



County, Kentucky. In December, 2001 Danny C. Hodges was prescribed, purchased and ingested the drug Vioxx, manufactured and marketed by Defendant Merck & Co. Inc. Danny Hodges continued to take Vioxx on prescription from his physician from December 2001 until after he heard of the September 30, 2004 recall of the drug by the manufacturer.

3. Defendant, Merck & Co., Inc. (hereinafter referred to as “Merck”) is a New Jersey corporation with its principal place of business at One Merck Drive, P.O. Box. 100, Whitehouse Station, New Jersey 08889.

4. Merck is in the business of designing, studying, manufacturing, and marketing prescription drugs.

5. Merck does, and at all times mentioned in this Complaint, did business in Kentucky through the sale of prescription drugs in this state.

6. Merck did business in the state of Kentucky through the sale of the prescription drug Vioxx in this state until September 30, 2004.

7. Danny C. Hodges died as a result of sudden cardiac death from the ingestion of Vioxx which occurred in Kentucky.

### **FACTUAL ALLEGATIONS**

8. Taking the drug Vioxx as prescribed caused the death of Danny C. Hodges at the age of 51. Mr. Hodges was prescribed Vioxx at 25mg per day. He was in good health, a non-smoker and had no cardiac disease or health infirmity. Vioxx caused Mr. Hodges to experience a sudden cardiac death. The autopsy report concluded he was determined to have died from “cardiac arrhythmic of unknown etiology.”

9. Vioxx is the brand name of rofecoxib, a prescription drug in the class of nonsteroidal inflammatory drugs known as Cox-2 inhibitors.

10. Merck submitted an Application to Market a New Drug for Human Use (“NDA”) for rofecoxib to the United States Food and Drug Administration (“FDA”) on November 23, 1998, for tablets, at doses of 12.5 mg and 25 mg, for treatment of osteoarthritic pain, acute pain, and menstrual pain. This application is designated as NDA 21-042 by the FDA.

11. Merck also submitted an NDA for rofecoxib to the FDA on November 23, 1998, for oral suspension, at doses of 12.5 mg/ml and 25 mg/ml, for treatment of osteoarthritic pain, acute pain, and menstrual pain.

12. On May 20, 1999, the FDA approved both the NDAs for treatment of osteoarthritic pain, acute pain, and menstrual pain. The FDA’s approval was based upon data from trials lasting 3 to 6 months and involving patients at low risk for cardiovascular illness.

13. Merck launched an aggressive marketing campaign for Vioxx immediately after its approval in May 1999. This campaign included extensive direct to consumer advertising, and its success would ultimately be demonstrated by sales growth leading to \$2.5 billion in sales for the year 2003.

14. Merck submitted a Supplemental New Drug Application (“SNDA”), designated as sNDA-007, with the goal of establishing a gastrointestinal safety claim for rofecoxib. To support this SNDA, Merck conducted a study known as the VIGOR (VIOXX GI Outcomes Research) study, between January 6, 1999 and March 17, 2000. The results of the VIGOR trial came in March 2000.

15. On March 9, 2000 Merck's research chief, Edward Scolnick, e-mailed colleagues that the cardiovascular events "are clearly there" and called it a "shame." Wall Street Journal, Nov. 1, 2004, p. A1. Merck's public statements (and specifically to prescribing doctors, through literature and sales rep visits, such as Mr. Hodge's prescribing physician, M.D.) continued to reject any link between Vioxx and increased cardiac risk. Plaintiff avers that had Merck truthfully disclosed what it knew, his treating physician, and/or a reasonably prudent treating physician, would never had prescribed Vioxx to Mr. Hodges in December 2001. For example, a November 21, 1996 memo by a Merck official wrote concerning conducting a study that Vioxx was gentler on the stomach bit that in any such study aspirin could not be taken and thus, in such a trial "there is a substantial chance that significantly higher rates" of cardiovascular problems would be seen in the Vioxx group. shame." Wall Street Journal, Nov. 1, 2004, p. A1. Another e-mail, dated Feb. 25, 1997 from Briggs Morrison, stated that unless patients in the Vioxx group also got aspirin "you will get more thrombotic events" -- i.e. blood clots -- "and kill [the drug]." Wall Street Journal, Nov. 1, 2004, p. A1. In response, Alise Reicin, now a Merck vice-president for clinical research, said in an e-mail that Merck was in a "no-win situation." Giving study subjects both Vioxx and aspirin, she wrote, could increase the "relative risk", apparently referring to GI problems. But, she added, "the possibility of CV [cardiovascular] events is of great concern. She added in the e-mail that people with high risk of cardiovascular problems be kept out of the study so the difference in the rate of cardiovascular problems between the Vioxx patients and others "would not be evident." Wall Street Journal, Nov. 1, 2004, p. A1.

