

IN THE CIRCUIT COURT OF THE
FOURTEENTH JUDICIAL CIRCUIT
IN AND FOR WASHINGTON COUNTY, FLORIDA

MARY COOKE, JAMES R. CLARK, JOYCE
ABARE, CHARLES D. HARVEY, CHARLES
H. HATCHER, JR. and BETTY NUNNERY,
individually and on behalf of all others
similarly situated,

Plaintiffs,

v.

Case No.67-05-CA-055
CLASS REPRESENTATION

MERCK & CO., INC.,

Defendant.

CLASS ACTION SECOND AMENDED COMPLAINT – JURY DEMAND

Plaintiffs, MARY COOKE, JAMES R. CLARK, JOYCE ABARE, CHARLES D. HARVEY, CHARLES H. HATCHER, JR. and BETTY NUNNERY (“Plaintiffs”) bring this class action against Defendant, MERCK & CO. INC., Inc. on behalf of themselves and all others similarly situated, (excluding those who assert personal injury claims) who purchased the drug Vioxx manufactured by Defendant and allege as follows:

NATURE OF THE CASE

1. MERCK & CO. INC. (“Merck”) received FDA approval in 1999 for Vioxx (rofecoxib), a prescription COX-2 selective, non-steroidal anti-inflammatory drug (NSAID), or painkiller, for the relief of the signs and symptoms of osteoarthritis, for the management of acute pain in adults, and for the treatment of menstrual symptoms. It was later approved for the relief of the signs and symptoms of rheumatoid arthritis in adults and children. More than 20 million

Americans have taken Vioxx, and sales reached \$2.5 billion in 2003. Vioxx was at all times substantially more expensive than the existing pain relievers.

2. After receiving FDA approval Merck engaged in a massive sales and promotional campaign that was directed at doctors and consumers. Merck's sales force blitzed doctors' offices with literature and verbal presentations designed to convince both doctors and consumers that Vioxx was a superior drug for treatment of osteoarthritis, acute pain in adults, painful menstrual cycles and other types of disease. It portrayed Vioxx as "excellent news" for patients with stomach problems. Merck aggressively promoted Vioxx as an improvement over other NSAIDs, like naproxen and ibuprofen, because it had a lower risk of side effects such as gastrointestinal ulcers and bleeding. Merck did not promote or provide any balanced presentation as to Vioxx as having an unacceptably high risk of other side effects, such as heart attack and stroke. But internal emails confirm that Merck executives knew that Vioxx had an adverse cardiovascular profile, the risk was "clearly there." And Merck's marketing literature included a document intended for its sales representatives that discussed how to evade safety questions about Vioxx, labeled "Dodge Ball Vioxx."¹ Five years of profits later, the truth has come out.

3. Merck's campaign was a tremendous success. Vioxx became a household name and a blockbuster drug, millions of citizens nationwide have used it.

4. On September 30, 2004, the Center for Drug Evaluation and Research of the Food and Drug Administration issued a Memorandum concluding that Vioxx has adverse cardiovascular effects, which were evident as early as the 2000 VIGOR study: "Rofecoxib increases the risk of serious coronary heart disease defined as acute myocardial infarction and sudden cardiac death....The observation of an increased risk was first noted with the VIGOR trial, where a 5-fold difference in risk was found between high-dose rofecoxib and naproxen. ***The manufacturer attributed this difference to a never before recognized protective effect of***

¹ Richard Horton, THE LANCET, *Vioxx, The Implosion of Merck, and Aftershocks at the FDA* (Nov. 5, 2004).

naproxen. To explain a 5-fold difference, naproxen would have had to be one of the most potent and effective cardio-protectants known. Three cohort studies and the present nested case-control study found no evidence of cardio-protection with naproxen. The three case-control studies that reported a protective effect were misleading. When analyzed in a manner comparable to the present study, ***no protective effect is shown.***²

5. On the same day, September 30, 2004, Merck issued a press release announcing the withdrawal of Vioxx based on “new” data indicating an increased risk of cardiovascular events, such as heart attack and stroke.³ Merck agreed to reimburse patients for Vioxx purchased but not used as of September 30, 2004. This does nothing, however, for the millions of patients in Illinois who have already purchased and consumed Vioxx and who paid more than they would have or should have because it was advertised as a premium drug with reduced side effects and/or who would not have purchased Vioxx in the first place had they know about its adverse cardiovascular effects. If Merck had told the truth from the outset, assuming that Vioxx would have even been viable, it would not have been billed as a premium drug with a cost that was much higher than alternative pain relievers. Naproxen retails for about \$0.06 per pill or \$6.00 per bottle. Vioxx, before it was withdrawn from the market sold for up to \$3.00 per pill, or \$300 per bottle.

6. When Merck & Co. pulled its big-selling painkiller Vioxx off the market in September, Chief Executive Raymond Gilmartin said the company was “really putting patient safety first.” He said the study findings prompting the withdrawal, which tied Vioxx to heart-attack and stroke risk, were “unexpected.”

7. But internal Merck e-mails and marketing materials as well as statements made by outside scientists show that the company fought forcefully for years to keep safety concerns from

² David J. Graham, MD, MPH, Associate Director for Science, Office of Drug Safety, Center for Drug Evaluation and Research, FDA, *Risk of Acute Myocardial Infarction and Sudden Cardiac Death in Patients Treated with COX-2 Selective and Non-selective NSAIDs* 13 (Sept. 30, 2004).

³ Merck, *Merck Announces Voluntary Withdrawal of VIOXX*, available at http://www.vioxx.com/vioxx/documents/english/vioxx_press_release.pdf (accessed Nov. 5, 2004).

destroying the drug's commercial prospects, thus enabling it to sell Vioxx as a premium drug when it was not.

8. Merck's first worry, in the mid-to-late 1990s, was that its drug would show greater heart risk than cheaper painkillers that were harsh on the stomach but were believed to reduce the risk of heart attacks. Several company officials discussed in e-mails how to design a study that would minimize the unflattering comparison, even while admitting to themselves that it would be difficult to conceal.

