

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA**

RUTH RAVNITSKY, Individually and On Behalf
of All Others Similarly Situated,

Plaintiff,

vs.

MERCK & CO., INC., KENNETH C. FRAZIER,
RICHARD C. HENRIQUES, RAYMOND V.
GILMARTIN, JUDY C. LEWENT and MARY
M. MCDONALD,

Defendants.

CASE NO.

**CLASS ACTION COMPLAINT
FOR VIOLATIONS OF
FEDERAL SECURITIES LAWS**

JURY TRIAL DEMANDED

Plaintiff has alleged the following based upon the investigation of plaintiff's counsel, which included a review of United States Securities and Exchange Commission ("SEC") filings by Merck & Co., Inc. ("Merck" or the "Company"), as well as regulatory filings and reports, securities analysts' reports and advisories about the Company, press releases, and media reports about the Company, and plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal class action on behalf of purchasers of the common stock of Merck between May 22, 1999 and October 22, 2003, inclusive (the "Class Period"), seeking to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Merck describes itself as a global research-focused pharmaceutical products company which discovers, develops, manufactures and markets a broad range of products to improve human and animal health, directly and through its joint ventures. During the Class Period, Merck developed, manufactured, and marketed the prescription painkilling drug Vioxx, generically known as rofecoxib. In May 1999, after obtaining approval from the Food and Drug Administration ("FDA") to use Vioxx in treating primary dysmenorrhea, managing acute pain in adults, and relieving symptoms relating to osteoarthritis, Merck began vigorously marketing Vioxx to health professionals in the United States by conducting audio conferences, making sales presentations, and issuing press releases, and continued to do so throughout the Class Period.

3. Unbeknownst to the investing public, however, beginning as early as May 1999, this marketing campaign included false and misleading investors which included false and misleading statements concerning the safety profile of Vioxx and Vioxx's superiority to its rival drug, Celebrex, manufactured by Merck's competitor, Pfizer. On November 16, 1999, the FDA sent defendants a letter stating that the *"promotional pieces . . . are false or misleading because they contain misrepresentations of Vioxx's safety profile, unsubstantiated comparative claims, and are lacking in fair balance."* (emphasis added).

4. Moreover, during the Class Period, defendants failed to disclose material information concerning the degree of the serious adverse side-effects of Vioxx, including significantly increased risks of heart attacks in patients taking the drug. Specifically, in March 2000, defendants released the results of a Merck-sponsored study called the Vioxx Gastrointestinal Outcomes Research (the "VIGOR study") which demonstrated *"significantly few heart attacks were observed in patients taking naproxen (0.1 percent) compared to the group taking Vioxx 50 mg (0.5 percent) in this study.* There was no difference in

cardiovascular mortality between the group treated with Vioxx or naproxen.” (Merck Annual Report 2000 posted on Merck website) (emphasis added). Defendants presented these results to the FDA in May 2000. In the August 2001 issue of *The Journal of the American Medical Association*, an article concerning the VIGOR study reiterated the necessity that “a cautionary flag” be raised concerning the risk of cardiovascular problems caused by taking Vioxx. In September 2001, defendants received a warning letter from the FDA (“FDA Warning Letter”) concerning Merck’s marketing of Vioxx during which, the Agency stated, Merck minimized the potentially serious risk of increased heart problems discovered in the VIGOR study and downplayed the adverse effects of using Vioxx with the drug Coumadin. The FDA concluded in the Warning Letter that Merck’s marketing of Vioxx was **“false, lacking in fair balance, or otherwise misleading[.]”** The Letter continued to state that Merck’s marketing **“minimizes the potentially serious cardiovascular findings that were observed in the VIGOR study, minimize the Vioxx/Coumadin drug interaction, omit crucial risk information associated with Vioxx therapy, contain unsubstantiated comparative claims, and promote unapproved uses.”** (emphasis added)

5. Despite available information, defendants failed to adequately disclose the degree of the serious adverse risks of Vioxx, contending that the FDA Warning Letter and other studies were inaccurate and/or inconclusive, and instead, continued to tout the efficacy of the drug and the revenues derived from the sale thereof.

6. During the Class Period, defendants were motivated to conceal the extent of the adverse risks of taking Vioxx in order to compete with other drug companies, including Pfizer. In addition, during the Class Period, defendants were motivated to boost sales of Vioxx as Merck was facing the expiration of the patent on one of its best revenue-generating drugs, Zocor, and

did not have other drugs in the pipeline to serve as a replacement. In addition, unlike its competitors, Merck failed to partner with other drug companies and biotech companies to obtain license rights of blockbuster drugs for cost-savings measures and to expand its research and development budget, forcing defendants to desperately rely upon the successful launch of Vioxx. Defendants' fraudulent scheme caused the price of Merck securities to be artificially inflated during the Class Period, enabling Company insiders to sell over 3.9 million shares of their personally-held Merck shares for \$175.6 million in proceeds, and causing plaintiff and other members of the Class suffered damages.

7. On October 22, 2003, minutes before the market closed, an article was published on *Reuters* reporting Merck's third quarter 2003 results entitled "Merck to cut 4,400 Jobs, Earnings Flat" in which the risks of taking Vioxx which were discovered in the VIGOR study were confirmed. The article stated that the "***arthritis drug is suffering from clinical trial data suggesting it might slightly raise the risk of heart attacks, and the growing perception that its pain-fighting capabilities are no better than traditional painkillers.***" (emphasis added). The market's reaction to this news was swift and dramatic. On the following day, October 23, 2003, the price of Merck common stock traded as low as \$44.85 per share, more than \$2.05 lower than its previous trading day high, to close at \$45.10.

8. On October 30, 2003, *The Wall Street Journal* explained the adverse results of the clinical trial mentioned above in an article entitled "Vioxx Study Sees Heart-Attack Risk." The article reported that the results of another study sponsored by Merck, presented at the annual meeting of the American College of Rheumatology, demonstrated an "***increased risk of heart attacks in patients taking the pill [Vioxx.]***" Further, the article stated that within the first 30 days of taking Vioxx, ***the risk of a heart attack was increased 39%*** in comparison with

Celebrex. This was a significant increase from the 0.5% discovered in the VIGOR study which compared Vioxx to naproxen, a nonsteroidal anti-inflammatory drug (“NSAID”). The market’s reaction to the news was swift and dramatic. On this news, the price per share of Merck stock fell \$0.97 per share, or 2.1%, from its previous day’s closing price, to close at \$43.56.

JURISDICTION AND VENUE

9. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act [15 U.S.C. §§ 78j(b) and 78t(a)] and Rule 10b-5 promulgated thereunder by the Securities and Exchange Commission (“SEC”) [17 C.F.R. § 240.10b-5].

10. The Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337 and Section 27 of the Exchange Act [15 U.S.C. § 78aa].

11. Venue is proper in this District pursuant to Section 27 of the Exchange Act, and 28 U.S.C. § 1391(b), and as many of the acts and practices complained of herein occurred in substantial part in this District.

12. In connection with the acts alleged in this complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications and the facilities of the national securities markets.

PARTIES

13. Plaintiff Ruth Ravnitsky, as set forth in the accompanying certification, incorporated by reference herein, purchased the common stock of Merck at artificially inflated prices during the Class Period and has been damaged thereby.

14. Defendant Merck, is a New Jersey corporation with its principal place of business located at One Merck Drive, Whitehouse Station, NJ 08889-0100. The Company is a global, research-driven, pharmaceutical company that discovers, develops, manufactures, and markets a

broad range of human and animal health products, and provides pharmaceutical benefit services through Merck-Medco Managed Care, L.L.C. ("Merck-Medco").

15. Defendant Raymond V. Gilmartin ("Gilmartin"), was, at all relevant times, Merck's Chairman, President and Chief Executive Officer.

16. Defendant Kenneth C. Frazier ("Frazier"), was Merck's Senior Vice President and General Counsel since December, 1999.

