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Vioxx - Overview

Vioxx, the trade name of the generic drug rofecoxib, was approved by the U.S. Food and Drug Administration (FDA) in May 1999, for the treatment of osteoarthritis, menstrual pain and the management of acute pain in adults. **On September 30, 2004 the manufacturer of Vioxx, Merck & Co., Inc. (Merck) announced that it was voluntarily withdrawing Vioxx from the market worldwide**, due to increased risks of cardiovascular problems (including heart attack and stroke) in users of the drug.

A member of the family of non-steroidal anti-inflammatory drugs (NSAIDs), Vioxx does not cure arthritis or other causes of acute pain, but helps to address their symptoms as long as it is taken.

How NSAIDs Work

Although steroids are considered safe for brief use to reduce inflammation, when taken for longer periods they can cause serious side effects like weight gain, fluid retention often visible in the face, sudden mood swings, muscle weakness, blurry vision, increased body hair, osteoporosis (bone weakening), high blood pressure, stomach irritation, and/or glaucoma. Consequently, NSAIDs are used to reduce inflammation if steroids can be avoided.

Vioxx works by preventing the formation of "inflammatory" prostaglandins. These compounds are produced by the enzyme "cyclooxygenase 2," commonly referred to as "Cox-2," and are believed to cause pain and inflammation, as well as prevent blood cells from sticking together. Vioxx is part of a group of drugs known as "Cox-2 inhibitors." Unlike other NSAIDs, Vioxx does not also block a second enzyme, commonly called "Cox-1," that monitors and maintains stomach tissue. Since this protects the stomach lining, Vioxx has been promoted as being able to reduce pain and inflammation without also causing ulcers and gastrointestinal bleeding.

Vioxx: History of Clinical Studies

In August 2001, Vioxx was linked in a study by researchers from The Cleveland Clinic to an increase in the risk of blood clots, heart attacks and strokes. Their study was published in the *Journal of the American Medical Association* and was based on a review and analysis of previous clinical trials.

Additional study results and articles continued to appear in medical journals, further supporting suspicions about Vioxx's effect on the heart. In September 2001, the American Heart Association, the National Stroke Association and the Arthritis Foundation asked Merck to test whether Vioxx increased the risk of heart attack and stroke.

After it reviewed all of its Vioxx studies, Merck claimed there was no evidence that, in comparison with other NSAIDs, the drug increased the risk of heart problems. Upset that Merck was minimizing the potential safety risks of Vioxx and promoting it for unapproved uses, the FDA sent Merck a "[Warning Letter](#)" dated September 17, 2001. The letter demanded that Merck discontinue promoting Vioxx to doctors for unofficial uses. It also required Merck to send letters about the deception to the medical community.

In April 2002, the FDA announced that it had added rheumatoid arthritis to the list of approved uses for Vioxx. It also presented new labeling and warnings for Vioxx, based on results of previous clinical studies.

Merck Voluntarily Withdraws Vioxx from Marketplace

On September 30, 2004, Merck & Co., Inc., the manufacturer of Vioxx, announced a voluntary withdrawal of the arthritis and pain relief drug from the worldwide drug market, after results from a clinical trial indicated that Vioxx users may have an increased risk of suffering a heart attack, stroke, or other cardiovascular event. Merck's action was not ordered by the U.S. Food and Drug Administration (FDA), but was initiated by Merck based on its own findings from the clinical trial. (Read the 9/30/04 [Press Release](#) from Merck)

Merck Announces \$4.85B Vioxx Settlement

On November 9, 2007, Merck & Co., Inc. announced that it will pay \$4.85 billion into a fund to settle most lawsuits filed over injuries or deaths allegedly caused by Vioxx. A [Merck Press Release](#) contains detailed information about the agreement and conditions for qualifying claims.

Vioxx: Getting Legal Help

While all medications have certain, anticipated side effects, a drug manufacturer has a duty to make its pharmaceutical products as reasonably safe as possible, and to inform the medical community and the public of known risks associated with its drugs. If a manufacturer fails to do so, it can be held responsible to patients who are injured as the result of inadequate warnings or the unreasonably dangerous nature of the drug, under a legal theory called "product liability."

If you have taken Vioxx and experienced any unusual side effects, you should contact your physician at once. You should also contact an experienced attorney to discuss and protect your legal rights in connection with any harm caused by Vioxx.

- Go [here](#) to learn more about an attorney's role in a product liability case.
- Click [here](#) to find an experienced product liability attorney near you.

See also:

- [Why Drugs Get Pulled from the Market](#)
- [Pharmaceutical Product Liability](#)

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