9. By 2000, one e-mail suggests Merck recognized that Vioxx didn't merely lack the protective features of old painkillers but that something about the drug itself was linked to an increased heart risk. On March 9, 2000, the company's powerful research chief, Edward Scolnick, e-mailed colleagues that the cardiovascular events "are clearly there" and called it a "shame." He compared Vioxx to other drugs with known side effects and wrote, "there is always a hazard." But the company's public statements after Dr. Scolnick's e-mail continued to reject the link between Vioxx and increased intrinsic risk.

10. As academic researchers increasingly raised questions about Vioxx's heart safety, the company struck back hard. It even sued one Spanish pharmacologist, trying unsuccessfully to force a correction of an article he wrote. In another case, it warned that a Stanford University researcher would "flame out" unless he stopped giving "anti-Merck" lectures, according to a letter of complaint written to Merck by a Stanford professor. A company training document listed potential tough questions about Vioxx and said in capital letters, "DODGE!" Dodge was a good nickname for Merck's strategy and its deceptive conduct allowed it to market Vioxx at a premium price, forcing businesses to pay far in excess of what they should have.

11. As detailed herein, Merck successfully dodged the meaningful revelation of adverse facts about Vioxx until September 30, 2004.

12. On November 5, 2004, the influential BRITISH MEDICAL JOURNAL published an analysis of all the clinical trials of Vioxx completed June 2001 and concluded that "our findings

indicate that Rofecoxib should have been withdrawn several years earlier.” If Merck had made proper disclosures, the drug Vioxx would have been withdrawn, not marketed and/or worth substantially less than the price paid by Florida consumers.

13. In this action, Plaintiffs seek damages and restitution and/or disgorgement arising out of Merck’s sale and promotion of Vioxx pursuant to practices and acts that are unfair, deceptive and unlawful in violation of the Florida Deceptive and Unfair Trade Practices Act, §§ 501.201-213, Florida Statutes (“FDUTPA”).

JURISDICTION AND VENUE

14. This is a class action for damages in excess of \$15,000, exclusive of interest, costs and attorney’s fees, brought under the FDUTPA.

15. Jurisdiction is proper in this Court.

16. Venue is proper in this Court because the events giving rise to the claims occurred in this judicial district.

PARTIES

17. Plaintiff, MARY COOKE, is an individual and resides in Washington County, Florida. She purchased and paid for Vioxx manufactured and marketed by Merck on numerous occasions within the four-year period immediately preceding the filing of this complaint. Had the truth been known about the serious adverse health effects from using Vioxx, Plaintiff Cooke would not have paid for Vioxx and/or certainly not at the price paid when it was substantially inflated.

18. Plaintiff, JAMES R. CLARK, is an individual and resides in Bay County, Florida. On or about March 11, 2004, he purchased and paid for Vioxx manufactured and marketed by Merck. Had the truth been known about the serious adverse health effects from using Vioxx,

Plaintiff Clark would not have paid for Vioxx and/or certainly not at the price paid when it was substantially inflated.

19. Plaintiff, JOYCE ABARE, is an individual and resides in Bay County, Florida. She started taking Vioxx several years ago when she lived in New York. She purchased and paid for Vioxx manufactured and marketed by Merck. Had the truth been known about the serious adverse health effects from using Vioxx, Plaintiff ABARE would not have paid for Vioxx and/or certainly not at the price paid when it was substantially inflated.

20. Plaintiff, CHARLES D. HARVEY, is an individual and resides in Gulf County, Florida. He purchased and paid for Vioxx manufactured and marketed by Merck from approximately 1999-2002. He paid a \$10-\$15 co-payment each time he had a prescription filled. Had the truth been known about the serious adverse health effects from using Vioxx, Plaintiff Harvey would not have paid for Vioxx and/or certainly not at the price paid when it was substantially inflated.

21. Plaintiff, CHARLES H. HATCHER, JR., is an individual and resides in Jackson County, Florida. He purchased and paid for Vioxx manufactured and marketed by Merck on numerous occasions within the four-year period immediately preceding the filing of this complaint. He paid a co-payment numerous times that he had his prescriptions filled. Had the truth been known about the serious adverse health effects from using Vioxx, Plaintiff HATCHER would not have paid for Vioxx and/or certainly not at the price paid when it was substantially inflated.

22. Plaintiff, BETTY NUNNERY, is an individual and resides in Gulf County, Florida. She purchased and paid for Vioxx manufactured and marketed by Merck on numerous occasions within a two-year period. Had the truth been known about the serious adverse health effects from using Vioxx, Plaintiff NUNNERY would not have paid for Vioxx and/or certainly not at the price paid when it was substantially inflated.

23. Plaintiffs pursue this class action on behalf of themselves and all others similarly situated.

24. Defendant Merck & Co., Inc. (“Merck”) is a New Jersey corporation conducting business in the State of Florida. At all relevant times, Merck has been engaged in the business of marketing and selling Vioxx in Florida.

FACTUAL ALLEGATIONS

A. Medical/Scientific Background Concerning Selective COX-2 Inhibition And Cardiovascular Risks

25. At issue in this case is the prescription drug Vioxx. Vioxx belongs to the class of pain medications called non-steroidal anti-inflammatory drugs (“NSAIDs”). Aspirin and ibuprofen are examples of well-known NSAIDs.

NSAIDs reduce pain by blocking the body’s production of pain transmission enzymes called cyclooxygenase or “COX.” There are two types of COX enzymes, COX-1 and COX-2.

26. In addition to transmitting pain sensations, COX-1 is involved in maintaining and repairing gastrointestinal tissue.

27. It is generally accepted in the medical community that blocking the COX-1 enzyme hampers the body’s ability to repair gastric tissue and causes harmful gastrointestinal side-effects, including stomach ulceration and bleeding.

28. In addition to transmitting pain sensations, COX-2 is involved in the production of prostacyclin, a substance responsible for preventing the formation of blood clots.

29. It is generally accepted in the medical community that blocking the COX-2 enzyme encourages the formation of blood clots and causes various clot-related cardiovascular events, including: heart attack, stroke, unstable angina, cardiac clotting and hypertension.

30. Traditional NSAIDs, like aspirin, reduce pain sensations by inhibiting both COX-1 and COX-2 enzymes. As would be expected, traditional NSAIDs cause gastrointestinal ulcers.

However, because of a complex chemical balance in the human body, traditional NSAIDs do not cause blood clots, but actually reduce the risk of clots and help to protect heart function.

