

Journal of Civil Rights and Economic Development

Volume 22
Issue 1 *Volume 22, Summer 2007, Issue 1*

Article 1

June 2007

Merck and the Vioxx Debacle: Deadly Loyalty

David R. Culp

Isobel Berry

Follow this and additional works at: <https://scholarship.law.stjohns.edu/jcred>

Recommended Citation

Culp, David R. and Berry, Isobel (2007) "Merck and the Vioxx Debacle: Deadly Loyalty," *Journal of Civil Rights and Economic Development*: Vol. 22 : Iss. 1 , Article 1.

Available at: <https://scholarship.law.stjohns.edu/jcred/vol22/iss1/1>

This Article is brought to you for free and open access by the Journals at St. John's Law Scholarship Repository. It has been accepted for inclusion in Journal of Civil Rights and Economic Development by an authorized editor of St. John's Law Scholarship Repository. For more information, please contact selbyc@stjohns.edu.

ARTICLES

MERCK AND THE VIOXX DEBACLE: DEADLY LOYALTY

BY DAVID R. CULP, LA SALLE UNIVERSITY*;

AND ISOBEL BERRY, DESALES UNIVERSITY**

ABSTRACT

This paper discusses the Vioxx tragedy, analyzes the cases tried to verdict, and sets out the arguments both for and against Merck's actions. It asks whether Merck acted unethically or whether Merck is the victim of overzealous attorneys and runaway juries. The article asks how ten

* David R. Culp, Assistant Professor, La Salle University. Adjunct, DeSales University. Adjunct, Rutgers State University School of Law. Co-President and Executive Secretary, Ethics Section of the Academy of Legal Studies in Business. President, Northeast Academy of Legal Studies in Business. Member, Berry and Culp, P.C.

** Isobel Berry, Adjunct, DeSales University. Co-President and Executive Secretary, Ethics Section of the Academy of Legal Studies in Business. Vice-President, Northeast Academy of Legal Studies in Business. President, Berry and Culp, P.C.

Merck employees from three different MBA classes can unequivocally and with righteous indignation argue that Merck acted ethically. The authors ask how employees learn to be so “loyal”? Is that deadly loyalty a product of our educational system, from kindergarten through MBA programs, and is the mantra that the purpose of business is to “maximize profits and create shareholder wealth” also a product of an educational system that has minimized the insidious evil and immorality of that doctrine?

INTRODUCTION

As law suits mount against Merck for its marketing of its blockbuster drug, Vioxx, employees of Merck in three different MBA classes at two different universities taught by the authors of this article have unabashedly supported Merck’s actions as being ethical. Angry at the suggestion that Merck hid the dangers of Vioxx and pulled the drug long after they suspected the drug caused an increased risk of serious cardiovascular events, including heart attacks, stroke, and death, their loyalty to Merck remains resolute. Is such loyalty deserved, or is there a disconnect with the facts, and if so, why?

In September 2004, Merck voluntarily pulled its blockbuster drug, Vioxx, from the market after an internal study showed that long-term use of Vioxx—eighteen-months or longer—created twice the risk of heart attacks and stroke as other drugs used to combat the pain of osteoarthritis and acute pain in adults.¹ Until Merck removed Vioxx from the marketplace, the drug had garnered huge profits for a company that had not had a blockbuster drug for several years.² In addition, during the 1999-01 period, Merck had lost its patent protection on five of its best-selling drugs: Vasotec, Pepcid, Mevacor, Priloxed, and Prinivil.³

¹ *Merck Pulls Vioxx Across the Globe*, (Sept. 20, 2004) available at <http://www.msnbc.msn.com/id/6139592> (noting Vioxx was “pulled off market after study confirmed” it heightened risks of heart attack and stroke).

² Chris Mondics, *Two Vioxx Critics Allege Pressure*, PHILADELPHIA INQUIRER, Nov. 19, 2004, at A1, A22 (stating “Vioxx generated sales of \$2.5 billion a year, making it a blockbuster product for a company that in recent years has had difficulty developing new medications, a problem faced by much of the pharmaceutical industry.”).

³ John Simons, *Will Merck Survive Vioxx? Looming Lawsuits, Angry Investors, Declining Profits: The Vioxx Debacle is Just the Late Giant.*, FORTUNE (Nov. 1, 2004), available at http://money.cnn.com/magazines/fortune/fortune_archive/2004/11/01/

And two of its celebrated cholesterol drugs, Zocor and Prayachol, were to lose their twenty-year patent protection and marketability by early 2007 when lower-priced generic imitations came on the market.⁴ From 1999-04, Vioxx picked up some of the slack, generating sales of \$2.5 billion a year, making it the best selling drug in the company's history.⁵

Merck and Vioxx have had a stormy relationship since the Food and Drug Administration's ("FDA") May 1999 approval of Vioxx as reports slowly filtered to the media that long before its removal of Vioxx from the marketplace, Merck knew that Vioxx was a dangerous drug and they nevertheless marketed it aggressively to doctors and an unsuspecting public.⁶

Merck is a company that traditionally has had high marks for its ethical practices and social conscience. In its mission/values statement, the company stresses that its "business is preserving and improving human life."⁷ Merck's Mission Statement continues, "[w]e value, above all, the ability to serve everyone who can benefit from the appropriate use of our products and services."⁸ Throughout its history, Merck has often lived up to its stated mission. In the 1930's after streptomycin was developed by a Merck scientist, Merck gave up its patent protection since it believed the drug was too important a medical breakthrough to keep to itself.⁹ Other companies were allowed to produce streptomycin, and Merck lost potential profits. Since the 1980's, when Merck found a cure for "river blindness" caused by a parasitic worm, the company has given away, free of charge, over forty-million pills a year to African nations to treat and cure this

8189593/index.htm (explaining Merck was soon to lose patent protection on some of its major drugs, sales of which represented over five billion dollars annually).

⁴ Alex Berenson, *Big Drug Makers See Sales Erode with Their Image*, N.Y. TIMES, Nov. 14, 2005, at A1 (highlighting that several drug companies would lose patent protection by 2007, including Merck).

⁵ See Mondics, *supra* note 2 at A22 (noting Vioxx's tremendous sales figures).

⁶ Robert Cohen, *Report: Merck Mised Doctors*, STAR-LEDGER, May 6, 2005, at 1 (describing House Committee on Government Reform's findings).

⁷ *Merck Corporate Philosophy-Mission Statement*, <http://www.merck.com/about/mission.html> (last visited Nov. 13, 2006) (listing Merck's mission and values).

⁸ *Id.*

⁹ Robert B. Zoellick, President and Chief Executive Officer of the Center for Strategic and Int'l Studies (CSIS), *Keynote Address before the Business-Humanitarian Forum in Geneva, Switzerland: Strategic Philanthropy for Business*, Jan. 27, 1999 (describing Merck's history of philanthropy and how it gave streptomycin to Japan to cure tuberculosis without earning anything in exchange).

disease.¹⁰ And in 2004 Merck offered to give medicines for free to low-income Medicare beneficiaries.¹¹ About 4.2 million senior citizens, with very low incomes, are eligible for a \$600 annual allowance toward drug costs on government-endorsed Medicare discount cards. Merck said it would provide its medicines free to those low-income beneficiaries who have exhausted the \$600 Medicare subsidy.¹²

But today, Merck stands awash in lawsuits by those who have taken Vioxx and suffered heart attacks or strokes. As of April 2006, Merck faced over 9,600 cases nationwide.¹³ That number did not include the cases brought by Great Britain residents who have taken Vioxx and suffered heart attacks or strokes. By December 2006, the number of law suits filed against Merck in the United States had risen to over 27,000, with an additional 265 potential class-action suits.¹⁴ Another 14,000 plaintiffs have entered into stipulations with Merck suspending the time limit for filing, and a Canadian judge has approved a class-action lawsuit for residents of Quebec.¹⁵ From 1999-04, over eighty-million people worldwide took Vioxx to treat pain.¹⁶ David Graham, a scientist with the FDA, estimates that in just the United States, Vioxx may have caused 140,000 heart attacks or strokes and 55,000 deaths.¹⁷

¹⁰ *Merck Expands Its Commitment to Eliminate River Blindness*, available at http://www.merck.com/about/feature_story/05192004_mectizan.html (last visited Nov. 13, 2006) (noting Merck donated Mectizan to many African and Latin American nations in order to help cure river blindness).

¹¹ Grace-Marie Turner & Joseph R. Antos, *Fixing the New Medicare Law # 3: How to Build on the Drug Discount Card*, available at <http://www.heritage.org/Research/HealthCare/bg1752.cfm> (Apr. 26, 2004) (describing Merck's philanthropy regarding low-income Medicare recipients).

¹² U.S. Dep't of Health and Human Services, *\$600 Credit and Discounts Combine to Give Low-Income Medicare Beneficiaries Significant Discounts on Prescription Drugs*, <http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1056> (last visited Nov. 13, 2006) (listing Merck as one of many medication donors to people with low-incomes).

¹³ Theresa Agovino, *Merck Loses Appeal; Faces Prospect of Nationwide Class-Action Vioxx Lawsuit*, (Mar. 31, 2006), available at http://legalsoapbox.freeadvice.com/n15868_Merck_loses_appeal;faces_prospect_of_nationwide_classaction_vioxx_lawsuit.htm (last visited Nov. 13, 2006) (noting Merck "faces over 9,600 Vioxx-related lawsuits.").

¹⁴ *Jury Rules in Merck's Favor in Alabama Vioxx Trial*, ASSOCIATED PRESS, (December 15, 2006), available at <http://www.foxnews.com/story/0,2933,236782,00.html>.

¹⁵ Janet McConaughy, *Jury Clears Merck in 11th Vioxx Trial; Drug Firm Has Won 3 of 4 Federal Cases*, WASH. POST, Nov. 16, 2006, at D3.

¹⁶ W. John Thomas, *The Vioxx Story: Would It Have Ended Differently in the European Union?*, 32 AM. J.L. & MED. 365, 365-66 (2006) (stating more than 105 million prescriptions were filled for Vioxx between May 20, 1999 and August 2004).

¹⁷ Marc Kaufman, *Merck CEO Resigns as Drug Probe Continues*, WASH. POST, May 6, 2005, at A1 (describing FDA officers' and others' estimations).

Merck and its employees argue emphatically that Merck has behaved responsibly and ethically. Company representatives claim that as soon as there was credible scientific evidence of Vioxx's negative health risks in those who had taken the drug for eighteen-months or longer, they pulled the drug.¹⁸ They did not wait for the FDA to decide whether to pull the drug, they did so themselves. Merck employees are incensed at the suggestion they acted unethically and to maximize profits, without consideration of the health of its customers.¹⁹

I. THE LITIGATION—PICKING THE WINNING HAND

Of the more than 27,000 cases in the pipeline, only 12 have reached a verdict, and most of these are on appeal. Merck has received a jury verdict in eight cases, and plaintiffs have won four. Merck has appealed the four losses and vows that it will try every case already in the legal system.²⁰ A ninth case in which Merck won a jury verdict, the trial court judge has overturned, and the case will be retried. With only 12 decisions out of over 27,000 cases, no clear pattern has emerged from the litigation, and experts say it may be years before a pattern is set. It has been estimated that Merck's potential liability could reach \$30-50 billion.²¹ That figure does not include Merck's legal costs to

¹⁸ *Major Victory for Merck in N.J. Vioxx Trial*, (Nov. 3, 2005), available at <http://www.msnbc.msn.com/id/9910674> (last visited Nov. 13, 2006) (providing Merck Senior Vice-President's and General Counsel, Kenneth C. Frazier's opinion that Merck acted responsibly from start to finish with Vioxx).

