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COMMONWEALTH OF KENTUCKY
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Case No. 2012-SC-000162
Court Of Appeals Case No. 2011-CA-000234-MR

JAMES RATLIFF, On Behalf Of Himself
And All Others Similarly Situated

On Appeal From The Pike Circuit Court
Action No. 04-CI-01493

V.

MERCK & CO., INC.

APPELLANT
FILED
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APPELLEE

BRIEF OF APPELLANT

This shall certify that this Brief Of Appellant was served by depositing true copies in the United States Mail, first class, postage prepaid, addressed to Susan J. Pope, Esq., Frost Brown Todd, LLC, 250 W. Main Street, Suite 2800, Lexington, Kentucky 40507; John H. Beisner, Esq. and Jessica D. Miller, Esq., Skadden, Arps, Slate, Meagher & Flom, LLP, 1440 New York Avenue, NW, Washington, D.C. 20005; Honorable Steven Combs, Judge, Pike Circuit Court, 423 Hall of Justice, 172 Division Street, Pikeville, Kentucky 41501; and Samuel P. Givens, Jr., Clerk, Kentucky Court of Appeals, 360 Democrat Drive, Frankfort, Kentucky 40601, on this the 14th day of January, 2013.

Respectfully submitted,



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I. INTRODUCTION

This case arises from Appellee Merck & Co., Inc.'s fraudulent and misleading marketing of the drug Vioxx between 1999 and 2004. The question to be considered by the Court is whether the Kentucky Court of Appeals erred in holding that the Trial Court abused its discretion in certifying a class of Kentucky consumers alleging common law claims of fraud and misrepresentation in connection with their purchase of the drug.

II. STATEMENT CONCERNING ORAL ARGUMENT

Appellant requests oral argument. This appeal turns on questions relating to a Trial Court's discretion to certify a class action with respect to common law fraud and misrepresentation claims, which are likely to recur in other actions, and oral argument would therefore assist the Court in the resolution of these issues.

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IV. STATEMENT OF THE CASE

This case presents a prime example of an irresponsible corporate citizen – a company that puts a product on the market, becomes aware of a product defect, and then spends millions of dollars attempting to obscure the danger and increase profits. It presents directly the issue of whether a company that spreads false or fraudulent information about its product to the public may be held accountable for its actions through common law claims asserted by a class seeking to obtain redress for relatively small monetary damages suffered by a mass group of consumers where the false or fraudulent statements are uniform in nature to all class members.

Here, even after the product was pulled from the market, Merck used every bad faith tactic to try to prevent those with claims too small to be brought individually from ever obtaining redress through a class action. Statutory and common laws are designed to prevent this type of activity, and where as here, thousands of individuals are harmed by the defective product; a class action is an appropriate means of providing redress for conduct involving uniformly the same false or fraudulent statements to all class members regarding a defective product.

A. Merck Is Put On Notice Regarding The Potential Health Risks Of Vioxx But Chooses To Keep Vioxx On The Market And Attempts To Minimize The Negative Reports Regarding Its Side Effects By Disseminating False And Misleading Information Regarding The Drug.

Merck is a foreign corporation with its principal place of business in New Jersey, and was in the business of manufacturing and/or promoting, marketing, and distributing the drug Vioxx among numerous other drugs. Merck does business in Kentucky and, between 1999 and 2004, sold Vioxx in Kentucky to thousands of Kentucky consumers.

(Memorandum in Support of Plaintiff's Motion to Certify Class Pursuant To CR 23.01 and CR 23.02 (hereinafter "Memorandum In Support Of Motion To Certify"), p. 2; R., v. 1, p. 40). Vioxx, generically known as rofecoxib, is a nonsteroidal anti-inflammatory drug ("NSAID"). It was introduced to the market on May 21, 1999. Merck promoted Vioxx as having a safety profile superior to other NSAIDs. (Id.).

In January 1999, however, the Vioxx GI Outcomes Research ("VIGOR") study conducted by Merck itself, showed that thrombotic events, including myocardial infarction (heart attack), occurred in more patients in the Vioxx treatment group than in the alternative treatment group. (Memorandum In Support Of Motion To Certify, p. 3; R., v. 1, p. 41). In an attempt to minimize the negative findings of the VIGOR study, Merck took the position that the difference in thrombotic event rates between Vioxx and the alternative drug was due to a cardioprotective effect of the alternative drug. Merck was aware, however, that there was another explanation for the difference in thrombotic event rates in the VIGOR study's treatment groups – that Vioxx had pro-thrombotic properties, or in other words, that Vioxx increased the risk of a thrombotic event such as a heart attack. (Memorandum In Support Of Motion To Certify, p. 3; R., v. 1, p. 4); see also In re Merck & Co., Inc. Sec., Derivative & "Erisa" Litig., 483 F. Supp. 2d 407, 412 (D. N.J. 2007) (Judgment was later reversed and remanded, but the facts cited are sound).

On June 29, 2000, Merck submitted the VIGOR data and analysis to the FDA, which concluded that Merck should include data on the Vioxx label about the higher incidence of cardiovascular events observed in the VIGOR study. Id. Studies subsequent to the VIGOR study in patients taking Vioxx also suggested a serious increased risk of

cardiovascular events. Despite a mounting body of evidence suggesting that Vioxx materially increased the risk of serious cardiovascular injury in patients taking the drug, Merck elected to continue to engage in promotional activities and disseminate on the public market materials for the marketing of Vioxx that were false or misleading, lacking in fair balance or otherwise misleading, while attempting to discredit studies that suggested the continued use of the drug posed a serious health risk to patients. In general, the statements discredited questions raised about the possibility that Vioxx is pro-thrombotic. Numerous press releases issued by Merck stated that Vioxx had an “excellent safety profile” and a “favorable cardiovascular safety profile.” In re Merck & Co., Inc., 483 F. Supp. 2d at 412. Based on information and belief, Merck spent in excess of \$100 million per year on direct-to-consumer advertising of Vioxx.

(Memorandum In Support Of Motion To Certify, p. 6; R., v. 1, p. 44;).

Even as Merck was making Vioxx into a bestseller, however, the company was putting pressure on independent doctors to keep them from discussing evidence of Vioxx’s potential safety problems. In 2005, National Public Radio (“NPR”) released a two-part report based on internal Merck documents that showed Merck exerted pressure not only on individual doctors, but also on several of the nation’s top medical schools. (Snigdha Prakash, All Things Considered, “Part 1: Documents Suggest Merck Tried to Censor Vioxx Critics” (June 9, 2005), transcript available at <http://www.npr.org/templates/story/story.php?storyId=4696609>, attached as Exhibit A to Memorandum In Support Of Motion To Certify; R., v. 1, p. 90).

The report alleges that Merck advised its sales representatives not to discuss Vioxx’s risks to the heart, and to have doctors send their questions to Merck’s corporate

headquarters. In fact, there have been allegations that Merck went so far as to instruct their sales representatives to intentionally “dodge” any questions posed by doctors regarding certain harmful effects of Vioxx through training programs like the “Vioxx Obstacle Dodge Ball Program” and the “JeopardXX” training game. Powell v. Merck & Co., Inc., 2007 WL 4097397, *3 (N.D. Miss. 2007) (finding that these allegations supported adding Merck sales representatives to the action as joint tortfeasors — they knew the health risks associated with Vioxx and intentionally misrepresented these risks to their physician clients).

B. Merck Is Criticized By The Department Of Health And Human Services In Connection With Its Deceptive Marketing Of Vioxx, And Is Later Forced To Remove The Drug From The Market.

Merck’s distortions and deceptions regarding the safety of Vioxx began almost immediately after Vioxx was introduced to the U.S. market in 1999. As early as December 1999, the U.S. Department of Health & Human Services (“DHHS”) objected to promotional materials being disseminated by Merck that misrepresented Vioxx’s safety profile, contained unsubstantiated comparative claims, and lacked fair balance. Despite the DHHS objection, Merck continued to distribute information and engage in conduct designed to distort and misrepresent the safety and efficacy of its drug and concealed the true side effects and serious risks of harm to those using the drug.

In September 2001, the DHHS issued a second formal eight-page “Warning Letter” in which it criticized Merck for its continual misleading promotional activities. Specifically, the letter referred to promotional Vioxx audio conferences given on behalf of Merck by various sales representatives and doctors. (2001 Warning Letter, attached as Exhibit B to Memorandum In Support Of Motion To Certify; R., v. 1, p. 104). Merck

was also accused, among other things, of making unsubstantiated superiority claims, promoting Vioxx for unapproved uses, and issuing a false and misleading press release entitled “Merck Confirms Favorable Cardiovascular Safety Profile of Vioxx.” In the Warning Letter, the FDA directed Merck to implement a corrective action plan, including ceasing the misleading promotion of Vioxx and issuing a letter to doctors to correct false information it had disseminated. (Id.)