31. For decades, in the absence of other treatment options, consumers seeking pain relief were forced to accept and live with the gastrointestinal risks of traditional NSAIDs. Many consumers without gastrointestinal problems also became accustomed to taking an “aspirin a day” to benefit from its cardio-protective effects.

32. Merck set out to develop a “selective” drug that would block only the COX-2 enzyme, thus supposedly allowing the proper maintenance of gastric tissue while still reducing pain sensations.

33. In the late 1990s Merck was facing the loss of patent protection on several top drugs and needed a big hit. However, it would be difficult to penetrate the mass market if doctors and patients believed that by choosing Vioxx, they were forgoing a potential heart benefit.

B. Early On Merck Is Aware of Dangers of Vioxx

34. A November 21, 1996, memo by a Merck official shows the company wrestling with this issue. It wanted to conduct a trial to prove Vioxx was gentler on the stomach than older painkillers. But to show the difference most clearly, the Vioxx patients couldn’t take any aspirin. In such a trial, “there is a substantial chance that significantly higher rates” of cardiovascular problems would be seen in the Vioxx group, the memo said.

35. A similar view was expressed in a February 25, 1997, e-mail by a Merck official, Briggs Morrison. He argued that unless patients in the Vioxx group also got aspirin, “you will get more thrombotic events” – that is, blood clots – “and kill [the] drug.”

36. In response, Alise Reicin, now a Merck vice president for clinical research, said in an e-mail that the company was in a “no-win situation.” Giving study subjects both Vioxx and aspirin, she wrote, could increase the “relative risk,” apparently referring to gastrointestinal problems. But, she added, “the possibility of increased CV [cardiovascular] events is of great concern.” From the context, it seems Dr. Reicin meant “increased” relative to older drugs.

37. She added in parentheses: “I just can’t wait to be the one to present those results to senior management!” She proposed that people with high risk of cardiovascular problems be kept out of the study so the difference in the rate of cardiovascular problems between the Vioxx patients and the others “would not be evident.”

C. The Vigor Trial

38. By 1996, Merck had developed a selective COX-2 inhibitor called MK-966 (later known as Vioxx) and announced its initiation of clinical trials.

39. In late 1996, Merck began to plan a large-scale, long-term, double-blind study of gastrointestinal toxicity in patients taking Vioxx or naproxen to treat arthritis. This study came to be called the Vioxx Gastrointestinal Outcomes Research study (“VIGOR”).

40. On November 21, 1996, a Merck memo discussing the design of the VIGOR trial suggested that participants be permitted to use aspirin during the study to mute the cardiovascular risks of Vioxx: “there is a substantial chance that significantly higher rates” of cardiovascular problems would be seen in the Vioxx group.

41. On February 25, 1997, Merck employee Briggs Morrison sent an e-mail about the design of the VIGOR trial. Morrison suggested that VIGOR participants be allowed to take aspirin to avoid disclosing the cardiovascular risks of Vioxx: unless patients in the Vioxx group could take aspirin, he warned, “you will get more thrombotic events and kill [the] drug.” A response to this e-mail from Alise Reicin, now a Merck vice president for clinical research, proposed that people at high risk of cardiovascular problems be excluded from the study so that the rate of cardiovascular problems in those participants taking Vioxx “would not be evident.”

42. In designing VIGOR, Merck obviously had significant concerns about how to conceal the expected manifestation of cardiovascular risks posed by Vioxx. Merck ultimately designed VIGOR to produce the absolute minimum number of cardiovascular events, both by excluding patients with known heart problems from the study and by allowing participants to

take aspirin during the study. In the event cardiovascular events occurred among the study population, Merck designed the reporting system to record them.

43. The VIGOR trial concluded in October 1998. After reviewing the VIGOR results, Merck knew that, despite its precautions against cardiovascular events, patients taking Vioxx suffered more than *twice* the number of adverse cardiovascular events and *five times* the number of heart attacks as patients taking naproxen. Merck's scientists understood that the difference in cardiovascular events was so great that it could not have come solely from naproxen's protective effect, but that it had to involve some sort of risk inherent to Vioxx.

44. On March 9, 2000, Merck's research chief Edward Skolnick e-mailed his colleagues that the cardiovascular results seen in VIGOR "are clearly there." Dr. Sklonick also wrote that Vioxx was to blame: "[the cardiovascular result] is mechanism based as we worried it was."

45. Thus, by the time the VIGOR trial had ended, Merck knew that Vioxx posed serious cardiovascular risks, including heart attack, stroke, unstable angina, cardiac clotting and hypertension, for anyone who took it, and presented a specific additional threat to anyone with existing heart disease or cardiovascular risk factors.

46. Despite knowing that Vioxx posed serious cardiovascular risks, Merck made a business decision to downplay these risks and push Vioxx to market on claimed improvements in gastrointestinal safety. This decision was made, in part, based on the fact that it would have been difficult for Vioxx to penetrate the mass market (and reap mass market sales) if doctors and patients knew that, by choosing Vioxx, they were exposing themselves to cardiovascular risks or foregoing the heart benefit offered by traditional NSAIDs.

47. From 1996 through 1998, Merck issued dozens of public statements that touted the efficacy and gastrointestinal safety of Vioxx. Not one of these statements mentioned cardiovascular safety issues or revealed any "mechanism based" problems with Vioxx. To the contrary, Merck repeatedly rejected any link between Vioxx and increased cardiovascular risk

and actually claimed that clinical results with Vioxx were consistent with the clot-preventing effects of naproxen.

48. On November 23, 1998, Merck submitted a New Drug Application for Vioxx to the U.S. Food and Drug Administration. The FDA granted expedited review of Merck's Vioxx submission by its Arthritis Drugs Advisory Committee ("the Committee").

49. The Committee reviewed the VIGOR gastrointestinal safety results, but did not touch on any cardiovascular safety issues. The reason for this was simple: Merck was not seeking any marketing approvals related to cardiovascular safety and had not yet published the VIGOR cardiovascular results.

50. On April 20, 1999, the Committee recommended to approve Vioxx for the treatment of osteoarthritis and acute pain but, in light of Merck's failure to substantiate claims of gastrointestinal superiority, that its package insert bear the same gastrointestinal warnings as traditional NSAIDs.