17. Defendant Richard C. Henriques ("Henriques"), was, at all relevant times, Merck's Vice President and Controller.

18. Defendant Judy C. Lewent ("Lewent"), was, at all relevant times, Merck's Senior Vice President and Chief Financial Officer.

19. Defendant Mary M. McDonald ("McDonald"), was Merck's Senior Vice President and General Counsel until her resignation in December, 1999.

20. Defendants Gilmartin, Frazier, Henriques, Lewent and McDonald are collectively referred to herein as the "Individual Defendants."

21. Because of the Individual Defendants' positions with the Company, they had access to the adverse undisclosed information about its business, operations, products, operational trends, financial statements, markets and present and future business prospects via access to internal corporate documents (including the Company's operating plans, budgets and forecasts and reports of actual operations compared thereto), conversations and connections with other corporate officers and employees, attendance at management and Board of Directors meetings and committees thereof and via reports and other information provided to them in connection therewith.

22. It is appropriate to treat the Individual Defendants as a group for pleading purposes and to presume that the false, misleading and incomplete information conveyed in the Company's public filings, press releases and other publications as alleged herein are the collective actions of the narrowly defined group of defendants identified above. Each of the above officers of Merck, by virtue of their high-level positions with the Company, directly participated in the management of the Company, was directly involved in the day-to-day operations of the Company at the highest levels and was privy to confidential proprietary information concerning the Company and its business, operations, products, growth, financial statements, and financial condition, as alleged herein. Said defendants were involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein, were aware or recklessly disregarded, that the false and misleading statements were being issued regarding the Company, and approved or ratified these statements, in violation of the federal securities laws.

23. As officers and controlling persons of a publicly-held company whose common stock was, and is, registered with the SEC pursuant to the Exchange Act, traded on the New York Stock Exchange during the Class Period, and governed by the provisions of the federal securities laws, the Individual Defendants each had a duty to disseminate promptly, accurate and truthful information with respect to the Company's financial condition and performance, growth, operations, financial statements, business, products, markets, management, earnings and present and future business prospects, and to correct any previously-issued statements that had become materially misleading or untrue, so that the market price of the Company's publicly-traded securities would be based upon truthful and accurate information. The Individual Defendants'

misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

24. The Individual Defendants participated in the drafting, preparation, and/or approval of the various public reports and other communications complained of herein and were aware of, or recklessly disregarded, the misstatements contained therein and omissions therefrom, and were aware of their materially false and misleading nature. Because of their Board membership and/or executive and managerial positions with Merck, each of the Individual Defendants had access to the adverse undisclosed information about Merck's business prospects and financial condition and performance as particularized herein and knew (or recklessly disregarded) that these adverse facts rendered the positive representations made by or about Merck and its business issued or adopted by the Company materially false and misleading.

25. The Individual Defendants, because of their positions of control and authority as officers and/or directors of the Company, were able to and did control the content of the various SEC filings, press releases and other public statements pertaining to the Company during the Class Period. Each Individual Defendant was provided with copies of the documents alleged herein to be misleading prior to or shortly after their issuance and/or had the ability and/or opportunity to prevent their issuance or cause them to be corrected. Accordingly, each of the Individual Defendants is responsible for the accuracy of the public reports and releases detailed herein and is therefore primarily liable for the representations contained therein.

26. Each of the defendants is liable as a participant in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Merck common stock by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme: (i) deceived the investing public regarding Merck's business, finances,

financial statements and the intrinsic value of Merck common stock; and (ii) caused plaintiff and other members of the Class to purchase Merck securities at artificially inflated prices.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

27. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired the securities of Merck between May 22, 1999 and October 22, 2003, inclusive, and who were damaged thereby. Excluded from the Class are defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

28. The members of the Class are so numerous that joinder of all members is impracticable. As of October 31, 2003, Merck had approximately 2.2 billion shares of common stock outstanding that were actively traded on the New York Stock Exchange ("NYSE"). While the exact number of Class members is unknown to plaintiff at this time and can only be ascertained through appropriate discovery, plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Merck or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

29. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

30. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

31. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by defendants' acts as alleged herein;

(b) whether statements made by defendants to the investing public during the Class Period misrepresented material facts about the business, operations and financial statements of Merck; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

32. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

SUBSTANTIVE ALLEGATIONS

MATERIALLY FALSE AND MISLEADING STATEMENTS MADE DURING THE CLASS PERIOD

33. On May 22, 1999, defendants issued a press release announcing Merck's financial results for the second quarter of 1999, the period ending June 30, 1999. For the quarter, defendants reported revenues of \$8.02 billion, as compared with revenues of \$6.47 billion in the same quarter of the prior year. Defendant, Gilmartin, commented on the Company's performance, stating, in pertinent part, as follows:

Sales growth for the quarter and the first half of 1999 was led by the established major products, including the 1999 launch of Vioxx, as well as growth from the Merck-Medco Managed Care business Solid volume gains in both our domestic and international operations as well as 3 point benefit attributable to the restructuring of Astra Merck, Inc. (AMI) contributed to the second quarter results.

34. On August 12, 1999, Merck filed with the SEC a quarterly report on a Form 10-Q confirming the results above. In the Form 10-Q, defendants stated in relevant part as follows:

Following a six month priority review, on May 20 the FDA cleared Vioxx, Merck's once daily COX-2 specific inhibitor, for the relief of the signs and symptoms of osteoarthritis, management of acute pain in adults, and treatment of menstrual pain. Since then, more than 400,000 U.S. patients have taken the product. Merck has introduced Vioxx in nine other countries including the United Kingdom, Switzerland, and Mexico. *The Company is conducting additional clinical studies with Vioxx to determine whether it is useful in treating rheumatoid arthritis and in preventing and treating Alzheimer's disease.* Studies will begin later this year to ascertain whether Vioxx might help prevent colon cancer. [Emphasis added.]

35. On October 21, 1999, defendants issued a press release announcing Merck's financial results for the third quarter of 1999, the period ending September 30, 1999. For the quarter, defendant s reported revenues of \$8.2 billion, as compared with revenues of \$6.8 billion in the same quarter of the prior year. In the release, defendant Gilmartin, commented on the Company's performance, stating, in pertinent part, as follows:

Sales growth for the quarter and nine months of 1999 was led by the established major products, the newer products, including Vioxx, and growth from the Merck-Mexco Managed Care business.... Solid volume gains in both our domestic and international operations contributed to the third quarter results. [Emphasis added.]

36. On or about November 1, 1999, defendants disseminated two "homemade" promotional pieces, entitled "TEN REASONS WHY VIOXX IS BETTER THAN CELEBREX," and "Vioxx vs. Celebrex Poem" in which defendants stated, among other things:

? “VIOXX HAS ENDOSCOPY STUDIES SHOWING A SAFER THAN PLACEBO INCIDENCE RATE OF GASTRODUODENAL ULCERS”

? “Your patients in pain – they give you their grief; A Cox-II is the answer for their pain relief”

? “Vioxx of course – the answer again, It’s stronger, lasts longer, is faster, and then its safer. . . “

37. On November 12, 1999, Merck filed with the SEC a quarterly report on a Form 10-Q, confirming its results for the period ending September 30, 1999 stated above. In the Form 10-Q, defendants stated in relevant part as follows:

In just 20 weeks on the market in the United States, Vioxx has become the country’s fastest growing prescription arthritis medicine. U.S. physicians have written more than 2 million prescriptions for Merck’s newest medicine, which is used to relieve the signs and symptoms of osteoarthritis, manage acute pain in adults and treat menstrual pain. In September, Merck entered an agreement with CollaGenex, a leader in dental products, to co-promote Vioxx to dentists, periodontist and oral surgeons in the U.S. Dentists in the U.S. write more than 1.8 million prescriptions monthly for the relief of pain.