Despite the drastic step of a DHHS “Warning Letter,” Merck continued its campaign to mislead consumers and to deny the real risks that the continued use of Vioxx posed to those who took the medication. On August 26, 2004, Merck issued a Press Release stating that it “strongly disagrees” with the conclusions of a study presented at the 20th International Conference of Pharmacoepidemiology & Therapeutic Risk Management that found, once again, that the use of Vioxx significantly increased the risk of serious cardiovascular events. Merck stated that its studies showed “no significant difference in the rate of serious cardiovascular thrombotic events in patients taking Vioxx vs. placebo,” and that “[b]ased on all of the data that are available from our clinical trials, Merck stands behind the efficacy and safety, including cardiovascular safety, of Vioxx.” In re Merck & Co., Inc., 483 F. Supp. 2d at 413. One month later, however, Merck withdrew Vioxx from the market, finally acknowledging the true dangers of its drug after three years of failing to do so, all the while spreading false information to the public. During this period, the profits generated by Vioxx continued to increase. (Merck, News Release (Sept. 30, 2004), attached as Exhibit C to Memorandum In Support Of Motion To Certify; R., v. 1, p. 114).

Following the withdrawal of Vioxx from the market, the FDA advised all patients who were currently taking Vioxx to contact their physician for guidance regarding discontinuation and alternative therapies. In a Press Release issued the same day, Merck acknowledged that patients who were currently taking Vioxx “should contact their health care providers to discuss discontinuing the use of Vioxx and possible alternative treatments.” (September 30, 2004 FDA Press Release, attached as Exhibit F to Memorandum In Support Of Motion To Certify; R., v. 1, p. 21).

C. Thousands Of Law Suits Are Filed Against Merck Alleging Personal And Consumer Injury Following The Withdrawal Of Vioxx From The Market.

After Vioxx was removed from the market, thousands of individual suits and numerous class actions were filed against Merck in state and federal courts throughout the country alleging various products liability, tort, fraud, securities, consumer, and warranty claims. On November 9, 2007, Merck entered into a Settlement Agreement (the “Agreement”) with certain plaintiffs’ counsel in order to establish a nationwide settlement program to resolve the personal injury claims of certain individuals who have suffered a heart attack, stroke, or sudden cardiac death resulting from their use of Vioxx (the “Vioxx Claimant(s)”). (Merck, News Release (November 9, 2007), Exhibit D, Plaintiff’s Memorandum in Support Of Motion To Certify; R., v. 1, p. 18). The claims asserted in the underlying action fall well outside the claims settled by the Agreement and are unaffected by these earlier settlement proceedings.

D. Merck Pleads Guilty To Criminal Charges Arising From Its False Marketing Of Vioxx And Agrees To Pay Criminal And Civil Penalties.

In April, 2012, Merck was sentenced by United States District Court Judge Patti B. Saris in Boston to pay a criminal fine in the amount of \$321,636,000 in connection with its guilty plea related to its promotion and marketing of Vioxx, after previously pleading guilty, in United States of America v. Merck Sharpe & Dhome Corp., Criminal Action No. 1:11-cr-10384-PBS, District of Massachusetts, to violating the Food, Drug, and Cosmetic Act (FDCA) for introducing Vioxx into interstate commerce as a misbranded drug. See Settlement and Plea Agreement, Appendix, Tab A.¹

In connection with the criminal plea, Merck also entered into a federal civil settlement in November 2011, under which it agreed to pay \$628,364,000 to resolve additional allegations regarding off-label marketing of Vioxx and false statements about the drug's cardiovascular safety. Of the total civil settlement, \$426,389,000 will be recovered by the United States, and the remaining share of \$201,975,000 will be distributed to the participating Medicaid states. Id.

The federal civil settlement resolved allegations asserted in litigation filed by several states against Merck that was consolidated into In re Vioxx Litigation, MDL No. 1657, which alleged Merck representatives made inaccurate, unsupported, or misleading statements about Vioxx's cardiovascular safety in order to increase sales of the drug, resulting in payments by the federal government. It also resolved allegations that Merck made false statements to state Medicaid agencies about the cardiovascular safety of Vioxx, and that those agencies relied on Merck's false claims in making payment

¹ Appellant respectfully requests the Court to take judicial notice of the Settlement and Plea Agreement, which is a matter of public record in the United States District Court of Massachusetts.

decisions about the drug. Finally, the civil settlement also recovered damages for allegedly false claims caused by Merck's unlawful promotion of Vioxx for rheumatoid arthritis. Id.

As part of the settlement, Merck has also agreed to enter into an expansive corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services (HHS-OIG), to strengthen the system of reviews and oversight procedures imposed on the company. Although Vioxx is no longer on the market, this ongoing monitoring of Merck's conduct is aimed to deter and detect similar conduct in the future. Id.

The sentencing concluded a long-running investigation of Merck's promotion of Vioxx by the federal government after the drug was removed from the market. The case was handled by the Justice Department's Civil Division and the U.S. Attorney's Office for the District of Massachusetts. The investigation was conducted by HHS-OIG, the FBI, the Office of Criminal Investigations for the FDA, the Veterans Administration's Office of Criminal Investigations, the Office of the Inspector General for the Office of Personnel Management, the National Association of Medicaid Fraud Control Units, and the offices of the various state attorneys general. Id.

E. Merck Settles Missouri Consumer Protection Class Action Alleging Claims Similar To Those Asserted In This Litigation.

In November, 2012, Merck announced it had reached a settlement in Plubell v. Merck, an economic class action lawsuit pending in the Missouri state courts. Plubell v. Merck, Civil Action No. 04-CV-235817-01, Jackson County, Missouri. The class consists of Missouri consumers who purchased Vioxx, but do not claim any physical injury. There, as here, the class action lawsuit involved claims alleging that Merck's

promotion and sale of Vioxx constituted unlawful and unfair business practices under the Missouri Merchandising Practices Act.² See Settlement Agreement, Appendix, Tab B.³

Under the settlement terms, qualifying Missouri consumers of Vioxx may be reimbursed in full for their Vioxx purchases. The common fund settlement provides for payment to class members under two options: (1) a one-time cash payment of \$180 to Settlement Class Members who submit a valid claim form with a declaration under oath (but no documentary proof of payment required) or (2) \$90 for each month of Vioxx purchases supported by a declaration under oath with documentary proof of payment, such as a letter from the prescribing physician. Id. In addition to paying the claims of qualifying class members, the settlement requires Merck to pay for all costs associated with the notice and administration of the settlement as well as court-approved attorneys' fees and expenses incurred by the Class. Id.

F. The Claims Of Class Representative Jim Ratliff Are Similar To Those Of The Class Certified In This Action – He Was Prescribed Vioxx During The Relevant Time Period, And Suffered Monetary Damages As A Result Of Merck’s Deceptive Marketing Practices.

As discussed in detail, supra, thousands of consumers throughout the United States have brought claims against Merck arising from its deceptive marketing of Vioxx that are similar to those asserted in this litigation. In those cases, as here, the plaintiffs were prescribed Vioxx during the relevant time period, and suffered monetary damages as a result of Merck’s fraudulent marketing practices. Jim Ratliff (“Ratliff” or

² The Missouri Merchandising Practices Act is nearly identical to the Kentucky Consumer Protection Act. Compare Mo. Rev. Stat. § 407.010, et seq., with KRS 367.220(1). See also Kentucky Court of Appeals Opinion, p. 11, fn. 4, Appendix, Tab C (noting that the Kentucky and Missouri statutes contain nearly identical language).

³ Appellant respectfully requests the Court to take judicial notice of the Settlement Agreement which is a matter of public record in Missouri.

“Appellant”), the lead Plaintiff in the class certified by the Trial Court, has claims that are similar to those of the class as a whole.

Ratliff is a resident of Pike County, Kentucky who was diagnosed with chronic osteoarthritis in 1994 at the age of 37. After experimenting with a bevy of anti-inflammatory drugs, including Daypro and Celebrex, his doctor recommended that he take Vioxx, a drug that was new to the market. In January of 2000, Ratliff began taking Vioxx twice daily. His insurance covered most of the \$66.49 price of the drug per month; however Ratliff still had to pay \$5 out-of-pocket each month to fill his Vioxx prescription. (Deposition of James Ratliff (“Ratliff Dep.”) 33:21-34:4; R., v. 3, pp. 305-306). Ratliff took Vioxx for three years, spending over \$75 to purchase the drug.

Two physicians prescribed Vioxx to Ratliff, and both testified that they relied extensively on the information and materials provided to them by Merck sales representatives in evaluating the health risks of the drug. (Deposition of K.D. Gibson (“Gibson Dep.”), 13:14-24, R., v. 3, pp. 345-346; Deposition of J. Pampati, (“Pampati Dep.”), 14:11-15:24, R., v. 3, pp. 359-360). The materials provided to these physicians, and physicians and consumers throughout the country, were misleading and deceptive, and minimized the potentially serious cardiovascular side effects of the drug that eventually forced Merck to remove the drug from the market. (See Section A, supra). Once Merck finally removed Vioxx from the market because of the inherent dangers of the drug, all physicians, including Ratliff’s doctors, were bound to cease prescribing the drug to their patients. (Gibson Dep. 37:8-11; R., v. 3, p. 555; Pampati Dep., 40:5-9, R., v. 3, p. 369).

