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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**LOREN ARNOFF, Individually And On
Behalf Of All Others Similarly Situated,**

Plaintiff,

v.

**MERCK & CO., INC., RICHARD V.
GILMARTIN, KENNETH C. FRAZIER,
AND RICHARD C. HENRIQUES,**

Defendants.

CIVIL ACTION NO.

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

JURY TRIAL DEMANDED

Plaintiff, individually and on behalf of all others similarly situated, by her undersigned attorneys, for her Complaint against defendants, alleges based upon, *inter alia*, the investigation conducted by and through her attorneys, which included, among other things, a review of the defendants' public documents, conference calls and announcements, Securities and Exchange Commission ("SEC") filings, news articles, wires and press releases regarding defendant Merck & Co., Inc. ("Merck" or the "Company"), medical journals, information available on the Internet, including information on the U.S. Food & Drug Administration ("FDA") web site, FDA regulations and guidelines, and her attorneys' knowledge of FDA regulatory procedures, as follows:

NATURE OF THE ACTION

1. This is a federal class action on behalf of the purchasers of Merck securities, including its common stock, between October 30, 2003 and September 29, 2004, inclusive (the "Class Period"), seeking to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act").

2. On September 30, 2004, Merck announced that it was pulling its blockbuster arthritis drug, Vioxx, from the worldwide market because clinical trials found an increased risk of heart attack and stroke among patients who ingested the drug. According to the Company, clinical data demonstrated that patients suffered an increased risk of heart attack and other cardiovascular complications approximately eighteen months after they started taking Vioxx. The data stems from a three-year study allegedly aimed at demonstrating that Vioxx, at a 25 milligram dose, prevents the recurrence of polyps in the colon and rectum. The Company announced that the trial was stopped after Company researchers discovered a higher incidence of heart attack risk compared to patients taking placebo.

3. Vioxx has been surrounded by controversy since its introduction, as several studies have indicated that it increased the risk of heart attack. Beginning in 2001, doctors at the Cleveland Clinic published a study in the Journal of the American Medical Association that re-analyzed then-existent data and concluded that Vioxx presented a potential heart attack risk.

4. To counter clinicians' criticism and the growing body of empirical evidence demonstrating that Vioxx presented cardiac risks, the Company engaged a massive public relations campaign both to hide information regarding the seriousness of Vioxx's adverse side-effects, including a significantly increased risk of heart attack, and to falsely portray the drug as possessing an adequate safety profile.

5. As detailed below, defendants have known for several years that Vioxx presented serious public health concerns. Defendants, however, employed extraordinary measures to keep Vioxx on the market. Indeed, defendants, aware that Vioxx presented serious health risks, continued to tout its efficacy and safety, dismissed clinical criticism of the drug, and sought and obtained approval to market Vioxx during the Class Period to treat juvenile arthritis and migraine headaches.

6. On September 30, 2004, Defendants could no longer hide the truth from patients, investors, and the FDA. The Company announced that it was voluntarily withdrawing Vioxx from world markets. Shockingly, this news came only one month after the Company issued a strongly worded press release refuting reputable clinicians' criticisms of Vioxx and its safety profile.

7. In addition to shocking millions of people who were misled and used Vioxx despite these serious risks, the above announcement caused the Company's common stock to plummet during September 30, 2004 trading by approximately 25%, or \$12 per share. The resulting market capitalization loss was a staggering \$26 billion.

JURISDICTION AND VENUE

8. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a) and the rules and regulations promulgated thereunder by the SEC, including Rule 10b-5, 17 C.F.R. § 240.10b-5.

9. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1331.

10. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391(b). Many of the acts and transactions constituting the violations of the

law alleged herein, including the preparation and dissemination to the investing public of false and misleading information, occurred in substantial part in this Judicial District. In addition, Merck maintains its principal place of business within this Judicial District.

11. In connection with the acts, transactions and conduct alleged herein, defendants, directly and indirectly, used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications and the facilities of the national securities exchanges.

THE PARTIES

12. Plaintiff purchased Merck securities during the Class Period at a value that was artificially inflated by defendants' misconduct and has suffered substantial economic damages as a result of defendants' admission that Vioxx's serious safety issues required that it be withdrawn from worldwide markets.

