

2. Vioxx and Celebrex are the subject of two of the largest direct-to-consumer marketing campaigns ever undertaken for prescription drugs. For example, in 2000, defendants spent some \$161 million on consumer advertising for Vioxx and \$79 million on consumer advertising for Celebrex. Based on those figures, Vioxx was the single most heavily-advertised prescription drug to consumers, while Celebrex ranked seventh. It appears that consumer marketing of Vioxx and Celebrex has increased significantly over the past two years.

3. Vioxx and Celebrex are most often prescribed to treat osteoarthritis pain. Osteoarthritis occurs frequently as people grow older and is the most common joint disease, afflicting over 21 million Americans. Defendants' consumer marketing campaigns for these drugs have focused on arthritis pain relief. For example, Merck has used 1976 Olympic figure skating champion Dorothy Hammill in widely-broadcast television commercials claiming that Vioxx relieves her arthritis pain.

4. Vioxx and Celebrex are non-steroidal anti-inflammatory drugs (NSAIDs). Scientific research has shown that traditional NSAIDs, which include aspirin, ibuprofen and naproxen (and which defendants' advertising campaigns seeks to replace with Vioxx and Celebrex at a much higher cost) have the effect of inhibiting the body's production of enzymes known as the cox-1 and cox-2 enzymes. The cox-2 enzyme is believed to play a role in causing arthritis pain and inflammation, so that using NSAIDs to suppress its production has the effect of reducing these symptoms. However, because the cox-1 enzyme is believed to have a gastrointestinal protective effect, traditional NSAIDs possess a risk of causing gastrointestinal problems by suppressing cox-1 production as well.

5. Defendants claim that Vioxx and Celebrex affect the cox-1 and cox-2 enzymes somewhat differently from traditional NSAIDs, in that they inhibit the cox-2 enzyme to a greater degree than the cox-1 enzyme. Defendants claim that, as a result of selectively targeting the cox-2 enzyme, these drugs suppress production of cox-1 to a lesser degree than traditional NSAIDs and therefore are safer on the stomach. Defendants have also marketed both drugs as being more effective than alternative NSAIDs that have traditionally been used to treat osteoarthritis pain. Notwithstanding these marketing claims, however, the Food & Drug Administration (“FDA”) has required consumer warnings for Vioxx and Celebrex stating that patients could suffer serious gastrointestinal problems, including potentially fatal internal bleeding, as a result of taking these drugs and has issued Warning Letters to the Defendants concerning their statements regarding the efficacy of Vioxx and Celebrex, statements that defendants’ own clinical trials, among other studies, do not support.

6. In addition, it appears that targeting the cox-2 enzyme for suppression has other dangerous effects. Most significantly, the cox-2 enzyme is known to play a role in preventing blood coagulation. Therefore, the inhibition of the cox-2 enzyme increases the propensity of the blood to clot, potentially leading to severe cardiovascular problems. Indeed, a study by Merck has shown people taking Vioxx suffer a significantly higher risk of cardiovascular events--including hypertension, stroke, and myocardial infarction (heart attack) among others -- than those who take traditional NSAIDs. Celebrex is chemically and pharmacologically equivalent to, and a therapeutic substitute for, Vioxx and has the propensity to produce the same blood clotting effects.

7. This action seeks as a remedy, *inter alia*, that medical monitoring be provided to all class members to provide periodic assessment of the cardiovascular damage caused by the enhanced blood clotting effects of Vioxx and Celebrex. The action also seeks damages incurred by plaintiffs and class members incidental to their procurement, taking and/or switching to Vioxx and Celebrex and seeks disgorgement of defendants' revenues from the sales and marketing of the drugs and restitution to the plaintiffs and class members.

FACTUAL ALLEGATIONS

8. Celebrex was approved by the FDA in early 1999. Celebrex is now Pharmacia's best selling drug. In 2001, 24.5 million prescriptions for Celebrex were filled in the United States, generating sales of \$3.1 billion.

9. Celebrex is marketed by Pharmacia, Pfizer and Searle as a drug that delivers powerful relief of pain and inflammation caused by, among other things, osteoarthritis. Patients who take Celebrex are advised by Pharmacia, Pfizer and Searle, directly and indirectly, including through the patients' own physicians, to continue to take Celebrex daily even when they are no longer in pain.

10. Vioxx was approved by the FDA on May 21, 1999. Vioxx is now Merck's second largest selling drug. In 2001, 23.7 million prescriptions for Vioxx were filled in the United States, and the drug's sales totaled \$2.6 billion.

11. Vioxx is marketed by Merck as a drug that relieves signs and symptoms of osteoarthritis, acute pain and painful menstrual cycles. Merck has reported to its shareholders that its launch of Vioxx was Merck's "biggest, fastest and best launch ever" for any drug.