After experiencing severe chest pains, labored breathing, lethargy, bleeding, and other uncomfortable side effects, Ratliff discontinued use of Vioxx in early 2004, months before the drug was removed from the market. Ratliff has since obtained the medical consultation suggested by the FDA, a consultation that cost approximately \$180, as well as a screening by a gastroenterologist to assess both his gastrointestinal bleeding and any cardiovascular damage he may have sustained because of his Vioxx use.⁴

The Plaintiff Ratliff brought this case as a class action on behalf of all Kentucky residents who have purchased and taken Vioxx and who, upon the recommendation and advice of the FDA and Merck, have contacted or will contact their physicians to seek advice regarding their use of Vioxx. Plaintiff seeks reimbursement for (a) the costs of such medical consultations, including the costs of any diagnostic testing recommended by the class members' physicians; (b) the lost income and related expenses the class members have, or will have to incur in undergoing such examinations and procedures; and (c) the cost of the Vioxx the class members purchased. Each plaintiff's claims will not exceed the sum of \$75,000, exclusive of interest and costs, and no plaintiff will seek to recover in this action for any personal injury he may have sustained as a consequence of taking Vioxx as prescribed. (Class Action Complaint; R., v. 1, at p. 1).

Ratliff's damages of approximately \$350 are much too small to pursue in litigation against a company the size of Merck. His situation mirrors that of several

⁴ Although Merck has attempted to discredit Ratliff's deposition testimony on this point by insinuating that he did not obtain this consultation, his testimony speaks for itself: "Q: And so, how did you arrive at the figure of \$180, do you remember? A: That's' what the cost was. Q: Okay. A: That's what they charged me. I didn't, you know, arrive at anything. That is what they charged me." (Ratliff Dep.; 57:13-19, R. v. 3, p. 317). Including damages arising from work missed as a result of the medical consultation and other consequential damages, Merck's misleading and deceptive marketing practices resulted in a direct monetary loss to Ratliff of approximately \$350.

hundred thousand Vioxx users across the Commonwealth. While his insurance covered most of the cost relating to the purchase of Vioxx, Ratliff was still spending several dollars a month to purchase a drug which had deadly undisclosed side-effects. The financial harm caused to Ratliff by Merck's misleading marketing practices is relatively small; however, if his total expenditures are added up and apply to a class of over approximately 200,000 individuals, the outlay of money is exponentially higher, resulting in a loss potentially in excess of 70 million dollars to Kentucky consumers. Seeking redress is impractical on an individual basis, but becomes feasible in the context of a class action, where Ratliff's loss is combined with the loss of others similarly situated.

G. Merck's Deliberate Scorched Earth Obstructive Litigation Tactics Have Resulted In Excessive Delay In The Progress Of This Class Action Litigation.

Since 2004, when Appellant filed the underlying action in the Pike Circuit Court, Merck has engaged in obstructive and abusive litigation techniques, making every effort to delay the progress of the litigation and prevent the putative class in this action from obtaining redress for the injuries they have suffered as a result of the Merck's deceptive and manipulative marketing practices. Merck, a multi-billion-dollar corporation, has personally attacked the integrity of the Circuit Judge, attempted to smear the credibility of Appellant, and has spent hundreds of thousands of dollars delaying this litigation in an apparent attempt to force the Appellant and Appellant's counsel to abandon this litigation – none of which will ever occur.

On November 29, 2004, Merck removed the action to Federal Court and also filed a Motion with the Judicial Panel on Multidistrict Litigation ("JPML") seeking to transfer this case to a single court for coordinated pretrial management pursuant to 28 U.S.C.

§1407. On January 1, 2005, Appellant filed a Motion To Remand. After a thorough analysis of the potential value of Appellant's and other potential class members' claims, and based upon its conclusion that Merck failed to show that the damages on each person's claims would exceed the jurisdiction threshold of \$75,000, the District Court ruled that it did not have jurisdiction over this cause of action. On March 3, 2005, District Judge Joseph M. Hood entered an Order remanding the action to the Pike Circuit Court.

Appellant thereafter sought an Order of the Pike Circuit Court certifying the action as a class action pursuant to CR 23.01 and CR 23.02 (c). Extensive briefs were filed in support of and in opposition to Appellant's Motion, and Merck also filed a Motion for Summary Judgment asking that Appellant's claims be dismissed on various bases. (Motion to Certify Class; R., v. 1, p. 29; Opposition To Motion To Certify Class; R., v. 2, p. 233).

Several hearings took place on the various motions and the Pike Circuit Court, after considering the briefs and oral argument from both sides, entered two separate Orders dated April 1, 2010 – one denying Merck's Motion for Summary Judgment, and one granting Appellant's Motion to Certify. (April 1, 2010 Order Certifying Class Action; R., v. 6, p. 822).

Despite the fact that established Kentucky precedent states that Petitions for Writs of Prohibition or Mandamus are not an appropriate means for challenging class certification orders, see Garrard County Bd. of Educ. v. Jackson, 12 S.W.3d 686 (Ky. 2000), Merck sought relief from the April 1, 2010 Class Certification Order by filing a Petition for Writ of Mandamus with the Court of Appeals, arguing that the Trial Court's

decision to certify the Class was in error and should be reversed. The Court of Appeals denied Merck's Petition by Order dated July 12, 2010. (Court of Appeals Order, attached as Exhibit B to Plaintiffs' Motion To Enter Amended Class certification Order; R., v. 6, p. 850). In so ruling, the Court of Appeals relied on the holding in Jackson, supra, and upon a finding that Merck had an adequate remedy of appeal following a final adjudication of the merits. Id. Merck further appealed to this Court the Court of Appeals decision denying the mandamus relief sought by it. This Court affirmed on the basis of the Jackson decision, and found that Merck had not demonstrated that it would be irreparably harmed by the Trial Court's decision to certify the class. (2010-SC-000529-MR).

H. The Amended Order Certifying Class Action Is Sufficient To Satisfy The Requirements Of CR 23.

Merck based its Petition for Writ of Mandamus partially upon its argument that the Order certifying Class Action failed to make specific findings supporting its ruling and was therefore inadequate. At the Trial Court level, however, Merck objected to the Plaintiffs' Motion To Enter Amended Order Certifying Class, and attempted to prevent the Trial Court from amplifying or clarifying the grounds for its earlier certification decision – in effect whipsawing the Trial Court in an effort to prejudice the Plaintiff class harmed by it. (Plaintiffs' Reply In Support Of Motion To Reconsider; R., v. 7, p. 1104). Merck, in essence, sought to have its cake and eat it too – telling the Court of Appeals that the Trial Court had not done its job while telling the Trial Court it could not continue to do its job by exercising its discretion to amplify an interlocutory Order that could be modified or added to at any time before a final Order was entered. See, e.g., Bellarmine College v. Hornung, 662 S.W.2d 847, 849 (Ky. Ct. App. 1983).

Attached to the Appellant's Motion to Enter Amended Order Certifying Class was a Proposed Amended Class Certification Order for the Court's consideration or modification. During the hearing on Plaintiff's Motion to Enter Amended Class Certification Order, Merck raised concerns regarding certain language contained in the Proposed Amended Class Certification Order as being conclusory as to the merits of Plaintiff's claims. In response, the Appellant represented that the Order would be further amended and submitted to the Court for consideration. Before the necessary edits deleting any allegedly conclusory statements were submitted, the Court entered an Order denying the Plaintiff's Motion to Enter Amended Class Certification Order on December 4, 2010, but approving the Proposed Notice of Settlement submitted to the Court. (Order Denying Plaintiffs' Motion To Amend Order Certifying Class; R., v. 7, p. 968; Plaintiffs' Motion To Reconsider Order Denying Motion to Alter Or Amend Order Certifying Class ("Motion to Reconsider"); R., v. 7, p. 969).

The Plaintiff's Motion to Reconsider was filed as an attempt to clarify the record and provide the Trial Court with an opportunity to consider the Amended Order submitted as Exhibit A to that Motion. On January 27, 2011, the Trial Court granted Appellant's Motion, and entered an Amended Order. (Am. Order, R., v. 8, p. 1112). The Amended Order entered by the Trial Court contains a detailed recitation of facts, a description of the class plaintiff and class allegations, and a complete Rule 23 analysis, with citation to relevant case law. (Id.). Specifically, the Trial Court found that the class is so numerous that joinder of all members is impracticable, that there are questions of law and fact common to the class, that the claims and defenses of the representative parties are typical of the claims and defenses of the class, that Ratliff will fairly and

adequately protect the interests of the class, that questions of law and fact common to the class predominate, that a class action is the superior means of adjudicating the claims at issue, and that resolution of the action as a class does not pose any particularly difficult management or administrative problems. (Id.).