13. Defendant Merck is a global pharmaceutical company that discovers, develops, manufacturers, and markets a broad range of human and animal health products. Merck's products include Vioxx for arthritis, Zocor for the treatment of elevated cholesterol, Propecia for male pattern hair loss, and Cozaar for hypertension. As of September 30, 2004, the Company had approximately 2.2 billion shares outstanding that traded on the New York Stock Exchange. Merck is located at One Merck Drive, P.O. Box 100, Whitehouse Station, Hunterdon County, New Jersey 08889.

14. Defendant Richard V. Gilmartin is the Company's Chairman, President and Chief Executive Officer.

15. Defendant Kenneth C. Frazier is Merck's Senior Vice President and General Counsel since December 1999.

16. Defendant Richard C. Henriques is Merck's Senior Vice President and Controller.

17. Defendants Gilmartin, Frazier, and Henriques are collectively referred to as the "Individual Defendants."

18. (a) The Individual Defendants identified above served, at all times material to the claims set forth herein, as senior officers and/or directors of Merck in the positions set forth above."

(b) Because of the Individual Defendants' positions with the Company, they had access to adverse, undisclosed information about its business operations, operational trends, finances, markets, and present and future business prospects via access to internal corporate documents (including the results of clinical tests of Vioxx), 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.

(c) The Company is operated as one business and is comprehensively managed by a single management team that reports to the Chief Executive Officer.

19. 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, growth, finances, and financial condition, as alleged herein. Said defendants were involved in the drafting, producing, reviewing and/or disseminating of the false and misleading statements and information alleged herein, were aware, or recklessly disregarded, that the false and misleading statements were being issued regarding Vioxx, and approved or ratified these statements in violation of the federal securities laws.

20. As officers and controlling persons of a publicly-held company whose securities were, and are, registered with the SEC pursuant to the Exchange Act, traded on the NYSE, and governed by the provisions of the federal securities laws, the Individual Defendants each had a duty to promptly disseminate accurate and truthful information with respect to the Company's financial condition and performance, growth, operations, business, markets, management, and earnings, 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.

21. In addition to making the materially misleading oral representations set forth herein, the Individual Defendants participated in the drafting, preparation, and/or approval of the various public shareholder and investor reports and the making of the 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. As a result of their executive and managerial positions with Merck, each of the Individual Defendants had access to the adverse undisclosed information about Merck's communications with the FDA and the safety of Vioxx as particularized herein and knew (or recklessly disregarded) that these adverse facts rendered the positive representations made by or about Merck and Vioxx issued or adopted by the Company, materially false and misleading.

22. The Individual Defendants, because of their positions of control and authority as officers 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.

23. 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 all persons and entities that purchased Merck securities between October 30, 2003 and September 30, 2004, by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme: (i) deceived plaintiff and the investing public regarding the intrinsic value of Merck's securities; and (ii) caused plaintiff and other members of the Class (defined below) to purchase Merck securities at artificially inflated prices.

CLASS ACTION ALLEGATIONS

24. Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3) on behalf of a class of all persons who purchased Merck common stock between October 30, 2003 and September 29, 2004, inclusive, (the "Class") and who were damaged thereby. Excluded from the Class are the defendants named herein, members of the immediate family of each of the Individual Defendants, any parent, subsidiary, affiliate, officer, director or employee of defendant Merck, any entity in which any excluded person has a controlling interest, and the legal representatives, heirs, successors and assigns of any excluded person.

25. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to plaintiff at the present time and can only be ascertained from books and records maintained by Merck and/or its

agent(s), plaintiff believes that there are thousands of members of the Class located throughout the United States.

26. Plaintiff will fairly and adequately represent and protect the interests of the members of the Class. Plaintiff has retained competent counsel experienced in class and securities litigation and intends to prosecute this action vigorously. Plaintiff is a member of the Class and does not have interests antagonistic to, or in conflict with, the other members of the Class.

27. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class purchased Merck securities at artificially inflated prices and have sustained damages arising out of the same wrongful course of conduct.

28. 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 and omissions as alleged herein;

(b) Whether defendants participated in and pursued the common course of conduct and fraudulent scheme complained of herein;

(c) Whether the documents, reports, filings, releases and statements disseminated to the investing public, including investors in Merck stock during the Class Period, omitted and/or misrepresented material facts about the safety of Merck's blockbuster drug, Vioxx;

(d) Whether defendants acted knowingly or recklessly in omitting to state and/or misrepresenting material facts;

(e) Whether the market price of Merck securities during the Class Period was artificially inflated due to the non-disclosures and/or misrepresentations complained of herein; and

(f) Whether plaintiff and the other members of the Class have sustained damages and, if so, the appropriate measure thereof.