16. The VIGOR study, a prospective, randomized, double-blind, one-year study, evaluated approximately 4,000 patients on the standard dose of naproxen (1000 mg per day), a

non steroidal anti-inflammatory drug (NSAID). The study was published in the New England Journal of Medicine, Volume 343:1520-1528 (November 23, 2000). Patients who were under treatment with low dose aspirin for heart attack prevention were excluded from the study.

17. The VIGOR study demonstrates that Vioxx is associated with a lower incidence of serious upper gastrointestinal adverse events of major bleeding, perforation, and obstruction compared to naproxen. The reduction in risk is over 50 percent in cumulative rates for Vioxx (0.52%) compared to naproxen (1.22%).

18. However, the VIGOR study also shows a higher cumulative rate of serious cardiovascular thromboembolic adverse events (such as heart attacks, angina pectoris, and peripheral vascular events) in the Vioxx group (1.8%) compared to the naproxen group (0.6%). Physicians at the Cleveland Clinic noted “a substantial excess of MIs in the VIGOR trial” and noted that in patients for whom aspirin was indicated because of a risk for coronary artery disease the risk ratio with Vioxx 4.9. 17 Cleveland Clinic Journal of Medicine No. 12 (December 2004). The Cleveland Clinic physicians called for a trial specifically assessing the cardiovascular risk of rofecoxib; however, Merck did not undertake a trial to ensure that rofecoxib was safe in patients from the standpoint of cardiovascular risk. Merck and its consultants claimed that the excess of MIs observed in the VIGOR trial, a number “higher than would have been anticipated from previous studies” was due to a “cardioprotective effect of naproxen.” However, whether naproxen was in fact cardioprotective “had never been proven or quantified.” 17 Cleveland Clinic Journal of Medicine No. 12 (December 2004).

19. In his March 9, 2000 e-mail Merck research chief Scolnick wrote “it is a shame but is a low incidence [of cardiovascular events] and its mechanism based as we worried it was.”

20. A study comparing Vioxx, Celebrex (another Cox-2 inhibitor), and aspirin was reported at a June 22, 2000, European League against Rheumatism (EULAR) meeting in Nice, France. This study shows that Vioxx reduces nighttime osteoarthritic pain more effectively than Celebrex or aspirin. Differences in the incidence of clinical adverse events for the three drugs were not reported in connection with this study.

21. A second study, a head-to-head safety study comparing Celebrex with Vioxx, was also presented at the EULAR meeting in Nice. This study shows that nearly 60% more patients on Vioxx than on Celebrex experienced significant systolic blood pressure elevations of 20 mmHg or more. This was observed as early as week two of the study, and was confirmed at week six.

22. Andrew Whelton, M.D., who presented the Celebrex vs. Vioxx study, and who is a nephrologist and adjunct professor of medicine at Johns Hopkins, commented:

“For the first time, we have a direct safety comparison of these compounds on a level playing field, in the same patient population, which helps us gain a better assessment of safety differences between these two COX-2 inhibitors.”

“This study provides compelling evidence that Celebrex and Vioxx affect hypertensive arthritis patients differently, suggesting that not all COX-2 inhibitors are the same.”

23. Merck contested the validity of cardiovascular risk findings in the Vioxx vs. Celebrex study in the August 2000 edition of *Pharmacy Today*, a newspaper published by the American Pharmacists Association.

24. On June 22, 1999, Merck contracted with Peter Holt, M.D., to conduct Vioxx promotional audio conferences, using content provided by Merck, which were to be presented to health care professionals as educational programs.