Importantly, while the Trial Court's Amended Class Certification Order references, in dicta, the fact that "[a]ll of the potential plaintiffs were victims of Merck's fraud upon the market..." the Trial Court's decision to certify the Appellant's fraud and misrepresentation claims was not based on a specific application of the fraud on the market theory to the claims at issue. Instead, it was based on a finding that under the facts of the case, "where plaintiffs are similarly situated, and seek recovery under identical theories of law and based upon the identical conduct of the defendant, common questions of law and fact predominate, making certification . . . appropriate[.]" Id.

I. The Court Of Appeals Erred In Finding That The Trial Court's Decision To Certify Appellant's Fraud And Misrepresentation Claims Was An Abuse Of Discretion.

On appeal, numerosity and the presence of common questions of law and fact under CR 23.01(a) and (b) were not disputed. Merck argued, however, that common questions of law and fact do not predominate under CR 23.02(c), that a class action is not the superior method for adjudication under CR 23.02(c), and that Ratliff is not a typical or adequate representative under CR 23.01(c) and (d). Specifically, Merck argued that the Trial Court abused its discretion in granting class certification with respect to Appellant's fraud-based claims because individual questions of reliance, causation and damages existed that would create mini-trials that would proliferate and prevent the

predominance, typicality and superiority requirements for the certification of a class from being met.

The Court of Appeals first addressed the argument by Merck regarding predominance under CR 23.02(c), and reversed the Trial Court, finding that the class members' claims of fraud, negligent misrepresentation, and unjust enrichment could not satisfy the predominance requirement under CR 23.02(c). See February 10, 2012 Court of Appeals Opinion (hereinafter "Opinion"), Appendix, Tab C. In so doing, however, the Court of Appeals first noted that it agreed with several aspects of the Trial Court's Amended Certification Order:

Nonetheless, it should first be acknowledged that that we agree with the trial court on several initial points. Indeed, we agree that Ratliff's and the putative class members' claims hinge upon whether Merck knowingly or negligently distributed false or misleading information while VIOXX was on the market. This common question threads through each potential class member's claims. We further acknowledge that predominance does not require that each and every possible issue be common to all class members, but only that common issues *substantially predominate* over those issues which are individual in nature.

Opinion, p. 10 (emphasis in original, citations omitted).

The Court of Appeals based its ruling that the class members' fraud and misrepresentation claims did not satisfy the predominance requirement under CR 23.02(c) on that fact that, under Kentucky law, the fraud claims each contain the element of reliance:

In the present case, each of the putative class members would have to show that his or her respective physicians individually relied upon the false or misleading information disseminated by Merck when prescribing Vioxx to them. It is exactly this type of individualized proof which generally makes class litigation inappropriate in fraud and misrepresentation cases.

Id. at 12.

The Court of Appeals went on to note, however, that in some cases involving fraud or misrepresentation, a “class action may still be appropriate where common issues predominate over individualized questions and arise from a single fraudulent scheme or conspiracy or from identical misrepresentations.” Id. at p. 13.

It has been the Appellant’s contention, in pleadings and on appeal, that Merck used a consistent pattern of deception lasting essentially the entire time that Vioxx was on the market, and that generalized proof could therefore be used to show the elements of fraud and misrepresentation in this case. The Court of Appeals analogized the Appellant’s argument to the rebuttable presumption of reliance and causation known in securities litigation under the fraud on the market theory. The Court declined, however, to extend the fraud on the market theory beyond the scope of securities litigation, noting that other jurisdictions have likewise refused to allow use of the theory in consumer litigation: “[T]he ‘fraud-on-the-market’ approach has never been recognized in this jurisdiction for a fraud or misrepresentation case.” Id. at 15. The Court therefore concluded that individual questions of causation, reliance and damages defeated class certification of the Appellant’s fraud and misrepresentation claims. Id.

Based on these conclusions, the Court of Appeals ruled that the Trial Court abused its discretion by entering the Amended Order Certifying Class, and reversed and remanded the matter to Pike Circuit Court with instructions for the Court to vacate its prior order. The Court of Appeals did not consider Merck’s arguments with respect to the adequacy of Ratliff as a class representative. Id.

J. The Court Of Appeals Opinion Does Not Reverse Class Certification With Respect To Appellant's Claims Arising Under The Kentucky Consumer Protection Act.

Importantly, the Court of Appeals' Opinion did not reverse the Trial Court's decision to certify the putative class with respect to the class claim raised under the Kentucky Consumer Protection Act ("KCPA"). In fact, the Court specifically concluded that the statutory claim does not have the same problems as the fraud-based common law claims with respect to class certification because a claim arising under the KCPA does not require proof of causation or reliance, and loss can be proved on a class wide basis under the "benefit-of-the-bargain" rule. Opinion, pp. 10-11.

In so finding, the Court quoted the KCPA, concluding that, "taking the allegations in the complaint as true for purposes of review, it is clear that Merck's actions would be unlawful under the Act." Opinion, p. 11. As cited by the Court, the language of the KCPA does not contain the element of reliance found in common law fraud claims. See KRS 367.220(1) ("Any person who purchases or leases goods or services primarily for personal, family, or household purposes and thereby suffers any ascertainable loss of money or property, real or personal, as a result of the use or employment by another person of a method, act or practice declared unlawful [under the Act] may bring [a civil action] in the Circuit Court.").

The Court then analogized the KCPA to the nearly identical Missouri Consumer Protection Statute at issue in Plubell v. Merck, 289 S.W.3d 707, 714 (Mo. Ct. App. 2009), in which the Missouri Court of Appeals affirmed a Trial Court's certification of a similar class asserting claims under that state's consumer statute based upon a finding that individual questions with respect to causation, reliance, and damages did not exist

under the statutory scheme. Opinion, p. 11. In Plubell, the Missouri Court of Appeals found that the Missouri consumer protection statute required that the consumer's economic loss result from the unlawful practice at issue, but not that the actual purchase of the product be caused by the unlawful conduct. The Kentucky Court of Appeals noted that: "[u]nder this interpretation, causation need not be shown with respect to each individual class member's decision to purchase Vioxx, but merely that a loss resulted from the practice." The Court of Appeals further referenced the Plubell opinion in support of its conclusion that the "benefit-of-the bargain" theory of loss could be applied on a class-wide basis to claims arising under the KCPA. Id. (citing Plubell, 289 S.W.3d at 715, for the proposition that damages are not measured by the purchase of the product in question, but by the difference in value between the product "as represented" and the "actual value" of the product received). The Court also relied upon a New Jersey opinion for its application of the benefit of the bargain method of determining loss with respect to claims arising under the KCPA. Opinion, p. 12 (citing Kleinmann v. Merck & Co., 8 A.3d 851 (N.J. 2009) (also applying a "benefit-of-the-bargain" theory of value/loss)).

In fact, and as the Court of Appeals decision makes quite clear, the analysis employed by that Court with respect to Appellant's fraud and misrepresentation claims cannot apply to a claim arising under the KCPA because, reading the statute on its face, reliance is not an element that must be established with respect to a KCPA claim. Apparently finding that the Trial Court's Amended Certification Order could not be separately considered with respect to each claim, however, the Court of Appeals reversed and remanded the matter to the Pike Circuit Court with instructions for the court to vacate its prior Order. Appellant has since filed a Motion with the Trial Court requesting entry

of an Amended Class Certification Order certifying the proposed class only with respect to the KCPA claims asserted in Appellant's Class Action Complaint – a request that is consistent with the Court of Appeals' Opinion.

V. **ARGUMENT**

A. **The Trial Court's Decision To Certify The Class In This Action Must Be Reviewed Under An Abuse Of Discretion Standard.**

Both Kentucky and Federal Courts apply an abuse of discretion standard in reviewing class certification orders. This standard is applied based on the recognition that “the trial court’s detailed knowledge of the facts place it in as favorable position as possible” to judge whether the requirements for class certification are satisfied, and also based on the Trial Court’s inherent authority to control the progress of litigation. Sowers v. Atkins, 646 S.W.2d 344, 346 (Ky. 1983); Reeb v. Ohio Dep’t of Rehab. & Corr., 435 F.3d 639, 643 (6th Cir. 2006) (“The district court maintains substantial discretion in determining whether to certify a class, as it possesses the inherent power to manage and control its own pending litigation.” (citing Stout v. J.D. Byrider, 228 F.3d 709, 716 (6th Cir. 2000))). The Trial Court has more intimate knowledge of the facts, which places it in a more favorable position to judge whether the requirements for class certification have been met. Id. at 346.

A Trial Court’s “decision certifying the class is subject to a very limited review and will be reversed only upon a strong showing that the district court’s decision was a clear abuse of discretion.” Olden v. LaFarge Corp., 383 F.3d 495, 507 (6th Cir. 2004) (internal quotation marks omitted). Absent an error of law or an abuse of discretion, an appellate tribunal has no warrant to upset the Trial Court’s ruling on class certification.