29. A class action is superior to other available methods for the fair and efficient adjudication of this controversy since, among other things, joinder of all members of the Class is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it virtually impossible for Class members individually to seek redress for the wrongful conduct alleged. Plaintiff does not foresee any difficulty in the management of this litigation that would preclude its maintenance as a class action.

30. Notice can be provided by a combination of published notice and first class mail using techniques and forms of notice similar to those customarily used in class actions arising under the federal securities laws.

FRAUD-ON-THE MARKET ALLEGATIONS

31. Plaintiff and the Class also rely on the fraud-on-the-market doctrine, which assumes the existence of an efficient market for Merck common stock. This doctrine is premised on the fact that brokers and investors nationwide have immediate access to press releases and trading information about Merck through computer and newswire systems. These systems display, within minutes of the release or transaction taking place, pertinent information and the most recent trades and prices.

**APPLICABILITY OF FRAUD ON THE MARKET
DOCTRINE AND THE PRESUMPTION OF RELIANCE**

32. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

- (a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- (b) The omissions and misrepresentations were material;
- (c) Merck's securities traded in efficient markets;
- (d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of Merck's securities; and
- (e) Plaintiff and the other members of the Class purchased Merck securities between the time defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

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

- (a) Merck common stock met the requirements for listing, and was listed and actively traded on the NYSE, a highly efficient market;
- (b) Merck common stock traded at a high average weekly volume during the Class Period;
- (c) As a regulated issuer, Merck filed periodic public reports with the SEC and the New York Stock Exchange;
- (d) Merck was followed by numerous securities analysts employed by major brokerage firms who wrote reports that 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; and

(e) Merck regularly issued press releases which were carried by national newswires. Each of these releases was publicly available and entered the public marketplace.

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

NO STATUTORY SAFE HARBOR

35. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the false or misleading statements pleaded in this Complaint because the statements pleaded herein were either not identified as "forward-looking statements" when made and/or did not refer to meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the statements accompanying those statements. In addition, defendants are liable for these false forward-looking statements that were identified as such, because at the time each of those statements were made, the speaker actually knew the forward-looking statement was false and/or misleading and the statement was authorized and/or approved by an executive officer of the Company, who actually knew those statements were false and/or misleading.

BACKGROUND FACTS

36. Vioxx is a member of a class of pain-killing compounds known as COX-2 inhibitors. The compound blocks an enzyme that causes pain, but does not allegedly interfere with COX-1, which protects the stomach's lining. The first COX-2 inhibitor was Pfizer's

Celebrex, launched in 1998 and is still the largest selling COX-2 inhibitor. Vioxx, however, boasts nearly 2 million patients and nearly 84 million have used it since its approval. Vioxx accounted for \$2.5 billion in sales in 2003.

37. In May 1999, after obtaining approval from the FDA to use Vioxx in treating adults with primary dysmenorrhea, managing acute pain, and relieving symptoms associated with osteoarthritis, Merck commenced an aggressive marketing campaign to market Vioxx to health professionals.

38. This marketing campaign, however, contained false and misleading statements concerning the safety profile of Vioxx and its superiority to Celebrex.

39. The Company also failed to disclose material information concerning the number of side-effects associated with Vioxx and their severity, including an increased risk of heart attack observed among Vioxx users.

40. The Company's efforts to deceive the public with respect to the safety profile of Vioxx continued through October 22, 2003, with the release of its third quarter 2003 results and the Company's announcement that it was cutting 4,400 jobs.

41. According to an article published by *Reuters*, entitled "Merck to Cut 4,400 Jobs, Posts Flat Earnings", sales of Vioxx were hurt due to the increased risk of heart attack, and the growing realization that Vioxx did not demonstrate greater efficacy than other drugs on the market:

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)

42. The following day, October 23, 2003, the price of Merck's stock declined, trading as low as \$44.85 per share, or more than \$2.05 lower than its previous trading day high, to close at \$45.10.