12. Vioxx and Celebrex are usually prescribed to treat osteoarthritis.

Osteoarthritis is the most common joint disease, afflicting 21 million Americans, mostly after age 45. Most people over 60 show signs of the disease on x-ray and approximately 33% demonstrate actual symptoms. Osteoarthritis is a condition that results from normal wear and tear on the joints, such as knees, hips and fingers, or from an injury. Although some people may have only mild discomfort, many people experience considerable pain, inflammation and loss of movement, as cartilage covering the ends of bones at the joints wears away. Osteoarthritis affects all parts of a joint, causing pain and stiffness, especially after physical activity.

13. Defendants have marketed Vioxx and Celebrex as highly effective, safe, prescription drugs that deliver powerful relief of pain and inflammation caused by, among other things, osteoarthritis. Both drugs have been marketed as being more effective than alternative NSAIDs that have traditionally been used to treat such conditions.

14. Vioxx and Celebrex are significantly more expensive than traditional NSAIDs. The cost of Vioxx and Celebrex is at least \$3-\$6 per day, while an over-the-counter NSAID can cost \$.50 or less per day. Both drugs have also been marketed as being safer than such alternative, more traditional pain relievers because each is purported to be less likely to cause stomach disorders such as ulcers.

15. As demonstrated by Merck's own research, patients who take Vioxx suffer heart attacks, strokes and other cardiovascular illness and are significantly more likely to suffer heart attacks, strokes and other cardiovascular illness than patients who take alternative, less expensive medications to treat conditions like osteoarthritis.

16. Defendants' marketing activities for Vioxx and Celebrex have substantially taken place in New York. Merck has employed DDB Worldwide Communications Group, Inc., an advertising agency located in New York City, in the marketing campaign for Vioxx. Pfizer has employed J. Walter Thompson Company, an advertising agency located in New York City, in the marketing campaign for Celebrex. Defendants have placed advertisements with print and broadcast media organizations located in New York that have been distributed nationwide and significant media strategy and marketing planning activities for Vioxx and Celebrex have taken place in New York.

17. In December 1999, the FDA issued a Warning Letter to Merck stating that Merck was unlawfully marketing Vioxx by promoting its efficacy and safety without presenting any information concerning the contraindications, warnings, precautions and adverse events associated with taking Vioxx.

18. In September 2001, the FDA issued a second Warning Letter stating that Merck was unlawfully misrepresenting the safety of Vioxx because, among other things, its promotional campaign minimized the "potentially serious cardiovascular findings" that were observed in Merck's own study. The FDA also found that Merck had made unsubstantiated superiority claims with respect to Vioxx in comparison to other NSAIDs and had promoted Vioxx for unapproved uses and in an unapproved dosing regimen.

19. The FDA issued three Warning Letters to Searle, in October 1999, April 2000, and November 2000, all finding that Searle was unlawfully making false or misleading statements concerning the safety and/or efficacy of Celebrex. The November 2000 letter cited two direct-to-consumer television advertisements that overstated the efficacy of Celebrex and the FDA ordered that Searle immediately cease distribution of

the misleading ads.

20. In February 2001, the FDA issued a Warning Letter to Pharmacia stating that promotional activities for marketing Celebrex were unlawful because they were “false, lacking in fair balance, or otherwise misleading.” The FDA found that Celebrex had been promoted for unapproved uses, in unapproved dosing regimens, and that the marketers had made unsupportable claims that Celebrex was safer and more effective than other NSAIDs.

21. In August 2001, it was revealed that Pharmacia had misrepresented the results of a post-marketing clinical study of Celebrex when submitting it for publication. Pharmacia selectively omitted portions of the data relating to adverse effects. The Washington Post reported on August 5, 2001, that “the study had lasted a year, not six months as . . . thought. Almost all of the ulcer complications that occurred during the second half of the study were in Celebrex users. When all of the data were considered, most of Celebrex’s apparent safety advantage [as compared to traditional NSAIDs] disappeared.” In a June 2002 editorial, the British Medical Journal called the study “misleading” and demanded that “the wide dissemination of the results of the . . . trial . . . be counterbalanced by the equally wide dissemination of the findings of the reanalysis according to the original protocol.”

22. Defendants have also suppressed material information from their own clinical studies and concealed and/or omitted material information that Vioxx and Celebrex are associated with increased propensity of blood clotting and with significant and dangerous cardiovascular events both independently and in comparison to traditional NSAIDs.

23. Most patients taking Vioxx and/or Celebrex are elderly and have a higher risk of developing cardiovascular problems to begin with. Thus, the benefit of reducing the possibility that they will develop a stomach ulcer is out-weighed by the increased risk that, by taking Vioxx or Celebrex, they will suffer increased propensity of blood clotting and suffer a heart attack, stroke or other cardiovascular illness.