25. The FDA sent a letter to Merck dated December 16, 1999, saying that certain Vioxx promotional pieces “are false and misleading because they contain representations of Vioxx’s safety profile, unsubstantiated comparative claims, and are lacking in fair balance.”

26. By November 18, 1999, the Data and Safety Monitoring Board of the VIGOR study, a committee independent from Merck, the sponsor, had become concerned over the “excess deaths and cardiovascular events experiences in Group A [Vioxx] compared to Group B [naproxen].” (See paragraph 32 for the quote source)

27. Dr. Peter Holt conducted six Vioxx promotional audio conferences, which were arranged by Merck, presented on behalf of Merck, and moderated by Merck employees: one on June 8, 2000; one on June 13, 2000; one on June 16, 2000; and three on June 21, 2000. Some of the content of these conferences was later found by the FDA to be “false or misleading in that they minimized the MI results of the VIGOR study, minimized the Vioxx/Coumadin drug interaction, omitted important risk information, made unsubstantiated superiority claims, and promoted Vioxx for unapproved uses and an unapproved dosing regimen.”

28. The FDA sent a letter to Merck dated December 12, 2000, asking Merck to explain its involvement in, and influence on, the initiation, preparation, development, and publication of the Holt audio conferences conducted in June 2000. This letter also asks Merck to tell the FDA about the nature of its relationship with Dr. Holt.

29. Merck responded to the FDA’s inquiry about Dr. Holt in a January 5, 2001 letter to the FDA, saying:

“Dr. Holt entered into a speaker contract with Merck on June 22, 1999.”

...

“Merck has determined that we arranged for Dr. Holt to speak at ten audio conferences in 2000. Merck Business Managers provided him with the

topic for the audio conferences, and for two of the audio conferences, asked him to address the safety profiles of Vioxx and other NSAIDs.”

30. An FDA report, written by Shari L. Targum, M.D., a Project Manager for the FDA’s Division of Anti-Inflammatory Drug Products, dated February 1, 2000, says:

“By November 18, 1999, the Data and Safety Monitoring Board of the VIGOR study, a committee independent from the sponsor, was concerned over the ‘excess deaths and cardiovascular events experiences in Group A [Vioxx group] compared to Group B [naproxen group] (52 v. 29 respectively).”

31. Results from the VIGOR study were submitted by Merck to the *New England Journal of Medicine* in the form of an article entitled “Comparison of upper gastrointestinal toxicity of rofecoxib and naproxen in patients with rheumatoid arthritis VIGOR Study Group,” which was published in the November 23, 2000 edition of the NEJM. This article had several co-authors, including Alise Reicin, Merck’s Vice President of Clinical Research. The lead author, Toronto rheumatologist Claire Bombardier, M.D., had then, and has since, various relationships with Merck, including serving as the chief investigator for the VIGOR study.

32. The Bombardier/Reicin article addresses adverse cardiovascular event data by stating that:

“The incidence of myocardial infarction was lower among patients in the naproxen group than among those in the rofecoxib group (0.1 percent vs. 0.4 percent; relative risk; 0.2; 95 percent confidence interval, 0.1 to 0.7); the overall mortality rate and the rate of death from cardiovascular causes were similar in the two groups.”

33. The conclusions reached in the Bombardier/Reicin article do not mention an increase in cardiovascular risks with Vioxx, saying only that “in patients with rheumatoid arthritis, treatment with rofecoxib, a selective inhibitor of cyclooxygenase-2, is associated with

significantly fewer clinically important upper gastrointestinal events than treatment with naproxen, a nonselective inhibitor.”

34. In response to growing public expressions of concern over the cardiovascular safety profile of Vioxx, Merck issued a press release entitled “Merck Confirms Favorable Cardiovascular Safety Profile of Vioxx,” dated May 22, 2001. This press release states that Vioxx has a “favorable cardiovascular safety profile.” The FDA would later tell Merck that:

“Your claim in the press release that Vioxx has a ‘favorable cardiovascular profile’ is simply incomprehensible, given the rate of MI [myocardial infarction] and serious cardiovascular events compared to naproxen. The implication that Vioxx’s cardiovascular profile is superior to other NSAIDs is misleading; in fact, serious cardiovascular events were twice as frequent in the VIOXX treatment group. . . as in the naproxen treatment group. . . in the VIGOR study.”