Califano v. Yamasaki, 442 U.S. 682, 703 (1979) (“[M]ost issues arising under Rule 23...[are] committed in the first instance to the discretion of the district court.”).

While a Trial Court has an obligation to conduct a “rigorous analysis” of the requirements of Rule 23 in determining whether the requirements of that Rule are met, a court should generally accept the substantive allegations of the complaint as true, and cannot consider the merits of the plaintiffs’ claims. Eisen v. Carlisle & Jacquelin, 417 U.S. 156, 177 (1974) (noting that nothing in Rule 23 “gives a court any authority to conduct a preliminary inquiry into the merits of a suit in order to determine whether it may be maintained as a class action”); In re Flash Memory Antitrust Litig., 2010 U.S. Dist. LEXIS 59491, *39 (N.D. Cal. 2010); Blackie v. Barrack, 524 F.2d 891, 901 n.17 (9th Cir. 1975) (“The court is bound to take the substantive allegations of the complaint as true, thus necessarily making the class order speculative in the sense that the plaintiff may be altogether unable to prove his allegations.”).

In this case, the Pike Circuit Court did not commit an error of law or abuse its discretion in certifying a class under CR 23.01 and 23.02(c). The Court carefully considered the arguments, facts, and law advanced by each party, and heard extensive oral argument. The Court considered the evidence presented by Merck with respect to commonality, typicality, and the adequacy of the class representative, and rejected them, relying on controlling precedent to find that the prerequisites of Kentucky Rules of Civil Procedure 23.01 and 23.02(c) were met. The Court of Appeals erred in failing to give deference to the Pike Circuit Court’s ruling on the Rule 23 elements, and this Court should overturn that decision, thereby upholding class certification of Appellant’s fraud

and misrepresentation claims and accepting the generalized use of in effect a fraud on the public or fraud on the market theory in this instance.

B. The Trial Court Properly Found That The Requirements Of Rule 23 Were Satisfied.

The prerequisites necessary for the certification of an action as a class action are set forth in CR 23.01: one or more members of a class may sue or be sued as representative parties on behalf of all only if (a) the class is so numerous that joinder of all members is impracticable, (b) there are questions of law or fact common to the class, (c) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (d) the representative parties will fairly and adequately protect the interests of the class. Thus, the requirements for class certification are numerosity, commonality, typicality, and adequacy of representation by the class representatives and counsel.

Once the prerequisites for class certification are met, the Trial Court may certify the action as a class action as long as one of the requirements of CR 23.02(a), (b), or (c) is satisfied. In the present case, the Trial Court granted certification under CR 23.02(c). Under this subsection, a class action may be maintained if “the court finds that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy.” CR 23.02(c).

On appeal, numerosity and the presence of common questions of law and fact under 23.01(a) and (b) were not disputed. Merck did, however, argue that questions of law do not predominate under CR 23.02(c), that a class action is not the superior method

for adjudication under CR 23.02(c), and that Ratliff is not a typical or adequate representative under CR 23.01 (c) and (d). As previously explained in detail, the Court of Appeals' decision to overturn the Trial Court's certification of the Appellant's fraud and misrepresentation claims turned on its conclusion that with respect to those claims the Trial Court abused its discretion in finding that common questions predominated under CR 23.02 (c) and that a class action was therefore a superior means of adjudicating the claims at issue. The Court did not reach the question of whether Ratliff is an adequate class representative. The focus of the analysis at issue in reviewing the Court of Appeals' opinion should therefore be ascertaining whether the Court of Appeals erred in concluding that the Trial Court committed an abuse of discretion in determining that class issues predominate over individualized issues and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy.

Predominance "tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation," Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 623 (1997). Generally, under CR 23.02(c), a Trial Court must find a sufficient mutuality of interests among the class members to justify the adjudication in a single action. 6 Kurt A. Phillips, Jr., and David V. Kramer, Kentucky Practice: Rules of Civil Procedure Annotated Rule 23.02 (6th ed. 2005). Under this prong, the "commonality" requirement does not require that the common questions be dispositive of the entire action but only that questions common to the class predominate over individual issues. Id.; see also Wiley v. Adkins, 48 S.W.3d 20, 23 (Ky. 2001). The "predominance requirement [of Rule 23] is satisfied unless it is clear that individual issues will overwhelm the common questions and render the class action valueless." Hyland v. Homeservices of Am., 2008

U.S. Dist. LEXIS 90892, *18 (W.D. Ky. Nov. 7, 2008) (internal citations omitted, emphases added).

Moreover, the Sixth Circuit has provided guidance on the types of cases that may be best suited to (b)(3) class adjudication, which is analogous to CR 23.02(c):

In complex, mass, toxic tort accidents, where no one set of operative facts establishes liability, no single proximate cause equally applies to each potential class member and each defendant, and individual issues outnumber common issues, the district court should properly question the appropriateness of a class action for resolving the controversy. However, where the defendant's liability can be determined on a class-wide basis because the cause of the disaster is a single course of conduct which is identical for each of the plaintiffs, a class action may be the best suited vehicle to resolve such a controversy.

Sterling v. Velsicol Chem. Corp., 855 F.2d 1188, 1197 (6th Cir. 1988).

The situation described in the aforementioned quote is similar to the one at issue in this case. Here, Appellant's claims of fraud and misrepresentation require establishment of the following six elements: (1) that the declarant made a material representation to the plaintiff, (2) that this representation was false, (3) that the declarant knew the representation was false or made it recklessly, (4) that the declarant induced the plaintiff to act upon the misrepresentation, (5) that the plaintiff relied upon the misrepresentation, and (6) that the misrepresentation caused injury to the plaintiff.

United Parcel Serv. Co. v. Rickert, 996 S.W.2d 464, (Ky. 1999); Flegles, Inc. v. TruServ Corp., 289 S.W.3d 544 (Ky. 2009). The first three elements of the claims center on the defendant's conduct, which in this matter is indisputably capable of class-wide proof.

The question of whether the issues of causation, reliance and damages create individual questions that defeat class certification is therefore the narrow question now to be considered.

The Amended Order Certifying Class Action found that common questions predominate with respect to the Appellant's fraud and misrepresentation claims because "[a]ll of the potential plaintiffs were prescribed Vioxx by doctors who relied on Merck's assertions that it was safe and effective to treat their individual ailments. All of the potential plaintiffs spent money to purchase Vioxx, and when it was removed from the market all were directed by Merck and the FDA to seek medical consultations relating to their use of the drug." The Pike Circuit Court further found that all potential plaintiffs were seeking relief under common law theories of fraudulent misrepresentation, negligent misrepresentation, and unjust enrichment. The Court concluded: "In such circumstances, where the plaintiffs are similarly situated, and seek recovery under identical theories of law and based on the identical conduct of the defendant, common questions of law and fact predominate, making certification of this action appropriate under CR 23.02." (Amended Order Certifying Class Action, p. 13; R., v. 8, p. 1112).

The conclusions of the Trial Court are supported by the record: 1) Vioxx was a drug that was only available by prescription; 2) Ratliff's doctors both testified that they relied on information provided by Merck sales representatives in evaluating the safety of Vioxx; 3) It was undisputed that individuals who were prescribed the drug had to spend money to obtain it; 4) It was undisputed that when Vioxx was removed from the market users were directed to seek medical consultations relating to their use of the drug. The veracity of the Trial Court's conclusions on these points has never been called into question, and certainly has not been demonstrated to be an abuse of discretion.

The Court of Appeals' Opinion nonetheless found that the Trial Court's decision to certify a class with respect to Appellant's fraud and misrepresentation claims was an

abuse of discretion because the element of reliance that must be established with respect to such claim precludes a finding that common questions predominate. As the Court of Appeals correctly noted, however, “in some cases involving fraud and/or misrepresentation, class action may still be appropriate where common issues predominate over individualized issues and arise from a single fraudulent scheme or conspiracy or from identical misrepresentations.” Opinion, p. 13. The Court went on to note that “[i]ndeed, fraud and misrepresentation claims only tend to be uniformly denied for class certification where there is a ‘material variation in the representations made [to the putative class members] or in the degrees of reliance thereupon.’” Id. (quoting Simon v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 482 F.2d 880, 882 (5th Cir. 1973)).