Merck has introduced Vioxx in 22 other countries, including the United Kingdom, Switzerland and Mexico. The company is conducting extensive clinical studies with Vioxx to evaluate its efficacy in the treatment of rheumatoid arthritis and in the prevention and treatment of Alzheimer’s disease. Studies will begin later this year to ascertain whether Vioxx might help prevent colon cancer. [Emphasis added.]

38. On November 12, 1999, the FDA sent a letter to defendants concerning Merck’s dissemination of the two homemade promotional materials on Vioxx, discussed herein, which may have been in violation of the Federal Food, Drug and Cosmetic Act and its regulations (the “FFDC Act”).

39. On December 16, 1999, following a review of defendants’ responses to the FDA’s November 12, 1999 letter, the FDA sent a letter to defendants, concluding that the “homemade”

promotional pieces were false and misleading in violation of the FFDC Act. The letter stated, in relevant part, as follows:

Dear Ms. Westrick:

Reference is made to Merck & Co., Inc.'s (Merck) letters, dated November 30, 1999, and December 15, 1999, in response to letters from the Division of Drug Marketing, Advertising, and Communications (DDMAC) dated, November 12, 1999, and December 1, 1999. Our letters concerned the alleged *dissemination of two "homemade" promotional pieces, entitled "TEN REASONS WHY VIOXX IS BETTER THAN CELEBREX," and "Vioxx vs. Celebrex Poem" distributed by or on behalf of Merck, that promoted Vioxx (rofecoxib) capsule in violation of the Federal Food, Drug and Cosmetic Act (Act) and its regulations. . . .*

* * *

We have reviewed these promotional pieces and have determined that they are false or misleading because they contain misrepresentations of Vioxx's safety profile, unsubstantiated comparative claims, and are lacking in fair balance. [Emphasis added.]

Misrepresentation of Safety Information

? *You present claims that misrepresent the safety profile of Vioxx, including but not limited to "VIOXX HAS ENDOSCOPY STUDIES SHOWING A SAFER THAN PLACEBO INCIDENCE RATE OF GASTRODUODENAL ULCERS."* However, this claim is in direct contrast with the approved product labeling (PI) that states, ". . . the studies cannot rule out at least some increase in the rate of endoscopic gastroduodenal ulcers when comparing Vioxx to placebo." . . .

Unsubstantiated Comparative Claims

* * *

? In the Vioxx vs. Celebrex Poem you claim, "Your patients in pain – they give you their grief; A Cox-II is the answer for their pain relief." . . . *However, this global superiority claim has not been demonstrated by substantial evidence, and therefore, is false and misleading. . .*

? *You also present several unsubstantiated comparative claims to Celebrex (celecoxib), including but not limited to, “Vioxx of course – the answer again, It’s stronger, lasts longer, is faster, and then its safer . . .”*

Fair Balance

* * *

? Although these pieces contain numerous claims for the efficacy and safety of Vioxx, you have not presented any risk information concerning the contradictions, warnings, precautions, or adverse events associated with Vioxx’s use. (emphasis added). ***Therefore, we consider these promotional pieces to be lacking in fair balance. Further, these promotional pieces are in violation of the Act because the approved product labeling for Vioxx did not accompany them.*** [Emphasis added.]

40. On January 26, 2000, Merck issued a press release announcing its financial results for the fourth quarter and full year 1999, the period ending December 31, 1999. For the year, defendants reported revenues of \$32.7 billion, as compared with revenues of \$26.9 billion in the prior year. Defendant, Gilmartin, commented on the Company’s performance, stating, in pertinent part, as follows:

Sales growth for the quarter and the year was led by the established products, the newer products, including Vioxx, as well as growth from the Merck-Mexco Managed Care business.

41. Merck’s financial results for the full year of 1999, the period ending December 31, 1999, were repeated in the Company’s Report on Form 10-K filed with the SEC on or about March 22, 2000, which was signed by defendants, Gilmartin, Lewent and Henriques, among others, and stated in pertinent part, as follows:

In May 1999, the US Food and Drug Administration (“FDA”) cleared Vioxx, a once-daily, anti-inflammatory COX-2 specific inhibitor, for marketing in the United States for relief of the signs and symptoms of osteoarthritis, management of acute pain in adults, and treatment of menstrual pain. Vioxx had now been launched in 47 other countries in addition to the United States. In

March, 1999, the FDA approved a new use indication for Mevacor...

In May 1999, following a six-month priority review, the FDA cleared Vioxx, Merck's once-daily agent that specifically inhibits COX-2, for relief of the signs and symptoms of osteoarthritis, management of acute pain in adults and treatment of menstrual pain. With its product relief profile for strength, safety and once daily simplicity, Vioxx remains the country's fastest growing prescription arthritis medicine. In the product's first seven months, U.S. physicians wrote more than five million prescriptions. Vioxx is also enjoying success in the 47 other countries in which it has been launched. Vioxx was the first agent that specifically inhibits COX-2 to receive mutual recognition approval for marketing in all of the European Union countries and quickly became the most successful pharmaceutical launch in the United Kingdom after its introduction. In September 1999, Merck entered into an agreement with a leader in dental products to copromote Vioxx to U.S. dentists, periodontists, and oral surgeons. The company is conducting extensive clinical studies with Vioxx to evaluate its efficacy in the treatment of rheumatoid arthritis and in the prevention and treatment of Alzheimer's disease. Merck also has begun studies in patients with colon polyps - a broad population at risk of developing colon cancer. Reducing the number of these polyps may reduce the incidence of colon cancer.

42. On April 24, 2000, Merck issued a press release announcing its financial results for the first quarter of 2000, the period ending March 31, 2000. For the quarter, defendants reported revenues of \$8.9 billion, as compared with revenues of \$7.5 billion in the same quarter of the prior year. Defendant Gilmartin, commented on the Company's performance, stating, in pertinent part, as follows:

Income growth for the quarter was driven by strong sales volume gains as well as manufacturing productivity improvements... The savings from productivity improvements helped fund selling and promotion programs to support our new products as well as research and development.

43. Merck's financial results for the first quarter of 2000, the period ending March 31, 2000, were repeated in the Company's Report on Form 10-Q filed with the SEC on or about May

12, 2000, which was signed by defendants, Frazier and Henriques, stating, in pertinent part, as follows:

Sales growth for the quarter was led by Vioxx, the fastest growing prescription arthritis medicine in the United States, other newer and established products and growth from the Merck-Medco Managed Care business. Overall, worldwide operations reported strong sales volume gains. Sales of Merck human health products increased 17% for the first quarter. Sales of Merck human health products outside of the United States accounted for 37% of Merck human health sales. Foreign exchange had essentially no effect on the human health sales growth for the first quarter. Income growth for the quarter was driven by strong sales volume gains as well as manufacturing productivity improvements. The savings from productivity improvements helped fund selling and promotion programs to support new products as well as research and development. Five key products - Vioxx, 'Zocor', 'Fosamax', 'Singulair' and 'Cozaar'/'Hyzaar'* - led Merck's growth, and now account for more than 50% of Merck's worldwide human health sales. Supply shipments to AstraZeneca LP also contributed to sales volume growth. ***Vioxx remains the fastest growing prescription arthritis medicine in the United States. More than 9 million prescriptions have been written for Vioxx since its U.S. introduction 10 months ago.*** In addition, it is the only medicine specifically inhibiting COX-2 that is indicated both for treatment of osteoarthritis and for relief of acute pain, such as pain following knee, hip replacement and dental surgery. Vioxx is enjoying strong success in the European countries where it has been launched, including the United Kingdom, Germany and Spain. In all, Vioxx has been launched in more than 50 countries. Merck is conducting extensive clinical studies with Vioxx to evaluate its efficacy in the treatment of rheumatoid arthritis and in the prevention and treatment of Alzheimer's disease. Merck has also begun studies to investigate whether Vioxx can reduce the number of colon polyps in patients who suffer from them - a broad population at risk of developing colon cancer. [Emphasis added.]