24. Merck has publicly denied that Vioxx causes heart attacks, strokes and other cardiovascular illness or that Vioxx causes an increased risk that patients will suffer those illnesses. These statements are contradicted by medical research that indicates that cox-2 inhibitors have “pro-thrombotic properties,” that is, they have the propensity to cause the blood to clot more easily. Moreover, Merck has admitted that patients who take certain competing NSAIDs are benefited because, unlike a cox-2 inhibitor such as Vioxx, those alternative drugs inhibit the body’s production of thromboxane. Thromboxane causes platelets in human blood to stick together, leading to blood clots, strokes, heart attacks and other cardiovascular illness.

25. Even if it were true, however, as Merck has stated, that cox-2 inhibitors like Vioxx and Celebrex do not directly cause heart attacks, strokes, and cardiovascular illness or the increased risk of those illnesses, it is still clear that switching from most alternative and competing NSAIDs to Vioxx and Celebrex for pain relief indirectly causes those illnesses and/or that increased risk because, by Merck’s own admission, the patient loses the anti-clotting benefits of the competing NSAIDs. For that reason, Vioxx and Celebrex have been and continue to be falsely marketed as being safer than alternative pain relievers which -- unlike Vioxx and Celebrex -- actually help prevent and reduce the likelihood that patients will suffer increased blood clotting propensity, heart

attacks, strokes and other cardiovascular illness.

26. Consumers, but particularly elderly consumers who already suffer from or have a higher risk of suffering cardiovascular disease, are being misled by defendants because they are not being advised that by switching from most alternative, more traditional NSAIDs to Vioxx and Celebrex, they are increasing the likelihood that they will suffer enhanced risk of blood clotting, heart attacks, strokes and other cardiovascular illness. The advertising, packaging, labels and other information made available to the public concerning both drugs do not alert patients to these serious health dangers and risks.

27. Plaintiffs seek, *inter alia*, the establishment of a Court-ordered and supervised medical monitoring program, funded by defendants, for patients who have taken Vioxx or Celebrex. Such a program is necessary in order to monitor patients for the significantly increased risks that Vioxx and Celebrex pose by increasing the blood's propensity to clot and to cause cardiovascular illness.

28. Plaintiffs also seek notice to class members and revised patient warnings in consumer advertising and package inserts so that class members will be informed of the hazardous side effects and serious health risks to which they have been exposed and are continuing to expose themselves by taking and/or switching to Vioxx and Celebrex from more traditional, less costly alternative pain relievers. The need for such warnings is demonstrated by, among other things, defendants' own research studies presented to the FDA showing that Vioxx and/or Celebrex cause patients who take these drugs to have heart attacks, strokes and other cardiac illnesses and that these drugs are no more effective at relieving pain than traditional NSAIDs. Notice to patients, as opposed solely

to physicians, is required in light of defendants' prior and ongoing massive consumer advertising campaign for these drugs to ensure that all persons taking Vioxx and Celebrex will receive the information.

29. Absent notice and revised patient warnings, at a minimum, hundreds of thousands -- if not millions -- of individuals will unwittingly continue treating osteoarthritis and similar conditions with Vioxx and Celebrex. That treatment will be based on these individuals' erroneous understanding, based on defendants' improper advertising and disclosure, that Vioxx and Celebrex are safer and more effective than alternative, less costly pain relief medications.

30. Class members should be afforded the opportunity to make an informed, educated choice as to whether they should continue to take Vioxx and Celebrex and risk cardiovascular illness based on the drug's propensity to increase blood clotting. They should also be afforded the opportunity to make an informed, educated choice as to whether they should switch to Vioxx and/or Celebrex from more traditional, alternative pain relief medications in light of the much higher cost of defendants' drugs.

31. Plaintiffs also seek, for themselves and other class members, disgorgement of revenues and refunds of all amounts paid to purchase Vioxx and Celebrex, as well as all other ascertainable economic and non-economic losses they have suffered and/or will continue to suffer and all such other relief to which they are entitled, including reasonable attorneys' and expert fees.

PARTIES

32. Plaintiff Alex Cain is a resident and citizen of the State of Georgia. At all times relevant herein, plaintiff took Vioxx and Celebrex, which were prescribed to him

for osteoarthritis, and was unaware of the shortcomings of and health risks posed by the drugs, as more fully set forth herein. As a result of his taking Vioxx and Celebrex, Mr. Cain recently suffered two cardiovascular illnesses, both of which required hospitalization.

33. Plaintiff Bobbie Moss is a resident and citizen of the State of Georgia. At all times relevant herein, plaintiff took Vioxx and Celebrex, which were prescribed to her for osteoarthritis. Ms. Moss was unaware of the health risks posed by the drugs. As a result of taking Vioxx and Celebrex, Ms. Moss suffered a cardiovascular event requiring hospitalization.