35. An article titled “Risk of Cardiovascular Events Associated with Selective COX-2 Inhibitors,” written by Drs. Mukherjee, Nissen, and Topol at the Cleveland Clinic, was published in the August 29, 2001 edition of the *Journal of the American Medical Association*.

36. These Cleveland Clinic doctors found that the risk of serious cardiovascular adverse events in the studies that they analyzed, including VIGOR, is 238% higher for Vioxx than naproxen.

37. Drs. Mukherjee, Nissen, and Topol conclude their article by stating that “the available data raise a cautionary flag about the risk of cardiovascular events with COX-2 inhibitors. Further prospective trial evaluation may characterize and determine the magnitude of risk.”

38. Rxintelligence is a non-profit pharmaceutical research organization founded by the Blue Cross and Blue Shield Association to study the risks, cost, and benefits of new drugs in comparison to older ones. On September 12, 2001, Rxintelligence, in conjunction with Blue

Cross/Blue Shield of Illinois, released the results of a comprehensive analysis of the Vioxx studies on file with the FDA at that time. This analysis shows a higher incidence of hypertension among those taking Vioxx than in those taking Celebrex.

39. Thomas W. Abrams, Director of Drug Marketing, Advertising and Communications at the FDA, issued a Warning Letter dated September 17, 2001, to Merck CEO Raymond V. Gilmartin, relating to “promotional activities and material for the marketing of Vioxx (rofecoxib) tablets.”

40. This Warning Letter states the following:

“[Merck] engaged in a promotional campaign for Vioxx that minimized the potentially serious cardiovascular findings that were observed in the Vioxx Gastrointestinal Outcomes Research (VIGOR) study, and thus, misrepresents the safety profile for Vioxx.

...

Specifically, your promotional campaign discounts the fact that in the VIGOR study, patients on Vioxx were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients on the comparator non-steroidal anti-inflammatory drug (NSAID), Naprosyn (naproxen).

...

The promotional activities and materials described above minimize the potentially serious Cardiovascular findings that were observed in the VIGOR study, minimized the VIOXX/Coumadin drug interaction, omit crucial risk information associated with Vioxx therapy, contain unsubstantiated comparative claims, and promote unapproved uses. On December 16, 1999, we also objected to your dissemination of promotional materials for Vioxx that misrepresented Vioxx’s safety profile, contained unsubstantiated comparative claims, and lacked fair balance.

Due to the seriousness of these violations, and the fact that your violative promotion of Vioxx has continued despite our prior written notification regarding similar violations, we request that you provide a detailed response to the issues raised in this Warning Letter on or before October 1, 2001.

This response should contain an action plan that includes a comprehensive

plan to disseminate corrective messages about the issues discussed in this letter to the audiences that received these misleading messages. This corrective action plan should also include:

Immediately ceasing all violative promotional activities, and the dissemination of violative promotional materials for Vioxx.

Issuing a “Dear Healthcare Provider” letter to correct false or misleading impressions and information. This proposed letter should be submitted to us for review prior to its release. After agreement is reached on the content and audience, the letter should be disseminated by direct mail to all healthcare providers who were, or may have been exposed to the violative promotion.

A written statement of your intent to comply with ‘1’ and ‘2’ above.”

41. An article entitled “Non-Steroidal Anti-Inflammatory Drugs and Risk of Serious Coronary Heart Disease: An Observational Cohort Study,” authored by Vanderbilt University researchers headed by Wayne Ray, was published in the January 12, 2002 edition of the *Lancet*. This article posits an explanation of how Cox-2 inhibitors promote thromboembolic events.

