

**IN THE CIRCUIT COURT OF THE SECOND JUDICIAL CIRCUIT  
IN AND FOR LEON COUNTY, FLORIDA**

STATE OF FLORIDA, OFFICE OF THE  
ATTORNEY GENERAL, DEPARTMENT OF  
LEGAL AFFAIRS,

Plaintiff,

v.

MERCK & CO., INC.,

Defendant.

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Case No.

**COMPLAINT**

Plaintiff, State of Florida, Office of the Attorney General, Department of Legal Affairs (the “Attorney General”), sues Merck & Co., Inc. (“Merck”) and alleges as follows:

**INTRODUCTION**

1. Merck is a global pharmaceutical company which transacted business in the State of Florida by, advertising, soliciting, selling, promoting and distributing prescription drugs, including Vioxx®, to purchasers in the State of Florida. From the time that Defendant started developing Vioxx® through the date of its withdrawal from the market (September 30, 2004), Merck misrepresented and suppressed evidence concerning the significant health hazards of Vioxx®. Departments and agencies of the State of Florida suffered substantial damages due to Merck’s unlawful conduct. The Florida Medicaid Program alone purchased at least \$80,000,000.00 of Vioxx® during the relevant time period.

**JURISDICTION AND VENUE**

2. The Attorney General is the chief legal officer of the State of Florida and an enforcing authority for Chapter 501, Part II, Florida Statutes.
3. Merck is a New Jersey corporation authorized to transact business in the State of Florida.

4. The Court has personal jurisdiction over Merck pursuant to section 48.193(2), Fla. Stat., because Merck has transacted substantial and not isolated business within the State of Florida. Venue is proper pursuant to section 47.051, Fla. Stat., because the cause of action asserted in this Complaint accrued in Leon County.
5. The amount in controversy exceeds \$15,000.00, exclusive of interest, costs, and attorney's fees.

### **BACKGROUND**

6. Vioxx® is the brand name of rofecoxib, a nonsteroidal anti-inflammatory drug ("NSAID") used in the treatment of arthritis and other acute pain. Most NSAIDs, such as aspirin, ibuprofen, and naproxen, function by inhibiting two enzymes: cyclooxygenase-1 ("COX-1"), which is associated with the maintenance of gastrointestinal ("GI") mucus and platelet aggregation, and cyclooxygenase-2 ("COX-2"), which is associated with the response to pain and inflammation. The inhibition of COX-1 leads to harmful GI side effects.
7. Because Vioxx® was designed to suppress COX-2 without affecting COX-1, Merck marketed Vioxx® as possessing the beneficial effects of traditional NSAIDs but without the harmful GI side effects associated with those drugs. Merck repeatedly touted the safety profile, sales, and commercial prospects of the drug in press releases, public statements, and marketing materials throughout the time Vioxx® was on the market.
8. Prior to the FDA's approval of Vioxx®, officials at Merck were aware and concerned that Vioxx® could cause harmful cardiovascular events, such as heart attacks. In 1998, an unpublished internal Merck clinical trial entitled Study 090 revealed that Vioxx® caused a greater incidence of cardiovascular events than a placebo or a different arthritis drug.

9. In January 1999, Merck commenced the Vioxx® Gastrointestinal Outcomes Research (“VIGOR”) study, which compared Vioxx® to naproxen, the active ingredient in brand-name pain relievers such as Aleve and Naprosyn. Although the study showed that Vioxx® had a GI safety profile superior to that of naproxen, it also showed that Vioxx® users had a higher incidence of cardiovascular events than naproxen users.
10. In January 1999, before the approval and launch of Vioxx®, Merck's marketing division conceived the ADVANTAGE clinical trial. Physician-investigators, participants, and institutional review board members were told that the purpose of the ADVANTAGE trial was to measure the gastrointestinal safety of Vioxx®.
11. Merck’s actual goal of ADVANTAGE was for investigators to gain experience with Vioxx® prior to and during the critical launch phase in order to seed the industry with the use of Vioxx® in lieu of other treatments or drugs.
12. Merck began marketing Vioxx® in May of 1999 with an aggressive and deceptive promotional campaign directed at both purchasers and health care professionals. This campaign included a concerted effort to obtain approval for both public and private drug plans and formularies across the United States.
13. On May 21, 1999 Merck issued a press release which announced that the United States Food and Drug Administration (“FDA”) had approved Vioxx® for the relief of osteoarthritis, menstrual pain, and other forms of acute pain. The press release included a list of common side effects but failed to include any reference to cardiovascular side effects.
14. Merck was aware of the potential for dangerous cardiovascular side effects associated with Vioxx® through internal studies including Study 090 which was conducted in 1998.