44. On July 24, 2000, Merck issued a press release announcing its financial results for the second quarter of 2000, the period ending June 30, 2000. For the quarter, defendant s reported revenues of \$9.5 billion, as compared with revenues of \$8 billion in the same quarter of the prior

year. Defendant, Gilmartin, commented on the Company's performance, stating, in pertinent part, as follows:

Sales growth for the quarter and the first half of 2000 was led by Vioxx, the other newer and established products and growth from the Merck-Mexco Managed Care business Strong volume gains in both the domestic and international operations contributed to the second quarter results.

45. Merck's financial results for the second quarter of 2000, the period ending June 30, 2000, were repeated in the Company's Report on Form 10-Q filed with the SEC on or about August 10, 2000, which was signed by defendants, Frazier and Henriques, and which stated, in pertinent part, as follows:

Vioxx, Merck's newest medicine for osteoarthritis and acute pain, has been launched in nearly 70 countries, including the United States, the United Kingdom, Germany, Spain, Mexico, Sweden, and Denmark. It remains the world's fastest growing prescription arthritis medicine, with more than 12 million prescriptions written since it was first introduced last year. ***In addition, Vioxx is the only medicine specifically inhibiting COX-2 that is indicated in the United States both for treatment of osteoarthritis and for relief of acute pain.***

In May, Merck presented results from the 8,000 patient Vioxx Gastrointestinal Outcomes Research (VIGOR) study in which Vioxx reduced the incidence of serious gastrointestinal side effects, such as ulcers and bleeding, by more than 50 percent compared to the nonsteroidal, anti-inflammatory drug, Naproxen. In June, Merck submitted a Supplemental New Drug Application for Vioxx to the U.S. Food and Drug Administration (FDA) to request labeling changes based on that study.

To expand the market for Vioxx, Merck continues clinical trials to determine whether Vioxx is effective in the treatment of rheumatoid arthritis and in the prevention and treatment of Alzheimer's disease. Merck has also begun studies to investigate whether Vioxx can reduce the number of colon polyps in patients who suffer from them - a broad population at risk of developing colon cancer. [Emphasis added.]

46. On or about October 20, 2000, Merck issued a press release announcing its financial results for the third quarter of 2000, the period ending September 30, 2000. For the quarter, defendant s reported revenues of \$10.56 billion, as compared with \$8.20 billion in the same quarter of the prior year. Defendant, Gilmartin, commented on the Company's performance, stating, in pertinent part, as follows:

Income growth for the quarter and first nine months reflect strong sales volume gains in the U.S. and international markets, as well as manufacturing productivity improvements These gains helped fund research and development and promotion programs in support of our key products.

47. Merck's financial results for the third quarter of 2000, the period ending September 30, 2000, were repeated in the Company's Report on Form 10-Q filed with the SEC on or about November 13, 2000, which was signed by defendant s, Frazier and Henriques, and which stated, in pertinent part, as follows:

The Company's newest medicine, 'Vioxx', together with 'Zocor', 'Cozaar'/'Hyzaar', 'Fosamax', and 'Singulair' are driving Merck's strong performance. These products accounted for 55% of Merck's worldwide human health sales for the first nine months.

More than 15 million prescriptions in the United States alone have been written for Vioxx, Merck's new medicine for osteoarthritis, since its successful launch last year, and it continues as the world's fastest growing prescription arthritis medicine. ***Vioxx has now achieved nearly \$1.5 billion in sales so far this year - more than \$600 million in this quarter alone. A key reason for its success is that Vioxx is the only COX-2 inhibitor approved by the FDA both for osteoarthritis and acute pain.***

A pilot study in osteoarthritis comparing Vioxx and celecoxib, a competitive product, presented at the European League Against Rheumatism in June, showed that Vioxx reduced osteoarthritis pain at night and at rest to a greater degree than either celecoxib 200 mg or acetaminophen 4,000 mg.

In June, Merck submitted a Supplemental New Drug for Vioxx to the FDA to request labeling changes based on the results of the 8,000 patient Vioxx Gastrointestinal Outcomes Research

(VIGOR) study. In this study, Vioxx reduced the incidence of serious gastrointestinal side effects, such as ulcers and bleeding, by more than 50% compared to the nonsteroidal antiinflammatory drug naproxen.

Clinical programs are underway to explore other potential benefits for Vioxx, including the treatment of chronic pain, rheumatoid arthritis and in the prevention and treatment of Alzheimer's disease. Merck has also begun studies to investigate whether Vioxx can reduce the number of colon polyps in patients who suffer from them - a broad population at risk of developing colon cancer. [Emphasis added.]

48. On January 23, 2001, Merck issued a press release announcing its financial results for the fourth quarter of 2000 and full year of 2000, the period ending December 31, 2000 for the full year of 2000, defendants reported revenues of \$40.4 billion, as compared with revenues of \$32.7 billion for the prior year. Defendant, Gilmartin, commented on the Company's performance, stating, in pertinent part, as follows:

Income growth for the quarter and the year reflects strong worldwide sales volume gains, as well as manufacturing productivity improvements.... These gains helped fund our ongoing research and development programs and promotional campaigns in support of our key products.

49. On or about February 2001, defendants posted on Merck's website as part of its 2000 annual report an article entitled "Vioxx: World's Fastest-Growing Rx Osteoarthritis Medicine in 2000" in which defendants stated, in relevant part, as follows:

In less than two years on the market, Vioxx has become the world's fastest-growing branded prescription drug for osteoarthritis and acute pain and Merck's second largest-selling medicine. Global sales are running at an annual rate of more than \$2 billion, bringing it level with the other entry in the COX-2 field, despite a later start in the United States, the world's largest market. Our drug already accounts for about half of all new COX-2 prescriptions written in the United States.

* * *

Nonselective nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen and naproxen are associated with serious gastrointestinal (GI) side effects in some patients. In November 2000, The New England Journal of Medicine published the results of VIGOR, our 8,000-patient study, which showed that Vioxx reduced the risk of serious GI complications by half when compared with the NSAID naproxen. The Food and Drug Administration Arthritis Advisory Committee recommended in February 2001 that the study's results, as well as data on certain cardiovascular events, should be included in the labeling. The FDA is not obligated to follow the advice of the Advisory Committee.

Although the VIGOR study was a GI outcomes study and was not designed to show differences in cardiovascular effects, significantly fewer heart attacks were observed in patients taking naproxen (0.1 percent) compared to the group taking Vioxx 50mg (0.5 percent) in this study. There was no difference in cardiovascular mortality between the group treated with Vioxx or naproxen.

Further growth prospects exist in potential new uses for Vioxx.
[Emphasis added.]

50. On April 20, 2001, Merck issued a press release announcing its financial results for the first quarter of 2001, the period ending March 31, 2001. For the quarter, defendants reported revenues of \$11.3 billion, as compared with revenues of \$8.9 billion in the same quarter of the prior year. Defendant, Gilmartin, commented on the Company's performance, stating, in pertinent part, as follows:

Income growth for the quarter reflects strong worldwide sales volume gains led by our five key growth drivers - ZOCOR, Vioxx, COZAAR/HYZAAR, FOSAMAX and SINGULAIR - which combined had increased sales of 30% over first quarter 2000 sales.

51. Merck's financial results for the first quarter of 2001, the period ending March 31, 2001, were repeated in the Company's quarterly report on Form 10-Q filed with the SEC on or about May 10, 2001, which was signed by defendants, Frazier and Henriques, and which stated in pertinent part, as follows:

Vioxx, a once-a-day medicine, is the only COX-2 selective agent indicated in the United States for both osteoarthritis and acute pain. Since its successful 1999 launch, Vioxx has become the world's fastest-growing branded prescription arthritis medicine, and it is already Merck's second largest selling medicine. Vioxx achieved \$485 billion in sales for the first quarter 2001.