43. Given these disclosures and the concomitant decline in the Company's stock price, a series of securities class actions was filed against the Company, defendant Gilmartin and other officers and directors of the Company. These actions were consolidated under the caption *Pringle v. Merck & Co., Inc., et al.*, and are pending in the United States District Court for the Eastern District of Louisiana, Case No. 03-3125. That consolidated action alleges a class action on behalf of Merck shareholders who bought Merck stock between May 21, 1999 and October 22, 2003.

44. Following the October 22, 2003 disclosures that gave rise to the *Pringle* litigation, the Company and defendant Gilmartin set upon a new course of malfeasance designed to rehabilitate the Company's reputation, assuage concerns revealed in the *Reuter's* article indicating that Vioxx was unsafe and failed to demonstrate substantial efficacy when compared to traditional painkillers, and to secure FDA approval to market Vioxx for additional medical indications.

45. Defendants were also highly motivated to keep Vioxx on the market and obtain approval to treat new medical indications because Zocor, -- the Company's blockbuster cholesterol reduction drug -- is scheduled to lose patent protection in 2006 and sales are expected to plunge against generic competition. In addition, expanding Vioxx's use was critical to the Company because it recently experienced the cancellation of research on four supposedly promising compounds last year, including late-stage tests on drugs for the treatment of diabetes and depression. Moreover, the Company has come under substantial pressure from Wall Street

and institutional investors for moving too slowly to improve the Company's pipeline through licensing arrangements.

The Class Period Begins

46. Against this backdrop, the Class Period begins on October 30, 2003, with an article published in *The Wall Street Journal* entitled, "Vioxx Study Sees Heart Attack Risk – Merck Funded Research After Concerns Were Raised About Its Painkilling Drug". According to

The Wall Street Journal:

The study, from Harvard University-affiliated Brigham & Women's Hospital in Boston and funded by Merck, found an increased risk of heart attack, or acute myocardial infarction, compared with patients taking a competing painkiller, Celebrex, from Pfizer Inc. The researchers also found Vioxx, which has annual sales of \$2.5 billion a year, was linked to an increased heart-attack risk compared with patients not taking any painkillers.

* * *

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%. After 90 days, there didn't appear to be any increased risk.

47. The Company immediately moved to counter the data generated by the study and to discount its conclusions. For example, as quoted in an article in *American Health Line* on October 31, 2003, Alise Reicin, Merck's executive director of clinical research stated:

Randomized clinical trials are the gold standard [and this isn't such a trial]. ... In our placebo-controlled randomized trials, we have found no significant difference between Vioxx and placebo.

48. Defendants' efforts were successful, as evidenced by the fact that the Company's common stock fell only approximately \$1, from \$44.92 on October 29, 2003 to \$43.94 on

October 30, 2003, and rallied on October 31, 2003 to close at \$44.25, reaching as high as \$44.96 on November 3, 2003.

49. On November 13, 2003, the Company filed its second quarter 2003 report on Form 10-Q with the SEC. The report was signed by defendants Frazier and Henriques.

50. The report contained several false and misleading statements and material omissions. First, concerning the earlier filed litigation pending in federal court in Louisiana, and other jurisdictions, the Company characterized the claims as “without merit,” though the Company was proceeding with several trials and other investigations concerning Vioxx and its safety profile which defendants knew was inadequate. Second, the Company touted Vioxx as the “most-widely prescribed and frequently preferred coxib on managed care formularies. . . [with] [m]ore than 85 million prescriptions. . .” – even though defendants knew, despite its alleged commercial success, that Vioxx was plagued with safety issues and its alleged preferential status would be lost once clinicians became aware that Vioxx was associated with serious cardiac incidents.

51. On December 9, 2003, the Company issued a press release over the *Business Wire* entitled “Merck Strategy To Deliver Long-Term Shareholder Value.” In the section entitled “Maximizing In-Line Franchises,” the Company stated that “each of its current products ranks either No. 1 or No. 2 in sales across large therapeutic areas.” With regard to Vioxx, the Company touted its pending NDAs for novel indications, absent any mention of the safety profile issues dogging the drug:

In terms of sales, Vioxx holds the No. 2 position in the competitive U.S. coxib market and is the No. 1 coxib in the European market. Merck has filed sNDAs with the FDA for an indication for migraine and juvenile rheumatoid arthritis. If approved, these uses are expected to enhance the efficacy profile of this product.