The results of Study 090 were not disclosed to the FDA or the public at the time of the product launch. Study 090 concluded that Vioxx® users were six (6) times more likely to suffer severe cardiovascular events than non-Vioxx® users.

15. In a March 9, 2000 email, Edward Scolnick, then President of Merck Research Laboratories, acknowledged the existence of cardiovascular events, commenting, “it is a shame but it is a low incidence and it is mechanism based as we worried it was.”
16. In a press release on March 27, 2000, Merck emphasized Vioxx®’s superior GI safety profile but explained away the results of the VIGOR study:

“[S]ignificantly fewer thromboembolic events were observed in patients taking naproxen in this GI outcomes study, which is consistent with naproxen’s ability to block platelet aggregation. This effect on these events had not been observed previously in any clinical studies for naproxen. Vioxx®, like all COX-2 selective medicines, does not block platelet aggregation and therefore would not be expected to have similar effects.” -Merck Press Release Dated March 27, 2000

and

“[a]n extensive review of safety data from all other completed and ongoing clinical trials, as well as the post-marketing experience with Vioxx®, showed no indication of a difference in the incidence of thromboembolic events between Vioxx®, placebo and comparator NSAIDs.” -Merck Press Release Dated March 27, 2000

17. The VIGOR study results were widely reported in the press, medical journals, and marketing materials distributed by Merck. To the extent that VIGOR results showed cardiovascular events could be a side effect of Vioxx®, Merck undertook an effort to explain away the results by attributing the findings to the beneficial effects of naproxen’s blocking of platelet aggregation rather than to the harmful effects of Vioxx® in causing thromboembolic events. Through other tests, studies and trials, Merck already knew that Vioxx® presented additional dangerous cardiovascular side effects.

18. On February 8, 2001, the FDA's Arthritis Advisory Committee ("AAC") held a public hearing to consider Merck's request to include the positive GI results from the VIGOR study in its Vioxx® labeling. During the AAC hearing, Alise Reicin, Executive Director of Clinical Research at Merck Research Laboratories, explained to the panel, "when you review the results of VIGOR in isolation you don't know whether the imbalance of cardiovascular events was caused by a decrease in events on a platelet-inhibiting NSAID, naproxen, or an increase in events on a COX-2 selective inhibitor." She suggested that naproxen was likely responsible for the difference in cardiovascular events observed in users of the two drugs.
19. Numerous additional press releases were issued by Merck in order to further promote and market Vioxx®. None of the press releases sufficiently referenced the adverse cardiovascular events that Merck knew of or made reference to internal study 090.
20. When promoting Vioxx® directly to purchasers and health care professionals, including those working for or on behalf of the State of Florida, Merck materially misrepresented the cardiovascular safety of Vioxx®.
21. Merck also misstated, overstated or exaggerated the efficacy of Vioxx® in comparison to similar medications.
22. Merck utilized internal studies, including but not limited to the VIGOR and ADVANTAGE studies, to further promote and support its representations made in regard to Vioxx®.
23. The ADVANTAGE study, along with other internal studies, were specifically designed to appear as if they answered scientific questions but were in fact primarily designed to fulfill marketing objectives.
24. In addition to the above actions undertaken by Merck, Merck also engaged in an elaborate scheme to create or publish scholarly articles under fake or ghost authors in order to further develop support for Vioxx®. These articles appeared in medical journals

and other industry publications including the Journal of the American Medical Association.