51. On May 21, 1999, the FDA accepted the Committee's recommendations and granted marketing approval for Vioxx.

52. In order to maximize its profits from the sale of Vioxx, Merck made a "business decision" to conceal the drug's cardiovascular risks from both doctors and the public. Merck intended to conceal this information by, among other things, initiating a marketing campaign that uniformly omitted to disclose cardiovascular safety risks, issuing repeated public denials of Vioxx cardiovascular risks, concealing information about the cardiovascular risks of Vioxx from doctors and consumers and refusing to fund independent studies of Vioxx cardiovascular safety.

53. Merck was well aware that the cardiovascular risks it sought to conceal were particularly relevant to consumers who use prescription arthritis pain relievers. Merck also knew that publicizing the cardiovascular risks associated with Vioxx would cut into its projected profits by reducing the number of people for whom Vioxx could be prescribed, making the drug

generally less attractive to doctors and patients, and necessitating a significant reduction in per tablet price.

54. In March 2000, the results of Vigor came in. They showed that Vioxx patients suffered fewer stomach problems than the naproxen group, but significantly more blood-clot-related problems – precisely the sort of result anticipated in the 1996-97 internal documents. The heart-attack rate in the Vioxx group appeared to be four times as high as the naproxen group. (Later analysis would show it to be five times as high.)

55. The difference was so wide that Dr. Scolnick, the Merck research chief, appeared to recognize it couldn't come solely from naproxen's protective effect but must involve some sort of risk inherent in Vioxx. In a March 9, 2000, e-mail with the subject line "Vigor," Dr. Scolnick said the results showed that the cardiovascular events "are clearly there." In an apparent acknowledgment that Vioxx's own mechanism was at least partially at fault for the heart data, he wrote: "it is a shame but it is a low incidence and it is mechanism based as we worried it was.

56. Dr. Scolnick wrote that he wanted other data available before the results were presented publicly, so "it is clear to the world that this" was an effect of the entire Cox-2 class, not just Vioxx. The research chief, by then nearing retirement after 15 years in his post, then recalled some of his greatest hits that also had side effects but were big sellers. In Vioxx, he wrote, "We have a great drug and like angioedema with vasotec and seizures with primaxin and myopathy with mevacor there is always a hazard. The class will do well and so will we." Dr. Scolnick didn't respond to phone messages seeking comment.

57. But in a news release that month, Merck offered no hint of Dr. Scolnick's suggestion that there was a "mechanism-based" problem with Vioxx or a "hazard" that went beyond Vioxx's failure to offer the protective benefits of other painkillers. Merck said the Vigor trial results were "consistent with" naproxen's favorable effects, implying that this could explain why Vioxx didn't do as well.

58. The next month Merck issued another news release headlined, “Merck confirms favorable cardiovascular safety profile of Vioxx.” While acknowledging the Vigor results, it said other trials and data had shown “NO DIFFERENCE in the incidence of cardiovascular events” between Vioxx and a placebo or between Vioxx and older painkillers.

D. Merck Developed A Uniform Marketing Strategy To Conceal The Cardiovascular Risks Of Vioxx Risks From Doctors and Consumers

59. Even before it received FDA approval to market Vioxx, Merck engaged in an intensive pre-release marketing campaign to bolster consumer interest and orders.

60. Merck’s pre-release marketing campaign conveyed the uniform message that Vioxx provided safe and effective pain relief while omitting any mention of cardiovascular risks.

61. Merck’s pre-release marketing campaign showed positive results. Sales projections for Vioxx based on early orders and inquiries surpassed \$2 billion per year. *Merck based this calculation on a proposed wholesale price of \$2.02 per tablet [] about one hundred times the cost of a generic aspirin.*

62. In June 1999, Merck released Vioxx for sale in the U.S. This release was accompanied by the largest direct-to-consumer marketing campaign in history. Merck’s Vioxx uniform marketing message was that Vioxx provided safe and effective pain relief, while omitting any mention of cardiovascular risk.

63. Merck spent more than \$161 million on direct-to-consumer marketing in 2000 alone to disseminate this message, and more than \$100 million in each of the following four years.

64. From its first day of release, Vioxx sales were aided by Merck’s huge marketing budget and sophisticated marketing plans, by the fact that Merck had an entire staff devoted to putting a positive spin on even the most damaging disclosures and had managed to delay release of the cardiovascular results of the VIGOR trial.

65. Merck's internal marketing documents were specifically intended to prevent the dissemination of damaging information about Vioxx safety concerns. For example, one Merck memo addressed to "all field personnel with responsibility for Vioxx," provided an "obstacle handling guide" for Vioxx questions. If a doctor expressed concerns that Vioxx might increase the risk of a heart attack, he was to be given the oblique answer that the drug "would not be expected to demonstrate reductions" in heart attacks or other cardiovascular problems and that it was "not a substitute for aspirin."

66. Another Merck training document, entitled "Dodge Ball Vioxx," listed a series of questions doctors might ask about Vioxx. Among these statements are, "I am concerned about the cardiovascular effects of Vioxx" and "the competition has been in my office telling me that the incidence of heart attacks is greater with Vioxx than with Celebrex." Merck's instructions to be followed in responding to these questions consist of a single word: "DODGE!"

67. In April 2000, Merck responded to early news reports that Vioxx posed serious cardiovascular risks by simply denying that any such risks existed: "Extensive review of data from the completed osteoarthritis trials and on-going clinical trials with Vioxx ... have shown *no difference* in the incidence of cardiovascular events, such as heart attack, among patients taking Vioxx..." (emphasis in original).

68. In October 2000, Merck sent its long-overdue cardiovascular data from the VIGOR trial to the FDA for review. This was the first time that Merck had made the cardiovascular data gathered during VIGOR available to anyone without ties to Merck.

69. In November 2000, Merck published the results of its VIGOR trial in the New England Journal of Medicine. The article, written by Merck employees and by academics who received consulting contracts and research grants from Merck, made a vague reference to cardiovascular incidents but, astonishingly, did not fully report on the statistical incidence of cardiovascular complications seen in the study.