¹⁹ Simons, *supra* note 3, at 90. Ray Gilmartin, Merck's chairman and CEO responded that when he got the bad news about Vioxx from research chief, Peter Kim, "my reaction . . . was that we were going to make a decision about Vioxx totally in the interest of patient safety."

²⁰ See Thomas Ginsberg, *Merck Defeat in Vioxx Verdict: The Drugmaker Hid Risks from the FDA, Jury Ruled*, PHILADELPHIA INQUIRER, Apr. 12, 2006, at A01. After the second Merck loss on April 11, 2006, in Atlantic City, New Jersey in the *McDarby v. Merck* case, Kenneth Frazier, Merck's General Counsel, vowed to fight each case, and his co-counsel, Chuck Harell, has echoed, "[w]e're in this for the long haul . . ." *Id.* Thomas Ginsberg, *3rd Vioxx Trial Ends in Hung Jury*, PHILADELPHIA INQUIRER, Dec. 13, 2005, at E01 [hereinafter *3rd Vioxx Trial Ends in Hung Jury*]. After a hung jury decision in Houston, Texas in December 2005, Frazier had proffered: "The Vioxx litigation will go on for years. We have the resources and the resolve to address these cases, one by one, in a reasonable and responsible manner." *Id.*

²¹ Barnaby J. Feder, *Federal Panel Consolidates Vioxx Suits*, N.Y. TIMES, Feb. 17, 2005, at C1 (noting that analysts estimate Merck could face as much as \$30 billion dollars in liabilities stemming from federal and state cases).

defend the Vioxx litigation. By November 2006, Merck's legal costs were "sizable: \$610 million so far."²²

In August 2005, after more than a month of testimony from scientific experts, a Texas state jury awarded \$24.4 million in compensatory damages and \$229 million in punitive damages to Carol Ernst, whose husband died in his sleep in 2001 after taking Vioxx for about eight months.²³ Under Texas's limitations on punitive damage awards, the verdict will be lowered to \$26.1 million. Jurors interviewed following the trial stated that the testimony and documents presented by plaintiff's counsel, Mark Lanier, had demonstrated to them that Merck had long been aware of Vioxx's potential heart risks and hid this information from patients.²⁴ In a statement issued after the verdict, Merck's general counsel, Kenneth Frazier, said that the "verdict in Texas was a disappointment to all of us at Merck because we know we acted responsibly We believe we have meritorious defenses, and we intend to vigorously defend individual Vioxx cases one by one."²⁵

On November 3, 2005, in Atlantic County, New Jersey, with Judge Carol Higbee presiding, Merck won its first jury verdict, a nine-member jury determining that Vioxx did not cause Mike Humeston's mild heart attack and that the company did not hide risk information.²⁶ Mike Humeston, sixty-years-of-age, an Idaho postal worker, claimed that Vioxx caused his heart attack in 2001, after less than two months of intermittent use of Vioxx. In an eight to one vote, the jurors found that Merck scientists in 2001 did not believe Vioxx increased the risks of heart attack and stroke and, therefore, were not obligated to warn physicians, including the doctor who had prescribed Vioxx

²² Avery Johnson & Heather Won Tesoriero, *Merck Adds Another Win In Vioxx Trials*, WALL ST. J., Nov. 16, 2006, at B1.

²³ See Alex Berenson, *For Merck, the Vioxx Paper Trail Won't Go Away*, N.Y. TIMES, Aug. 21, 2005, at 1 [hereinafter *For Merck, the Vioxx Paper Trail Won't Go Away*] (reporting "Texas jury found Merck liable for the death of Robert C. Ernst, who died in May 2001 after taking Vioxx . . .").

²⁴ See *id.* (explaining "[t]o the jurors, the evidence added up to a mass of damaging bad facts that overwhelmed the company's defense").

²⁵ *Id.*

²⁶ See Thomas Ginsberg, *Vioxx Victory Key for Merck Jurors Said the Drug Did Not Cause a Heart Attack. Merck Victory in Trial on Vioxx - 6,400 to go*, PHILADELPHIA INQUIRER, Nov. 4, 2005, at A01 [hereinafter *Vioxx Victory Key for Merck*] (calling case "key victory").

to Humeston.²⁷ Voting nine to zero, the jury also rejected Humeston's consumer fraud claim that Merck had engaged in "unconscionable commercial practices" in marketing Vioxx, and finding that Merck did not "intentionally suppress, conceal or omit material information" about the potential for cardiovascular problems.²⁸ Although the jurors were not required to vote on the issue of "causation," several jurors said they did not believe that Vioxx caused Humeston's heart attack. One juror noted that he "only took it for two months, and he was taking a lot of other stuff," and a second juror stated that "Humeston had way too many other risk factors to blame it on Vioxx."²⁹

The Merck victory was short-lived. During the trial, Merck's attorneys used Humeston's medical records to demonstrate to the jury that he took Vioxx intermittently over the course of two months, while clinical trials had proved a higher risk of heart attack existed only after eighteen-months of daily use.³⁰ Merck's defense at trial that clinical studies proved Vioxx created an increased cardiovascular risk only after eighteen months of taking Vioxx became the centerpiece for plaintiff's post-trial motions asking the verdict to be set aside and for a new trial. On August 17, 2006, Judge Higbee granted plaintiff's post-trial motions. Judge Higbee vacated the jury verdict and ordered a new trial after Humeston's lawyers presented evidence that during the trial Merck had withheld evidence which demonstrated that the company knew Vioxx posed an increased risk of heart attacks even when taken for less than 18 months.³¹

On February 17, 2006, Merck won a retrial of a Vioxx suit in a New Orleans federal district court.³² The first trial had ended in a hung jury, after the jury was unable to reach consensus on

²⁷ See *id.* Humeston's knee pain resulted from a prior shrapnel wound.

²⁸ See *id.* (noting jury's rejection of Humeston's consumer-fraud claim).

²⁹ *Id.*

³⁰ See *id.* Humeston's medical records revealed he ingested fifty-four pills intermittently for two months, doubling his dose at times when he felt pain.

³¹ Joshua Pantesco, *New Jersey Judge Vacates Merck Vioxx Trial Win*, PAPER CHASE NEWSBURST (Aug. 17, 2006), available at <http://jurist.law.pitt.edu/paperchase/2006/08/new-jersey-judge-vacates-merck-vioxx.php>.

³² See *Merck Buoyed by Vioxx Trial Win*, MARKETWATCH (Feb. 21, 2006), available at <http://www.marketwatch.com/news/story/merck-shares-gain-following-vioxx/story.aspx?guid=%7B357A3A2F-3767-4D2E-A90C-F9A74EF9DC28%7D%09%09%09%09%09%09&> (last visited Jan. 9, 2007) (explaining this as Merck's third liability case relating to Vioxx and highlighting that Merck had been found liable in a Texas case and not liable in a previous New Jersey case).

Merck's liability to a plaintiff, Richard Irvin, a fifty-three-year-old Florida resident, who died from a heart attack in 2001 after taking Vioxx for less than a month.³³ The second jury reached a verdict, finding that Vioxx was not the cause of the plaintiff's heart attack and death.³⁴ Merck's lawyers had argued at trial that Irvin's age, gender, and diet all put him at risk for a heart attack. Irvin's widow, a daughter, and a son all testified that Irvin's health had been excellent up to his heart attack.³⁵ District Court Judge Eldon Fallon had ruled shortly before trial that two of the plaintiff's experts—a cardiologist and a pathologist—could not testify that Vioxx was the cause of Irvin's heart attack because they were experts in their fields but not about Vioxx.³⁶

On April 5, 2006, in a consolidated case in Atlantic City, New Jersey, Merck lost to plaintiff John McDarby and won a defense verdict against the second plaintiff, Thomas Cona.³⁷ The McDarby case was Merck's second loss. In the first phase of a five-week trial, the jury concluded that the company concealed the dangers of Vioxx from McDarby, seventy-seven, and Cona, sixty, and their doctors, and failed to warn them about the drug's dangers.³⁸ The jury awarded John McDarby \$3 million and his wife \$1.5 million in compensatory damages after concluding Vioxx caused his heart attack in 2004 after four years of use.³⁹ The heart attack has left McDarby extremely weak and frail.⁴⁰

³³ See *id.* (explaining this was retrial, because previous trial had ended in hung jury).

³⁴ See *id.* (announcing "federal jury in New Orleans rejected a claim that short-term use of Vioxx played a role in the 2001 death of a 53-year-old Florida man.")

³⁵ *Jury Sides With Merck in Vioxx Trial*, USA TODAY, (Feb. 17, 2006), at http://www.usatoday.com/money/industries/health/drugs/2006-02-17-merck-vioxx-case_x.htm (stating Irvin's daughter, son and wife all testified that Irvin had been in excellent health prior to his heart attack).

³⁶ See *id.* (noting that the most problematic aspect of the case came when Judge Eldon Fallon would not permit testimony as to whether Vioxx caused Irvin's heart attack because plaintiff's experts were experts in medicine, but not about Vioxx).

³⁷ Thomas Ginsberg, *Ex-Merck CEO Takes the Stand in Penalty Phase of Vioxx Case*, PHILADELPHIA INQUIRER, Apr. 7, 2006, at C1 [hereinafter *Ex-Merck-CEO Takes the Stand*] (explaining jury awarded just one of plaintiffs, McDarby of Park Ridge, N.J., \$3 million and his wife \$1.5 million, while rejecting other plaintiff's claim, Thomas Cona, sixty, of Cherry Hill).

³⁸ *Id.* (stating "first phase, the jury of six women and two men concluded the company concealed the dangers of Vioxx to two plaintiffs and their doctors, and failed to warn them about the drug's dangers.")

³⁹ *Id.* (highlighting the jury's verdict in favor of McDarby).

⁴⁰ See Thomas Ginsberg, *Merck Defeat in Vioxx Verdict: The Drugmaker Hid Risks from the FDA, Jury Ruled*, PHILADELPHIA INQUIRER, Apr. 12, 2006, at A01 [hereinafter *Merck Defeat in Vioxx Verdict*] (quoting McDarby's wife's statements regarding her husband's condition).