25. Numerous departments and agencies of the State of Florida approved the inclusion of Vioxx® as a covered or preferred drug and agreed to pay for or reimburse its expense under certain plans and programs.
26. Merck intentionally misrepresented the safety and efficacy of Vioxx® in order to garner acceptance on formulary and drug plans and to quickly capture market share.
27. Merck's representations that Vioxx® was a safer alternative to traditional NSAIDS was false in that Vioxx® also posed a risk of ulcers and gastrointestinal side effects. More importantly, Vioxx® produced a high rate of cardiovascular events including heart attacks and strokes.
28. Merck failed to disclose information about known side effects.
29. Merck's actions resulted in purchases and/or reimbursements by departments and agencies of the State of Florida which would not have otherwise occurred.
30. For over five (5) years Merck continued to market and advertise Vioxx® within the State of Florida while knowing about the dangerous side effects and lack of efficacy.
31. For the entire period of time Vioxx® was on the market, Merck's advertisements and promotional activities misrepresented Vioxx®'s cardiovascular safety and failed to include information then known to Merck.
32. All practices, acts, and omissions alleged herein were committed by Defendant's officers, directors, employees or agents who at all times acted on behalf of Defendant and whose practices, acts or omissions were authorized or ratified by Defendant.

**Violation of Florida's Deceptive and Unfair Trade Practices Act**

33. The Attorney General repeats and realleges each and every allegation contained in paragraphs 1 – 32.
34. This is an action pursuant to Chapter 501, Part II, Fla. Stat., the Florida Deceptive and

Unfair Trade Practices Act. Section 501.204(1) of the Act provides that, “unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful.”

35. The promotion of Vioxx® involves the conduct of “trade or commerce” within the meaning of section 501.203(8), Fla. Stat.
36. The Attorney General is an enforcing authority of the Act pursuant to section 501.203(2), Fla. Stat. The statutory violations alleged herein affected more than one judicial circuit in the State of Florida.
37. The Attorney General is authorized to seek damages and other statutory relief on behalf of governmental entities who have been damaged by violations of the Act pursuant to section 501.207(1)(c), Fla. Stat. The Attorney General brings this action on behalf of certain governmental entities, namely the agencies and departments of the State of Florida. These agencies and departments have suffered actual damages due to Merck’s violations of the Act.
38. The Attorney General has reviewed this matter and determined that an enforcement action serves the public interest.
39. As set forth above, Merck has engaged in representations and omissions which are material, and which have the tendency or capacity, or which are likely, to mislead governmental entities acting reasonably under the circumstances.
40. Merck has engaged in acts and practices which are unconscionable, unfair or deceptive and has committed acts or practices in trade or commerce which offend established public policy and are unethical, oppressive, unscrupulous or substantially injurious to governmental entities. Thus, Merck has engaged in unfair or deceptive acts or practices

in the conduct of any trade or commerce in violation of section 501.204(1), Fla. Stat. (2007).

41. The aforesaid acts and practices of Merck were to the injury and prejudice of the public and governmental entities, including the departments and agencies of the State of Florida.
42. Merck's conduct as outlined in this Complaint was willful within the meaning of the Act.

**Prayer for Relief**

**WHEREFORE, the Attorney General asks for judgment:**

- A. Awarding the Attorney General actual damages on behalf of the agencies and departments of the State of Florida that purchased or reimbursed the purchase of the pharmaceutical product known as Vioxx®, and that were injured by the unconscionable, deceptive or unfair acts or practices of Merck, in accordance with section 501.207(1)(c), Fla. Stat. (2007);
- B. Assessing Merck civil penalties in the amount of ten thousand dollars (\$10,000) for each violation of the Act, pursuant to section 501.2075, Fla. Stat. (2007);
- C. Awarding reasonable attorney's fees and costs to the Attorney General, pursuant to sections 501.2105, and 501.2075, Fla. Stat. (2007);
- D. Awarding restitution for the agencies and departments of the State of Florida that have been injured by Merck's unlawful actions;
- E. Requiring that Merck disgorge all revenues generated as a result of the unconscionable, unfair or deceptive acts or practices set forth herein;
- F. Awarding prejudgment interest; and
- G. Awarding such other and further relief as this Court deems just and proper.

**Demand for Jury Trial**

The Attorney General hereby demands a trial by jury on all issues so triable.

Respectfully submitted, this 29<sup>th</sup> day of September 2008.

**BILL McCOLLUM**  
**Attorney General**

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