52. On January 27, 2004, the Company announced full-year 2003 earnings and fourth-quarter 2003 results.

Global sales of Vioxx, Merck's first once-a-day coxib, reached \$731 million for the fourth quarter and \$2.5 billion for the year. Full-year 2003 sales represented a 2% increase over 2002. U.S. mail-order-adjusted prescription levels for Vioxx decreased by 5% during the quarter. In the aggregate, estimated wholesaler buy-in for Vioxx had a favorable impact of \$40 million on revenues for the quarter.

Vioxx continues as the most widely available coxib on managed care formularies in the United States. Vioxx is the only coxib in the United States that offers 24-hour pain relief in a once-daily tablet for all indications, with more than 91 million prescriptions written in the United States since its introduction in 1999. Outside the United States, Vioxx is the best-selling arthritis and pain medicine. Supplemental NDAs are under review with the FDA for additional indications for migraine and juvenile rheumatoid arthritis. If approved, these uses are expected to enhance the efficacy profile of this product.

53. This statement was false and misleading and omitted material information because it failed to disclose that while the Company, was pursuing additional approvals for novel indications, the Company was also investigating whether Vioxx caused serious cardiac side-effects, including heart attacks.

54. On February 5, 2004, *Bloomberg News* reported that defendant Gilmartin "Reaps \$35 Million Profit on Options." According to *Bloomberg*, Gilmartin garnered this massive profit by exercising stock options for the first time in his decade as Chairman and Chief Executive Officer.

55. On March 10, 2004, *Bloomberg* reported that Vioxx "may carry risk of heart attack" and that:

Merck & Co.'s Vioxx was linked to a higher risk of heart attack for patients with high blood pressure, according to a study funded by Pfizer Inc. that examined possible risk for an array of painkillers.

Patients taking Vioxx or non-steroidal anti-inflammatory pain drugs called NSAIDS were at greater risk of a heart attack or other complication than those taking Pfizer's Celebrex or no pain medicines at all, researchers said. NSAIDS include drugs like ibuprofen. The risk was higher with Vioxx than any of the NSAID drugs, researchers said.

The findings, while not conclusive, add to research suggesting Vioxx poses a heart risk. Vioxx's label includes results from earlier Merck studies where patients on the drug had more heart complications than those taking other painkillers.

"The message to doctors is to be careful if you're using these drugs in an individual who is being treated for hypertension because if a non-steroidal drug or Vioxx is added, blood pressure may go up and that may result in cardiovascular complications," said Andrew Whelton, an adjunct professor of medicine at Johns Hopkins University, who helped lead the study.

Whelton presented the data at the American College of Cardiology's annual meeting in New Orleans.

The group looked at health claims information from a private insurance network in New England, tracking 34,000 arthritis patients who filled prescriptions for painkiller consistently over the 30 months of the study.

56. Despite these pointed criticisms leveled by experienced clinicians, the Company continued its campaign to falsely promote Vioxx as both safe and effective and to belittle any criticism that would hamper the sale of Vioxx or threaten its approval for the treatment of migraines and juvenile arthritis. Specifically, Merck spokeswoman, Mary-Elizabeth Blake, stated that the Company disagreed with the findings, that the study wasn't designed well, and that Merck was carrying out large clinical trials of Vioxx that would pinpoint the drug's safety profile.

57. On April 4, 2004, the Company announced that the FDA approved Vioxx for the treatment of acute migraines in adults, and that it "is the first and only COX-2 specific inhibitor

approved to relieve migraine pain and associated migraine symptoms.” With respect to potential side effects, the Company misleadingly stated the following:

The most common adverse events occurring in patients taking Vioxx compared to placebo in the single-dose studies were dizziness, nausea, somnolence and dyspepsia. In a three-month extension of one migraine study, the most common adverse events among patients taking Vioxx were dizziness, dry mouth, nausea and vomiting.

* * *

Commonly reported side effects in clinical trials with Vioxx have included upper-respiratory infections, diarrhea, nausea and high blood pressure.

58. On April 22, 2004, the Company announced first-quarter 2004 results and again touted Vioxx and its new applications:

Worldwide sales of Vioxx, Merck’s arthritis and pain medicine, reached \$661 million for the first quarter of 2004. U.S. mail-order-adjusted prescription levels for Vioxx decreased by 3% during the quarter. In markets outside of the United States, Vioxx continues to be the best selling arthritis and pain medicine.