The McDarby case was tried with a second case, and in the second case, the jury rendered a defense verdict for Merck, on the basis that Cona had not taken Vioxx as long as he claimed (twenty-five months) and did not prove the drug caused his heart attack.⁴¹

In the second phase of jury deliberations, the jury awarded punitive damages to McDarby in the amount of \$9 million.⁴² To win punitive damages, McDarby convinced the jury “by clear and convincing evidence” that Merck “knowingly withheld or misrepresented” information about Vioxx.⁴³ The jury was also given instructions by the presiding judge, Superior Court Judge Carol Higbee, to determine whether Merck had acted with “willful and wanton” disregard for others.⁴⁴ After the verdict, Kenneth Frazier, Merck’s general counsel, asserted that Merck would appeal what he considered to be mistaken verdicts in both phases of the trial.⁴⁵ Of the cases nationwide, about 4,200 are in the New Jersey Superior Court, and all are assigned to Atlantic County Judge Higbee.⁴⁶

On April 21, 2006, Merck lost its third case when a state court jury in South Texas awarded \$32 million in damages to the family of Leonel Garza, a seventy-one-year-old retiree, who died of a heart attack in 2001 after briefly taking Vioxx.⁴⁷ Mr. Garza’s family claimed that he had taken Vioxx twenty-five days before his heart attack. Mr. Garza had a history of heart disease. He had a heart attack in 1981, had quadruple bypass in 1985, and was a smoker who was overweight and had high blood pressure. The family’s attorney, Joe Escobedo, argued to the jury that Vioxx was especially dangerous to Mr. Garza because of these other risk factors and, thus, it should not have been prescribed to

⁴¹ See *Ex-Merck-CEO Takes the Stand*, *supra* note 37 (stating jury “rejected the claim by . . . Thomas Cona, sixty, of Cherry Hill, that Vioxx caused his 2004 heart attack after he could not prove he took the drug as long as claimed”).

⁴² See *Merck Defeat in Vioxx Verdict*, *supra* note 40 (explaining jury awarded \$9,000,000 in punitive damages, bringing total award to \$13,500,000).

⁴³ *Id.*

⁴⁴ See *id.* (noting jurors were asked to decide whether Merck acted with “willful and wanton” disregard for others).

⁴⁵ See *id.* (providing Frazier believed trial “riddled with improper rulings from Higbee”).

⁴⁶ *Id.* (highlighting that Merck’s headquarters are located in Whitehouse Station, N.J.).

⁴⁷ Alex Berenson, *Merck Loses Vioxx Suit in Texas*, N.Y. TIMES, Apr. 22, 2006, at C1 [hereinafter *Merck Loses Vioxx Suit in Texas*].

him.⁴⁸ Lawyers for Merck denounced the verdict and said that Judge Alex Gabert should have dismissed the case before it reached a jury because there “really isn’t any good science to indicate that Vioxx can cause a heart attack in less than 30 days.”⁴⁹ The case is particularly significant in that the jury rejected Merck’s argument that Vioxx can only cause cardiovascular problems after long-term use.⁵⁰ Merck attorney Richard Josephson said they expected the verdict would be overturned on appeal and that juries in South Texas have a history of returning large verdicts for local plaintiffs against companies with headquarters outside the state.⁵¹

On July 13, 2006, Merck won its third Vioxx case when a New Jersey state court jury ruled that Vioxx was not a cause of the 2004 heart attack of a sixty-eight-year-old woman, Elaine Doherty.⁵² The jury also ruled that although Merck had not warned her about the drug, the company had warned her doctor of risk factors. The company attributed Ms. Doherty’s heart attack to her age, weight, diabetes, cholesterol, blood pressure, and clogged arteries.⁵³ Ms. Doherty, who is five feet, three inches, once weighed 265 pounds, and is diabetic. Although she had lost nearly one-hundred-pounds, her blood pressure was normal, and her diabetes and cholesterol level were improving, the jury “simply believed that the risk factors were too insurmountable.”⁵⁴

From August 2006 through January 2007, Merck lost one case and won five others. On August 2, 2006, a Los Angeles state court jury returned a defense verdict in *Grossberg v. Merck*. In

⁴⁸ *Id.* (quoting Mr. Escobedo: “Mr. Garza was the last person in the world that should have been taking Vioxx”).

⁴⁹ *Id.*; see Christopher Bowe, *New Vioxx Study Contradicts Key Merck Defense*, FIN. TIMES, May 3, 2006. Despite Merck’s assertion, a recent report from McGill University in Montreal, Canada, has confirmed the dangers of short-term Vioxx use. The study looked at the government health records about 114,000 elderly Quebec people treated with Vioxx and found that about 25% of the Vioxx users who suffered heart attacks had the heart attacks within the first two weeks of taking the drug.

⁵⁰ See *Merck Loses Vioxx Suit in Texas*, *supra* note 47, at C1 (stating Merck’s lawyers believed case should have been dismissed prior to reaching jury, due to lack of evidence that Vioxx caused Mr. Garza’s heart attack).

⁵¹ See *id.* (highlighting Merck’s confidence that verdict would be reversed on appeal and noting plaintiff was well-known resident of county where trial was held).

⁵² *Merck Wins Vioxx Case in New Jersey*, N.Y. TIMES, July 14, 2006, at C4 (providing jury’s findings).

⁵³ See *id.* (highlighting Ms. Doherty’s risk factors).

⁵⁴ *Id.*

that case, the jury rejected plaintiff's claims that his 2001 heart attack was caused by his intermittent, sporadic use of Vioxx.⁵⁵

On August 17, 2006, a New Orleans federal jury returned a verdict for the plaintiff, Gerald Barnett, who at age 58 suffered a serious, but non-fatal heart attack after taking Vioxx for 33 months.⁵⁶ Merck lawyers had argued to the jury that Barnett, who had high blood pressure, a family history of heart disease, and had cardiovascular disease, "was at increased risk for a heart attack regardless of whether he was taking Vioxx."⁵⁷ The jury rejected Merck's defense and awarded Barnett \$50 million dollars in compensatory damages after he suffered a heart attack and lost ten years of his life expectancy.⁵⁸ The jury also awarded Barnett \$1 million in punitive damages.⁵⁹ The jury found that Merck "knowingly misrepresented or failed to disclose" information to Barnett's doctors about the risks associated with taking Vioxx and had "acted in wanton, malicious, willful or reckless disregard for the plaintiff's rights."⁶⁰ On August 30, 2006, federal district court judge Eldon Fallon ruled that the compensatory damages were excessive and ordered a retrial on the amount of damages to be assessed against Merck.⁶¹

From September 2006 through January 2007, Merck won four jury verdicts. On September 28, 2006, a federal jury ruled in favor of Merck, the jury finding that Vioxx was not linked to Robert Smith, who at age 52 had a heart attack while shoveling snow after he had taken Vioxx for knee pain for about four months.⁶² As in the other cases, Merck argued that plaintiff had

⁵⁵ *Merck Wins First California Vioxx Case*, VIOXX (rofecoxib) Information Center (Aug. 2, 2006), http://www.merck.com/newsroom/press_releases/corporate/2006_0802.html.

⁵⁶ Helen Steele, *Merck Ordered to Pay Damages in Vioxx Case*, EARTHTIMES.ORG (Aug. 18, 2006), <http://www.earthtimes.org/articles/show/8218.html>.

⁵⁷ *Breaking News: Merck Loses Latest Vioxx Trial*, WALL ST. J. ONLINE ED. (Aug. 17, 2006), <http://blogs.wsj.com/law/2006/08/17/breaking-news-merck-loses-latest-vioxx-trial>.

⁵⁸ *See Judge Tosses 'Grossly Excessive' \$50 Million Award in Vioxx Case*, FOXNEWS.COM (Aug. 30, 2006), [*hereinafter* \$50 Million Award], available at <http://www.foxnews.com/story,0,2933,211317,00.html>.

⁵⁹ *See Breaking News: Merck Loses Latest Vioxx Trial*, *supra* note 57.

⁶⁰ *See Merck Ordered to Pay Damages in Vioxx Case*, *supra* note 56.

⁶¹ *Statement of Phil Beck on Today's Ruling Overturning an Excessive VIOXX Damage Award*, VIOXX (rofecoxib) Information Center (Aug. 30, 2006), http://www.merck.com/newsroom/vioxx/pdf/barnettdamages_overturned_statement_phil_beck.pdf.

⁶² *Merck Wins Federal VIOXX Product Liability Case: Smith v. Merck & Co., Inc.*, VIOXX (rofecoxib) Information Center (Sept. 26, 2006), http://www.merck.com/newsroom/pressreleases/corporate/2006_0926.html.

pre-existing risk factors for a heart attack, such as high blood pressure, high cholesterol, a family history of cardiac problems, coronary heart disease, and he was considered medically obese.⁶³ Merck argued that these increased risk factors, not Vioxx, caused his heart attack.⁶⁴

On November 16, 2006, a New Orleans federal jury exonerated Merck for the heart attack of Ron Mason, 64, who was seeking \$690,000 in lost wages and other damages for a 2003 heart attack after taking Vioxx for 10 1/2 months.⁶⁵ In closing arguments, Merck lawyers argued that Vioxx could not have caused Mason's heart attack because he took the painkiller for less than a year and stopped taking it four days before the heart attack.⁶⁶ Merck's defense strategy that Vioxx is dangerous only after a patient ingests the drug continuously for at least 18 months is the same argument that Merck has used to defend other cases, including the Humeston case. As set out *supra*, the trial court judge in the Humeston case overturned the jury verdict for Merck and ordered a new trial on the basis that Merck had withheld evidence during the Humeston trial which demonstrated the company knew Vioxx posed an increased risk of heart attacks even when taken for less than 18 months.

On December 13, 2006, a New Orleans federal court jury found in favor of Merck, rejecting Anthony Diedrick's claim that his heart attack at age forty-seven was caused by taking Vioxx for six months prior to the heart attack.⁶⁷ Merck followed its patterned defense. Merck lawyers argued that Diedrick was at increased risk for a heart attack, suffering from high blood pressure, high cholesterol and diabetes, and Diedrick, therefore, would have suffered a heart attack whether he took Vioxx or not.⁶⁸ On December 15, 2006, Merck won again when an Alabama federal court jury found that Vioxx did not cause Gary

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ See McConnaughey, *supra* note 15.

⁶⁶ *Id.*

⁶⁷ *Merck Wins Federal VIOXX Product Liability Case*, VIOXX (rofecoxib) Information Center (Dec. 13, 2006), http://www.merck.com/newsroom/press_releases/corporate/2006_1213.html.

⁶⁸ *Id.*

Albright's "small heart attack."⁶⁹ Merck's lawyers argued that Albright had hypertension, diabetes, high blood pressure, high cholesterol, and was overweight.⁷⁰ After the case, jurors stated that Albright had too many health problems to blame his heart attack on Vioxx.⁷¹

On January 19, 2007, a Los Angeles state trial court judge declared mistrials after a jury failed to return verdicts in lawsuits filed by two Vioxx users who claimed that Vioxx was a major cause of their heart attacks.⁷² The cases will be retried.