34. Plaintiff William Watkins is a resident and citizen of the State of Georgia. At all times relevant herein, plaintiff took Vioxx, which was prescribed to him for osteoarthritis, after Mr. Watkins had had a cardiac event requiring hospitalization. Mr. Watkins was unaware of the shortcomings of and health risks posed by the drugs.

35. Defendant Merck has its principal place of business and is incorporated in New Jersey. At all times relevant hereto, Merck was engaged in the business of developing, manufacturing, marketing and selling Vioxx. Merck does substantial business in New York and in this federal district. At all times relevant hereto, Merck developed, manufactured, marketed and sold Vioxx in interstate commerce and in New York.

36. Defendant Pharmacia has its principal place of business in New Jersey and is incorporated in Delaware. At all times relevant hereto, Pharmacia was engaged in the business of developing, manufacturing, marketing and selling Celebrex. Pharmacia does substantial business in New York and in this federal district. At all times relevant hereto,

Pharmacia, directly and indirectly through its subsidiary, Searle, developed and manufactured and then, with Pfizer, marketed and sold Celebrex in interstate commerce and in New York.

37. Defendant Pfizer has its principal place of business in New York and is incorporated in Delaware. At all times relevant hereto, Pfizer was engaged in the business of marketing and selling Celebrex with Pharmacia and Searle and their marketing activities, marketing strategy and other aspects of their alleged conduct took place at Pfizer's principal place of business in New York. Pfizer does substantial business in New York and in this federal district. At all times relevant hereto, Pfizer marketed and sold Celebrex in interstate commerce and in New York.

38. Defendant Searle has its principal place of business in Illinois and is incorporated in Delaware. At all times relevant hereto, Searle was engaged in the business of developing, manufacturing, marketing and selling Celebrex. Searle does substantial business in New York and in this federal district. At all times relevant hereto, Searle developed, manufactured, marketed and sold Celebrex in interstate commerce and in New York.

JURISDICTION

39. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(a)(1) because the amount in controversy exceeds \$75,000 as to plaintiffs and as to every member of the proposed class; because the individual plaintiffs' damage claims exceed said amount; and because the Class has an undivided interest in obtaining injunctive and equitable relief, including notice, revised drug warnings and medical monitoring, that exceeds \$75,000 in value.

40. There is complete diversity of citizenship between plaintiffs and defendants.

CLASS ACTION ALLEGATIONS

41. Plaintiffs bring this action as a class action for equitable, injunctive, monetary and declaratory relief pursuant to Rules 23(b) and (c) of the Federal Rules of Civil Procedure, as representatives of a class of persons consisting of all persons in the United States, including their successors in interest, who have taken Vioxx and/or Celebrex since those products were first made available to patients in 1999.

42. Plaintiffs are members of the class they seek to represent. The members of the class, estimated to be millions of individuals, are so numerous that joinder is impractical. The questions of law and fact common to the members of the class predominate over any questions affecting only individual class members, because defendants have acted on grounds generally applicable to the class.

43. There are numerous questions of law and fact common to the class and all class members including, but not limited to:

- (a) Whether Vioxx and Celebrex cause users of these drugs to suffer from an increased propensity of their blood to clot and to have heart attacks, strokes and other cardiovascular illness, as well as cause an increased risk that patients will suffer those illnesses, as compared to patients who take alternative, less expensive pain relief medications (NSAIDs) to treat the same and/or similar medical conditions, such that medical monitoring of these patients is warranted;

- (b) Whether Vioxx and Celebrex are any more effective in reducing pain and inflammation than alternative, less costly pain relief medications;
- (c) Whether defendants adequately warned patients in their marketing and advertising to consumers of the hazardous side-effects and serious health dangers and risks to which they have exposed and are continuing to expose themselves by taking and/or switching to Vioxx and Celebrex from more traditional, alternative pain relief medications;
- (d) Whether defendants knowingly, willfully, intentionally or negligently made misstatements regarding the efficacy of Vioxx and Celebrex in their marketing and advertising to consumers;
- (e) Whether defendants suppressed material information from clinical studies or otherwise concealed or omitted material information that Vioxx and Celebrex are associated with an increased propensity of the blood to clot and with significant and dangerous cardiovascular events both independently and in comparison to traditional NSAIDs;
- (f) Whether defendants' failure to warn patients of such hazardous side-effects and serious health dangers and risks was intentional, reckless or negligent;
- (g) Whether notice and revised patient warnings should be disseminated to class members to ensure that they are informed of the hazardous side-effects and serious health dangers and risks to which they have exposed and are continuing to expose themselves by taking Vioxx and Celebrex

and/or switching to Vioxx and Celebrex from more traditional, alternative pain relief medications;