The Court of Appeals Opinion did not make a specific finding as to why, in this case, questions regarding reliance defeated the predominance requirement. Instead, the Court of Appeals simply rejected what it perceived to be an application of the fraud-on-the-market-theory by the Trial Court and then concluded, without support or discussion of the record, that because questions regarding “causation, reliance and damages” must be shown on an individual basis, “mini-trials” would have to be conducted on these issues thereby defeating the predominance requirement. This holding completely ignores the fact that the Trial Court reviewed and considered extensive briefing on the question as to whether, despite some individualized issues, the requirement of predominance was nonetheless present with respect to the Appellant’s fraud and misrepresentation claims. A close review of the record demonstrates that the conclusions of the Trial Court are amply supported, and that the Court of Appeals was not justified in its finding that the Trial Court abused its discretion on this question.

i. **Merck's Uniform Dissemination Of False Representations To The Class Market Regarding The Safety Of Vioxx Justifies Permitting Generalized Proof Of Reliance And Causation, Thereby Satisfying The Predominance Requirement For Class Certification.**

To establish the elements of reliance and causation with respect to the common-law fraud and misrepresentation claims asserted by the class certified in this action, there must be proof that class members relied on Merck's false and misleading information regarding the drug in making the decision to purchase the product. In the context of prescription drugs, this reliance element is capable of class-wide determination because each patient is required to obtain the drug through a prescription provided by a doctor. And, assuming that the jury finds Merck misrepresented and withheld information concerning the risks associated with Vioxx, it is impossible that the class members could have received complete information from any of their physicians about the drug. Indeed, it is axiomatic that patients operate under the assumption that their physicians prescribe medication based on complete and accurate information. Therefore, while the parties can argue as to whether each individual physician would have changed his or her prescription decision had Merck not misrepresented the risks associated with Vioxx, it is indisputable that every class member – assuming Merck engaged in the wrongdoing alleged in Appellant's Complaint – relied on physicians that were equipped with false and fraudulently distributed information. It is also indisputable that after the true risks associated with Vioxx were revealed, and the product was removed from the market, every physician ceased prescribing the medication,⁵ and no class member was thereafter able to purchase the drug.

⁵

The record is undisputed that when the true risks associated with Vioxx were revealed and the drug was removed from the market, Ratliff's doctors both immediately ceased prescribing the drug

In this circumstance, because every patient in the class must have received a prescription to obtain Vioxx, every patient in the class obtained a service from his or her physician that was based on an incomplete and inaccurate understanding of the risks associated with Vioxx, and therefore every patient purchased and ingested Vioxx in reliance on Merck's fraudulent and/or negligent misrepresentations regarding the safety of the drug. See also West v. Searle & Co., 806 S.W.2d 608, 613 (Ark. 1991) (“[A] physician must prescribe the drug, the patient relies upon the physician’s judgment in selecting the drug, and the patient relies upon the physician’s advice in using the drug.”).

Other jurisdictions also permit a presumption or inference of reliance and causation, where undisclosed fraudulent conduct, concealment, or omissions of material fact are common to the class in the context of common law fraud and or misrepresentation claims. See, e.g., Krell v. Prudential Ins. Co. of Am. (In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions), 148 F.3d 283 (3d Cir. 1998) (affirming trial court’s finding that an insurance company’s national sales scheme presented predominating common issues – the class comprised several million life insurance policyholders in 51 jurisdictions alleging common law fraud, unjust enrichment and other claims, all based on Prudential’s deceptive sales practices); Vasquez v. Superior Court of San Joaquin County, 4 Cal.3d 800 (Cal. 1971); Wilner v. Sunset Life Ins. Co., 78 Cal. App. 4th 952 (Cal. 2000) (applying Vasquez); Grace v. Perception Tech. Corp., 128 F.R.D. 165, 171 (D. Mass. 1989) (certifying common law fraud and negligent misrepresentation claims); In re Neurontin Mktg. & Sales Practices Litig., 2011 U.S.

and that Ratliff’s doctors relied on the misleading information given them by Merck’s sales representatives in making decisions regarding whether and to whom Vioxx should be prescribed. (Gibson Dep., 13:14-24, 37:8-11; R., v. 3, p. 345-355, Pampati Dep., 14:11-15:24, 40:5-9; R., v. 3, p. 359-369).

Dist. LEXIS 61636 at *52 (D. Mass. May 17, 2011) (addressing similar facts and finding that where the defendant's conduct with respect to the dissemination of information is uniform throughout the market, common issues may predominate with respect to the issue of liability); Adams v. Little Missouri Minerals Ass'n, 143 N.W.2d 659, 684-85 (N.D. 1966) (inference of reliance is necessary where material facts are suppressed); Cope v. Metro. Life Ins. Co., 696 N.E.2d 1001 (Ohio 1998) (reversing a trial court's denial of class certification with respect to common law fraud claims, finding that element of reliance could be inferred from uniform misrepresentations or omissions).

The reasoning applied by the Cope court, supra, which specifically refers to language from the Civil Rule advisory notes, is particularly illustrative of this point. In Cope, which was not a securities case, appellant life insurance policy holders filed a complaint that alleged the appellee insurance company improperly used the cash values, dividends, and interest that had accumulated in their policies to finance their purchases of additional life insurance. The trial court denied class certification, finding that individual issues relating to the element of reliance prevented the predominance requirement from being met. The Court of Appeals agreed, and affirmed. However, the Ohio Supreme Court disagreed with the two lower courts, and reversed. The Court noted that "a claim will meet the predominance requirement when there exists generalized evidence which proves or disproves an element on a simultaneous, class-wide basis, since such proof obviates the need to examine each class member's individual position." Id. at 1004 (citing Lockwood Motors, Inc. v. Gen. Motors Corp., 162 F.R.D. 569, 580 (D. Minn. 1995)).

With respect to class-wide proof in common law fraud cases, the court found:

Courts generally find that the existence of common misrepresentations obviates the need to elicit individual testimony as to each element of a fraud or misrepresentation claim, especially where written misrepresentations or omissions are involved. They recognize that when a common fraud is perpetrated on a class of persons, those persons should be able to pursue an avenue of proof that does not focus on questions affecting only individual members. If a fraud was accomplished on a common basis, there is no valid reason why those affected should be foreclosed from proving it on that basis.

Id. (citing Shields v. Lefta, Inc., 888 F. Supp. 891, 893 (N.D. Ill. 1995); Murray v. Sevier, 156 F.R.D. 235, 248-249 (D. Kan. 1994); Davis v. Southern Bell Tel. & Tel. Co., 158 F.R.D. 173, 176-179 (S.D. Fla. 1994); Mayo v. Sears, Roebuck & Co., 148 F.R.D. 576, 583 (1993 S.D. Ohio); Heastie v. Cmty. Bank of Greater Peoria, 125 F.R.D. 669, 678 (N.D. Ill. 1989); Skalbania v. Simmons, 443 N.E.2d 352, 360 (Ind. App. 1982)).

The Court concluded that “class action treatment is appropriate where claims arise from standardized forms or routinized procedures, notwithstanding the need to prove reliance.” Cope, supra, at 1008:

It is not necessary to establish inducement and reliance upon material omissions by direct evidence. When there is nondisclosure of a material fact, courts permit inferences or presumptions of inducement and reliance. Thus, cases involving common omissions across the entire class are generally certified as class actions, notwithstanding the need for each class member to prove these elements.

Id. (citations omitted).

As noted by the Advisory Committee notes to FRCP 23(b), in considering the predominance requirement, “[t]he court is required to find, as a condition of holding that a class action may be maintained under this subdivision, that the questions common to the class predominate over the questions affecting individual members. . . . In this view, a fraud perpetrated on numerous persons by the use of similar misrepresentations may be an appealing situation for a class action, and it may remain so despite the need, if liability is found, for separate determination of the damages suffered by individuals within the class” (emphasis added). Moreover, even without such a presumption, potential individual questions of reliance should not preclude a finding of predominance at this

stage. See, e.g., 1 Newberg § 4.25 at 4-104 (“Challenges based on...reliance have usually been rejected and will not bar predominance satisfaction because [reliance pertains] to the right of a class member to recover in contrast to the underlying common issues of defendant’s liability.”); Amchem Prods. v. Windsor, *supra*, at 625 (noting that “predominance is a test readily met in certain cases alleging consumer or securities fraud or violations of the antitrust laws” (emphasis added)); Simpson v. Prudential Ins. Co. of Am., 1994 Ohio App. LEXIS 3431 (Aug. 8, 1994) (noting that there is no rule excluding claims containing an element of reliance from class certification, and that “[t]he drafters of Civ. R. 23 could easily have expressed such an exclusion had that been their intent”).

Given the foregoing reasoning as to the use of generalized proof of reliance and causation, the application of the “fraud on the market” theory utilized in securities fraud cases is therefore not necessary to affirm the Trial Court’s decision to certify the Appellant’s common law fraud and negligent misrepresentation claims under an abuse of discretion standard. The Court of Appeals was therefore in error when it summarily concluded the certification was an abuse of discretion in the absence of an extension of the fraud on the market theory to this context.

ii. **Application Of The Principles Underlying The Fraud On The Market Theory Is Appropriate In This Context.**

In finding that the predominance requirement of CR 23(b) was met, the Trial Court analogized the factual scenario to that present in In re Texas Int’l Sec. Litig., 114 F.R.D. 33 (W. D. Okla. 1987), a case involving similar class-wide conduct by the defendant. There, the Oklahoma District Court held that the complaint, which alleged that a corporation engaged in a common and continuous course of conduct by issuing a series of reports and statements containing interrelated and cumulative misleading data to

the investing public in order to inflate the price of the corporation's stock, sufficiently presented common issues of law with respect to the issues of materiality and scienter to support certification of the class action, despite the fact that the alleged misrepresentations occurred at different times and were contained in different documents during the class period. Id. at 40.