Earlier this month, Merck received an approvable letter from the FDA regarding the Company's application for changes to prescribing information for Vioxx based on results from the Vioxx Gastrointestinal Outcomes Research (VIGOR) study. An approvable letter is defined by the FDA as a written statement that the FDA will approve the application if specific additional information of material is submitted or specific conditions are met. An approvable letter does not constitute approval of the application. Approval letters may result in additional time for completion of the FDA review. [Emphasis added.]

52. On May 22, 2001, defendants confirmed the safety cardiovascular profile of Vioxx in light of the VIGOR study. On the same day, an article appearing on *PR Newswire* stated, in relevant part, as follows: ***“In response to news and analyst reports of data the Company first release a year ago, Merck & Co., Inc. today reconfirmed the favorable cardiovascular safety profile of Vioxx (R)”***.

53. On July 20, 2001, Merck issued a press release announcing its financial results for the second quarter of 2001, the period ending June 30, 2001. For the quarter, defendant s reported revenues of \$11.9 billion, as compared with revenues of \$9.5 billion in the same quarter of the prior year. Defendant, Gilmartin, commented on the Company's performance, stating, in pertinent part, as follows:

Income growth for the first six months reflects strong worldwide sales volume gains led by our five key growth drivers [ZOCOR, Vioxx, COZAAR/HYZAAR, FOSAMAX and SINGULAIR], which combined increased 28% over the first six months 2000 sales.

54. Merck's financial results for the second quarter of 2001, the period ending June 30, 2001, were repeated in the Company's Report on Form 10-Q filed with the SEC on or about

August 10, 2001, which was signed by defendants, Frazier and Henriques, and which stated, in pertinent part, as follows:

Merck's human health sales were drive by its five key growth drivers - Zocor, Vioxx, Cozaar and Hyzaar, Fosamax, and Singulair...

Vioxx, a once-a-day medicine, is the only COX-2 selective agent indicated in the United States for both osteoarthritis and acute pain. Since its 1999 launch, Vioxx has become the world's fastest growing branded prescription arthritis medicine, and it is already Merck's second largest-selling medicine. In 2001, Vioxx achieved new prescription leadership within the coxib market in the United States, demonstrating that physicians continue to recognize the medicine's benefits to patients. Vioxx achieved \$725 million in sales for the second quarter.

New scientific data supporting the efficacy and overall safety profile of Vioxx were presented at medical meetings during the quarter. These data included the results of the ADVANTAGE trial, presented at the Digestive Diseases Week conference in May. In this study, fewer patients on Vioxx stopped taking their medicine because of gastrointestinal side effects compared to patients taking naproxen, a commonly prescribed non-steroidal, anti-inflammatory drug.

In April 2001, Merck filed a Supplemental New Drug Application for Vioxx with the FDA for the treatment of rheumatoid arthritis.

55. On August 22, 2001, following the announcement of the result of the Merck-sponsored VIGOR study of Vioxx, the *Journal of the American Medical Association* published an article authored by three medical doctors entitled "*Risk of Cardiovascular Events Associated With Selective COX-2 Inhibitors*", which stated, in relevant part, as follows:

Our search yielded 2 major randomized trials, the Vioxx Gastrointestinal Outcomes Research Study (VIGOR; 8076 patients) and the Celecoxib Long-term Arthritis Safety Study (CLASS; 8059 patients), as well as 2 smaller trials with approximately 1000 patients each. The results from VIGOR showed that the relative risk of developing a confirmed adjudicated thrombotic cardiovascular event (myocardial infarction, unstable angina, cardiac thrombus, resuscitated cardiac arrest, sudden or unexplained death, ischemic stroke, and transient ischemic

attacks). . . ***The annualized myocardial infarction rates for COX-2 inhibitors in both VIGOR and CLASS were significantly higher than that in the placebo group of a recent meta-analysis of 23 407 patients . . .***

The available data raise a cautionary flag about the risk of cardiovascular events with COX-2 inhibitors. Further prospective trial evaluation may characterize and determine the magnitude of the risk. [Emphasis added.]

56. On September 17, 2001, the FDA sent the Warning Letter to defendants concerning the Company's marketing of Vioxx. In the Letter, the FDA stated, in relevant part, as follows:

Dear Mr. Gilmartin:

This Warning Letter concerns Merck & Co. Inc's (Merck) promotional activities and material for the marketing of Vioxx (rofecoxib) tablets. Specifically, we refer to promotional audio conferences given on behalf of Merck by Peter Holt, MD, a press release, and oral representations made by Merck sales representatives to promote Vioxx. ***As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed your promotional activities and materials and has concluded that they are false, lacking in fair balance, or otherwise misleading in violation of the Federal, Food, Drug, and Cosmetic Act (the Act) and applicable regulations. See 21 U.S.C. §§ 331(a) and (b), 352(a), (f), and (n), and 355(a).***

You have engaged in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the [VIGOR] study, and thus, misrepresents the safety profile for Vioxx. Specifically, your promotional campaign discounts the fact that in the VIGOR study, patients, on Vioxx were observed to have four to five fold increase in myocardial infarctions (MIs) compared to patients on the comparator non-steroidal anti-inflammatory drug (NSAID), Naprosyn (naproxen).

Although the exact reason for the increased rate of MIs observed in the Vioxx treatment group is unknown, your promotional campaign selectively presents the following hypothetical explanation for the observed increase in MIs. ***You assert that***

Vioxx does not increase the risk of MIs and that the VIGOR finding is consistent with naproxen’s ability to block platelet aggregation like aspirin. That is a possible explanation, but you fail to disclose that your explanation is hypothetical, has not been demonstrated by substantial evidence, and that there is another reasonable explanation, that Vioxx may have pro-thrombotic properties.

You have also engaged in promotional activities that minimize the Vioxx/Coumadin (warfarin) drug interaction, omit important risk information, make unsubstantiated superiority claims against other NSAIDs, and promote Vioxx for unapproved uses and an unapproved dosing regimen. In addition, in misrepresenting the Vioxx/warfarin drug interaction you also misrepresent Vioxx’s safety profile by minimizing the potentially serious risk of significant bleeding that can result from using Vioxx and warfarin concomitantly.

* * *

Promotional Audio Conferences

We are aware of six promotional audio conferences, presented on behalf of Merck by Peter Hold, MD that are in violation of the Act and its implementing regulations. . . .

* * *

The promotional audio conferences . . . were false or misleading in that they minimized the MI results of the VIGOR study, minimized the Vioxx/Coumadin drug interaction, omitted important risk information, made unsubstantiated superiority claims, and promoted Vioxx for unapproved uses and unapproved dosing regimen.

* * *

Press Release

We have identified a Merck press release entitled, “Merck Confirms Favorable Cardiovascular Safety Profile of Vioxx,” dated May 22, 2001, that is also false or misleading for similar reasons stated above. Additionally, your claim in the press release that Vioxx has a “favorable cardiovascular safety profile,” is simply incomprehensible, given the rate of MI and serious cardiovascular events compared to naproxen. The implication that Vioxx’s cardiovascular profile is superior to other NSAIDs is misleading; in fact, serious cardiovascular events were twice as frequent in the VIOXX treatment group (101 events,

2.5%) as in the naproxen treatment group (46 events, 1.1%) in the VIGOR study.

Oral Representations

Merck sales representatives have engaged in false or misleading promotional activities that also minimize the potentially serious MI results observed in the VIGOR trial. Specifically, Merck sales representatives made false or misleading statements to DDMAC reviewers at two different professional meetings. At your exhibit booth during the 119th Annual Meeting of the Maryland Pharmacists Association (MPhA), in Ocean City, Maryland, June 9 – June 12, 2001, your representative stated that the increased MI rate seen in patients on Vioxx in the VIGOR study is due to the fact that naproxen works just like aspirin (i.e., inhibits clotting and platelet aggregation). In addition, during the Annual Meeting of the American Society of Health –Systems Pharmacists (ASHP), in Los Angeles, California, June 3 – June 6, 2001, your representatives stated that Vioxx had a greater MI rate in the VIGOR trial because naproxen is cardioprotective, having platelet effects similar to aspirin. These statements made by your sales representatives are misleading for the reasons stated above.