With 27,000 cases still to be tried, and only 12 having reached a verdict, with most of those on appeal, it is too early in the process, which will take years to unfold, to predict the pattern that may emerge from the Vioxx litigation. Merck's defense strategy, however, is clear. The plaintiffs are not "perfect" plaintiffs: Many were at increased risk for cardiovascular events because of pre-existing hypertension, or being overweight, or having a family history of cardiac problems. Merck hopes these factors will persuade jurors that plaintiffs would have suffered a heart attack or stroke even if they never took Vioxx. Merck's argument is that plaintiffs cannot meet their burden of proof that Vioxx was the "proximate cause" or a major contributor to plaintiff's cardiovascular problems. Some juries have agreed with Merck, and others have not. Some juries have agreed with Merck that the company did not fail to warn or give information about the dangers of using Vioxx, while others have found not only that Merck negligently failed to warn consumers of the increased risks of taking Vioxx, but that Merck "knowingly withheld or misrepresented" information about Vioxx and had acted with "willful and wanton" disregard for the rights and health of Vioxx users who have suffered a heart attack or stroke, and that these malicious and reckless actions justify punitive damage awards of several million or more.

⁶⁹ See *Jury Rules in Merck's Favor in Alabama Vioxx Trial*, *supra* note 14 (stating that Merck attorney Mike Brock told jurors that Albright had only a "small heart attack" that did not cause lasting damage to his lifestyle).

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² See *VIOXX Plaintiffs Failed to Prove Their Cases*, VIOXX (rofecoxib) Information Center (Jan. 18, 2007), http://www.merck.com/newsroom/press_releases/corporate/2007_0118.html.

Although no clear pattern is discernable after twelve cases, there likely may develop a correlation between using Vioxx continuously for more than a few months and the seriousness of the harm to a plaintiff. In two of the plaintiffs' decisions, in the Ernst case, the plaintiff used Vioxx continuously for eight months and died from a heart attack, and in the McDarby case, plaintiff took Vioxx for four years and suffered a near-fatal heart attack. In the Merck defense verdicts, in the Humeston case plaintiff took Vioxx for two months intermittently and suffered a mild heart attack; in the Irvin case plaintiff died of a heart attack after taking Vioxx for less than a month; and in the Cona case, plaintiff said he took Vioxx for twenty-five months before suffering a heart attack, although jurors after the verdict said they did not believe that Cona had taken the drug for as long as he had claimed. The Garza case, in which a Texas jury gave a plaintiff's verdict for the death of seventy-one-year old, Leonel Garza, who had taken the drug for less than a month and had other risk factors, may or may not be an anomaly. Certainly, it shows, as Merck general counsel Kenneth Frazier noted, that the "realities of the world are that jury cases have uncertain outcomes."⁷³ It also shows that Merck is at risk in the Vioxx cases.

In the McDarby case, the attorney representing plaintiff was Mark Lanier. This was his second win against Merck, and until the Garza verdict, he was the only attorney to have won a Vioxx case. This has raised questions as to whether Lanier is simply a superior attorney who wins cases that most other attorneys would lose. Is he such a charismatic and master spin artist that he subverts the truth and justice? In the cases Lanier has tried, Merck certainly believes the jury has been blind and misguided. Or has Merck been myopic and short-sighted in its handling of the Vioxx debacle? The Merck-Vioxx controversy raises issues as to whether Merck acted unethically and callously or whether Merck is, as many of its employees claim, a victim of overzealous lawyers and their clients as well as of other pharmaceutical companies jealous of Merck's reputation which wish to damage that reputation to drive Merck's profits down and theirs up.⁷⁴

⁷³ See *Merck Loses Vioxx Suit in Texas*, *supra* note 47, at C1.

⁷⁴ In fall 2005 and winter 2006 MBA courses this author taught, there were six Merck employees who were in the two classes. In the winter 2006 class, one Merck employee

II. WHAT DID THE COMPANY KNOW AND WHEN DID THEY KNOW IT?

A. Merck's Defense

Merck has defended the Vioxx cases on two grounds. First, that they acted responsibly by voluntarily withdrawing Vioxx from the marketplace in 2004 after the first reliable study showed that long-term use of Vioxx increased the risk of serious cardiovascular events.⁷⁵ Thus, Merck did not hide credible information of Vioxx's risks from consumers. Second, Merck has argued that in none of the cases to date has plaintiff met his burden of proof that Vioxx "caused" his heart attack.⁷⁶

Merck's has argued that the company had no reliable scientific evidence that Vioxx increased the risk of cardiovascular events until September 2004 when a clinical trial, designed to see if Vioxx could prevent colon polyps, showed an increased risk of heart attack and stroke among patients taking Vioxx for eighteen-months as compared to those who took placebos.⁷⁷ Merck immediately contacted the FDA on September 27, 2004, and in a meeting with the FDA on September 28, Merck informed the agency it would voluntarily withdraw Vioxx.⁷⁸ Two days later

argued that he thought the Vioxx controversy partially stemmed from other pharmaceutical companies jealous of Merck's reputation as an ethical company who had a blockbuster drug. All six employees believed that Merck had acted ethically and that the fault for the litigation was greedy plaintiff attorneys and their clients, who were playing the great American lottery game—the jury system.

⁷⁵ See *Merck Loses Vioxx Suit in Texas*, *supra* note 47, at C1 (noting Merck's withdrawal of Vioxx after clinical trial revealed an increased risk of heart attack and stroke when compared with placebos); see also *Merck Wins Vioxx Case in New Jersey*, *supra* note 52, at C4 (stating that Merck withdrew Vioxx after a trial which showed that it doubled the risk of heart attack when taken for eighteen months).

⁷⁶ See *Merck Loses Vioxx Suit in Texas*, *supra* note 47, at C1 (pointing to decedent's medical history prior to his use of Vioxx including quadruple heart bypass and a history of smoking and weight problems); see also *Merck Wins Vioxx Case in New Jersey*, *supra* note 48, at C4 (attributing heart attack not to Vioxx, but rather to other risk factors such as age, weight, diabetes, cholesterol, blood pressure, and clogged arteries).

⁷⁷ Press Release, U.S. Food and Drug Administration, *FDA Issues Public Health Advisory on Vioxx as its Manufacturer Voluntarily Withdraws the Product* (Sept. 30, 2004) [hereinafter *FDA Issues Public Health Advisory on Vioxx*], available at <http://www.fda.gov/bbs/topics/news/2004/NEW01122.html> (explaining nature and results of Merck's studies).

⁷⁸ See *id.* (stating that Merck chose to voluntarily remove Vioxx from market following learning of these risks).

Merck announced its withdrawal.⁷⁹ “Merck did the right thing by promptly reporting these findings to FDA and voluntarily withdrawing the product from the market,” said the Acting FDA Commissioner Dr. Lester M. Crawford.⁸⁰ He continued, “[a]lthough the risk that an individual patient would have a heart attack or stroke related to Vioxx is very small,” the study shows “that patients taking the drug chronically face twice the risk of a heart attack compared to patients receiving a placebo.”⁸¹

At the McDarby trial, on April 6, 2006, Raymond Gilmartin, Merck’s ex-CEO,⁸² testified on cross-examination by Lanier that he never knowingly masked safety data.⁸³ When asked why Merck had not turned over to the FDA an October 2000 internal analysis showing the risk of heart attack by Vioxx users ranged from zero to five-fold over other pain relievers, Gilmartin testified that Merck had not been obligated to turn the internal analysis over to the FDA.⁸⁴ The October 2000 internal analysis by Merck scientist Deborah Shapiro was titled “preliminary” summary of data. “What we gave” to the FDA, Gilmartin testified, “was the raw data, and they do their own analysis.”⁸⁵ Lanier asked, “[a]re you saying it was important enough for Merck to do this study, but not important enough to send to the FDA?”⁸⁶ “No, I’m not telling you that at all,” Gilmartin replied, stating that Merck’s analysis was only preliminary and thus potentially flawed.⁸⁷ He added, “[w]e submit what we believe is the appropriate analysis, and I’m confident we submitted the

⁷⁹ *Id.* The FDA announced the voluntary withdrawal of Vioxx from the market on September 30, 2004, two days after its meeting with Merck wherein Merck disclosed its finding concerning colon polyps.

⁸⁰ *Id.* (commending Vioxx for voluntary withdrawal despite FDA’s increased scrutiny of that drug).

⁸¹ *Id.*

⁸² See Kaufman, *supra* note 17, at A1. Gilmartin resigned as CEO on May 5, 2005, the same day that congressional investigators released a slew of documents detailing how the company continued to aggressively promote Vioxx after it knew of potentially serious safety concerns.

⁸³ See *Ex-Merck-CEO Takes the Stand*, *supra* note 37, at C1. Responding to an email presented by the Plaintiff in which Merck chief scientist complained of a lack of freedom under the new CEO, Gilmartin reaffirmed his statement that he never knowingly withheld data and stated that the scientist “did have freedom.” *Id.*

⁸⁴ See *id.* (admitting Merck failed to turn over potentially “damning internal analysis”).

⁸⁵ *Ex-Merck-CEO Takes the Stand*, *supra* note 37, at C1.

⁸⁶ *Id.*

⁸⁷ See *id.* (denying Lanier’s accusations).

data.”⁸⁸ On redirect examination, Gilmartin testified that Merck had submitted to the FDA a different analysis, dated 2001, containing all the same data, but laid out in a different form.⁸⁹

In addition, Merck has argued that it acted responsibly in submitting to the FDA in June 2000, the results of a study called VIGOR,⁹⁰ which showed a four-time increase in the risk of serious cardiovascular events compared to naproxen.⁹¹ Merck also released this information to the media, although they did not directly contact physicians prescribing Vioxx.⁹² Merck has claimed that any wide-awake physician would have known of the published research on the VIGOR studies. In April 2002, the FDA asked for changes in the labeling of Vioxx to warn physicians and patients of the risks, and Merck complied with the FDA request.⁹³

Those defending Merck have argued that no drug is without risk. They reason that drugs cannot be made perfectly safe, and even aspirin can have side effects. Thus, a person who takes

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ See Report of John S. Martin, Jr. to the Special Comm. of the Bd. of Dir. of Merck & Co., Inc. Concerning the Conduct of Senior Mgmt in the Dev. and Mktg. of Vioxx (Sept. 5, 2006), available at http://www.merck.com/newsroom/vioxx/pdf/005_exhibit_4_glossary_of_terms.pdf (defining VIGOR as Vioxx Gastrointestinal Outcomes Research and explaining it as “[d]ouble-blind study by MRL assessing the comparative efficacy and gastrointestinal safety of Vioxx 50 mg and naproxen 1000 mg; found a statistically significant decrease in PUBs among patients on Vioxx and a statistically significant difference in cardiovascular adverse events favoring naproxen.”).

⁹¹ See *FDA Issues Public Health Advisory on Vioxx*, *supra* note 77 (discussing Merck’s June 2000 submission of the VIGOR safety study to the FDA and quoting Acting FDA Commissioner Dr. Lester M. Crawford: “Merck did the right thing by promptly reporting these findings to FDA and voluntarily withdrawing the product from the market”).

