange for a release of your claim against it, or (2) a trial, where the jury returns a verdict in your favor and decides how much Merck must pay you.

Merck has not settled any Vioxx cases and has not indicated willingness to settle. Vioxx court trials are years away, other than in lawsuits filed long before the drug went off the market in 2004.

An estimated 100,000 Americans are making Vioxx injury or death claims. If there is no settlement program with Merck, it will take ten years or more to get this many cases to trial. We believe there will be a settlement program at some point, because Merck will not want ten years of litigation any more than Vioxx plaintiffs do. This could be years off though.

For now we are focusing on common benefit issues vital to all cases, such as proof that Merck was negligent in failing to adequately warn of Vioxx's cardiovascular risks. Withdrawal of Vioxx is not a legal admission of wrongdoing. It still needs to be proved.

Merck is not going to settle any case, until it decides that settlement is in its interest. The best thing for your case is to increase pressure on Merck to make this decision sooner rather than later, and the key to accomplishing this is developing the common benefit issues.

Vioxx Client Service Center open for business

Hill appointed to MDL committee

Attorney Barry Hill from the Hill Toriseva & Williams law firm has been appointed by federal district judge Eldon Fallon to serve on the State Liaison Committee in Vioxx multi-district litigation (MDL) in New Orleans.

Hill is one of nine lawyers from eight states named to the committee. The committee is charged with coordination between the federal MDL and state courts with Vioxx cases pending. Sol Weiss of the Anapol Schwartz law firm in Philadelphia, our local counsel in New Jersey state court cases, was also appointed. The other members are from Louisiana, New Mexico, Colorado, California, Texas, and Florida.

How are we doing?

If you have a complaint, an idea, or a suggestion as to how we can serve you better, let us know. We want to hear from you. Send emails to Barry Hill at bhill@htwlaw.us, or call the Vioxx Client Service Center at (800) 647-7003.

The permanent files for our Vioxx clients are kept at our Vioxx Client Service Center in Columbus, Ohio.

Files that had been at offices in West Virginia have been transferred to the Service Center.

The Service Center provides a central site for efficient file management.

If you have questions about your claim, call the Service Center at (800) 647-7003.

The Center is operated as part of the offices of Clark Perdue Arnold & Scott at 471 East Broad Street, Suite 1400, Columbus OH 43215.

Partner Andrew List, pictured to the right, supervises the Service Center.



Attorney Andrew List

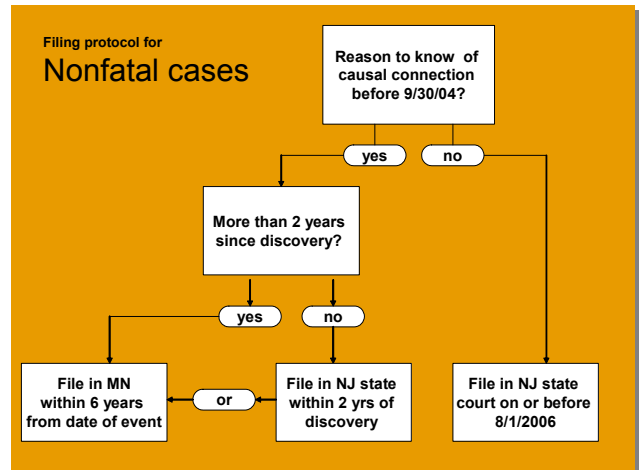
Individual case development on track

Careful evaluation of every Vioxx claim is important.

Individual causation is the big issue in every claim. Individual causation deals with whether it can be shown that Vioxx was a substantial contributing cause of a cardiovascular event, such as a heart attack or stroke.

There is no controlling scientific authority on this subject, and there have been no court rulings to help gauge where other courts will draw the line. Merck continues to claim in the press that individual causation cannot be proven in any case.

We are working with world class experts to develop a sound scientific method of proving individual causation. That can be applied to all, or most all, Vioxx claims.



Filing protocol mindful of statute of limitations

How do we decide the order in which we evaluate Vioxx claims? The first consideration is the statute of limitations. All things being equal, a claim with a statute of limitations that expires sooner will be evaluated before one with a statute that expires later. The statute of limitations date for each client's claim is in our master database of cases, and it allows us to list cases in order

according to expiration date.

A claim passing evaluation will be filed as a lawsuit or put on a tolling agreement. (See *tolling agreement story on p. 2.*) Whether a claim is filed in court or put on a tolling agreement should have no meaningful impact on when the case is ultimately resolved, and it will have no effect on how we treat the claim.

Vioxx Newsletter

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