57. On October 18, 2001, Merck issued a press release announcing its financial results for the third quarter of 2001, the period ending September 30, 2001. For the quarter, defendants reported revenues of \$11.9 billion, as compared with revenues of \$10.6 billion in the same quarter of the prior year. Defendant Gilmartin, commented on the Company's performance, stating, in pertinent part, as follows:

Our five key growth drivers [ZOCOR, VIOXX, COZAAR/HYZAAR, FOSAMAX and SINGULAIR], which had increased sales of nearly 30% over the first nine months of 2000 and now account for two-thirds of Merck's worldwide human health sales, continued to lead Merck's income growth.

58. Merck's financial results for the third quarter of 2001, the period ending September 30, 2001, were repeated in the Company's Report on Form 10-Q filed with the SEC on or about November 13, 2001, which was signed by defendants, Henriques and Frazier, and which stated, in pertinent part:

Vioxx, a once-a-day medicine, is the only COX-2 selective agent approved in the United States for both osteoarthritis and acute pain. Available in more than 70 countries, Vioxx is Merck's second largest-selling medicine. In the third quarter, Vioxx continued new prescription leadership within the coxib market in the United States and in many European and Latin American countries. Vioxx became the first and only coxib approved for acute pain in a European Union country when it launched with that indication in the United Kingdom in September 2001. In the third quarter, Vioxx achieved \$795 million in sales, an increase of 29% over the same quarter last year.

In a continuing worldwide dispute between Merck and Pharmacia Corporation (Pharmacia) over competing claims to the patent rights to the class of compounds that include rofecoxib, the active ingredient in Vioxx, the federal district court in Washington D.C., recently dismissed a Pharmacia claim for damages for Merck's sale of Vioxx. Pharmacia may seek an appeal of this decision. Merck has also received favorable decisions regarding the patent status of

Vioxx from courts in the U.K., Holland, and Spain, while receiving no adverse claims in any country. The Company also noted that a number of federal and state lawsuits, involving individual claims as well as purported class actions, have been filed against the Company with respect to Vioxx. Some of the lawsuits also name as defendants Pfizer Inc. and Pharmacia, which market a competing product, Celebrex. The lawsuits include allegations regarding gastrointestinal bleeding and cardiovascular events. The Company believes that these lawsuits are completely without merit and will vigorously defend them.

59. On January 22, 2002, Merck issued a press release announcing its financial results for the full year of 2001, the period ending December 31, 2001. For the year, defendants reported revenues of \$47.7 billion, as compared with revenues of \$40.4 billion in the prior year. defendant, Gilmartin, commented on the Company's performance, stating, in pertinent part, as follows:

Our five key growth drivers, which also are our five largest products, now account for 68% of Merck's worldwide human health sales and continue to lead Merck's income growth. These medicines are true breakthroughs - they offer novel approaches to disease treatment, help large, underserved patient populations and

are effective, well-tolerated and convenient. The market-growth potential for these medicines remains strong.

60. Merck's financial results for the full year of 2001, the period ending December 31, 2001, were repeated in the Company's Report on Form 10-K filed with the SEC on or about March 21, 2002, which was signed by defendants, Gilmartin, Lewent and Henriques, among others, and, which stated, in pertinent part, the following:

The Company also noted that a number of federal and state lawsuits, involving individual claims as well as purported class actions, have been filed against the Company with respect to Vioxx. Some of the lawsuits also name as defendants Pfizer Inc. and Pharmacia, which market a competing product. The lawsuits include allegations regarding gastrointestinal bleeding and cardiovascular events. The Company believes that these lawsuits are completely without merit and will vigorously defend them.

61. On April 18, 2002, Merck issued a press release announcing its financial results for the first quarter of 2002, the period ending March 31, 2002. For the quarter, defendants reported revenues of \$12.2 billion, as compared with revenues of \$11.3 billion in the same quarter of the prior year. The press release also discussed Merck's previously-announced filing of a registration statement with the SEC for an initial public offering of Merck-Medco.

Defendant, Gilmartin, commented on this development, stating, in pertinent part, as follows:

The separation of Merck-Medco will allow Merck to focus more fully on its priorities of turning cutting-edge science into breakthrough medicines and supporting them through targeted and well executed marketing With the continued growth of our five key franchises - ZOCOR, Vioxx, COZAAR/HYZAAR, FOSAMAX and SINGULAIR - along with our plans to file or launch 11 new medicines by 2006, we expect the core pharmaceutical business to deliver doubledigit earnings per share growth in 2003 and top-tier performance over the longer term.

62. Merck's financial results for the first quarter of 2002, the period ending March 31, 2002, were repeated in the Company's Report on Form 10-Q filed with the SEC on or about May

13, 2002, which was signed by defendants, Frazier and Henriques, and which stated, in pertinent part, the following:

Vioxx the Company's second-largest-selling medicine, continues to gain acceptance among physicians and patients worldwide. Global sales for the quarter were \$650 million. *In April 2002, Merck announced that the FDA has approved changes to the prescribing information for Vioxx, under the gastrointestinal (GI) warning section, to include results from the landmark Vioxx Gastrointestinal Outcomes Research (VIGOR) study. The FDA also approved Vioxx 25 mg for the relief of the signs of rheumatoid arthritis in adults. Vioxx is now the first and only medicine that selectively inhibits the COX-2 enzyme that is proven to reduce the risk of developing clinically important GI side effects in patients with or without the risk factors for such GI side effects compared to the nonsteroidal anti-inflammatory drug (NSAID) naproxen. In this study, the number of patients with serious cardiovascular thrombotic events in the group treated with Vioxx 50 mg was higher than in the group taking naproxen. In a placebo-controlled database derived from two other studies, the number of patients with serious cardiovascular thrombotic events among those receiving Vioxx 25 mg was 21 compared to 35 for patients taking placebo. In these two-placebo controlled studies, mortality due to cardiovascular thrombotic events was eight versus three for Vioxx versus placebo, respectively. These data also are reflected in the prescribing information. The significance of the cardiovascular findings from these three studies (VIGOR and the placebo-controlled studies) is unknown.*

In addition, new data presented at the American Academy of Pain Management meeting in the first quarter showed a single dose of Vioxx 50 mg provided superior pain relief over six hours compared to the narcotic oxycodone 5 mg/acetaminophen 325 mg in patients with moderate to severe pain following dental surgery. Vioxx remains the only medicine that selectively inhibits COX-2 to offer once-daily 24-hour relief for osteoarthritis, rheumatoid arthritis, and acute pain. [Emphasis added.]

63. Merck's financial results for the second quarter of 2002, the period ending June 30, 2002, were repeated in the Company's Report on Form 10-Q filed with the SEC on or about August 13, 2002, which was signed by defendants, Frazier and Henriques, and which stated, in pertinent part, the following:

Global sales of `Vioxx`, the Company's second-largest selling medicine, were \$845 million this quarter, an increase of 17% over the 2001 second quarter. On a year-to-date basis, `Vioxx` sales totaled \$1.5 billion, an increase of 24% over the first half of 2001. Wholesaler buying patterns favorably impacted second quarter and year-to-date sales by approximately \$155 billion and \$115 million, respectively. ***In April, the FDA approved changes to the prescribing information to include results from the landmark `Vioxx` Gastrointestinal Outcomes Research (VIGOR) study and a new indication with `Vioxx` 25 mg. for the relief of the signs and symptoms of rheumatoid arthritis in adults. `Vioxx` now is the only COX-2 specific inhibitor with a label demonstrating the proven risk reductions in clinically important gastrointestinal events compared to the non-steroidal anti-inflammatory drug (NSAID) naproxen and the only COX-2 specific inhibitor to offer once-daily 24-hour relief for osteoarthritis, rheumatoid arthritis and acute pain.*** [Emphasis added.]