⁹² See, e.g., Claire Bombardier M.D. et al., *Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis*, *NEW ENG. J. MED.* 1520, 1522-1525 (2000) (assessing rofecoxib’s efficacy in first scholarly article dealing with effects of drugs like Vioxx based on information provided by Merck employees); Eric J. Topol, M.D., *Failing the Public Health – Rofecoxib, Merck, and the FDA*, *NEW ENG. J. MED.* 351:17, 1707, 1707 (2004) (criticizing Merck’s failure to release data on drug until November 23, 2000, when *New England Journal of Medicine* reported data in Bombardier article that later became subject of attack on Merck because data was found to be based on incomplete information).

⁹³ See Report of John S. Martin, Jr. to the Special Comm. of the Bd. of Dir. of Merck & Co., Inc. Concerning the Conduct of Senior Mgmt in the Dev. and Mktg. of Vioxx (Sept. 5, 2006), available at http://www.merck.com/newsroom/vioxx/pdf/032_appendix_n_fda_analysis_of_vioxx_cardiovascular_data_and_label_issues.pdf. The FDA and Merck negotiated over revisions to the Vioxx label that were approved on April 12, 2002. Merck’s final version incorporated the FDA’s proposals, “which included specifying that the serious cardiovascular events in the VIGOR Trial included sudden death . . . Merck also accepted the FDA’s request to relocate cautionary language concerning the use of Vioxx by patients with a medical history of ischemic heart disease from the end of the cardiovascular precaution to the beginning.” *Id.*

drugs must understand that there are side effects and take responsibility for his/her decision to take any medication.⁹⁴ In addition, the risk of a heart attack or stroke from using Vioxx is still a small risk.⁹⁵

B. The Case Against Merck

i. The Vioxx Clinical Trials

Prior to the FDA's approval of Vioxx in May 1999, there was evidence that Merck had concerns that the drug may cause serious cardiovascular events.⁹⁶ Internal Merck documents showed that company executives and scientists were worried about Vioxx's potential cardiovascular risks as early as November 1996—more than two years before selling the drug—but rejected plans to conduct a study evaluating these risks.⁹⁷ A November 1996 internal memorandum by a Merck official indicated the company was struggling with a marketing dilemma, as Vioxx had limited market potential unless it could gain acceptance in the mass market for pain killers and be preferred to cheap over-the-counter drugs such as aspirin or ibuprofen, which cost about five cents a pill versus several dollars for Vioxx.⁹⁸ The author of the memorandum noted that Merck was reluctant to conduct a trial to prove Vioxx was gentler on the

⁹⁴ These comments were made by students in the author's MBA class on Business Ethics discussing Vioxx during the fall 2005 semester at La Salle University. Although these comments may not have been made by Merck scientists and executives, they nevertheless represent the "maximization of profits" mindset.

⁹⁵ See *FDA Issues Public Health Advisory on Vioxx*, *supra* note 77. Acting FDA Commissioner Dr. Lester M. Crawford stated that "[a]lthough the risk that an individual patient would have a heart attack or stroke related to Vioxx is very small . . . " patients taking Vioxx nonetheless were at twice the risk of suffering heart attacks when compared to patients given placebos. *Id.*

⁹⁶ See Alex Berenson, *Jury Calls Merck Liable in Death of Man on Vioxx*, N.Y. TIMES, Aug. 20, 2005, at A1 [hereinafter *Jury Calls Merck Liable*] (stating that documents and emails from Merck scientists discussed these potential heart risks in 1997).

⁹⁷ See Berenson, *supra* note 4, at A17 (citing internal Merck documents).

⁹⁸ See generally Marc Kaufman, *New Study Criticizes Painkiller Marketing*, WASH. POST, Jan. 25, 2005, A1 [hereinafter *New Study Criticizes Painkiller Marketing*]. A study published in "Archives of Internal Medicine" asserted that the majority of patients who were persuaded by direct-to-consumer advertising campaigns of prescription arthritis drugs such as Vioxx would have experienced similar results on older, cheaper medications. The study stated that the aggressive direct-to-consumer advertising campaigns launched in 1998 and 1999 lead to the drug's overuse by patients and doctors. Advertising reports indicated that Merck spent \$79.2 million on Vioxx ads in 2003, making Vioxx one of the most heavily advertised drugs of all time.

stomach than older painkillers because in order to clearly show this difference, the patients using Vioxx could not also take aspirin, which reduces the risk of heart attacks. This created a dilemma because if patients could take only Vioxx but not any aspirin there was “a substantial chance that significantly higher rates” of cardiovascular problems would occur in this group.⁹⁹ In a 1997 e-mail message, Dr. Alise Reicin, a Merck scientist wrote: “The possibility of increased C.V. events is of great concern.”¹⁰⁰ C.V. “is a scientific shorthand for cardiovascular problems” such as heart attack or stroke.¹⁰¹ “I just can’t wait to be the one to present those results to senior management,” she continued.¹⁰²

A 1998 Merck clinical trial called “Study 090” involving 978 patients showed that serious cardiovascular events, including heart attack and stroke, occurred almost six times more often in patients taking Vioxx than in patients taking another arthritis drug or a placebo.¹⁰³ Merck did not publish the clinical trial.¹⁰⁴

In 1998 medical researchers at the University of Pennsylvania reported findings that Cox-2 inhibitors, such as Vioxx, might interfere with enzymes thought to play key roles in warding off cardiovascular disease. The findings were communicated to the companies such as Merck developing Cox-2 inhibitors and were also published.¹⁰⁵

In May 1999, the FDA approved the use of Vioxx for the reduction of pain and inflammation caused by osteoarthritis, for acute pain in adults, and for the treatment of menstrual pain.¹⁰⁶

⁹⁹ See Anna Wilde Mathews & Barbara Martinez, *Warning Signs: Emails Suggest Merck Knew Vioxx's Dangers at Early Stage — As Heart-Risk Evidence Rose, Officials Played Hardball; Internal Message: 'Dodge!' — Company Says 'Out of Context'*, WALL ST. J., Nov. 1 2004, at A1. Merck officials acknowledged that unless these patients also took aspirin more blood clots would occur.

¹⁰⁰ *For Merck, Paper Trail Won't Go Away*, *supra* note 23, at 1.

¹⁰¹ *See id.* (explaining this term).

¹⁰² *Id.*

¹⁰³ *See 60 Minutes: Prescription for Trouble* (CBS television broadcast Nov. 14, 2004), available at <http://www.cbsnews.com/stories/2004/11/14/60minutes/main655577.shtml> (describing results from Dr. Eric Topol's, chief of cardiovascular medicine at Cleveland Clinic, statistical analysis on Vioxx).

¹⁰⁴ *See id.* (explaining Merck considered study too small and statistically insignificant to warrant conclusive evidence).

¹⁰⁵ Simons, *supra* note 3 (quoting study's author as saying “[w]e immediately postulated to the companies developing COX-2 inhibitors, and subsequently reported in print, that this was something that could lead to heart attacks and strokes”).

¹⁰⁶ *See* Sandra Kweder, M.D., Deputy Director of the Office of New Drugs at the Center for Drug Evaluation and Research (“CDER”), and FDA, Statement Before U.S. Senate, Committee on Finance, (Nov. 18, 2004), available at <http://www.fda.gov/ola/>

At the time of approval, the FDA reviewer, Dr. Villalba, wrote a memorandum expressing his concern that the data available seemed to suggest that cardiovascular events are more frequent in patients taking Vioxx rather than a placebo.¹⁰⁷

Although Merck scientists and executives, as well as other scientists, had concerns about the cardiovascular effect of Vioxx prior to its FDA approval, the company failed to conduct cardiovascular trials that would directly examine whether there were increased cardiovascular events associated with taking Vioxx. The failure of Merck to conduct cardiovascular trials to measure cardiovascular events continued from 1999 until 2004, when Merck pulled the drug from the market. Merck never performed a study dedicated to measure cardiovascular effects. Several scientists have claimed that Merck conducted studies that would place Vioxx in the best light possible to market the drug, and not to find out the extent, if any, to which Vioxx caused cardiovascular problems.¹⁰⁸

In June 2000 Merck submitted to the FDA the final data from VIGOR, which showed a decrease in gastrointestinal problems, but a four-fold higher risk of heart attack compared with naproxen.¹⁰⁹ Merck had conducted the study to see if Vioxx had a lower risk of gastrointestinal ulcers and bleeding than other drugs such as ibuprofen and naproxen. Merck reported the results of the study in the *New England Journal of Medicine*, but did not notify physicians of the findings.

Subsequent to reviewing the VIGOR study and results from other controlled clinical trials, the FDA conferred with its Arthritis Advisory Committee in February of 2001 in reference to this new safety information.¹¹⁰ Fourteen months later, in April 2002, the FDA implemented labeling changes to reflect these

2004/vioxx1118.html (noting "FDA approved Vioxx in May 1999 for the reduction of signs and symptoms of osteoarthritis, as well as for acute pain in adults and for the treatment of primary dysmenorrhea.").

¹⁰⁷ Eric J. Topol, M.D., *Rofecoxib, Merck, and the FDA*, *NEW ENG. J. MED.* 351:27, 2875, 2877 (2004) (describing Dr. Villalba's statements at time of Vioxx's approval in May 1999).

¹⁰⁸ See *id.* at 2877-78 (discussing previous studies and comments made by some scientists involved).

¹⁰⁹ See *FDA Issues Public Health Advisory on Vioxx*, *supra* note 77 (noting both benefit of decreased gastrointestinal side effects and increased risk of cardiovascular events compared to other drugs).

¹¹⁰ *Id.*

new findings.¹¹¹ The labeling changes required that Merck warn consumers about the heightened risk of cardiovascular side-effects, namely, “heart attack and stroke.”¹¹² Nevertheless, from the time that Merck submitted the information to the FDA twenty-months elapsed before physicians were notified of the dangers of using Vioxx, as shown by the VIGOR study.

Despite the cardiovascular risks, Merck engaged in misdirection and down-played the results of the VIGOR study. As the FDA and other scientists have noted, the VIGOR study showed cardiovascular events increased five-fold from use of the drug, not four-fold as Merck claimed.¹¹³ Additionally, Merck could have chosen to notify prescribing physicians of their findings in March 2000, when they received the results of the VIGOR study; yet, they chose not to do so. Merck’s argument that a wide-awake physician would have read the *New England Journal of Medicine* belies the reality of a medical practitioner’s life. Doctors do not read every piece of professional literature any more than attorneys do. Doctors rely on the salesperson to give them accurate information about the drug.¹¹⁴ Moreover, the legal standard is not whether the FDA was notified or there was a journal article discussing the VIGOR study, but whether Merck adequately notified treating physicians of Vioxx’s risks of cardiovascular events that Merck either knew or should have known about.¹¹⁵ Until forced by the FDA in April 2002 to change its labeling to reflect the increased risks of cardiovascular events, Merck chose to ignore the health implications shown by the

¹¹¹ *Id.*

¹¹² *See id.* (describing types of risks Vioxx labels had to explain).