42. Merck’s Vice President of Clinical Research, Dr. Alise Reicin, and others authored an article in defense of Vioxx’s cardiovascular risk profile titled “Cardiovascular thrombotic events in controlled, clinical trials of rofecoxib,” which was published in the November 6, 2001 edition of the journal *Circulation*. Dr. Reicin and her companion authors summarize their assessment of Vioxx as follows:

“This analysis provides no evidence for an excess of CV [cardiovascular] events for rofecoxib [Vioxx] relative to either placebo or the non-naproxen NSAIDs that were studied. Differences observed between rofecoxib and naproxen are likely the result of the antiplatelet effects of the latter agent.”

43. A work sponsored by Merck and conducted and written by Merck employees led by Alise Reicin, Merck’s Vice President of Clinical Research, titled “Comparison of

cardiovascular thrombotic events in patients with osteoarthritis treated with Rofecoxib versus nonselective nonsteroidal anti-inflammatory drugs (Ibuprofen, Diclofenac, and Nabumetone),” was published in the January 15, 2002 edition of the *American Journal of Cardiology*. The Merck authors, seeking to defend Vioxx, conclude the following:

“... an analysis from the rofecoxib osteoarthritis development program found no difference between rofecoxib, comparator nonselective NSAIDs, and placebo in the risks of cardiovascular thrombotic events.”

44. An article titled “Why Do Cyclooxygenase-2 Inhibitors Cause Cardiovascular Events?” authored by Drs. Bing, Lomnicka, and others at the Department of Experimental Cardiology at the Huntington Medical Research Institutes was published in the journal *Pharmacology* on February 6, 2002. The authors explain that a selective Cox-2 inhibitor, such as Vioxx, can promote adverse cardiovascular events by tipping the balance of prostacyclin and thromboxane in favor of thromboxane. This imbalance promotes both platelet aggregation and vasoconstriction, which can lead to catastrophic cardiovascular events, including stroke, heart attack, and pulmonary embolism.

45. Merck also conducted studies on Vioxx as a potential drug for Alzheimer’s patients. In these studies Merck found that mortality was unexpectedly higher for patients on Vioxx than placebo. Merck, however, failed to notify physicians of this adverse mortality data. On September 27, 2005, Edward Scolnick, former president of Merck Research Laboratories, testified via deposition in a New Jersey case (*Humeston v. Merck*) that doctors prescribing Vioxx should have been told about data from the Alzheimer’s studies in 2001:

46. An article by FitzGerald, Cheng, and others at the University of Pennsylvania entitled “Role of Prostacyclin in the Cardiovascular Response to Thromboxane A<sub>2</sub>,” published in

the April 19, 2002 *Journal of Science*, explains the following:

“...PGI2 modulates platelet-vascular interactions in vivo and specifically limits the response to TxA2. This interplay may help explain the adverse cardiovascular effects associated with selective COX-2 inhibitors, which, unlike aspirin and nonsteroidal anti-inflammatory drugs (NSAIDs), inhibit PGI2 but not TxA2.”

47. In April 2002 a new Vioxx label went into effect that added information about heart attacks and strokes. Merck prepared an internal marketing document to “all field personnel with responsibility for Vioxx” that was “an obstacle handling guide.” If doctors asked about cardiac risk and Vioxx, sales reps were told to say Vioxx “would not be expected to demonstrate reductions” in heart attacks or other cardiovascular problems and that “it was not a substitute for aspirin.” One training document was titled “Dodge Ball Vioxx” and consists of 16 pages. Each page lists one “obstacle” apparently representing statements that might be made by a doctor. One question, for example, is “I am concerned about the cardiovascular effects of Vioxx.” The final four pages each contain a single word in capital letters: “DODGE.”

48. Merck acted actively to suppress information to physicians and the health care community. Merck canceled lectures and presentations by Dr. Gurkirpal Singh at Stanford after he gave presentations that showed a man hiding under a blanket as to the issue of missing data on cardiac safety. Merck also suggested to a Stanford professor “that if this continued Dr. Singh would ‘flame out’ and there would be consequences [to the Stanford professor, Dr. Fries] and Stanford.” *Wall Street Journal*, Nov. 1, 2004, p. A1. Merck phoned a physician (Dr. Simon) at the Beth Israel Hospital in Boston, Massachusetts to complain that another physician there (Dr. Lee Simon who had publicly mentioned data showing that Vioxx might be associated with high blood pressure and swelling) was giving lectures slanted against Vioxx. Dr. Simon stated Merck “was attempting to suppress a discussion about this data.” *Wall Street Journal*, Nov. 1, 2004, p.