On March 26, the FDA approved a supplemental New Drug Application (sNDA) for Vioxx for the acute treatment of migraine attacks with or without aura in adults. Vioxx is the first and only coxib approved to relieve migraine pain and associated migraine symptoms. During the first quarter, the FDA also accepted for filing another sNDA for Vioxx based on studies in juvenile rheumatoid arthritis, and has granted an additional six months of marketing exclusivity in the United States for Vioxx based on that filing. Indications for Vioxx for migraine and juvenile rheumatoid arthritis also are being sought outside of the United States.

59. On May 7, 2004, the Company filed its quarterly report on Form 10-Q with the SEC, signed by defendants Henriques and Frazier. The report stated that sales had reached \$661 million for the first quarter of 2004, a 30% increase over the comparable period.

60. The Company reiterated that it was seeking supplemental approval to market Vioxx to children for the treatment of rheumatoid arthritis.

61. On May 18, 2004, the Company's pattern of deceit continued when it announced that it insisted that one of its epidemiologists – Carolyn C. Cannuscio – be removed from the list of researchers on a study that suggested Vioxx may be linked to heart attacks. According to a May 18, 2004 *Bloomberg* report:

Merck & Co. had ordered the name of one of its epidemiologists removed from the list of authors on a research paper after the study drew negative conclusions about Vioxx, a painkiller made by the Company, the Wall Street Journal said.

Carolyn C. Cannuscio, a Merck epidemiologist, was removed from the list of researchers on study that suggested that in a small percentage of cases, the multibillion-dollar pill Vioxx may be linked to heart attacks, the paper said. The research was originally presented last October at a rheumatology meeting.

Company spokeswoman Mary Elizabeth Blake said New Jersey-based Merck disagreed with the conclusions and didn't think it was appropriate to have a Merck employee's name appear on the study, the Journal said. (*Wall Street Journal* 5-18 Online).

62. On July 22, 2004, the Company released second-quarter 2004 earnings over the *Business Wire*. Concerning Vioxx, the Company touted its approval to treat a number of disorders and that it is the best selling arthritis and medicine in the United States. Despite these extremely positive pronouncements, defendants omitted material information concerning the drug's questionable safety profile and that it was linked to cardiac incidents in patients who used the drug for more than 18 months:

Worldwide sales of VIOXX, Merck's arthritis and pain medicine, were \$653 million for the second quarter and \$1.3 billion for the first six months. U.S. mail-order-adjusted prescription levels for VIOXX decreased by 5 percent during the quarter, as compared to the second quarter of 2003. Following FDA approval for the acute treatment of migraine in late March, VIOXX is now approved for treating more types of painful conditions than any other coxib in the United States and remains the only coxib approved to relieve migraine pain and associated migraine symptoms. Merck continues to seek new uses for VIOXX to extend the clinical benefits of the product to new populations. A supplemental NDA for VIOXX is

under review by the FDA for the treatment of juvenile rheumatoid arthritis. Outside of the United States, VIOXX continues to be the best-selling arthritis and pain medicine. Indications for VIOXX for migraine and juvenile rheumatoid arthritis also are being sought outside of the United States.

63. On August 26, 2004, Merck issued a strongly worded press release over the *Business Wire* refuting a series of criticisms leveled against Vioxx by respected clinicians at the International Medical Meeting:

Merck Stands Behind the Efficacy, Overall Safety and Cardiovascular Safety of Vioxx®.

Merck strongly disagrees with the conclusions of an observational analysis by Graham et al; presented at an international medical meeting (1) this week, which evaluated the rate of cardiovascular events in patients taking COX-2 specific inhibitors Vioxx® (rofecoxib) and Celebrex® (celecoxib) and in patients taking non-selective NSAIDS. This analysis is a retrospective database analysis – not a clinical trial. Observational analyses have limitations, often conflict with each other, and must be interpreted within the context of data from large, randomized, controlled clinical trials. Randomized, controlled clinical trials are the gold standard to evaluate safety and efficacy. It is important to note that, although the analysis was funded by the Food and Drug Administration (FDA) under contract with Kaiser Permanente, the conclusions presented by the authors do not necessarily reflect the views of the FDA.