70. In February 2001, a full 19 months after Vioxx went on the market, the FDA published a Memorandum on the Vioxx cardiovascular safety data gathered during VIGOR. In this Memorandum, the FDA concluded that there “is an increased risk of cardiovascular thrombotic events, particularly [heart attack], in the [Vioxx] group compared with the naproxen group.” The FDA considered and rejected each of the defenses raised by Merck to explain the statistically significant increase of cardiovascular incidents among Vioxx users.

71. Merck immediately responded to the FDA’s Memorandum with a press release announcing its confidence “that the data presented today supports the excellent safety profile of Vioxx” and that “in the completed osteoarthritis trials and on-going clinical trials with Vioxx... there was *no difference* in the incidence of cardiovascular events, such as heart attacks among patients taking Vioxx, other NSAIDs and placebo” (emphasis in original).

72. In February 2001, the FDA also concluded that Merck should have to add a cardiovascular warning to its Vioxx packaging: “it would be difficult to imagine inclusion of VIGOR results in the [Vioxx] labeling without mentioning cardiovascular safety results in the study description as well as the Warnings sections.”

73. Merck responded immediately with a press release stating its confidence “that the data presented today support the excellent safety profile of Vioxx.” Merck’s press release directly contradicted the FDA’s findings by claiming, as it had before release of the VIGOR cardiovascular data, that “there was no difference in cardiovascular mortality between the groups treated with Vioxx or naproxen... [and] *no difference* in the incidence of cardiovascular events, such as heart attacks, among patients taking Vioxx...” (emphasis in original).

74. Behind closed doors, Merck entered into negotiations with the FDA concerning the warning language to be used in its Vioxx labeling. These negotiations went on for another fourteen months while doctors and consumers continued to wait for work on the cardiovascular risks of a drug used by millions.

75. On May 22, 2001, Merck issued the first of a relentless series of publications touting the “favorable cardiovascular safety profile of Vioxx.” In this release, disregarding the results of its own trial and the FDA’s review, Merck stated “that there was no difference in cardiovascular mortality between the groups treated with Vioxx or naproxen... [and] *no difference* in the incidence of cardiovascular events, such as heart attacks, among patients taking Vioxx...” (emphasis in original).

76. These statements were repeated in countless continuing medical education symposiums and complimented by numerous papers in peer-reviewed medical literature by Merck employees and consultants, all of which attempted to debunk concerns about the adverse cardiovascular effects of Vioxx.

77. On August 21, 2001, independent doctors from the Cleveland Clinic performed their own meta-analysis of Vioxx trials on the issue of cardiovascular safety. Their conclusion was that Vioxx posed an increased risk of adverse cardiovascular events compared to naproxen. These doctors, concerned more with the increased number of heart attacks experienced by patients taking selective COX-2 inhibitors than with maximizing Merck’s profits, urged Merck to conduct further trials to quantify the specific cardiovascular risks of Vioxx.

78. In response to the Cleveland Clinic article, Merck issued a press release touting “the overall and cardiovascular safety profile ... of Vioxx” and flatly denying the existence of any cardiovascular safety issues: “there is no increase in the risk of cardiovascular events as a result of treatment with Vioxx.”

79. Merck also asked the Cleveland Clinic Journal to run a rebuttal to this article, enforcing the cardiovascular safety profile of Vioxx. When it refused, Merck sent “Dear Doctor” letters to thousands of physicians nationwide that “strongly supported the cardiovascular safety profile” of Vioxx. Merck also sent “Dear Patient” letters to thousands of consumers nationwide identified from a prescription database that specifically minimized the risk of “heart attacks and strokes” and emphasized that Vioxx was “innovative, effective and safe.”

80. In September 2001, the FDA sent a warning letter to Merck identifying Vioxx marketing materials and a press release that violated the Federal Food, Drug and Cosmetic Act because they minimized the cardiovascular findings observed in the VIGOR study, failed to present significant risks associated with Vioxx and made several unsubstantiated superiority claims with regard to other NSAIDs. The FDA specifically faulted Merck for downplaying the cardiovascular risks of Vioxx: “Your promotional campaign discounts the fact” that in the trial, “patients on Vioxx were observed to have a four to five-fold increase” in heart attacks compared with patients on naproxen. The FDA also warned Merck that its recent press releases “confirming the favorable cardiovascular safety profile of Vioxx” were “simply incomprehensible” given the rate of heart attacks and “serious cardiovascular events compared to naproxen.”

81. Merck responded to this warning letter by pulling or revising the complained-of promotional materials, but persisted in refusing to include a cardiovascular warning in any of its direct-to-consumer advertisements. But Merck’s misleading statements were already in the market and influencing the demand for its products. As Merck noted in its 2003 annual report, Vioxx is the best selling arthritis and pain medicine.

82. In April 2002, after fourteen months of negotiations with the FDA had resulted in the creation of a satisfactorily vague cardiovascular warning, Merck issued a press release that entirely minimized the importance of the risks it had been required to disclose: “The significance of the cardiovascular findings from [the VIGOR study] is unknown... Merck is confident in the efficacy and safety profile of Vioxx.” Thus, while someone with enough medical knowledge to make sense of Merck’s warning could have made sense of what Merck had known for years, it was still highly unlikely that the average consumer understood Vioxx to pose any serious cardiovascular risk.

E. Doubts Arise Over Merck Attacks

83. John Abramson, a family doctor and clinical instructor at Harvard Medical School, scrutinized detailed data on the Vigor trial provided by Merck to the FDA and posted on the FDA Web site. In a book published this summer, “Overdosed America: The Broken Promise of American Medicine,” he concluded that even those without a history of heart trouble doubled their risk of developing a cardiovascular problem by taking Vioxx instead of naproxen.

84. Gregory Curfman, executive editor of the New England Journal, says the journal “didn’t have all the details that the FDA had later on.” Given the available data, he says editors “spent a great deal of time trying to make sure that these unexpected cardiovascular side effects were fairly and accurately represented” in the article.

85. By 2001, the Vigor data had clearly caused the debate to shift. The main question was no longer whether Vioxx lacked the benefits of older painkillers and if so whether that was significant. Now the issue was squarely Vioxx itself: Was the drug intrinsically risky?

86. In February 2001, the FDA presented its analysis of the Vigor data to an agency advisory committee. It showed that the number of people who had a digestive problem while taking naproxen was about double the figure for Vioxx takers – but that difference was almost exactly the same as the additional number of Vioxx users who suffered a cardiovascular problem such as a stroke.