A1. A similar “inappropriate” phone call was made Dr. Thomas Stillman at the University of Minnesota (who also discussed high blood pressure and swelling data in his lectures). Wall Street Journal, Nov. 1, 2004, p. A1. Wall Street Journal, Nov. 1, 2004, p. A1.

49. Dr. Reicin continued her defense of Vioxx in an article entitled “Selective COX-2 inhibition and cardiovascular effects: a review of the rofecoxib development program,” which was published in the October 1, 2003 edition of the *American Heart Journal*. In this publication, Dr. Reicin and her colleagues state the following:

“Rofecoxib [Vioxx] was not associated with excess CV [cardiovascular] thrombotic events compared with either placebo or non-naproxen NSAIDs. Again, naproxen appeared to be the outlier, suggesting a cardio protective benefit of naproxen.”

“The totality of data is not consistent with an increased CV[cardiovascular] risk among patients taking rofecoxib [Vioxx].”

50. An article by Solomon and others at the Harvard Medical School, entitled “Relationship Between Selective Cyclooxygenase-2 Inhibitors and Acute Myocardial Infarction in Older Adults,” was published in the April 2004 edition of the journal *Circulation*. The Harvard authors concluded the following from their study:

“... rofecoxib [Vioxx] use was associated with an elevated relative risk of AMI [acute myocardial infarction] compared with celecoxib [Celebrex] use and no NSAID use. Dosages of rofecoxib [greater than] 25 mg were associated with a higher risk than dosages [less than or equal to] 25 mg.”

51. An article by H.K. Choi in the May 1, 2004 edition of the *American Journal of Medicine*, entitled “Effects of rofecoxib and naproxen on life expectancy among patients with rheumatoid arthritis: a decision analysis,” concludes the following:

“Our analysis suggests a longer life expectancy with naproxen than rofecoxib [Vioxx] . . . except in those at low risk of myocardial infarction or at a high risk of upper gastrointestinal toxicity.”

52. David Graham, M.D., made a poster presentation entitled “Risk of Acute Myocardial Infarction and Sudden Cardiac Death with Use of COX-2 Selective and Non-Selective NSAIDs” at the 20<sup>th</sup> International Conference on Pharmacoepidemiology and Therapeutic Risk Management, held from August 22-25, 2004, in Bordeaux, France. The data for the presentation was taken from a study done by Kaiser Permanente under a contract funded by the FDA.

53. Vioxx taken at more than 25 mg per day increased the risk of heart attack and sudden cardiac death by 300% in those enrolled in the Kaiser Permanente study. This study was subsequently published in the prestigious peer-reviewed publication THE LANCET (2005): 365:475-91. The study classified “sudden cardiac death” as including “conductive disorders” and “death from an unknown cause.” Danny C. Hodges’ final diagnosis at autopsy was “No anatomic or toxicologic cause of death in this case. Death is attributed to cardiac arrhythmic of unknown etiology.”

54. On August 26, 2004, Peter Kim, President of Merck Research Laboratories, issued a press release stating the following:

“Merck strongly disagrees with the conclusions of an observational analysis by Graham, et al., presented at an international medical meeting this week. . .”

“Merck stands behind the efficacy and safety, including cardiovascular safety, of VIOXX.”

55. On September 27, 2004, Merck informed the FDA that the Data Safety Monitoring Board for an ongoing long-term study of Vioxx, known as the APPROVe study, had recommended that the study be stopped early for safety reasons.

56. The APPROVe study was not intended to be a cardiovascular risk assessment study. It was commissioned by Merck to look at the effect of Vioxx in people at risk for developing recurrent colon polyps.

57. The APPROVe study demonstrates an increased risk of cardiovascular adverse events, including heart attacks and strokes, for the Vioxx population relative to the placebo population in the study, particularly for people taking Vioxx for more than 18 months.