64. Merck's financial results for the third quarter of 2002, the period ending September 30, 2002, were repeated in the Company's Report on Form 10-Q filed with the SEC on or about November 13" 2002, which was signed by defendants, Frazier and Henriques, and which stated, in pertinent part, the following:

Vioxx, the Company's second-largest selling medicine, achieved \$755 million in worldwide sales in the third quarter, an increase of 3% over the 2001 third quarter. On a year-to-date basis, Vioxx sales totaled \$2.1 billion, an increase of 17% over the first nine months of 2001. While wholesaler buying patterns favorably impacted third quarter and year-to-date sales by approximately \$133 million and \$238 million, respectively, the Company expects that wholesaler buying patterns will have an unfavorable impact in the fourth quarter. Full-year 2002 sales of "Vioxx" and "Arcoxia", which is discussed below, are expected to approximate \$2.6 to \$2.8 billion. Gastrointestinal (GI) safety remains an important consideration when physicians are choosing a medication for the treatment of arthritis. ***Since the GI outcomes data from the landmark 8,000-patient Vioxx Gastrointestinal Outcomes Research (VIGOR) study were added to the labeling for Vioxx, the number of key managed care accounts with Vioxx in an advantaged position among coxibs continues to grow. More than 20 million people now have exclusive or preferred access to Vioxx through their managed care plans.*** [Emphasis added.]

In acute dental pain studies, Vioxx has demonstrated superior efficacy to codeine 60 mg with acetaminophen 600 mg as well as oxycodone 5 mg with acetaminophen 325 mg. Outside the United States, Vioxx maintains its leadership position as the most widely prescribed COX-2 inhibitor in Latin America, Canada and Europe, where it is the coxib with the broadest range of indications, including acute pain.

65. Merck's financial results for the Annual Report of 2002 were repeated in the Company's Report on Form 10-Q filed with the SEC on or about March 21, 2003, which was signed by defendants, Frazier and Henriques, and which stated, in pertinent part, the following:

Vioxx, Merck's once-a-day coxib, remains the largest and most prescribed arthritis pain medication across many markets worldwide, including Europe, Canada and Latin America. For the year, Vioxx sales grew 8% over 2001, achieving \$2.5 billion in sales. Excluding the estimated impact of wholesaler buying patterns, the year-on-year growth of Vioxx approximated 1%. In 2003, worldwide sales of coxibs, Vioxx and Arcoxia, are expected to approximate \$2.6 billion to \$2.8 billion.

Pain relief and gastrointestinal (GI) safety remain important considerations when physicians are choosing a medication for the treatment of arthritis. ***Since the GI outcomes data from the landmark 8,000-patient Vioxx Gastrointestinal Outcomes Research (VIGOR) study were added to the labeling for Vioxx, the number of key managed care accounts with Vioxx in an advantaged position among coxibs continues to grow. More than 35 million people now have exclusive or preferred access to Vioxx through their managed care plans.***

An updated analysis combining data from 20 clinical trials of more than 17,000 arthritis patients was presented at the American College of Rheumatology in the fourth quarter of 2002 and underscores the proven GI safety profile of Vioxx. This new data showed that Vioxx significantly reduced by 62 percent the incidence of confirmed upper-GI perforations, ulcers and bleeds compared to four widely used non-selective non-steroidal antiinflammatory drugs (NSAIDs). The analysis is consistent with the significant reduction of clinically important GI events versus naproxen seen in the VIGOR study.

Also in clinical studies in acute pain, Vioxx has demonstrated superior efficacy to codeine 60 mg with acetaminophen 600 mg as well as oxycodone 5 mg with acetaminophen 325 mg.

... A number of federal and state lawsuits, involving individual claims as well as purported class actions, have been filed against the Company with respect to Vioxx. Some of the lawsuits also name as defendants Pfizer Inc. and Pharmacia, which market a competing product. The lawsuits include allegations regarding gastrointestinal bleeding and cardiovascular events. The Company believes that these lawsuits are completely without merit and will vigorously defend against them. [Emphasis added.]

66. Merck's financial results for the first quarter of 2003, the period ending March 31, 2003, were repeated in the Company's Report on Form 10-Q filed with the SEC on or about May 14, 2003, which was signed by defendants, Frazier and Henriques, and which stated, in pertinent part, the following:

Merck's once-a-day coxib, Vioxx, has been launched in 77 countries worldwide. In the United States, Vioxx is the most widely prescribed and frequently preferred coxib on managed care formularies. Vioxx is the leading coxib outside the United States. Global sales for the quarter were \$527 million, 12% lower than the first quarter of 2002. Wholesaler buying patterns unfavorably impacted the quarter by approximately \$70 million. In 2003, worldwide sales of coxibs, "Vioxx" and "Arcoxia", which is discussed below, are expected to approximate \$2.6 to \$2.8 billion.

67. Merck's financial results for the second quarter of 2003, the period ending June 30, 2003, were repeated in the Company's Report on Form 10-Q filed with the SEC on or about August 13, 2003, which was signed by defendants, Frazier and Henriques, and which stated, in pertinent part, the following:

Worldwide sales of Merck's first once-a-day coxib, Vioxx, were \$801 million during the second quarter, representing a 1 % increase compared to the 2002 same period. In the United States, Vioxx is the most widely prescribed and frequently preferred coxib on managed care formularies. Vioxx is also the leading coxib outside the United States. Mail-order-adjusted prescription levels in the United States for Vioxx decreased by approximately 7 percent for the quarter. In June, the Company increased the price of Vioxx in the United States. In the aggregate, estimated wholesaler buy-in for Vioxx had a favorable impact of \$160 million for the quarter. This is expected to have an unfavorable

impact on wholesaler purchases for Vioxx in the remaining quarters of 2003. Estimated wholesaler inventory levels for

Vioxx remained within a range customary for Merck products. In 2003, worldwide sales of coxibs, "Vioxx" and "Arcoxia", which is discussed below, are expected to approximate \$2.5 to \$2.7 billion.

Data presented at the 55th Annual Scientific Meeting of the American Academy of Neurology in April profiled research results for Vioxx in the treatment of acute migraine headaches. Vioxx 25 mg once daily and 50 mg once daily relieved acute migraine pain within two hours and reduced certain symptoms associated with migraine headaches of moderate to severe intensity. Vioxx was well tolerated compared to placebo in this 557-patient study.

68. The statements referenced above in paragraphs 33-37, 40-54, 57-67 were each materially false and misleading when made because they failed to disclose and/or misrepresented the following adverse facts, among others: (i) that defendants' claims that Vioxx was superior to other pain relieving drugs, including Celebrex, was untrue when made; (ii) that Vioxx's safety profile was inaccurate; (iv) that defendants' campaign to sell Vioxx, upon which commercial success of the product was dependent, included materially false and misleading statement about the cardiovascular events of taking Vioxx; (v) that the FDA had twice issued a warning letter to defendants concluding that its promotional materials were false and misleading, lacking in fair balance, and unsubstantiated; (vi) that the risk of risk of cardiovascular events increased significantly among patients taking Vioxx compared to those who took Celebrex or nothing at all; and (vii) that medical studies, including studies sponsored by Merck, demonstrated safety concerns with Vioxx and/or evidence of lack of efficacy.