¹¹³ *See Healthwatch: Timeline Of Vioxx-Related Events* (CBS television broadcast Apr. 5, 2006), available at <http://www.cbsnews.com/stories/2006/04/05/health/main1476188.shtml>. “June 2000: Merck gives FDA results of VIGOR study, which shows Vioxx users suffered five times as many heart attacks as users of the older painkiller naproxen . . .” *Id.*

¹¹⁴ *See* Kevin Freking, *Selling Vioxx: Merck Used Code-Named Projects to Boost Their Sales Despite Safety Concerns*, SEATTLE TIMES, May 5, 2005, at Nation & World (testifying before House Government Reform Committee about how drugs are marketed to doctors, Dr. Michael Wilkes, vice dean for medical education at University of California-Davis, admitted doctors are busy and look for shortcuts to get information).

¹¹⁵ *See Vioxx Victory Key for Merck*, *supra* note 26, at A01. In the Humeston case, the trial court judge gave the jury the following instruction: “Did Merck fail to provide an adequate warning to prescribing physicians of an association between Vioxx and an increased risk of serious cardiovascular events that the defendant either knew or should have known about prior to Mr. Humeston’s heart attack?” *Id.* In an 8-1 vote, the Humeston jury sided with Merck, finding there was no failure to warn since Merck did not believe in 2001 at the time of Humeston’s mild heart attack that Vioxx increased the risk of cardiovascular events.

VIGOR study. Despite ex-CEO Gilmartin's testimony at trial that Merck "wanted" to place a warning label on the Vioxx medicine,¹¹⁶ internal Merck documents show otherwise.¹¹⁷ Lanier introduced in the Ernst trial internal Merck documents which reveal that Merck resisted the FDA's efforts to add warnings to Vioxx's label and eventually complied in ways that the Ernst jury found obscure. "You had to dig three levels to see it," one juror stated.¹¹⁸

In addition, Merck downplayed the VIGOR results, hypothesizing that naproxen, like aspirin, benefited the heart and that Vioxx did no harm.¹¹⁹ Merck did not conduct trials to test this hypothesis,¹²⁰ but that did not stop Merck from marketing the drug and downplaying the VIGOR study.

In March 2000, when Merck became aware of the VIGOR study's findings of a significant increase in cardiovascular events for those taking Vioxx over naproxen, Merck scientists expressed concern. In an e-mail message written in March 2000, Dr. Edward Scolnick, who was then Merck's head of research, stated that the VIGOR clinical trial had shown that Vioxx increased heart risks.¹²¹ "The CV events were clearly there," he wrote.¹²²

Despite clear warnings, Merck decided against conducting studies on the heart risks because marketing executives worried it might hurt Vioxx's sales.¹²³ Internal Merck analyses in 2001

¹¹⁶ See *Ex-Merck-CEO Takes the Stand*, *supra* note 37, at C1 (responding to assertions that Merck was influenced by potential lost sales that if new warning label were placed on Vioxx).

¹¹⁷ See *For Merck, the Vioxx Trail Won't Go Away*, *supra* note 23, at 1. In the *Ernst* trial jurors were presented by the plaintiff with a series of e-mails and internal Merck documents which indicated that Merck had resisted the F.D.A.'s efforts to add warnings of potential heart risks to the Vioxx label).

¹¹⁸ *Id.* (describing one version of the drug's labeling).

¹¹⁹ See Rita Rubin, *Merck Repeats: We Didn't Know of Vioxx Threat*, USA TODAY, Oct. 14, 2004 (providing "company credited naproxen for preventing blood clots from forming and causing heart attacks or stroke.").

¹²⁰ *Id.* "Animal studies suggested that was the case, said Alise Reicin, vice president of clinical research at Merck Research Laboratories. However, Merck wrote in a March 2000 press release, there had been no human trials to confirm that naproxen did indeed protect against heart attacks and strokes." *Id.*

¹²¹ See Alex Berenson, *In Training Video, Merck Said Vioxx Did Not Increase Risk of Heart Attack*, N.Y. TIMES, July 21, 2005, at C4 [hereinafter *In Training Video, Merck Said Vioxx Did Not Increase Risk of Heart Attack*] (indicating evidence was introduced to jury in Robert Ernst's case).

¹²² *Id.*

¹²³ See *For Merck, the Vioxx Paper Trail Won't Go Away*, *supra* note 23 (describing ways in which sales representatives were trained to dodge questions about Vioxx's heart risks).

and 2002 also showed that Merck was worried about lost profits if warnings or precautions were put on its label.¹²⁴ During that period, Merck was in private negotiations with the FDA over changes to its Vioxx label. David Anstice, who, at that time, was the president of Merck's Human Health division, projected that a strict warning would reduce sales by at least 50%.¹²⁵

After the VIGOR study findings in March 2000, a second internal Merck analysis performed in October 2000 also showed a significant increase in cardiovascular events for those taking Vioxx.¹²⁶ The Merck analysis, plaintiff's attorney Mark Lanier has argued, was never presented to the FDA nor to the media, and certainly was not given to the physicians prescribing Vioxx.¹²⁷ The analysis was simply buried inside Merck. Gilmartin's response during examination by Lanier at McDarby's trial was that the analysis was "preliminary" and "potentially flawed"; the FDA received the raw data and could do their own analysis; and Merck was not obligated by FDA rules to do more.¹²⁸ The internal analysis, called a meta-analysis, revealed that patients taking Vioxx were twice as likely to suffer heart attacks as those taking other painkillers.¹²⁹ Merck's analysis included the review of 20,000 study patients from five trials. Although some findings from the study were given to the FDA in January 2001 in preparation for a regulatory meeting, Merck did not include the portion that measured the rates at which Vioxx users suffered heart attacks.¹³⁰

¹²⁴ See *id.* (stating that "\$229 million punitive damages figure was not picked at random, but referred to a 2001 Merck estimate of additional profit the company might make if it could delay an F.D.A. warning on Vioxx's heart risk.").

¹²⁵ See Thomas Ginsberg, *Merck's Former Chief Executive Denies Concealing Safety Data*, PHILADELPHIA INQUIRER, Apr. 6, 2006. Gilmartin's response was that the lost profit analysis "didn't have any influence over the discussion" with the FDA, that "it had nothing to do with our negotiations" and that Merck "wanted that label." *Id.*

¹²⁶ See Peter Loftus, *Jury Says Merck Misled FDA, Awards Another \$9M to Heart Attack Victim*, N.Y. SUN, Apr. 12, 2006, at 12 (discussing case of seventy-seven-year-old man who had heart attack after taking Vioxx and highlighting this memo's use as evidence at trial).

¹²⁷ See *id.* (noting Lanier's statements regarding Merck's failure to release this information).

¹²⁸ See *id.* (stating that "Merck argued that the analysis was preliminary and not required by the FDA, and said it did submit the underlying clinical data.").

¹²⁹ See Ed Silverman, *Links to Heart Attacks Withheld; Merck Says it Didn't Need to Report its Findings on Vioxx to the FDA*, POST-STANDARD, July 5, 2005, at B6 (highlighting that Merck conducted "internal analysis . . . that revealed patients taking the drug were twice as likely to suffer heart attacks as those on similar painkillers.").

¹³⁰ See *id.* (describing Merck's omission of this portion of data).

Despite clear danger signals in 2000 from VIGOR and meta-analysis studies and a request in 2001 from a group of scientists that Merck conduct dedicated cardiovascular trials, Merck did not do so,¹³¹ preferring instead to conduct trials that would show the potential benefits of Vioxx. Such trials included the VIGOR trial (dedicated to showing whether Vioxx decreased the risk of gastrointestinal problems sometimes associated with other pain relievers) and the APPROVe¹³² and VICTOR¹³³ trials (dedicated to measuring whether Vioxx prevented the formation of colon polyps and was helpful in treating patients with a history of colon cancer).

Aided by Merck's masking negative trial results and failure to conduct dedicated cardiovascular trials, the FDA approval process failed. The pre-approval trials to determine the safety of the drug lasted less than twelve months, even though many people taking Vioxx for arthritis would likely take the drug for much longer periods of time.¹³⁴ Swiss Scientist Matthew Eggar and a co-scientist analyzed the results from eighteen randomized clinical trials and eleven observational studies—many completed before 2001—and determined that Vioxx could have, and should have, been pulled from the market long before September 2004.¹³⁵ Egger stated that “[i]f we can do this kind of analysis,

¹³¹ See Topol, *supra* note 107, at 1707 (asserting Dr. Eric Topol, M.D. and his colleagues asked Merck to perform dedicated cardiovascular trials specifically designed to compare the incidence of serious cardiovascular events in patients taking Vioxx as compared with those taking other pain relievers or placebo).

¹³² See *Vioxx Timeline Key Dates for VIGOR and Long-Term, Placebo-Controlled Studies Implemented to Provide Cardiovascular Safety Data*, http://www.merck.com/newsroom/vioxx/pdf/vioxx_timeline.pdf (last visited Nov. 13, 2006) (stating “APPROVe was a multi-center, randomized, placebo-controlled, double-blind study to determine the effect of 156 weeks (3 years) of treatment with rofecoxib on the recurrence of adenomatous polyps of the large bowel in patients with a history of colorectal adenomas.”).

¹³³ See *id.* (explaining “VICTOR was a randomized, double-blind, placebo-controlled, international, multicenter study of VIOXX in 7,000 colorectal cancer patients following potentially curative therapy.”).

¹³⁴ See Martin & Jones, *Vioxx Lawsuit*, <http://www.vioxx-recall-lawsuit.com/> (last visited Nov. 13, 2006) (stating “problems with Vioxx began before the drug was approved for sale in the United States.”).

¹³⁵ See Anna Gosline, *Vioxx Heart Risks Apparent for Years*, NEWSSCIENTIST.COM (Nov. 5, 2004), <http://www.newscientist.com/article/dn6627-vioxx-heart-risks-apparent-for-years.html> (noting “[s]cientific evidence of increased heart attack risk associated with popular arthritis drug Vioxx was available as early as 2000 . . . although the drug was only withdrawn in September 2004.”).

it's difficult to see why it wasn't done by the drug company or the licensing authorities years ago."¹³⁶

ii. Marketing of Vioxx

Instead of heeding the warning signals and the available data, Merck and its employees aggressively marketed Vioxx to doctors and an unsuspecting public. One memorandum, dated February 9, 2001, prohibited sales representatives from initiating "discussions on a study that raised heart concerns."¹³⁷ "Another document describe[d] 'obstacle handling' to overcome physician concerns" about Vioxx's safety.¹³⁸ Internal Merck documents made public by the House Committee on Government Reform investigating how drugs are marketed to doctors revealed that Merck instructed its salespersons to avoid discussions with doctors regarding the cardiovascular risks found by the VIGOR study.¹³⁹ "Sales representatives were told instead to rely on a 'Cardiovascular Card' that said Vioxx was protecting the heart rather than potentially harming it."¹⁴⁰ To market Vioxx, Merck prepared an in-house training game for Vioxx sales representatives dubbed "Dodge Ball." Sales trainees could only move on to the next round of the card game if they gave Merck-approved answers to doctors' questions raising Vioxx safety concerns, or dodged such questions altogether.¹⁴¹ The hearings found evidence of a disconnect between the science and the sales pitch used by the company's field staff. Merck, for example, instructed its sales representatives to provide only certain approved study results to doctors.¹⁴² "By contrast, those studies

¹³⁶ *Id.* Egger suggests that many participants in Vioxx trials were at a much lower risk of cardiovascular events than the elderly population who generally uses arthritis medications. Given a representative profile of the population using Vioxx, he believed the drug could increase the risk of heart attacks or stroke by up to eight times. *Id.*

¹³⁷ See Freking, *supra* note 114, at Nation & World. The document was present during a congressional inquiry by the House Government Reform Committee in May 2005.