58. Merck representatives informed the FDA in a September 28, 2004 meeting that Merck would withdraw Vioxx from the United States market.

59. Merck and the FDA each announced the withdrawal of Vioxx from the United States market on September 30 2004. Merck also announced worldwide withdrawal the same day.

60. An FDA analysis, based on data from the Kaiser Permanente study, projects that 27,785 heart attacks and sudden cardiac deaths “would have been avoided” had Celebrex been used instead of Vioxx.

61. Approximately 20 million people in the United States took Vioxx between its introduction in 1999 and its withdrawal in 2004.

## **CAUSES OF ACTION**

### **A. Strict Liability**

62. Merck developed, patented, studied, manufactured, and marketed Vioxx.

63. The Vioxx taken by Danny Hodges was not materially altered between the time it was placed into the stream of commerce by Merck and the time it was taken by Danny Hodges.

64. Vioxx is a defective product in the sense that it is not reasonably safe for its

intended use, based on an objective analysis weighing its risks and benefits against those of alternative pain relief drugs, which were available throughout the time Vioxx was on the market.

65. The design of the chemical formula for Vioxx is defective.

66. Vioxx is also defective because it was not accompanied by adequate warnings to health care professionals or to those who took the drug of its cardiovascular adverse event risks. Moreover, the warnings that were given were diluted and substantially rendered ineffective by Merck's misleading promotional efforts directed at both health care professionals and the public.

67. Vioxx's risk of cardiovascular adverse events made it more dangerous than its consumers would expect or anticipate.

68. Danny Hodges did not know, and a reasonable person under the same or similar circumstances would not have had reason to know, of Vioxx's defects.

69. Danny Hodges took Vioxx under circumstances that were within the range of intended uses that were anticipated by Merck.

#### **B. Restatement of Torts §402B Liability**

70. Merck's Vioxx marketing, including direct-to-consumer advertising and promotions directed toward health care professionals, was a sustained campaign for more than five years, characterized by misrepresentations by commission and omission as to the risks and benefits, particularly as to cardiovascular adverse event risks, of the drug.

71. The public, including Danny Hodges, and prescribing physicians, including Mr. Hodges' prescribing physician, reasonably relied upon Merck's misrepresentations as to Vioxx's risks and benefits in deciding to take it and prescribe it.

#### **C. Negligence**

72. Merck did not use reasonable care in designing Vioxx.

73. Merck did an unreasonably poor job of studying the cardiovascular risks of Vioxx before seeking approval to market it.

74. Merck acted unreasonably each year Vioxx was on the market by not initiating a study to assess its cardiovascular risks in light of mounting evidence that Vioxx could be contributing to avoidable heart attacks, strokes, and other cardiovascular adverse events.

75. Merck unreasonably failed to advise health care professionals and the public to restrict the use of Vioxx to short term therapy for those at high risk for gastrointestinal adverse events.

76. Merck unreasonably failed to adequately warn of Vioxx's risk of cardiovascular adverse events.

77. Merck unreasonably presented unsubstantiated, false, and/or misleading information as to the risks and benefits of Vioxx to health care professionals and to the public.

78. It was unreasonable for Merck to eviscerate the cardiovascular risk information in Vioxx's prescribing information by minimizing these risks, making unsubstantiated comparison claims, and exaggerating the benefits and approved uses of the drug in Merck's promotional campaigns for Vioxx.

79. Merck acted unreasonably in making a series of marketing decisions to defend Vioxx, despite growing evidence that it contributes to serious and sometimes fatal cardiovascular events, in an effort to maintain the share of the Cox-2 inhibitor market represented by Vioxx, until Merck could get its new Cox-2 inhibitor, Arcoxia, on the market to replace Vioxx.

#### **D. Breach of Implied Warranty**

80. A warranty that a product is reasonably fit for its intended purpose is imposed by law on the seller of the product, including Merck in the sale of Vioxx.

81. Merck breached this implied warranty, because Vioxx is not reasonably fit for its intended purpose for the reasons explained above.

82. Danny Hodges reasonably relied upon the belief that Vioxx is reasonably safe for its intended purpose in making the decision to take the drug.