- (h) Whether defendants negligently designed, manufactured, marketed, and/or failed to issue warnings about Vioxx and Celebrex;
- (i) Whether defendants conducted, either directly or indirectly, appropriate pre- and post-release testing of Vioxx and Celebrex;
- (j) Whether defendants were unjustly enriched on account of their misconduct;
- (k) Whether defendants' conduct constitutes deceptive acts in violation of New York General Business Law § 349;
- (l) Whether individuals who have taken Vioxx and Celebrex are entitled to monetary relief and/or other forms of compensation for the economic injuries caused by defendants' conduct; and
- (m) Whether the increased risk to users of Vioxx and Celebrex of blood clotting and contracting cardiovascular illness makes periodic diagnostic medical examinations reasonably necessary.

44. Plaintiffs' claims are typical of the members of the class. Plaintiffs and all other class members took Vioxx and/or Celebrex based on the advertising, marketing and the misrepresentation of defendants to relieve medical conditions like pain and inflammation and have suffered the increased propensity of their blood to clot and other dangers of these drugs. Plaintiffs and all other class members were, are, and continue to be harmed by the same wrongful conduct of defendants.

45. Plaintiffs will fairly and adequately represent and protect the interests of all class members. Plaintiffs have retained counsel competent and experienced in complex class action litigation. The interests of the plaintiffs are coincident with, and not antagonistic to, the interests of the other class members.

46. Notice can be provided to class members by a combination of published notice, Internet notice, and first-class mail using techniques and forms of notice similar to those customarily used in drug-related product liability, personal injury and other consumer class actions.

47. Class certification is appropriate because defendants have acted, or refused to act, on grounds generally applicable to the class, making appropriate preliminary and final injunctive and declaratory relief, including medical monitoring, notice, and revised patient warnings with respect to plaintiffs and other class members. In addition, the prosecution of separate actions by or against individual class members would create a risk of incompatible standards of conduct for defendants and inconsistent or varying adjudications for all parties.

48. Class action treatment is a superior method to the alternatives, if any, for the fair and efficient adjudication of this controversy, in that, among other things, the questions of law or fact common to the members of the class predominate over any questions only affecting individual members, it permits a large number of similarly situated persons to prosecute their claims against a limited number of defendants in a single forum simultaneously, efficiently and without unnecessary duplication of evidence, effort and expense.

**FIRST CLAIM FOR RELIEF
STRICT PRODUCT LIABILITY
(FAILURE TO WARN)**

49. Plaintiffs incorporate by reference paragraphs 1 through 48 of this complaint as if fully set forth herein.

50. Vioxx and Celebrex, as manufactured and/or supplied by defendants, have been and continue to be unaccompanied by adequate warnings regarding the fact that they cause increased propensity of the blood to clot, heart attacks, strokes and other cardiovascular illness, as well as cause the increased risk that patients taking these drugs will suffer those illnesses. There are no warnings to patients taking these drugs alerting them to the serious health dangers and risks to which they have exposed and are continuing to expose themselves by taking Vioxx or Celebrex, as compared with their taking alternative, less expensive, more traditional pain relief medications for the same and/or similar medical conditions.

51. Defendants failed to perform adequate testing prior to manufacturing, marketing and selling Vioxx and Celebrex to patients. Adequate testing would have shown that patients who take and/or switch to Vioxx and Celebrex from more traditional, alternative pain relief medications suffer a greater propensity of the blood to clot and are substantially more likely to suffer heart attacks, strokes and other cardiovascular illness. Adequate testing would have shown that taking and/or switching to Vioxx and Celebrex from alternative, more traditional pain relief medications cause those conditions.

52. Vioxx and Celebrex, as manufactured and/or supplied by defendants, were defective products due to defendants' inadequate post-marketing warnings and instructions. Moreover, after defendants knew or should have known that Vioxx and Celebrex posed greater health dangers and risks to patients than more traditional,

alternative medications, defendants failed to take steps to warn and/or cause patients to be advised of such dangers and risks. Defendants also failed to take steps to warn and/or cause patients to be advised of the serious health dangers and risks to which they have exposed and are continuing to expose themselves by switching from most alternative, more traditional pain relievers to Vioxx and Celebrex.

53. As the proximate cause and legal result of the defective and/or hazardous condition of Vioxx and Celebrex as manufactured and/or supplied by defendants, plaintiffs and other class members require updated warnings and notification so that they will fully understand the serious health dangers and risks to which they have exposed and are continuing to expose themselves by taking and continuing to take Vioxx and Celebrex. Absent such equitable relief, plaintiffs and other class members will continue to suffer irreparable injury for which there is no adequate remedy at law.