¹³⁸ *Id.*

¹³⁹ Kaufman, *supra* note 17, at A1 (announcing Gilmartin's resignation on same day incriminating documents were made public).

¹⁴⁰ *Id.*

¹⁴¹ See Vioxx Exec Explains Ethics, "Dodge Ball", CNN.COM. (July 19, 2005), <http://www.cnn.com/2005/LAW/07/19/vioxx.trial.ap/index.html>. Nancy Santanello of Merck's department of epidemiology nonetheless asserted that participants who dodged all of the questions could not win the game.

¹⁴² See Freking, *supra* note 114, at Nation & World (stating "when doctors asked about heart risks, the sales reps were to provide a 'cardiovascular card' with data

that raised safety questions about drugs were considered background studies. Distributing the results of a background study was 'a clear violation of company policy'.¹⁴³

On September 17, 2001, the FDA issued a "Warning Letter" to Merck for its concerns as to its marketing of Vioxx.¹⁴⁴ After reviewing Merck's marketing activities and promotional materials, it concluded that "they are false, lacking in fair balance, or otherwise misleading in violation of the Federal Food, Drug, and Cosmetic Act."¹⁴⁵ The Letter chastised Merck for engaging "in a promotional campaign for Vioxx that minimized the potentially serious cardiovascular findings that were observed" in the VIGOR study.¹⁴⁶ Regarding Merck's explanation for the VIGOR results that naproxen benefits the heart but that Vioxx does no harm, the FDA stated that Merck had failed "to disclose" that its "explanation is hypothetical, has not been demonstrated by substantial evidence, and that there is another reasonable explanation," that Vioxx may simply increase the risks of cardiovascular events.¹⁴⁷ "As you know," the FDA explained to Gilmartin, "the reason for the difference between Vioxx and naproxen has not been determined."¹⁴⁸ The FDA identified the following Merck press release from May 22, 2001, "Merck Confirms Favorable Cardiovascular Safety Profile of Vioxx," which the FDA concluded was also "false or misleading."¹⁴⁹ "Your claim in the press release," the FDA wrote, "that Vioxx has a 'favorable cardiovascular safety profile,' is simply incomprehensible, given the rate of MI and serious cardiovascular events compared to naproxen."¹⁵⁰ In addition, the Letter continued, "Merck sales representatives have engaged in

suggesting that Vioxx could be eight to 11 times safer than other anti-inflammatory drugs.").

¹⁴³ See Henry Waxman, *The Lessons of Vioxx—Drug Safety and Sales*, 352 NEW ENG. J. MED. 2576, 2577 (2004). Waxman, a Democrat, is a House representative from California and participated in the congressional hearings on May 5, 2005, before the Government Reform Committee of the U.S. House.

¹⁴⁴ See generally, FDA Warning Letter to Raymond V. Gilmartin, President and CEO Merck & Co., Inc., (Sept. 17, 2001), available at www.fda.gov/foi/warning_letters/g1751d.pdf. FDA experts had publicly expressed serious concerns to the agency's advisory committee about its promotional and marketing activities deeming Vioxx safe.

¹⁴⁵ *Id.* at 1.

¹⁴⁶ *Id.*

¹⁴⁷ *Id.* at 1-2.

¹⁴⁸ *Id.* at 3-4.

¹⁴⁹ *Id.* at 6.

¹⁵⁰ *Id.*

false or misleading promotional activities that also minimize the potentially serious MI results observed in the VIGOR trial.”¹⁵¹ The FDA 2001 Warning Letter noted that on December 16, 1999, the FDA had objected to Merck’s “dissemination of promotional materials for Vioxx that misrepresented Vioxx’s safety profile, contained unsubstantiated comparative claims, and lacked fair balance,” but that Merck had taken no action to remedy these violations.¹⁵²

iii. Silencing Critics

In addition to aggressive and misleading marketing strategies, Merck, along with the FDA, has been accused of harassing Vioxx’s critics.¹⁵³ In an investigation by the Senate Finance Committee, two leading scientists testified that they were “pressured to back off criticism of Vioxx” after expressing concern that the drug might increase the risks of heart attacks and strokes.¹⁵⁴ David Graham, a scientist at FDA, said that “when he raised questions about the safety of Vioxx with other FDA officials, he was pressured to keep quiet.”¹⁵⁵ He also said the FDA tried to prevent him from publishing his findings on Vioxx.¹⁵⁶ Gurkirpal Singh, a professor at Stanford University’s medical school, said that a Merck senior executive had contacted his superiors to warn that if Singh continued to express his concerns about Vioxx he would have career problems in the future. Singh explained, “I was warned that if I persisted in this fashion, there would be serious consequences for me.”¹⁵⁷ Singh testified that “questions about Vioxx’s safety were known to Merck years before its introduction, and he accused the company

¹⁵¹ *Id.* at 7.

¹⁵² *See id.* (stating that Merck continued its behavior despite written notification of similar violations).

¹⁵³ *See* Mondics, *supra* note 2, at A1.

¹⁵⁴ *See id.* As a result of this internal pressure, an F.D.A. scientist expressed his opinion that as currently configured the FDA is “incapable of protecting America against another Vioxx.” *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ *FDA and Merck Vioxx Probe by House Energy and Commerce Committee*, MED. NEWS TODAY (Nov. 24, 2004), available at <http://www.medicalnewstoday.com/printerfriendlynews.php?newsid=16822> (commenting that Graham’s bosses at FDA tried to prevent him from publishing his Vioxx findings).

¹⁵⁷ *See* Mondics, *supra* note 2, at A1.

of designing studies that would emphasize the benefits while minimizing the risks.”¹⁵⁸

C. Merck's Escalating Legal Problems over Vioxx

The 9,650 individual Vioxx law suits filed as of April 2006 may be just the start of the roller coaster ride for Merck.¹⁵⁹ In 2005, the Texas Attorney General filed suit against the company, demanding \$168 million in damages for willfully misrepresenting Vioxx's safety to the state, which filled an estimated 700,000 subscriptions through Medicaid.¹⁶⁰ If the punitive damage award handed down in New Jersey on April 11, 2006 in the McDarby case is upheld, experts said that this could trigger a state criminal investigation.¹⁶¹ In the federal sector, the Justice Department has already launched a criminal investigation related to Merck's research, marketing, and selling of Vioxx, and the Securities and Exchange Committee is conducting an informal inquiry.¹⁶² The House Energy and Commerce Committee held public hearings in November, 2004, on Merck and the FDA's handling of the drug's safety issues.¹⁶³ On May 5, 2005, the House Government Reform Committee conducted public hearings on FDA reform, focusing on Merck and Vioxx.¹⁶⁴ In addition to governmental investigations, a class action lawsuit has been filed in federal court in New Jersey on behalf of

¹⁵⁸ See *id.* (explaining Singh's statements).

¹⁵⁹ See *Vioxx Plaintiff Gets \$13.5 Million in Damages: Jury Finds that Merck Failed to Warn N.J. Man of Heart Attack Risks*, MSNBC.COM (Apr. 12, 2006) [hereinafter *Vioxx Plaintiff Gets \$13.5 Million in Damages*], available at <http://www.msnbc.msn.com/id.12267697> (estimating number of lawsuits filed in state and federal courts against Merck).

¹⁶⁰ See *Texas Sues Merck in Vioxx Recall Case* (July 1, 2005), available at <http://www.nynippon.com/vioxx/?p=8> (commenting further that allegations against Merck include violating Medicaid fraud law in order to gain profits for company).

¹⁶¹ See *Vioxx Plaintiff Gets \$13.5 Million in Damages*, *supra* note 159 (stating that ruling in McDarby could lead to investigation by state Attorney's General's Office).

¹⁶² See *Canadian Shares Cautiously Climb at Open*, THOMPSON FIN. CORP. GROUP (Nov. 9, 2004), available at <http://www.prnewswire.com/cgi-bin/stories> (summarizing Justice Department's commencement of criminal investigation regarding how Merck handled Vioxx).

¹⁶³ See Letter from Joe Barton, Chairman, U.S. House of Representatives Committee on Energy and Commerce, to Raymond Gilmartin (Nov. 23, 2004), available at http://energycommerce.house.gov/108/News/11232004_1413.htm (concerning issues relating to Vioxx's withdrawal from marketplace).

¹⁶⁴ See *House Government Reform Committee to Meet on FDA* (May 5, 2005), available at <http://gooznews.com/archives/000121.html> (looking to give FDA "safety officials more power to pull drugs from the market and order new clinical trials.").

participants and beneficiaries of Merck's Savings and Security Plan and Employee Stock Purchase and Security plan.¹⁶⁵ The suit alleges that Merck breached its fiduciary duties under the Employee Retirement Income Security Act by, among other things, failing to prudently manage the Plan and its assets, and "failing to provide complete and accurate information to participants and beneficiaries."¹⁶⁶

Whatever profit Merck made from Vioxx will be wiped out by the litigation.¹⁶⁷ As to whether that litigation is warranted, or the result of greedy attorneys and their clients taking a shot at the great American lottery—the jury system—it seems clear that the litigation against Merck is well-founded.¹⁶⁸ The company and its thousands of employees have hidden information and reports from prescribing doctors and the public and have fraudulently and aggressively marketed Vioxx after studies showed, both before and after FDA approval, that there was a two to five times increase in cardiovascular risks for those taking Vioxx over other painkillers or a placebo.¹⁶⁹ Merck's insistence that they responded appropriately to evidence of risks and released all reliable medical data to the FDA and the public, is simply a smokescreen and rationalization to make executives and

¹⁶⁵ See *Merck & Co. ERISA Litigation*, KELLER ROHRBACK LAW OFFICES, available at <http://www.erisafraud.com/Default.aspx?tabid=1031> (last visited Nov. 13, 2006) (explaining complaint was filed in District Court of New Jersey and providing associated court documents).

¹⁶⁶ See *id.* (noting amended complaint was filed during class period alleging variety of reasons for Merck's breach of their fiduciary duty).

¹⁶⁷ See Mondics, *supra* note 2, at A1 (highlighting that Vioxx generated sales in excess of \$2.5 billion per year since Vioxx was introduced in 1999); see also *Vioxx Recall Lawsuits to Exceed 100,000* (May 24, 2005), available at <http://www.mynippon.com/vioxx/2005/05/vioxx-recall-lawsuits-to-exceed-1000000.html> (noting that Merck's often cited legal liability is \$18 billion, but some estimates say it could reach \$55 billion).