Vioxx has been extensively studied; more than 24,000 patients have been treated with Vioxx in randomized, controlled clinical trials. Two randomized, placebo-controlled studies (n=2,142) discussed in the labeling for Vioxx showed no significant difference in the rate of serious cardiovascular thrombotic events in patients taking Vioxx vs. placebo. The gastrointestinal (GI) outcomes study known as VIGOR showed a higher incidence of serious cardiovascular thrombotic events in patients receiving Vioxx 50 mg compared to patients treated with naproxen.

“This retrospective analysis is based only on a database review. Observational analyses do not have the rigor of randomized, controlled clinical trials. The robust clinical trial data available support the safety of Vioxx. Based on all of the data that are available from our clinical trials, Merck stands behind the efficacy and safety, including cardiovascular safety, of Vioxx,” said Peter

S. Kim, PhD., President, Merck Research Laboratories. "Nothing is more important to Merck than the safety of our medicines. We believe that the prescribing information for Vioxx accurately and appropriately reflects the efficacy and safety of Vioxx. Merck is also conducting large prospective clinical trials that, when added to the extensive data from clinical trials that are already available, will provide an even more comprehensive picture of the cardiovascular safety profile of Vioxx."

* * *

Merck believes that Vioxx is an appropriate and efficacious therapy for the relief of the signs and symptoms of osteoarthritis (12.5 mg or 2.5 mg once daily) and adult rheumatoid arthritis (25 mg once daily) and for the management of acute pain and primary dysmenorrhea (50 mg daily) and the acute treatment of migraine (25 mg or 50 mg), as outlined in the prescribing information for VIOXX.

64. On September 8, 2004, the Company issued a press release touting its receipt of FDA approval to market Vioxx as a treatment for juvenile rheumatoid arthritis. With respect to the safety profile of Vioxx and the underlying data supporting FDA approval, the Company stated:

The FDA approval of Vioxx for JRA was based on the largest JRA study ever conducted, which included 310 pediatric and adolescent patients aged two to 17 with active pauciarticular or polyarticular JRA. Results from the pivotal 12-week multi-national, double-blind study showed once-daily Vioxx provided measurable improvement in reducing joint symptoms. Improvement was evaluated based on JRA DOI 30 criterion, a core set of standardized criteria to measure arthritis impact. A one-year open-label extension to the pivotal study also was conducted to evaluate the long-term safety of Vioxx.

Vioxx was generally well tolerated among pediatric and adolescent patients in the study. The most commonly reported adverse events in patients taking Vioxx over the 12-week period were upper abdominal pain, nasopharyngitis (viral infection of the upper respiratory passages), diarrhea, upper respiratory tract infection, abdominal pain, headache and rhinitis.

Vioxx is available in tablet and strawberry-flavored liquid formulation for children.

65. The foregoing statements concerning Vioxx, its allegedly sufficient safety profile, that clinicians had unfairly criticized Vioxx, and that the Company's prospects were bright due in part to Vioxx's sales going-forward, were false and misleading for several reasons:

- Defendants promoted Vioxx as possessing an adequate safety profile even though they knew as early as 1999 that the use of Vioxx was associated with serious cardiovascular events, including heart attacks.
- Defendants' statements concerning Vioxx's potential limited "side effects" were false because defendants omitted material information, concerning the known cardiovascular incidents associated with the use of Vioxx - information defendants knew from years of clinical data generated both internally and by third parties demonstrating Vioxx presented serious health risks.
- Defendants engaged a marketing campaign to promote Vioxx, touting its safety profile and superior efficacy, even though they knew or were reckless in not knowing that the Company's own clinical data demonstrated that patients using Vioxx experienced a significantly increased risk of heart attacks.

THE TRUTH IS REVEALED

66. Despite years of denying that Vioxx presented a public health hazard and its use was linked to severe cardiac incidents, on September 30, 2004, the Company finally withdrew Vioxx from world-markets. Coming on the heels of the Company's voluntary withdrawal, the FDA (which had just recently approved Vioxx for the treatment of juvenile rheumatoid arthritis), issued a Public Health Advisory to Vioxx users informing them of Merck's action and that they should consult with their physician about alternative medications. Merck's withdrawal of Vioxx

came after a data safety monitoring board overseeing a long-term study of the drug recommended that the study be halted because of an increased risk of serious cardiovascular events among members of the study group.