87. FDA officials wanted to highlight the cardiovascular risk prominently on Vioxx’s label. Merck resisted, complaining that the agency was putting more weight on the negative findings than on the positive gastrointestinal aspects. In the end, the two sides compromised. The new Vioxx label, which went into effect in April 2002, listed the good news about fewer upset stomachs first. Then it added two tables with the bad news about more heart attacks and strokes.

88. The agency, meanwhile, had become increasingly concerned about Merck’s marketing of the drug to doctors. It complained in a September 17, 2001, warning letter about a Merck-sponsored presentation by a doctor in June 2000. The doctor had said the Vigor trial

showed that naproxen was “a wonderful drug” for reducing the risk of heart problems – not that there was anything wrong with Vioxx. Such statements, the FDA said, “minimized the potentially serious cardiovascular findings” of Vigor.

89. A Merck internal marketing document reviewed by The Wall Street Journal, addressed to “all field personnel with responsibility for Vioxx,” provided an “obstacle handling guide.” If a doctor said he was worried that Vioxx might raise the risk of a heart attack, he was to be told that the drug “would not be expected to demonstrate reductions” in heart attacks or other cardiovascular problems and that it was “not a substitute for aspirin.” This wasn’t a direct answer.

90. One training document is titled “Dodge Ball Vioxx” and consists of 16 pages. Each of the first 12 pages lists one “obstacle,” apparently representing statements that might be made by a doctor. Among them are, “I am concerned about the cardiovascular effects of Vioxx” and “The competition has been in my office telling me that the incidence of heart attacks is greater with Vioxx than Celebrex.” The final four pages each contain a single word in capital letters: “DODGE!”

91. Merck also went on the offensive against academic researchers who began to question Vioxx’s safety. Gurkirpal Singh of Stanford University, a prominent Cox-2 expert who was giving lectures sponsored by Merck and other companies, says he pressed Merck repeatedly for more cardiovascular safety data. When Merck refused, Dr. Singh added a slide to his presentations that showed a man – representing the missing data – hiding under a blanket. “This was the first time they didn’t answer my questions,” he says. “With Vigor, suddenly it was a clampdown.”

92. Merck canceled several presentations by Dr. Singh that it had been scheduled to sponsor, and it didn’t stop there. In October 2000, a Merck official, Louis Sherwood, called James Fries, a Stanford University Medical School professor, to complain that Dr. Singh’s lectures were “irresponsibly anti-Merck and specifically anti-Vioxx,” as Dr. Fries described the

call in a January 2001 letter to Mr. Gilmartin, the Merck chief executive. The Merck official “suggested that if this continued, Dr. Singh would ‘flame out’ and there would be consequences for myself and for Stanford,” Dr. Fries wrote.

93. Dr. Fries struck back. “There is a line that you can’t go across. ... It had gone over that line,” he says. He wrote to the Merck chief that researchers at several other top medical schools complained about “a consistent pattern of intimidation of investigators by Merck” on Vioxx.

94. Mr. Gilmartin responded that Merck had a “deep and abiding commitment to the highest ethical standards in all our dealings with physicians and other healthcare providers.” Dr. Fries and other researchers mentioned in the letter say the company did try to repair relations subsequently. Dr. Singh, now an adjunct clinical professor at Stanford, says he stopped using the blanket slide after Merck gave him more data.

95. According to the WALL STREET JOURNAL,⁴ Lee Simon, a rheumatologist at Beth Israel Deaconess Medical Center in Boston, says he publicly mentioned data showing Vioxx might be associated with a risk of high blood pressure and swelling. While Dr. Simon was closely involved with research on the rival Cox-2 drug Celebrex, he had worked with Merck in another area. Merck’s Dr. Sherwood called Dr. Simon and one of his superiors at the hospital to complain that Dr. Simon’s lectures were slanted against Vioxx.

96. “I was shocked that there was a phone call made like that,” Dr. Simon says. “The company was attempting to suppress a discussion about this data.”

97. In August 2001, researchers at the Cleveland Clinic published an analysis in the Journal of the American Medical Association that once again raised concerns about Vioxx’s cardiovascular risks. Before it came out, Merck’s Dr. Reicin and other officials met with the authors, arguing that “they didn’t think there was a problem with the drug,” says Steven Nissen,

⁴ 11/1/2004.

one of the Cleveland Clinic researchers. The company also asked the journal to run a Merck rebuttal but it refused, people with knowledge of the matter said at the time.

98. One of Merck's most aggressive moves came against Joan-Ramon Laporte of the Catalan Institute of Pharmacology in Barcelona, Spain. In the summer of 2002, a publication of the institute edited by Dr. Laporte repeated criticisms of Merck's handling of Vioxx that had been published in the British journal *Lancet*. Soon after, Dr. Laporte says, Merck officials sent him a "rectification" to publish, but he responded that there would be no correction. After Merck officials approached him twice more, the company filed suit in a Spanish court against Dr. Laporte and the institute, taking advantage of a Spanish law that allows plaintiffs to demand a public correction of inaccurate published information.

99. In January of this year, a judge ruled that Dr. Laporte's publication accurately reflected the medical debate about the cardiovascular safety of Vioxx, and ordered Merck to pay court costs.

100. This March, Dr. Laporte was a featured speaker at an annual update on the pharmaceutical world for about 1,000 Spanish family physicians. Merck had helped pay for the meeting for the previous eight years. It contacted the organizer, Ramon Morera i Castell, and told him that the company "preferred" if Dr. Laporte stayed off the program this year, says Dr. Morera. After Dr. Morera rejected the request, Merck withdrew its financing -- about \$140,000. Though there wasn't any specific threat, "the message was clear," says Dr. Morera.

F. The Withdrawal of Vioxx

101. On September 30, 2004, the Center for Drug Evaluation and Research of the Food and Drug Administration issued a Memorandum concluding that Vioxx has adverse cardiovascular effects, which were evident as early as the 2000 VIGOR study: "***Rofecoxib increases the risk of serious coronary heart disease defined as acute myocardial infarction and sudden cardiac death.*** . . . The observation of an increased risk was first noted with the VIGOR trial, where a 5-fold difference in risk was found between high-dose rofecoxib and naproxen.

