

THE VIOXX DISASTER

"... unparalleled in the history of the United States."

Dr. David Graham

By D. Andrew List

On September 30, 2004, the pharmaceutical giant Merck withdrew Vioxx – its blockbuster painkiller – from the market. In doing so, Merck revealed that a recent clinical trial (the unpublished APPROVe study) indicated that patients taking Vioxx had a 3.5 percent incidence of heart attacks and strokes compared to 1.9 percent for those taking a placebo. Testifying before the Senate Finance Committee, Dr. David Graham, a member of the Food and Drug Administration's Office of Drug Safety, defined the scope of the harm:

"This estimate [of additional heart attacks and strokes] ranges from 88,000 to 139,000 Americans. Of these, 30 to 40 percent have probably died. Now, imagine we were talking about jetliners. If there were an average of 150 to 200 people on an aircraft, this range of 88,000 to 139,000 would be the rough equivalent of 500 to 900 aircraft dropping from the sky. This translates to two to four aircraft every week – week in, week out – for the past five years."

Given these staggering numbers – and the media attention surrounding the Vioxx debacle – many attorneys will be contacted by someone who has taken Vioxx. Before undertaking a Vioxx claim, all of us should follow several initial steps to determine whether the claim is viable.

First, we need to remember that Vioxx was withdrawn from the market for a specific reason: an increased risk of adverse cardiovascular events, including heart attack, stroke and pulmonary embolism. While many people who have taken Vioxx have claimed to experience other conditions – increased blood pressure, chest pain, irregular heartbeat, kidney failure, gastrointestinal bleeding, and many others – the APPROVe study did not relate those conditions to Vioxx. Accordingly, any attorney representing patients who have not experienced a heart attack, stroke, or pulmonary embolism, will not benefit from the medical findings that caused Merck to withdraw Vioxx from the market.

Second, attorneys evaluating potential Vioxx claims need a basic understanding of the required dosage and duration of use that has been linked to an increased risk of heart attack and stroke. The APPROVe study involved patients taking 25 milligrams of Vioxx over a period of 18 months. This was a common dosage among Vioxx patients, and there is substantial medical authority to suggest that this dosage posed a significant risk to Vioxx users.

However, some patients received prescriptions of less than 25 mg. In those cases, attorneys should determine whether the person actually took more Vioxx than the prescribed dosage. Just like the headache sufferer who takes more than two aspirin, many Vioxx patients – particularly those for whom Vioxx was prescribed for acute pain – took more than the prescribed dosage in an effort to stop the pain. Accordingly, we should be careful not to summarily reject potential clients based upon seemingly insufficient dosage.



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The necessary duration – the period of time during which a person ingested Vioxx – for increased risk of an adverse cardiovascular event is disputed. Although the APPROVe study demonstrated harm after 18 months of use, other studies have demonstrated an increased risk of heart attack and stroke associated with Vioxx after only 30 days of use. Moreover, the APPROVe study data remains unpublished, and it may eventually substantiate harm to a larger group of patients than Merck has previously revealed. Accordingly, attorneys should be careful not to reject potential clients because the duration of use was only days or weeks.

Additionally, we should be careful not to pursue claims where an adverse event occurred long after a patient last ingested Vioxx. At present, there is no medical evidence to suggest any latent harm resulting from Vioxx, because it had a relatively short half-life (11 hours), and it cleared a patient's system very quickly. Thus, it would be difficult, if not impossible, to causally relate any heart attack, stroke or pulmonary embolism that occurred later than a day or two after Vioxx was last ingested.

Finally, as is true in any case, we need to remember that a viable claim is viable only against the responsible party – Merck. We are not pursuing any claims against physicians, recognizing that Merck misled physicians about the risks of Vioxx, just as it misled American consumers. In 2003 alone, Merck spent nearly \$300 million in marketing Vioxx through advertisements in medical journals, television commercials, free samples given to doctors, and salesperson's visits to doctors' offices. None of this marketing disclosed the true risks that were finally revealed when Merck withdrew Vioxx from the market.

In the end, Dr. Eric Topol, writing in *The New England Journal of Medicine*, summed up the public "indictment" of Merck's misconduct:

"Sadly, it is clear to me that Merck's commercial interest in [Vioxx] sales exceeded its concern about the drug's potential cardiovascular toxicity. Had the company not valued sales over safety, a suitable trial could have been initiated rapidly at a fraction of the cost of Merck's direct-to-consumer advertising campaign."



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