

COMMONWEALTH OF KENTUCKY
SUPREME COURT OF KENTUCKY
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

APPELLANT

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

MERCK & COMPANY, INC.
n/k/a MERCK SHARP & DOHME CORP.

APPELLEE

BRIEF OF APPELLEE
MERCK SHARP & DOHME CORP.

This shall certify this brief was served by depositing true copies in the United States Mail, first class, postage prepaid, addressed to each of the following: Richard A. Getty and Jessica Case, Getty & Childers, PLLC, 250 West Main Street, Suite 1900, Lexington, KY 40507; Hon. Sam Givens, Clerk of the Kentucky Court of Appeals, 360 Democrat Drive, Frankfort, KY 40601; Hon. Steven Combs, Pike Circuit Court Judge, 423 Hall of Justice, 172 Division Street, Pikeville, KY 41501; W. David Deskins, Clerk of the Pike Circuit Court, Pike County Hall of Justice, P.O. Box 1002, Pikeville, KY 41502-1002 on this the 18th day of March, 2013.

Respectfully submitted,

SUSAN J. POPE
FROST BROWN TODD LLC
250 W. Main Street, Suite 2800
Lexington, KY 40507-1749
(859) 231-0000
Counsel for Appellee

JOHN H. BEISNER
JESSICA DAVIDSON MILLER
SKADDEN, ARPS, SLATE, MEAGHER
& FLOM LLP
1440 New York Avenue, NW
Washington, DC 20005
(202) 371-7000
Of Counsel for Appellee
Pro Hac Vice

By:

STATEMENT CONCERNING ORAL ARGUMENT

Appellee Merck & Co., Inc., now known as Merck Sharp & Dohme Corp.

("Merck"), does not oppose Plaintiff-Appellant James Ratliff ("appellant")'s request for oral argument.

COUNTERSTATEMENT OF POINTS AND AUTHORITIES

	Page
STATEMENT CONCERNING ORAL ARGUMENT	i
COUNTERSTATEMENT OF POINTS & AUTHORITIES	ii
COUNTERSTATEMENT OF THE CASE	1
A. Nature Of The Vioxx Litigation And Appellant’s Claims	1
<i>In re Vioxx Prods. Liab. Litig. (Dier v. Merck & Co.),</i> 388 F. App’x 391 (5th Cir. 2010)	2, 3
<i>Plunkett v. Merck & Co.</i> , 401 F. Supp. 2d 565 (E.D. La. 2005).....	2
<i>In re Vioxx Prods. Liab. Litig.</i> , 360 F. Supp. 2d 1352 (J.P.M.L. 2005)	2
<i>Polley v. Allen</i> , 132 S.W.3d 223 (Ky. App. 2004).....	3
<i>Gent v. Cuna Mut. Ins. Soc’y</i> , 611 F.3d 79 (1st Cir. 2010)	3
<i>Hardin v. Reliance Trust Co.</i> , No. 1:04 CV 2079, 2006 U.S. Dist. LEXIS 70818 (N.D. Ohio Sept. 29, 2006).....	3
<i>In re Vioxx Prods. Liab. Litig.</i> , 574 F. Supp. 2d 606 (E.D. La. 2008).....	3
<i>In re Vioxx Prods. Liab. Litig.</i> , 869 F. Supp. 2d 719 (E.D. La. 2012).....	3
<i>In re Vioxx Prods. Liab. Litig.</i> , MDL No. 1657, 2010 U.S. Dist. LEXIS 142767 (E.D. La. Mar. 31, 2010)	3-4
<i>Plubell v. Merck & Co.</i> , 289 S.W.3d 707 (Mo. Ct. App. 2009).	8
California Consumer Legal Remedies Act, Cal. Civ. Code §§ 1750 et seq.	8
Unfair Competition Law, Cal. Bus. & Profs. Code §§ 17200 et seq.	8
<i>In re Vioxx Class Cases</i> , 180 Cal. App. 4th 116 (Cal. App. 2d Dist. 2009).....	8
<i>Kleinman v. Merck & Co., Inc.</i> , 8 A.3d 851 (N.J. Super. Law Div. 2009).....	8
B. Course Of the Proceedings Leading To Appeal	8
28 U.S.C. §§ 1332(a), 1441(b).....	9