The manufacturer attributed this difference to a never before recognized protective effect of naproxen. To explain a 5-fold difference, naproxen would have had to be one of the most potent and effective cardio-protectants known. Three cohort studies and the present nested case-control study found no evidence of cardio-protection with naproxen. The three case-control studies that reported a protective effect were misleading. When analyzed in a manner comparable to the present study, ***no protective effect is shown.***⁵

102. On that same day, September 30, 2004, Merck issued a press release announcing the withdrawal of Vioxx based on “new” data indicating an increased risk of cardiovascular events, such as heart attack and stroke for those taking the drug eighteen months or longer.⁶ The decision came after the Data Safety Monitoring Board for an ongoing study of Vioxx (APPROVe) recommended that the study be stopped early for safety reasons based on the first three years of results.⁷ APPROVe, or Adenomatous Polyp Prevention on Vioxx, was a trial of rofecoxib for the prevention of recurrence of colorectal polyps in patients with a history of colorectal adenomas. An article in *The Lancet*, a respected British medical journal, pointed out that the “voluntary withdrawal of rofecoxib by its manufacturer, Merck, on the basis of a fairly small trial that was designed for a different purpose raises several questions.”⁸ The critical question is when Merck knew that Vioxx was associated with an unacceptably high risk of adverse cardiovascular events, such as heart attack and stroke.

103. To establish whether robust evidence on the adverse effects of rofecoxib was available before the withdrawal of Vioxx from the market, meta-analysis of randomized controlled trials and observational studies was conducted and its results were recently published

⁵ David J. Graham, MD, MPH, Associate Director for Science, Office of Drug Safety, Center for Drug Evaluation and Research, FDA, *Risk of Acute Myocardial Infarction and Sudden Cardiac Death in Patients Treated with COX-2 Selective and Non-selective NSAIDs* 13 (Sept. 30, 2004).

⁶ Merck, *Merck Announces Voluntary Withdrawal of VIOXX*, available at http://www.vioxx.com/vioxx/documents/english/vioxx_press_release.pdf (accessed Nov. 5, 2004).

⁷ FDA, *FDA Public Health Advisory: Safety of Vioxx*, available at http://www.fda.gov/cder/drug/infopage/vioxx/PHA_vioxx.htm (accessed Nov. 5, 2004).

⁸ Peter Juni, et al., *THE LANCET, Risk of Cardiovascular Events and Rofecoxib: Cumulative Meta-Analysis* 4 (Nov. 5, 2004).

in The Lancet: “***Our cumulative meta-analysis of randomized controlled trials indicates that an increased risk of myocardial infarction was evident from 2000 onwards.*** At the end of 2000, the effect was both substantial and unlikely to be a chance finding. We found an increased risk of myocardial infarction in trials of both short and long duration, which is in contrast to the unpublished results from the APPROVe trial. . . . [T]he reassuring statement by Merck, that there is no excess risk in the first 18 months, is not supported by our data. . . . [D]ata from these studies indicate that if a protective effect of naproxen exists, it is . . . not large enough to explain the findings of VIGOR. By contrast to our findings, two earlier meta-analyses from Merck Research Laboratories showed no evidence of a rise in cardiovascular risk or an increase in risk that was restricted to trials comparing rofecoxib with naproxen. . . . ***To clarify the reasons behind the misleading results of Merck’s meta-analysis of cardiovascular events in clinical trials of rofecoxib will be important.*** . . . If Merck’s statement in their recent press release that ‘given the availability of alternate therapies, and the questions raised by the data, we concluded that a voluntary withdrawal is the responsible course to take’ was appropriate in September, 2004, then ***the same statement could and should have been made several years earlier, when the data summarised here first became available. Instead, Merck continued to market the safety of rofecoxib.***”⁹

104. Merck has agreed to reimburse patients for Vioxx purchased but not used as of September 30, 2004. But this does nothing for Plaintiffs and others similarly situated or the millions of patients nationwide who have already purchased and/or consumed Vioxx and who paid more than they would have or should have because it was advertised as a premium drug with reduced side effects and/or who would not have purchased Vioxx at all had they know about its adverse cardiovascular effects.

⁹ Peter Juni, et al., THE LANCET, *Risk of Cardiovascular Events and Rofecoxib: Cumulative Meta-Analysis* 5-7 (Nov. 5, 2004).

CLASS REPRESENTATION ALLEGATIONS

105. The case is maintainable on behalf of the Class under Rule 1.220 of the Florida Rules of Civil Procedure, subsections (b)2 with respect to declaratory, equitable and injunctive relief and (b)(3) with respect to monetary relief.

106. There are questions of law and fact common to the claims of the Plaintiffs and the Class members, including, but not limited to:

a. whether Vioxx poses an increased risk of blood clots, heart attack, stroke, unstable angina, cardiac clotting and hypertension as opposed to traditional NSAIDs;

b. whether Defendant made misrepresentations or omissions about the cardiovascular risks associated with using Vioxx and regarding the effectiveness of Vioxx;

c. whether such misrepresentations and omissions were likely to mislead and deceive a consumer acting reasonably; and

d. whether members of the Class are entitled to damages based on their payments for Vioxx, and, if so, the nature and amount of such damages; and

107. Plaintiff's claims and defenses are typical of the claims and defenses belonging to absent members of the Class, because Defendant uniformly misrepresented that Vioxx is safer and more effective than traditional NSAIDs and uniformly omitted to disclose the material cardiovascular risks associated with Vioxx. Defendant's actions have deprived Plaintiffs and the members of the Class of their ability to make an informed decision about whether to pay for Vioxx.

108. The members of the Class are so numerous that joinder of all their members would be impractical. Vioxx has been purchased by thousands, if not millions, of persons in Florida.

109. The class is defined and described as follows:

All persons or entities in the State of Florida who, on or after 4 years before the filing of this suit, have paid some or all of the purchase price for Vioxx.

Excluded from the proposed class are (i) Defendant, any entity in which Defendant has a controlling interest or which has a controlling interest in Defendant, and Defendant's legal representatives, predecessors, successors and assigns and (ii) the judge and staff to whom this case is assigned, and any member of the judge's immediate family. The requirements for maintaining this action as a class action are satisfied as follows.