¹⁶⁸ See, e.g., Henry Waxman, *The Marketing of Vioxx to Physicians*, Memorandum to Democratic Members of the Government Reform Committee (May 5, 2005), available at <http://www.democrats.reform.house.gov/story.asp?ID=848&Issue=Prescription+Drugs> (citing a recent study that "estimated that as many as 88,000 to 140,000 Americans have suffered Vioxx-related heart attacks, strokes, and other serious medical complications.").

¹⁶⁹ See Kaufman, *supra* note 17, at A1. Merck "directed its 3,000 person Vioxx sales force to avoid discussions with doctors" about cardiovascular risks, and coached representatives to be "aggressive salesman." *Id.* See also Alex Berenson, et al., *Despite Warnings, Drug Giant Took Long Path to Vioxx Recall*, N.Y. TIMES (Nov. 14, 2004), [hereinafter *Despite Warnings, Drug Giant Took Long Path to Vioxx Recall*], available at <http://www.nytimes.com>. Merck ignored countless warning signs. Even before Vioxx's approval, the FDA cited conceivable harm to the heart. Furthermore, in 2000, the VIGOR study stated that those taking Vioxx were clearly at a greater cardiovascular risk than those taking naproxen. The FDA even sent a letter to Merck in 2001, telling them "to correct false or misleading impressions and information," yet the drug was not removed from the market until September of 2004. *Id.*

employees feel better when they wake up in the morning.¹⁷⁰ It is analogous to the seven tobacco industry executives in the 1980's standing before a Congressional committee and swearing under oath that they did not believe tobacco was addictive. During the Congressional Reform Committee hearings in May 2005, one Congressman defended Merck's marketing scheme by proffering that there was no indication the sales tactics were illegal.¹⁷¹ The frosty response from one congressman was, "[i]sn't there a role of ethics to play here?"¹⁷²

Juries will likely punish Merck severely as jurors place themselves in the shoes of plaintiffs suffering from a heart attack or stroke who either died like Robert Ernst or are seriously debilitated like John McDarby or Gerald Barnett. Those less severely debilitated by heart attack or stroke after taking Vioxx for only a short time, on the other hand, may have difficulty persuading a jury that Vioxx was the "cause" of their cardiovascular event.¹⁷³ But the Ernsts and McDarbys and Barnetts are likely to jump the "causation" hurdle with juries.¹⁷⁴ In aggressively and with abandon, continuing to market Vioxx after several studies showed an increased risk from taking Vioxx, Merck and its employees murdered people.¹⁷⁵

D. What Makes Employees so Deadly Loyal?

The evidence is so overwhelming that it is difficult to understand how Merck's employees can still wholeheartedly support the company's actions. And yet, ten Merck employees, in three MBA business ethics classes, at two different universities

¹⁷⁰ See, e.g., Kaufman, *supra* note 17, at A1 (quoting Merck's vice president saying Merck acted "appropriately and extensively" in its studies of Vioxx, and in disclosing information).

¹⁷¹ See Freking, *supra* note 114, at Nation & World, May 5, 2005 (describing lawmakers' statements).

¹⁷² *Id.* (quoting Representative Gil Gutknecht of Minnesota).

¹⁷³ See, e.g., *Merck Wins Judgment in Vioxx Case*, INT'L HERALD TRIB. (Sept. 27, 2006), available at <http://www.ihf.com/articles/2006/09/27/business/vioxx.php> (reporting that federal jury ruled in favor of Merck in lawsuit by fifty-six-year-old man who survived heart attack after taking Vioxx for only four-and-a-half months).

¹⁷⁴ See, e.g., *\$50 Million Award*, *supra* note 58 (citing Barnett v. Merck case, where jury awarded litigant \$50 million dollars after he suffered heart attack and lost ten years of his life expectancy).

¹⁷⁵ See Kaufman, *supra* note 17, at A1 (elaborating on Merck's aggressive marketing); see also *Despite Warnings, Drug Giant Took Long Path to Vioxx Recall*, *supra* note 169 (proposing FDA scientist, David Graham's estimate that Vioxx is associated with more than 27,000 heart attacks or deaths linked to cardiac problems).

unabashedly are incensed at the suggestion that Merck did anything unethical. They point to past examples of Merck releasing its patent on streptomycin, giving away medications to combat “river blindness,” and providing free prescriptions for the elderly. The ten employees accept without reservation Gilmartin’s defense that no “credible” scientific evidence existed to show Vioxx was dangerous until the September 2004 analysis of the colon polyps study. But this is simply wishful thinking; and Merck turned a blind eye to any study that had negative results. In discussing how employees sublimated safety concerns and marketed Vioxx, one Merck employee in a moment of candor reflected: “Perhaps we were guilty of ‘group think’.”¹⁷⁶

Employees simply accepted their boss’s explanations without thinking, much like most MBA students accept the mantra of “maximizing profits” simply because this is what they have been taught since their first year undergraduate business courses. In fact, one study of 2000 graduate students from the top thirteen business schools found that a business school MBA education not only fails to improve the moral character of the students, it actually weakens it as students become indoctrinated with the belief that the prime responsibility of the corporation is to maximize profit and shareholder value.¹⁷⁷

Merck employees simply accepted the corporate rationale—they were good team players. “Loyalty” is a hallowed word—revered and rewarded. Employee evaluations and promotions are based on being “loyal” and a “team player.” Do what is best for the organization. As such, employees often bury their own internal moral code, as well as their intellect. They go into the deep freeze, as they often blindly follow those in authority. Or does that statement seem too bold? But if it is, then how can we explain the Vioxx debacle? Why did not a single employee blow the whistle on Merck and its marketing practices?

Perhaps it is because our whole educational system, as well as the corporatocracy, teaches us to defer to authority. It teaches us to be followers, to be loyal, and to suspend our intellect. A study

¹⁷⁶ The Merck employee was in the author’s MBA Business Ethics class at DeSales University during the winter 2006 term.

¹⁷⁷ Dennis A. Gioia, *Business Education’s Role in the Crisis of Corporate Confidence*, Penn State Smeal College of Business, (Aug. 2002), available at <http://www.smeal.psu.edu/news/releases/aug02/business.html> (arguing this is not influence we as society should want to have).

of MBA graduates from Harvard several years after entering the business world reveals the truth about corporations—they want minions, not critical thinkers with a functioning internal moral core. The MBA study revealed informal but powerful “commandments,” which corporations communicated to the graduates early in their careers: Among those commandments—performance is what really counts so make your numbers; be loyal and show you are a team player; and don’t over invest in ethical behavior.¹⁷⁸ The Harvard study shows the premium on being loyal and being a follower.

But teaching students to be drones begins not during an MBA program, but in childhood and continues throughout much of the educational experience. At an early age, we are taught our place in the hierarchy. We are taught not to question authority, and we call teachers by last names to show us that in the pecking order they are above us and are to be respected and followed. John Gatto, a former “teacher of the year” for the City of New York as well as “teacher of the year” for the state of New York, has described how a public school education harms our kids and society.¹⁷⁹ His article traces the history of public schools in the United States. He discusses Alexander Inglis’s 1918 book, *Principles of Secondary Education*, a book that traces the purpose of education in this country. Inglis, for whom a lecture in education at Harvard is named, makes it clear “that compulsory schooling on this continent was intended to be just what it had been for Prussia in the 1820s, a fifth column into the burgeoning democratic movement that threatened to give the peasants and the proletarians a voice at the bargaining table.”¹⁸⁰ Inglis breaks down the actual purpose of modern schooling into specific functions. One function served by schools is that they “are to establish fixed habits of reaction to authority. This, of course, precludes critical judgment completely.”¹⁸¹ A second purpose of education is to make children as alike as possible, since people who conform are predictable, and “this is of great

¹⁷⁸ GEORGE STEINER & JOHN STEINER, BUSINESS GOVERNMENT, AND SOCIETY 198 (McGraw-Hill 11th ed. 2005).

¹⁷⁹ John Taylor Gatto, *Against School*, HARPER’S MAG. (Sept. 2003), available at <http://www.spinninglobe.net/againstschool.htm>. Gatto discusses that the public school system is not proficient in educating society’s youth.

¹⁸⁰ See *id.* at 36 (quoting Inglis).

¹⁸¹ *Id.*

use to those who wish to harness and manipulate a large labor force.”¹⁸² He continues. “[s]chools are meant to tag the unfit - with poor grades, remedial placement, and other punishments”¹⁸³ The societal system implied by these rules will require an elite group of caretakers who will be taught how to manage and “control a population deliberately dumbed down and declawed in order that government might proceed unchallenged and corporations might never want for obedient labor.”¹⁸⁴

Thus, Gatto proffers, school trains children to obey reflexively, without questioning or using critical judgment.¹⁸⁵ He warns that our schools are “drill centers for the habits and attitudes that corporate society demands.”¹⁸⁶ “Mandatory education serves children only incidentally; its real purpose is to turn them into servants.”¹⁸⁷ The experience of the corporate world gives credence to Gatto’s and Inglis’s views on our educational system. Surveys, for example, have shown that the “behavior and example of superiors is listed by managers as the most important single influence on ethical or unethical behavior in companies.”¹⁸⁸ Stated differently, the study shows that generally employees are “loyal” and “defer to authority” and in the workplace sublimate their own internal moral code.

In the case of the Vioxx debacle, Merck’s employees were good team players and good servants, but they lost their moral compass. Executives and employees buried their morality in order to sell its blockbuster drug, Vioxx. As many as 55,000 people in the United States may have died as a result, while the death toll of the millions of people taking Vioxx throughout the rest of the world is still not known. The Vioxx debacle is an example of the evil of the “maximizing profits” mantra drummed into and followed by business students. After a four-year undergraduate business program and a three-year MBA

¹⁸² *Id.*

¹⁸³ *Id.* at 37.

¹⁸⁴ *Id.*

¹⁸⁵ Gatto, *supra* note 179 (arguing children’s use of critical judgment should be one of public school systems’ main goals).

¹⁸⁶ *Id.* at 38.

¹⁸⁷ *Id.*

¹⁸⁸ GEORGE STEINER & JOHN STEINER, BUSINESS, GOVERNMENT, AND SOCIETY 185 (McGraw Hill 7th ed. 1994).

program, most students have been brainwashed to the point that the mantra seems like manifest destiny. Perhaps it is time for business schools and corporate America to rethink the mantra.

CONCLUSION

How did the Vioxx debacle happen in a company that has always appeared to have such high ethical standards? The answer perhaps lies in the first paragraph of this article. Between 1999-01 Merck lost its patent protection on five of its best-selling drugs; two other drugs were to lose their patent protection by 2007, and Merck had not had a blockbuster drug for years. Merck was feeling the stress of losing market share and profits. Merck was under pressure to maximize its profits in a company whose profits had flattened. And yet the issue was life and death. During the Ernst trial, one of the Merck witnesses, Dr. Santanello, grew irritated as Mark Lanier asked her whether Mr. Ernst had risk factors for heart attacks beyond the use of Vioxx. "You're playing this game," she said.¹⁸⁹ "This is not a game," he responded. "My client's dead."¹⁹⁰

¹⁸⁹ *In Training Video, Merck Said Vioxx Did Not Increase Risk of Heart Attack, supra* note 121, at C4.

¹⁹⁰ *Id.*