#### **E. Breach of Express Warranty**

83. Merck created an express warranty that Vioxx is reasonably safe for its intended purpose through the representations made to health care professionals and to the public, which were described above.

84. Merck breached this express warranty, because Vioxx is not reasonably safe for its intended purpose.

85. Danny Hodges reasonably relied upon Merck's express warranty in making the decision to take the drug.

#### **G. Intentional, Reckless, and/or Malicious Conduct**

86. The totality of Merck's conduct, as described in this Complaint, is susceptible of being interpreted by reasonable people as demonstrating an irresponsible attitude toward drug safety, and as being willful, intentional, reckless, and/or malicious, justifying an award of punitive damages.

### **G. Injuries**

87. Danny Hodges began taking Vioxx in December 2001, and continued to take said prescription medication up to after the date of his last prescription (September 10, 2004).

88. On December 4, 2004, Danny Hodges died a sudden cardiac death.

89. Danny Hodges' ingestion of Vioxx was a substantial contributing factor, or a proximate legal cause of his death.

90. Merck's conduct, as identified in any one, all, or a combination of the five bases of liability identified in this Complaint, was a substantial contributing cause, or a proximate legal cause, of his stroke.

91. Danny Hodges could not possibly have discovered the dangerous and defective nature of Vioxx until after he learned of Merck's withdrawal of Vioxx (which Merck announced on September 30, 2004). His family and Estate had no reason to know that Vioxx had caused any injury or damage to Mr. Hodges until his sudden death on December 4, 2004.

### **H. Economic and Non-Economic Damages**

92. As a direct and proximate result of the negligent, intentional, willful, reckless, malicious, and other conduct of Merck as alleged herein, plaintiff's decedent, Danny Hodges, suffered severe injuries and a wrongful death. Plaintiff sues for the decedent's pain and suffering at and prior to death. Plaintiff sues to recover the loss to the estate as defined as the destruction of the decedent's power to labor and earn money. Plaintiff sues for loss of spousal and parental consortium. Plaintiff sues for burial and funeral expenses.

KRS 411.130(1) allows recovery in wrongful death actions for punitive damages where the act causing death is willful or grossly negligent. Plaintiff seeks punitive damages.

93. As a further direct and proximate result of this conduct, Danny Hodges incurred bills for medical care, attention, and treatment.

94. As a further direct and proximate result of the conduct of Merck, Danny Hodges suffered conscious pain and suffering, lost wages, and loss of earning power.

95. Plaintiff therefore asks for judgment against the defendants for all available economic and non-economic compensatory damages as more fully set forth above and herein.

### **I. Punitive Damages**

96. Plaintiff also seeks judgment against Merck for punitive damages in an amount found by a jury to represent fair punishment for a company with Merck's financial resources for willfully, intentionally, recklessly, irresponsibly, and/or maliciously breaching its duty to act in the interest of public safety and in the interest of the health of its customers, and which will deter Merck and other pharmaceutical manufacturers from the same or similar disregard for the public's future trust, health and safety.

97. Plaintiff also seeks pre-judgment interest on any verdict in his/her favor to the full extent allowable by Kentucky law.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays for compensatory damages in an amount which meets this Court's jurisdictional limit, including pre- and post-judgment interest, attorney fees, costs, and any other relief that this Court deems appropriate. Plaintiff also seeks punitive damages against defendant Merck to punish, deter, set an example of, and prevent such illegal and dangerous conduct from affecting and placing others at similar risk in the future.

LAW OFFICE OF DAVID RANDOLPH SMITH  
& EDMUND J. SCHMIDT, III  
1913 21<sup>st</sup> Avenue South  
Nashville, Tennessee 37212  
(615) 742-1775  
(615) 742-1223 (fax)  
<http://www.drslawfirm.com>  
[info@drslawfirm.com](mailto:info@drslawfirm.com)

-and-

WHITFIELD & COX, P.S.C.  
29 East Center Street  
Madisonville, Kentucky 42341  
(270) 821-0656  
(270) 825-1163  
Attorneys for Plaintiff

By: \_\_\_\_\_  
David Randolph Smith  
John C. Whitfield