**SECOND CLAIM FOR RELIEF
STRICT PRODUCT LIABILITY**

54. Plaintiffs incorporate by reference paragraphs 1 through 53 of this complaint as if fully set forth herein.

55. Vioxx and Celebrex, as manufactured and/or supplied by defendants, were defective and/or hazardous in design or formulation, in that, when those drugs left the hands of the manufacturers and/or suppliers, the foreseeable risks to patients who would take the drugs exceeded the benefits associated with their design or formulation.

56. Alternatively, Vioxx and Celebrex, as manufactured and/or supplied by defendants, were defective and/or hazardous in design or formulation, in that, when the drugs left the hands of the manufacturers and/or suppliers, the drugs were unreasonably

dangerous, more dangerous than an ordinary consumer would expect, and more dangerous than other forms of more traditional NSAIDs.

57. Vioxx and Celebrex, as manufactured and/or supplied by defendants, were defective and/or hazardous to patients due to inadequate warnings and instructions. The defendants knew or should have known that Vioxx and Celebrex would pose significant health dangers and risks to patients, as compared to traditional, prescription and non-prescription pain relief medications that patients usually took for the same or similar medical conditions. The defendants also knew or should have known that Vioxx and Celebrex were particularly dangerous for patients who switched to these drugs from more traditional NSAIDs.

58. As the proximate cause and legal result of the defective and/or hazardous condition of Vioxx and Celebrex as manufactured and/or supplied by defendants, plaintiffs and other class members require updated warnings and notification so that they will fully understand the serious health dangers and risks to which they have exposed and are continuing to expose themselves by continuing to take Vioxx and Celebrex. Absent such equitable relief, plaintiffs and other class members will continue to suffer irreparable injury for which there is no adequate remedy at law.

THIRD CLAIM FOR RELIEF NEGLIGENCE

59. Plaintiffs incorporate by reference paragraphs 1 through 58 of this complaint as if fully set forth herein.

60. Defendants had and continue to have a duty to exercise reasonable care in the development, manufacture, sale and/or distribution of Vioxx and Celebrex into the stream of commerce, including a duty to ensure that the drugs work safely and effectively

for their intended uses, which reasonably and foreseeably included a reduction of inflammation, swelling, stiffness and pain without causing patients to suffer heart attacks, strokes and other cardiovascular illness and without causing patients to have an increased risk of suffering those illnesses, or increasing the propensity for the blood to clot.

61. Defendants have failed to exercise reasonable care in the development, manufacture, sale, testing, quality assurance, quality control and/or distribution of Vioxx and Celebrex into interstate commerce in that defendants knew or should have known that Vioxx and Celebrex cause an increased propensity for the blood to clot, heart attacks, strokes and other cardiovascular illness. Defendants also knew or should have known that Vioxx and Celebrex cause patients who take, or switch to these drugs from more traditional NSAIDs to be more likely to suffer a greater propensity of the blood to clot, heart attacks, strokes and other cardiovascular illness.

62. Defendants were negligent in the design, manufacture, testing, advertising, warning, marketing, sale of and provision of warnings with respect to Vioxx and Celebrex in that they:

- (a) Failed to use reasonable care in designing and manufacturing Vioxx and Celebrex so as to avoid the aforementioned risks to individuals who were prescribed, switched to, and/or took these drugs;
- (b) Failed to accompany these products with proper warnings regarding all possible adverse drug effects and potential health dangers and risks that could result from patients' taking Vioxx or Celebrex and/or switching to Vioxx or Celebrex from more traditional NSAIDs;
- (c) Failed to conduct adequate pre-clinical and clinical testing and post-

marketing surveillance to determine the effective use and safety of Vioxx and Celebrex;

- (d) Failed to provide adequate training and information to physicians and other medical care providers concerning the appropriate use -- and serious health dangers and risks that would arise from patients' use -- of Vioxx and Celebrex;
- (e) Failed to warn plaintiffs and other class members, in their marketing and distribution of Vioxx and Celebrex, either directly or indirectly through physicians, orally or in writing, that taking and/or switching to Vioxx and Celebrex from more traditional NSAIDs would cause increased propensity for their blood to clot, heart attacks, strokes and other cardiovascular illness as well as the increased likelihood that patients would suffer those illnesses; and
- (f) Were otherwise careless or negligent.

63. Despite the fact that defendants knew or should have known that taking and/or switching to Vioxx and Celebrex from more traditional, alternative pain relief medications posed serious health dangers and risks to patients, defendants have continued to market Vioxx and Celebrex without disclosing those serious health dangers and risks.

64. Defendants knew or should have known that consumers such as plaintiffs and other class members would suffer foreseeable injury as a result of defendants' failure to exercise ordinary care, including irreparable injury which has been and will continue to be suffered by unsuspecting patients who take and/or switch to these drugs, absent a grant

of the equitable relief described above.