110. Plaintiffs will fairly and adequately assert and protect the interests of absent members of the Class because has retained counsel competent and experienced in complex class action litigation and has no interest adverse to any absent Class members.

111. Class certification is proper under Florida Rule of Civil Procedure 1.220(b)(2), because Defendant has acted, or refused to act, on grounds generally applicable to the Class, thereby making final injunctive relief or corresponding declaratory relief appropriate for the Class.

112. Class certification is proper under Florida Rule of Civil Procedure 1.220(b)(3), because common issues of law and fact predominate over any questions affecting only individual members of the Class, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy. The common issues of law and fact that predominate over questions affecting individual members are set forth above in paragraph 105. Class certification is superior because it will avoid a repetition of the same evidence in multiple proceedings, Class members will have little interest in controlling the litigation of separate claims given the relatively small monetary damages suffered by each, there is no pending litigation of which Plaintiffs are aware that adjudicates whether the Defendant has violated the FDUTPA, the forum is desirable in that the case is limited to persons who purchased Vioxx in Florida during the class period, and there should not be significant difficulties in the management of the case given that the damages will be readily ascertainable as will be the identities of class members through notice procedures typically utilized in like cases.

COUNT I
(Violation of the FDUTPA)

113. Plaintiffs incorporate by reference the preceding paragraphs as if they were fully set forth herein.

114. The Plaintiffs and the Class are “consumers” within the meaning of the FDUTPA.

115. The Plaintiffs and the Class purchased and paid for Vioxx manufactured, promoted and sold by the Defendant within the applicable limitations period.

116. At all relevant times, there was in effect the FDUTPA. The FDUTPA forbids unconscionable acts or practices and unfair or deceptive acts or practices in the conduct of any trade or commerce.

117. The Defendant’s manufacture, promotion and sale of Vioxx to the Plaintiffs and the Class members constitute “trade or commerce” within the meaning of the FDUTPA

118. Pursuant to said Act, Defendant had a statutory duty to refrain from unfair or deceptive acts or practices in the manufacture, promotion, and sale of Vioxx to Plaintiffs and the Class members.

119. Defendant intended that Plaintiffs and the Class members rely on its materially deceptive acts and practices and purchase Vioxx as a consequence of the deceptive practices and acts, including Defendant’s misrepresentations and omissions of material fact with respect to the true nature of Vioxx:

(a) Defendant’s promotions of Vioxx as a safe drug for the treatment of pain and as having fewer side effects than comparable drugs on the market were deceptive, unfair, and unlawful in that Vioxx actually had an unacceptably high risk of adverse cardiovascular events and was promoted solely for financial reasons and not due to any material increase in medical safety;

(b) Defendant’s conduct was unfair, unlawful and deceptive in that Defendant knew Vioxx was unsafe and increased the risk of adverse cardiovascular events, such as heart

attack and stroke, to unacceptable levels, but omitted to disclose these facts to doctors and patients until September 2004;

(c) Defendant omitted material information known to it in order to induce doctors to prescribe Vioxx and consumers to purchase Vioxx at a price that exceeded its actual worth; and

(d) Defendant committed unlawful acts by promoting and advertising Vioxx in a manner that violated the Federal Food, Drug and Cosmetic Act. See 21 U.S.C. §§ 331(a) and (b), 352(a), (f) and (n) and 355(a).

120. Defendant's deceptive and unfair representations and material omissions to Plaintiffs and the Class members were, and are unfair and deceptive acts and practices.

121. The Defendant's unfair and deceptive practices and acts were and are likely to mislead and deceive a consumer acting reasonably.

122. As a proximate result of the Defendant's unfair and deceptive practices and act, Plaintiffs and the Class members have suffered ascertainable losses, in an amount to be determined at trial.

COUNT II (Unjust Enrichment)

123. Plaintiffs incorporate by reference the preceding paragraphs as if they were fully set forth herein.

124. The Plaintiffs and the Class members purchased Vioxx manufactured, promoted and sold by the Defendant and thereby conferred a benefit on the Defendant which the Defendant accepted and retained.

125. To the detriment of Plaintiffs and members of the Class, Defendant has been, and continues to be, unjustly enriched as a result of the unlawful and/or wrongful collection of, inter alia, payments for Vioxx.

126. Defendant has unjustly benefited through the unlawful and/or wrongful collection of, inter alia, payments for Vioxx and continues to so benefit to the detriment and at the expense of Plaintiffs and members of the Class.

127. Accordingly, Plaintiffs and members of the Class seek full restitution of the Defendant's enrichment, benefits and ill-gotten gains acquired as a result of the unlawful and/or wrongful conduct alleged herein.

I. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that:

A. The Court determine that this action may be maintained as a class action pursuant to Rule 1.220(b)(2) of the Florida Rules of Civil Procedure with respect to Plaintiffs' claims for declaratory, equitable and injunctive relief, and Rule 1.220(b)(3) of the Florida Rules of Civil Procedure with respect to the claims for damages, and certify the Plaintiffs as representative of the Class and Plaintiffs' counsel as counsel for the Class;

B. The conduct alleged herein be declared, adjudged and decreed to be unlawful pursuant to §501.211 of the FDUTPA;

C. The Plaintiffs and the Class be granted an award of damages in such amount to be determined at trial as provided by law;

E. Defendant be enjoined from continuing the illegal activities alleged herein pursuant to §501.211 of the FDUTPA;

F. The Plaintiffs and the Class recover their costs of suit, including reasonable attorneys' fees and expenses as provided by applicable law; and

G. The Plaintiffs and the Class be granted such other, further, and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

II. DEMAND FOR JURY TRIAL

The Plaintiffs demands a jury trial on all issues so triable.



By: _____

C. Wes Pittman
Fla. Bar No. 220507
PITTMAN & PERRY, P.A.
432 McKenzie Avenue
Panama City, FL 32401
(850) 784-9000
(850) 763-6787 (fax)

John C. Davis
Fla. Bar No. 0827770
LAW OFFICE OF JOHN C. DAVIS
623 Beard Street
Tallahassee, FL 32303
(850) 222-4770
(850) 222-3119 (fax)

Garve Ivey, Jr.
Barry A. Ragsdale
IVEY & RAGSDALE
P.O. Box 1349
315 West 19th St.
Jasper, AL 35502-1349
Telephone: (205) 221-4644