Here, the Trial Court did not find that the fraud on the market theory was specifically applicable with respect to the class claims at issue in this litigation, but rather concluded that the theory underlying the application of the fraud on the market approach to generalized proof of the element of reliance in securities litigation likewise supported acceptance of generalized proof with respect to the reliance and causation elements under the facts present in this consumer litigation.

The fraud on the market theory, established by the Supreme Court's opinion in Basic Inc. v. Levinson, 485 U.S. 224, 241-245 (1988), is based on the hypothesis that, in an open and developed securities market, the price of a company's stock is determined by the available material information regarding the company and its business. Misleading statements will therefore defraud purchasers of stock even if the purchasers do not directly rely on the misstatements.

In essence, the fraud on the market theory adopted by the Supreme Court in Basic, supra, was a judicially crafted remedy to avoid such injustice. Id. at 242 (noting that the presumption of reliance created by the fraud on the market theory provided a practical resolution to the problem of balancing the substantive requirement of proof of reliance in securities cases against the procedural requisites of Civil Rule 23). Here, as in the securities litigation at issue in Basic, supra, requiring proof of individualized reliance

from each member of the proposed plaintiff class effectively prevents consumers affected by a corporate actor's blatant misrepresentations from proceeding as a class on common law fraud claims. Although courts have admittedly been hesitant to allow such generalized proof of reliance in connection with common law fraud or misrepresentation claims, there is simply no good reason for refusing to adopt the common sense approach already approved by the Supreme Court in the securities context as to Merck's dissemination of false and misleading information concerning Vioxx to the public. Importantly, however, and as set forth, supra, such application is not necessary to uphold the Trial Court's decision to certify the Appellant's fraud and misrepresentation claims under an abuse of discretion standard.

iii. The Learned Intermediary Doctrine Does Not Defeat Class Certification.

In concluding that it is the doctors' thought process that must be examined in order to establish the reliance and causation elements, the Court of Appeals applied a "derivative reliance" argument that did not focus on the reliance of the class members themselves. In so doing, the Court implicitly employed the "learned intermediary" doctrine, which is in fact an affirmative defense to the claims asserted by Appellant. Indeed, in this case the learned intermediary doctrine may have no application – there is evidence that the dissemination of false and misleading into the market by Merck prevented the doctors from becoming "learned intermediaries" capable of making educated decisions regarding whether or not to prescribe the drug, and there was pervasive direct to the consumer advertising as to Vioxx.

A fundamental requirement for the application of the learned intermediary doctrine is full and complete disclosure to the doctors. Larkin v. Pfizer, Inc., 153 S.W.3d

758 (Ky. 2004). See also Pittman v. Upjohn Co., 890 S.W.2d 425, 429 (Tenn. 1994) (“The learned intermediary doctrine does not shield a drug manufacturer from liability for inadequate warnings to the physician.”); McEwen v. Ortho Pharm. Corp., 270 Ore. 375, 528 P.2d 522, 529 (Or. 1974) (holding that if the manufacturer fails to adequately warn the learned intermediary, then it may be liable to the injured patient-consumer). Cf. Proctor v. Davis, 682 N.E.2d 1203, 1213 (Ill. App. Ct. 1997) (manufacturer cannot evade duty to warn physician by hoping doctors will learn of dangers themselves). The Appellant here has specifically alleged that Merck withheld information from the health care industry, which obviously includes doctors and the public. The adequacy of Merck’s representations regarding the safety of Vioxx to the health care industry, and therefore the question of whether the learned intermediary doctrine will apply to shield Merck from liability, is a question that can be determined on the basis of class-wide proof that has not yet been presented or evaluated.

In fact, given the massive direct-to-consumer advertising that took place in connection with the marketing of Vioxx, the fundamental justification for the doctrine – that patients rely solely on their doctors to choose which prescription drugs they take – simply may not exist in this case. “The learned intermediary doctrine arises when a product manufacturer has little or no contact with the ultimate user.” Bean v. Baxter Healthcare Corp., 965 S.W.2d 656 (Tex. Ct. App. 1998). Courts have held that “consumer-directed advertising of pharmaceuticals thus belies each of the theories upon which the learned intermediary doctrine rests.” Perez v. Wyeth Labs., Inc., 734 A.2d 1245 (N.J. 1999). The New Jersey Supreme Court has specifically rejected application of the learned intermediary doctrine in cases of direct-to-consumer advertising. Id. In

Perez, the New Jersey Court observed that “[w]hen mass marketing of prescription drugs seeks to influence a patient’s choice of a drug, the pharmaceutical manufacturer that makes direct claims to consumers for the efficacy of its product should not be unqualifiedly relieved of a duty to provide proper warnings of the dangers or side effects of the product.” Id. at 5 (holding that when a drug manufacturer has advertised its drug directly to consumers, the role of the physician in prescribing drugs does not break the chain of causation for manufacturer’s failure to warn patient of harmful side effects); see also Stephens v. G.D. Searle & Co., 602 F. Supp. 379 (E.D. Mich. 1985) (applying Michigan law); Hill v. Searle Labs., 884 F.2d 1064, 1070-71 (8th Cir. 1989) (holding that manufacturers of contraceptives are required to warn the consumers of their products based, in part, on the fact that they directly advertise the product to consumers); Garside v. Osco Drug, Inc., 764 F. Supp. 208, 211 (D. Mass. 1991) (recognizing the validity of the direct-to-consumer advertising exception to the learned intermediary doctrine), rev’d on other grounds, 976 F.2d 77 (1st Cir. 1992).

iv. **Individualized Questions Concerning Damages Do Not Defeat A Finding Of Predominance.**

Even though the Court of Appeals Opinion did not directly consider the question of whether the Trial Court abused its discretion in determining that individualized questions relating to damages did not prevent a finding of predominance, Appellant respectfully asserts that the finding was justified by the record and the applicable law. Issues surrounding the individualized nature of each class member’s loss or damages do not overwhelm the common questions of law and fact at stake in this case. See, e.g., Hyland, supra, at *18 (“The mere fact that questions peculiar to each individual member of the class action remain after the common questions of the defendant’s liability have

been resolved does not dictate the conclusion that a class action is impermissible.”). In fact, courts have held that “[c]ommon issues may predominate when liability can be determined on a class-wide basis, even [with] individualized damage issues.” In re Scrap Metal Antitrust Litig., 527 F.3d 517, 535 (6th Cir. 2008) (quoting In re Visa Check/MasterMoney Antitrust Litig., 280 F.3d 124 (2nd Cir. 2001), overruled on other grounds).

C. **A Class Action Is The Superior Means Of Adjudicating Appellant’s Claims.**

The Court of Appeals based its finding that a class action is not the superior means to adjudicate the Appellant’s claims on its underlying conclusion that individualized questions relating to reliance and causation would overtake the litigation. Notably, the Court of Appeals did not make any specific finding as to why the Trial Court’s opposite conclusion on this point was an abuse of discretion. Regardless, however, as the underlying premise for the Court of Appeals’ finding was in error, as established, supra, and as a class action is clearly the only means by which the claims at issue will be adjudicated, this Court should reject the Court of Appeals’ conclusion with respect to this element of the class certification decision.

The second requirement that must be satisfied before an action may be certified under Rule 23.02(c) is that this Court find that a class action is superior to other methods for the fair and efficient adjudication of this controversy. Wright & Miller, Federal Practice & Procedure (2d ed.), Civil § 1779; Watson v. Shell Oil Co., 979 F.2d 1014 (5th Cir. 1992), on reh’g, 53 F.3d 663 (5th Cir. 1994). Four factors are listed in the subsection for consideration when certification is sought under subdivision (c): (i) the interest of the class in individually controlling the prosecution or defense of separate actions; (ii) the

extent and nature of any litigation concerning the controversy already commenced by or against members of the class; (iii) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and (iv) the difficulties likely to be encountered in the management of the class action. No single factor is determinative. In the instant action, each factor weighs in favor of class certification.

i. **Where, As Here, The Monetary Value Of Each Appellant's Claim Is Relatively Small, It Is In The Appellants' Best Interests To Pursue Their Claims As A Class.**

The class action's "historic mission of taking care of the smaller guy" has been widely recognized. See Marvin E. Frankel, Amended Rule 23 From a Judge's Point of View, 32 Antitrust L.J. 295, 299 (1966) (quotation omitted). For example, the United States Supreme Court observed that the drafters of the federal class-action rule sought to vindicate "the rights of groups of people who individually would be without effective strength to bring their opponents into court at all." Amchem Prods., supra, at 617. The Court continued:

The policy at the very core of the class action mechanism is to overcome the problem that small recoveries do not provide the incentive for any individual to bring a solo action prosecuting his or her rights. A class action solves this problem by aggregating the relatively paltry potential recoveries into something worth someone's (usually an attorney's) labor.