**FOURTH CLAIM FOR RELIEF
BREACH OF EXPRESS WARRANTY**

65. Plaintiffs incorporate by reference paragraphs 1 through 64 of this complaint as if fully set forth herein.

66. Defendants have expressly warranted that Vioxx and Celebrex are safe and effective drugs.

67. Vioxx and Celebrex do not conform to this express representation in that the information provided by defendants concerning these drugs fails to advise patients that, as a result of their taking and/or switching to Vioxx and Celebrex from more traditional NSAIDs, patients will suffer a greater propensity of the blood to clot, heart attacks, strokes and other cardiovascular illness as well as increase the risk that they will suffer such illnesses. The information provided by defendants also fails to advise patients that alternative, less expensive, more traditional NSAIDs used to treat the same or similar medical conditions for which Vioxx and Celebrex are prescribed do not present such risks and are equally as effective at relieving pain. Defendants have never advised and, to this day, continue to refuse to advise patients or cause patients to be advised, of the serious health dangers and risks to which they have exposed and are continuing to expose themselves by taking Vioxx and Celebrex and/or by switching to Vioxx and Celebrex from more NSAIDs.

68. As a direct and proximate result of the breach of said warranties, plaintiffs and other class members have suffered and will continue to suffer economic and non-economic loss in amounts to be proven at trial including damages based upon the difference between the value of the goods actually obtained and the value of the goods if

they had been as warranted.

**FIFTH CLAIM FOR RELIEF
BREACH OF IMPLIED WARRANTY**

69. Plaintiffs incorporate by reference paragraphs 1 through 68 of this complaint as if fully set forth herein.

70. At the time defendants marketed, sold, and distributed Vioxx and Celebrex, defendants knew the uses for which Vioxx and Celebrex were intended and impliedly warranted the products to be of merchantable quality and fit for such uses.

71. Plaintiffs and other class members and their physicians reasonably relied upon the skill and judgment of defendants as to whether Vioxx and Celebrex were of merchantable quality and fit for their intended uses.

72. Contrary to such implied warranties, Vioxx and Celebrex were neither of merchantable quality nor fit for their intended uses. Because of the serious health dangers and risks posed by the drugs, the drugs were unfit for the ordinary purposes for which they were prescribed and used, as described above.

73. As a direct and proximate result of the breach of said warranties, plaintiffs and other class members have suffered and will continue to suffer economic and non-economic loss in amounts to be proven at trial including damages based upon the difference between the value of the goods actually obtained and the value of the goods if they had been as warranted.

**SIXTH CLAIM FOR RELIEF
MEDICAL MONITORING**

74. Plaintiffs incorporate by reference paragraphs 1 through 73 of this complaint as if fully set forth herein.

75. As a result of taking Vioxx and/or Celebrex, plaintiffs and other class members have been exposed to hazardous substances proven to significantly increase the risk of blood clotting and cardiovascular illness through the negligent or fraudulent actions of the defendants.

76. As a proximate result of exposure, plaintiffs and other class members suffer a significantly increased risk of blood clotting and contracting serious cardiovascular diseases.

77. The increased risk makes periodic diagnostic medical examination reasonably necessary.

78. Monitoring and testing procedures exist which make the early detection and treatment of such increased blood clotting and cardiovascular diseases possible and beneficial.

**SEVENTH CLAIM FOR RELIEF
UNJUST ENRICHMENT**

79. Plaintiffs incorporate by reference paragraphs 1 through 78 of this complaint as if fully set forth herein.

80. As a direct and proximate result of defendants misconduct as set forth above, defendants have been unjustly enriched.

81. Specifically, defendants' knowing misrepresentations, omissions, suppression and/or concealment of material facts in connection with the advertising, marketing, promotion and sale of Vioxx and Celebrex has resulted in a wrongful conferral of benefits on the defendants through their wrongful receipt of revenue. Defendants will be unjustly enriched unless ordered to disgorge revenues and to make restitution to the plaintiffs and class members.

**EIGHTH CLAIM FOR RELIEF
VIOLATIONS OF NEW YORK DECEPTIVE ACTS
AND PRACTICES STATUTE (N.Y. GEN. BUS. LAW § 349)**

82. Plaintiffs incorporate by reference paragraphs 1 through 81 of this complaint as if fully set forth herein.

83. Plaintiffs and class members are “persons” within the meaning of New York General Business Law § 349(h).

84. Section 349(a) of New York’s General Business Law provides:

Deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state are hereby declared unlawful.

85. Defendants have engaged in materially deceptive acts and practices in the conduct of business, trade, and commerce in the state of New York in violation of New York General Business Law § 349 by their knowing misrepresentations, omissions, suppression and/or concealment of material facts in connection with the advertising, marketing, promotion, and sale of and development of marketing campaigns for Vioxx and Celebrex to consumers that took place in New York.