THE TRUTH IS REVEALED

69. On October 22, 2003, minutes before the market closed, an article published on *Reuters* entitled "Merck to Cut 4,400 Jobs, Posts Flat Earnings", confirmed the potentially serious cardiovascular side-effects of taking Vioxx, reporting, in relevant part, as follows:

Merck & Co. Inc. said on Wednesday it would cut 4,400 jobs and reported disappointing earnings, *hurt by falling sales of arthritis medicine Vioxx and a paucity of profitable new drugs. . . Sales of Vioxx fell 32 percent in the period to \$510 million. The arthritis drug is suffering from clinical trial data suggesting it might slightly raise the risk of heart attacks, and the growing perception that its pain-fighting capabilities are no better than traditional painkillers.* [Emphasis added.]

70. On October 30, 2003, *The Wall Street Journal* published an article explaining the adverse clinical data from a Vioxx study. The article, entitled "Vioxx Study Sees Heart-Attack Risk", revealed that a Merck- funded study at Harvard University-affiliated Brigham and Women's Hospital in Boston found an increased risk of acute myocardial infarction compared with patients taking a competing drug, Celebrex, which is manufactured by Pfizer, as well as an increased risk in those who were taking Vioxx compared with those who were not taking any painkillers. The article stated, in relevant part, as follows:

Brigham & Women's Hospital rheumatologist and epidemiologist Daniel H. Solomon headed the study, which looked at records of 54,475 Medicare patients, all of them over 65.

Researchers found that the apparent cardiac risk was greatest in the first 90 days in which a patient is taking Vioxx, which generically is known as rofecoxib. In the first 30 days, the researchers found, Vioxx was linked to a 39% increased heart-attack risk compared with Celebrex. Between 30 and 90 days, that increased relative risk was 37%. . .

* * *

Eric J. Topol, chairman of cardiovascular medicine at the Cleveland Clinic and one of the authors who first raised the issue two years ago, called the research "the best study to date."

* * *

The new study, Dr. Topol said, "greatly substantiates our concerns about the cardiac side effects." He observed that the possible cardiac effects of Vioxx appear "worse with the higher doses." [Emphasis added.]

71. On the same day, *The Wall Street Journal* published an article entitled, "Merck's Slide May Dislodge Company's CEO" which stated, in relevant part, as follows:

Last week, the usually low-profile chief executive [Defendant Gilmartin] began to exhibit a sense of urgency. He announced he was laying off 5% of Merck's 63,000 employees and tried to reach out to investors, answering questions on a quarterly earnings conference call and appearing on CNBC. But that didn't stop the company's stock price from falling 6.5% on the day of the announcement.

Ms. Ryan, the Deutsche Bank analyst, wonders why he kept repeating a forecast for double-digit profit growth this year until abandoning it last week. 'You'd have to be crazy at this point to believe their guidance,' she said. Merck's 2003 net income is expected to fall for the second straight year. [Emphasis added.]

ADDITIONAL SCIENTER ALLEGATIONS

72. As alleged herein, defendants acted with scienter in that defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, defendants, by virtue of their receipt of information reflecting the true facts regarding Merck, their control over, and/or receipt and/or modification of Merck's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Merck, participated in the fraudulent scheme alleged herein. Additionally, during the Class Period, Merck insiders, including the Individual Defendants, unjustly benefited from their positions with the Company and their receipt of material inside information by engaging in a massive insider selling campaign of over **3.9 million** shares of their holdings of Merck securities, reaping over **\$175.6 million** in proceeds. The total shares sold by Merck insiders and the

proceeds of the sales during the Class Period are set forth in the list of Insider Sales annexed hereto.

**APPLICABILITY OF PRESUMPTION OF RELIANCE:
FRAUD-ON-THE-MARKET DOCTRINE**

73. At all relevant times, the market for Merck's securities was an efficient market for the following reasons, among others:

(a) Merck's stock met the requirements for listing, and was listed and actively traded on the NYSE, a highly efficient and automated market;

(b) As a regulated issuer, Merck filed periodic public reports with the SEC and the NYSE;

(c) Merck regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) Merck was followed by several securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

74. As a result of the foregoing, the market for Merck's securities promptly digested current information regarding Merck from all publicly available sources and reflected such information in Merck's stock price. Under these circumstances, all purchasers of Merck's securities during the Class Period suffered similar injury through their purchase of Merck's securities at artificially inflated prices and a presumption of reliance applies.

NO SAFE HARBOR

75. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this complaint. Many of the specific statements pleaded herein were not identified as “forward-looking statements” when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Merck who knew that those statements were false when made.

FIRST CLAIM

Violation Of Section 10(b) Of The Exchange Act Against And Rule 10b-5 Promulgated Thereunder Against All Defendants

76. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

77. During the Class Period, Merck and the Individual Defendants, and each of them, carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Merck’s securities; and (iii) cause plaintiff and other members of the Class to purchase Merck’s securities at artificially

inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

78. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Merck's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

79. In addition to the duties of full disclosure imposed on defendants as a result of their making of affirmative statements and reports, or participation in the making of affirmative statements and reports to the investing public, defendants had a duty to promptly disseminate truthful information that would be material to investors in compliance with the integrated disclosure provisions of the SEC as embodied in SEC Regulation S-X (17 C.F.R. Sections 210.01 et seq.) and Regulation S-K (17 C.F.R. Sections 229.10 et seq.) and other SEC regulations, including accurate and truthful information with respect to the Company's operations, financial condition and earnings so that the market price of the Company's securities would be based on truthful, complete and accurate information.

80. Merck and the Individual Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, operations and future prospects of Merck as specified herein.

81. These defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Merck's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about Merck and its business operations and future prospects in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of Merck's securities during the Class Period.

82. Each of the Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of his responsibilities and activities as a senior officer and/or director of the Company was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of and had access to other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

83. The defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Merck's operating condition and future business prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by defendants' overstatements and misstatements of the Company's business, operations and earnings throughout the Class Period, defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

84. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Merck's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of Merck's publicly-traded securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by defendants, or upon the integrity of the market in which the securities trade, and/or on the absence of material adverse information that was known to or recklessly disregarded by defendants but not disclosed in public statements by defendants during the Class Period, plaintiff and the other members of the Class acquired Merck securities during the Class Period at artificially high prices and were damaged thereby.

85. At the time of said misrepresentations and omissions, plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had plaintiff and the other members of the Class and the marketplace known of the true financial condition and

business prospects of Merck, which were not disclosed by defendants, plaintiff and other members of the Class would not have purchased or otherwise acquired their Merck securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

86. By virtue of the foregoing, defendants have violated Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

87. As a direct and proximate result of defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

SECOND CLAIM

Violation Of Section 20(a) Of The Exchange Act Against The Individual Defendants

88. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

89. The Individual Defendants acted as controlling persons of Merck within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which plaintiff contends are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by plaintiff to be misleading prior to and/or shortly after

these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

90. In particular, each of these defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

91. As set forth above, Merck and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of defendants' wrongful conduct, plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

WHEREFORE, plaintiff prays for relief and judgment, as follows:

- (A) Determining that this action is a proper class action and appointing plaintiff as Lead Plaintiff and his counsel as Lead Counsel for the Class and certifying her as class representatives under Rule 23 of the Federal Rules of Civil Procedure;
- (B) Awarding compensatory damages in favor of plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;
- (C) Awarding plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(D) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: January 16, 2004

**KAHN GAUTHIER LAW
GROUP, LLC**

By: _____
Lewis Kahn (Bar Roll # 23805)
Rebecca Matthews (Bar Roll
#28387)
One Galleria Boulevard, Suite 1726
Metairie, LA 70001
(504) 455-1400

**MILBERG WEISS BERSHAD
HYNES & LERACH LLP**

Steven G. Schulman
Peter E. Seidman
Sharon M. Lee
One Pennsylvania Plaza
New York, NY 10119-0165
(212) 594-5300

**LAW OFFICE OF
ALFRED G. YATES JR., P.C.**

Alfred G. Yates Jr.
Gerald L. Rutledge
429 Forbes Avenue
519 Allegheny Building
Pittsburgh, Pennsylvania 15219
(412) 391-5164

Attorneys for Plaintiff