(Id. at 617 (quotation omitted))

See also Deposit Guar. Nat'l Bank of Jackson, Miss. v. Roper, 445 U.S. 326, 339 (1980) ("Where it is not economically feasible to obtain relief within the traditional framework of a multiplicity of small individual suits for damages, aggrieved persons may be without any effective redress unless they may employ the class-action device."). When one inflicts minor harm across a dispersed population, "the defendant is, as a practical matter,

immune from liability unless a class is certified.” Stephen C. Yeazell, Civil Procedure 966 (5th ed. 2000).

The class action device is therefore specifically designed to facilitate the resolution of claims similar to those asserted here - that is, claims with relatively small monetary value that would not be tried on an individual basis but with respect to which there is an incentive to try in the aggregate. Merck has inflicted a relatively small harm to each individual across a large group of consumers – through false marketing practices it induced consumers to purchase a product with undisclosed and potentially fatal side effects. As a result, these consumers were harmed to the extent that they expended money in purchasing the product and in seeking the physician consultation subsequently recommended by Merck and the FDA. See, e.g., Iliadis v. Wal-Mart Stores, Inc., 922 A.2d 710, 714-731 (N.J. 2007).

In Iliadis, supra, the plaintiffs alleged that Wal-Mart, in an effort to reduce labor costs and increase profits, systematically declined to honor its contractual promises concerning rest and meal breaks. The plaintiffs also maintained that Wal-Mart failed to compensate its employees for all time worked by forcing employees to work through meal breaks, by locking employees in retail stores after they had clocked out, and by coercing employees to work off-the-clock. The plaintiffs sought to certify a class of all current and former hourly employees of Wal-Mart in the State of New Jersey during a nine-year period, a class consisting of approximately 72,000 workers.

In discussing the purpose of the class action device under federal and New Jersey law, the court noted that the class action device “helps to equalize adversaries, a purpose that is even more compelling when the proposed class consists of people with small

claims.” The court pointed out that “[i]n such disputes, where the claims are, in isolation, ‘too small ... to warrant recourse to litigation,’ the class-action device equalizes the claimants’ ability to zealously advocate their positions.” Id. (“In short, the class action’s equalization function opens the courthouse doors for those who cannot enter alone.”).

The court overturned the decision of the Court of Appeals, which had affirmed the Trial Court’s denial of the plaintiffs’ motion to certify a class:

If each victim were remitted to an individual suit, the remedy could be illusory, for the individual loss may be too small to warrant a suit or the victim too disadvantaged to seek relief. Thus the wrongs would go without redress and there would be no deterrence to further aggressions.

(Id. at 720 (citations omitted)).

The class members’ “lack of financial wherewithal” is an “important factor” in the superiority analysis. Saldana v. City of Camden, 599 A.2d 582 (N.J. App.Div. 1991). The United States Court of Appeals for the Fifth Circuit has declared that a claim’s “negative value” is the “most compelling rationale for finding superiority in a class action.” Castano v. Am. Tobacco Co., 84 F.3d 734, 748 (5th Cir. 1998). Because of the very real likelihood that class members will not bring individual actions, class actions are “often the superior form of adjudication when the claims of the individual class members are small.” Weber v. Goodman, 9 F. Supp. 2d 163, 170-71 (E.D.N.Y. 1998).

Here, the potential class plaintiffs are individuals who lack the financial resources of their corporate adversary. The equalizing mechanism of representative litigation allows them to adequately seek redress. This Court cannot ignore the fact that if the Trial Court’s certification of the proposed class is not affirmed, hundreds of thousands of aggrieved consumers will not seek redress for Merck’s alleged wrongdoing. See

Carnegie v. Household Int'l, Inc., 376 F.3d 656, 661 (7th Cir. 2004) (“The realistic alternative to a class action is not ... million[s of] individual suits, but zero individual suits.”), cert. denied, 543 U.S. 1051 (2005). As one court proclaimed, “a negative determination may sound the death knell of the action as one for a class of persons or entities.” In re Sugar Indus. Antitrust Litig., 73 F.R.D. 322, 356 (E.D. Pa. 1976).

This Court should also consider that Merck will benefit from having this litigation concentrated in one forum. Addressing the claims of all Kentucky consumers for economic harm arising from use of Vioxx in one action will protect Merck from being subjected to the expensive ordeal of continually having to demonstrate its purported innocence at trial. Galloway v. Am. Brands, Inc., 81 F.R.D. 580 (E.D. N.C. 1978).

D. The Trial Court Properly Found That Ratliff Is An Adequate Class Representative.

The Court of Appeals likewise did not reach the question of whether Ratliff is an adequate class representative. On appeal, Merck argued that even if the requirements for certification under Rule 23.02(c) were met, the Trial Court nonetheless erred in granting Appellant’s Motion for Certification because Ratliff cannot “adequately” represent absent class members as required by Rule 23.01(c) and (d). Merck claims that Ratliff is an inadequate representative because the evidence is conflicting regarding whether he has consulted a doctor concerning the risks of Vioxx.

Of course, defendants typically contest the adequacy of class representatives, but courts have recognized that these statements should be viewed skeptically and they are often rejected. As the Seventh Circuit succinctly put it in Eggleston v. Chicago Journeyman Plumbers Local Union No. 130, 657 F.2d 890 (7th Cir. 1981), cert. denied, 455 U.S. 1017 (1982):

It is often the defendant, preferring not to be successfully sued by anyone, who supposedly undertakes to assist the court in determining whether a putative class should be certified. When it comes, for instance, to determining whether 'the representative parties will fairly and adequately protect the interest of the class,' or the plaintiffs' ability to finance the litigation, it is a bit like permitting a fox, although with pious countenance, to take charge of the chicken house.

Id. at 895.

Although Ratliff admittedly occasionally had difficulty remembering the precise circumstances surrounding past events, courts in Kentucky have held that such difficulties should not result in a denial of certification. For example, the United States District Court for the Western District of Kentucky held that "the only issue before a court on a motion for class certification is whether plaintiff is asserting a claim which, assuming its merit, will satisfy the requirements of Rule 23...as such, [a] Rule 23 determination is wholly procedural and has nothing to do with whether a plaintiff will ultimately prevail on the substantive merits of its claim." See Hyland, supra, at *10 (W.D. Ky. 2008) (citing Little Caesar Enter. v. Smith, 172 F.R.D. 236, 241 (E.D. Mich. 1997)) (emphasis added). Furthermore, the Court should not conduct an inquiry into the merits of a plaintiff's claims, and should "assume that the substantive allegations of the complaint are true." See Hyland, supra, at 10.

Accordingly, because any alleged inadequacies in Appellant's deposition testimony are ultimately an issue of credibility and the merits of his claims, the Trial Court acted properly in refusing to consider these alleged inadequacies when making its certification decision. All that is required is that (1) Ratliff's claims are common with those of the unnamed members of the class, and that (2) Ratliff will vigorously prosecute his claims through adequate class counsel. See Hyland, supra, at 15. See also Plubell v. Merck, 289 S.W.3d 707, 714 (noting that "credibility issues do not make class

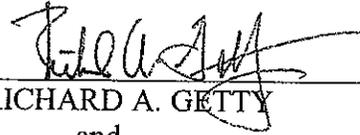
representatives inadequate as long as their interests do not conflict with the interests of the putative class and the class is vigorously prosecuted”). Merck does not dispute that Ratliff has and will vigorously continue to prosecute his claims on behalf of the other class members.

VI. CONCLUSION

The class action device is specifically designed to facilitate the resolution of claims similar to those asserted here – that is, claims with relatively small monetary value that would not be tried on an individual basis but with respect to which there is an incentive to try in the aggregate. Merck has inflicted a relatively small individual harm across a large group of consumers –through false marketing practices it fraudulently or negligently induced consumers to purchase a product with undisclosed and potentially fatal side effects. As a result, these consumers were harmed to the extent that they expended money in purchasing the product and in seeking the physician consultation subsequently recommended by Merck and the FDA.

A class action is the only way in which the proposed class Appellant can obtain redress, and the decision of the Pike Circuit Court to certify the class at issue, as embodied in the Amended Order Certifying Class, was not an abuse of discretion. The Trial Court, which is in the best position to judge the nature and validity of the evidence and arguments on the class certification issue, entered an Order that sets forth a valid analysis of the CR 23.01 and 23.02(c) requirements. The Trial Court’s decision was not an abuse of discretion and does not contain reversible errors of law, and the Court of Appeals holding to the contrary with respect to the Appellant’s fraud and misrepresentation claims was in error.

Respectfully submitted,



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