86. By reason of defendants’ materially deceptive acts and practices, plaintiffs and class members have been injured by being induced to purchase Vioxx or Celebrex instead of less expensive traditional NSAIDs to treat their pain, without knowledge of the increased risk of blood clotting, hypertension, stroke, heart attack, and other cardiovascular illness caused by the use of Vioxx and Celebrex and without knowledge that traditional NSAIDs are equally as effective at relieving pain.

87. Defendants’ actions were knowing or willful and plaintiffs and class members are entitled to treble their individual actual damages suffered as a result of defendants’ materially deceptive acts and practices or one thousand dollars, whichever is

greater. Plaintiffs and class members are also entitled to recover their attorneys fees as provided by New York General Business Law § 349(h).

PRAYER FOR RELIEF

88. Plaintiffs incorporate by reference paragraphs 1 through 87 of this complaint as if fully set forth herein.

89. Plaintiffs' and other class members' current cardiovascular illnesses and/or their increased risk of suffering a greater propensity for their blood to clot, and to suffer heart attacks, strokes, and other cardiovascular illness as a result of their taking and/or switching to Vioxx and Celebrex from more traditional NSAIDs makes periodic diagnostic and medical examinations necessary and reasonable. Easily administered, cost-effective medical monitoring procedures exist which may be applied to plaintiffs and other class members.

90. Defendants have a continuing duty to warn plaintiffs, other class members, and the public of all potential health risks and dangers of which they become or should become aware. There have been studies conducted, some of which are continuing, regarding these risks and dangers. As a proximate result of defendants' conduct as described herein, plaintiffs, on behalf of themselves and all others similarly situated, are entitled to damages and/or equitable relief in the form of notice, revised drug warnings and/or equivalent remedial and corrective action, to accurately reflect and publicize all known health dangers and risks to which individuals taking Vioxx and Celebrex and/or switching to Vioxx and Celebrex from more traditional NSAIDs have exposed and are continuing to expose themselves.

91. Defendants should be required to provide information, including appropriate and updated product warnings, to individuals who currently take and/or have previously taken Vioxx and Celebrex to apprise them of updated information concerning these drugs and of the serious health dangers and risks to which they have been and continue to be exposed by taking and/or switching to these drugs.

92. Plaintiffs and other class members are entitled to damages for their injuries incurred as a result of taking Vioxx and Celebrex and/or their switching to Vioxx and Celebrex from more traditional NSAIDs including damages based upon the difference between the value of the goods actually received and the value that the goods would have had they had been as warranted. Plaintiffs do not seek in this action damages arising from any physical injury caused by taking Vioxx or Celebrex.

93. WHEREFORE, PLAINTIFFS PRAY FOR RELIEF AS FOLLOWS:

- (a) That this action be certified as a class action under Rule 23 of the Federal Rules of Civil Procedure on behalf of the proposed class of individuals who have taken Vioxx and/or Celebrex, that the named plaintiffs be designated as representatives of the class, and that named counsel be designated class counsel;
- (b) That defendants be ordered to implement a comprehensive, Court-supervised program which will:
 - (1) Create a trust fund, paid for by defendants, to finance a medical monitoring program to deliver services, including but not limited to periodic diagnostic testing, preventive screening and

- surveillance for conditions resulting from, or potentially resulting from, the use of Vioxx and Celebrex;
- (2) Locate and notify all persons who have taken Vioxx and/or Celebrex of the serious health dangers and risks to which they have been and will continue to be exposed by taking and/or switching to these drugs, as compared with their taking more traditional, less costly NSAIDs used to treat the same or similar medical conditions;
 - (3) Provide class members with revised and updated warnings in drug advertising and on drug labels and drug packaging; and
 - (4) Include new warnings on defendants' Internet websites and in the U.S. Product Prescribing Information for Vioxx and Celebrex that appear in the Physicians' Desk Reference.
- (c) That plaintiffs and other class members be awarded damages incidental to their procurement, taking and/or switching to Vioxx and Celebrex from alternative pain relievers, including damages based upon the value of the goods accepted and the value the goods would have had if they had been as warranted.
- (d) That defendants be ordered to disgorge all revenues received from the sales of Vioxx and Celebrex and make restitution of all monies procured from the sale of Vioxx and Celebrex to plaintiffs and other class members;

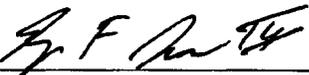
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- (e) That plaintiffs and other class members be awarded treble damages based on defendants' knowing and willful conduct in accordance with New York General Business Law § 349.
 - (f) That plaintiffs and other class members be awarded attorneys fees, expert fees, expenses, and costs of this action; and
 - (g) That plaintiffs and other class members be awarded such other, further and different relief as the nature of this case may require or as this Court may deem necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, of all issues triable by jury.

Dated: New York, New York
September 18, 2002

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