67. Specifically, the withdrawal was a function of data generated from a three-year study that demonstrated patients who took Vioxx for more than 18 months faced twice the risk of a heart attack compared with those who took a placebo.

68. News of the withdrawal and that the Company retracted its third-quarter profit forecast and cut its full-year estimate by 50 cents to 60 cents per share, caused the Company's stock to tumble \$12.07 to \$33, a 26% one day decline. The Company's market capitalization also declined by approximately \$26 billion as investors absorbed the news that the Company lost its fourth-biggest product and billions of dollars in future sales.

SCIENTER ALLEGATIONS

69. As alleged herein, defendants acted with scienter in that they: 1) knew or recklessly disregarded that the public documents and statements issued or disseminated by them were materially false and misleading and/or omitted to state material facts necessary to make their statements not misleading; 2) knew or recklessly disregarded that such statements or documents would be issued or disseminated to the investing public; and 3) knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws.

COUNT I

VIOLATION OF SECTION 10(b) OF THE EXCHANGE ACT AND RULE 10b-5 OF THE SECURITIES AND EXCHANGE COMMISSION

70. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

71. This Count is asserted against all defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder.

72. During the Class Period, defendants directly engaged in a common plan, scheme, and unlawful course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices, and courses of business which operated as a fraud and deceit upon plaintiff and the other members of the Class, and made various deceptive and untrue statements of material facts and omitted to state material facts in order to make the statements made, in light of the circumstances under which they were made, not misleading to plaintiff and the other members of the Class. The purpose and effect of said scheme, plan, and unlawful course of conduct was, among other things, to induce Plaintiff and the other members of the Class to purchase Merck securities during the Class Period at artificially inflated prices.

73. During the Class Period, defendants, pursuant to said scheme, plan, and unlawful course of conduct, knowingly and recklessly issued, caused to be issued, and participated in, the preparation and issuance of materially false and misleading statements to the investing public, as particularized above.

74. As a result of the dissemination of the false and misleading statements set forth above, the market prices of Merck securities were artificially inflated during the Class Period. In ignorance of the false and misleading nature of the statements described above and the deceptive and manipulative devices and contrivances employed by said defendants, plaintiff and the other members of the Class relied, to their detriment, on the integrity of the market prices of Merck securities in purchasing those securities. Had Plaintiff and the other members of the Class known the truth, they would not have purchased said securities or would not have purchased them at the inflated prices that were paid.

75. Plaintiff and the other members of the Class have suffered substantial damages as a result of the wrongs alleged herein in an amount to be proved at trial.

76. By reason of the foregoing, defendants directly violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder in that they: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material facts or omitted to state material facts in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class in connection with their purchases of Merck securities during the Class Period.

COUNT II

FOR VIOLATION OF SECTION 20(a) OF THE EXCHANGE ACT (AGAINST THE INDIVIDUAL DEFENDANTS)

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

78. The Individual Defendants acted as controlling persons of the Company within the meaning of Section 20(a) of the Exchange Act, as alleged herein. By virtue of their high-level positions, participation in and/or awareness of the Company's operations, and/or intimate knowledge of the Company's plans and implementation thereof, each 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 that plaintiff contends are false and misleading. Each Individual Defendant was 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 false and misleading prior to and/or shortly after these

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

79. In particular, they had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, are 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.

80. By virtue of his/her position as a controlling person, each of the Individual Defendants is liable pursuant to section 20(a) of the Exchange Act. As a direct and proximate result of the wrongful conduct complained herein, plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's equity securities during the Class Period.

81. WHEREFORE, plaintiff, on her own behalf and on behalf of the Class, prays for judgment as follows:

(a) Declaring this action to be a proper class action and certifying Plaintiff as class representative under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of plaintiff and the other members of the Class against the defendants for the damages sustained as a result of the wrongdoings of the defendants, together with interest thereon;

(c) Awarding Plaintiff the fees and expenses incurred in this action, including reasonable allowance of fees for plaintiff's attorneys and experts;

(d) Granting such other and further relief as the Court may deem just and proper.

PLAINTIFF DEMANDS A TRIAL BY JURY

Dated: October 1, 2004
Chatham Township, New Jersey

By: _____



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