<i>Ratliff v. Merck & Co., Inc.</i> , 359 F. Supp. 2d 571 (E.D. Ky. 2005)	9
CR 23	10
<i>In re Hydrogen Peroxide Antitrust Litig.</i> , 552 F.3d 305(3d Cir. 2008)	10
<i>Ex parte Mayflower Nat'l Life Ins. Co.</i> , 771 So. 2d 459 (Ala. 2000).....	10
<i>Dorsey v. Bale</i> , 521 S.W.2d 76 (Ky. App. 1975)	10-11
CR 23.01	11
CR 76.36	11
<i>Garrard County Board of Education v. Jackson</i> , 12 S.W.3d 686 (Ky. 2000).....	11
CR 23.06	12
C. The Court Of Appeals' Reversal	15
<i>Plubell v. Merck & Co</i> , 289 S.W.3d 707 (Mo. Ct. App. 2009).	16-18
<i>Kleinman v. Merck & Co., Inc.</i> , 8 A.3d 851 (N.J. Super. Law Div. 2009).....	16-18
New Jersey Consumer Fraud Act, N.J. Stat. Ann. §§ 56:8-1 et seq.	16
<i>Catron v. Citizens Union Bank</i> , 229 S.W.3d 54 (Ky. App. 2006).....	17
<i>Grange Mut. Ins. Co. v. Trude</i> , 151 S.W.3d 803 (Ky. 2004)	17
<i>Ratliff v. Merck & Co., Inc.</i> , No. 04-CI-01493 (Pike Cir. Ct. Jan. 17, 2013).....	18
ARGUMENT	18
CR 23.01	18-19
CR 23.02	18
<i>Gevedon v. Purdue Pharma</i> , 212 F.R.D. 333 (E.D. Ky. 2002)	18
<i>Wal-Mart Stores, Inc. v. Dukes</i> , 131 S. Ct. 2541 (2011)	19, 20
<i>Blades v. Monsanto Co.</i> , 400 F.3d 562 (8th Cir. 2005).....	19
<i>In re Hydrogen Peroxide Antitrust Litig.</i> , 552 F.3d 305 (3d Cir. 2008).....	19

<i>In re Flash Memory Antitrust Litig.</i> , No. C 07-0086 SBA, 2010 U.S. Dist. LEXIS 59491 (N.D. Cal. June 9, 2010).....	19
<i>In re New Motor Vehicles Canadian Export Antitrust Litig.</i> , 522 F.3d 6 (1st Cir. 2008).....	19
<i>Eisen v. Carlisle & Jacquelin</i> , 417 U.S. 156 (1974).....	20
<i>Sowers v. Atkins</i> , 646 S.W.2d 344 (Ky. 1983).....	20
<i>Commonwealth v. English</i> , 993 S.W.2d 941 (Ky. 1999).....	20
<i>CertainTeed Corp. v. Dexter</i> , 330 S.W.3d 64 (Ky. 2010).....	20
<i>Vega v. T-Mobile USA</i> , 564 F.3d 1256 (11th Cir. 2009).....	20
<i>Steering Comm. v. Exxon Mobil Corp.</i> , 461 F.3d 598 (5th Cir. 2006).....	20
<i>Commonwealth, Energy & Env't Cabinet v. Shepherd</i> , 366 S.W.3d 1 (Ky. 2012).....	21
<i>O'Neil v. Appel</i> , 165 F.R.D. 479 (W.D. Mich. 1996).....	21
<i>Cammer v. Bloom</i> , 711 F. Supp. 1264 (D.N.J. 1989).....	21
I. THE COURT OF APPEALS PROPERLY HELD THAT INDIVIDUALIZED ISSUES PRECLUDE CLASS TREATMENT OF ANY OF APPELLANT'S CLAIMS.	22
<i>In re Hydrogen Peroxide Antitrust Litig.</i> , 552 F.3d 305 (3d Cir. 2008).....	22
<i>Adams v. Fed. Materials Co.</i> , No. 5:05-CV-90-R, 2006 WL 3772065 (W.D. Ky. Dec. 19, 2006).....	22, 23
<i>Luna v. Del Monte Fresh Produce (Southeast), Inc.</i> , 354 F. App'x 422 (11th Cir. 2009).....	22
<i>Sandwich Chef of Tex., Inc. v. Reliance Nat'l Indem. Ins. Co.</i> , 319 F.3d 205 (5th Cir. 2003)	22
<i>Zinser v. Accufix Research Inst., Inc.</i> , 253 F.3d 1180 (9th Cir. 2001)	23
KRS 367.220(1).....	23
<i>Rivermont Inn, Inc. v. Bass Hotels Resorts, Inc.</i> , 113 S.W.3d 636 (Ky. App. 2003).....	23

<i>Ann Taylor, Inc. v. Heritage Ins. Servs.</i> , 259 S.W.3d 494 (Ky. App. 2008).....	23
A. The Court of Appeals Properly Held That The Causation/Reliance Inquiry Will Turn On Individualized Proof.	24
<i>Kleinman v. Merck & Co., Inc.</i> , 8 A.3d 851 (N.J. Super. Law Div. 2009).....	25, 27-29
N.J. Stat. Ann. § 56:8-19.....	25
<i>Harman v. Sullivan Univ. Sys., Inc.</i> , No. 03-738-C, 2005 U.S. Dist. LEXIS 10904 (W.D. Ky. June 6, 2005).....	26
<i>Sanford Constr. Co. v. S&H Contractors, Inc.</i> , 443 S.W.2d 227 (Ky. 1969).....	26
KRS 367.220(1).....	26
<i>Stahl v. St. Elizabeth Med. Ctr.</i> , 948 S.W.2d 419 (Ky. App. 1997)	26
<i>In re Vioxx Class Cases</i> , 180 Cal. App. 4th 116 (Cal. App. 2d Dist. 2009).....	26, 29-31
<i>In re Vioxx Prods. Liab. Litig.</i> , MDL No. 1657, 2010 U.S. Dist. LEXIS 142767 (E.D. La. Mar. 31, 2010)	26
<i>In re St. Jude Med., Inc.</i> , 522 F.3d 836 (8th Cir. 2008).....	27
<i>In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Relevant Prods. Liab. Litig.</i> , 275 F.R.D. 270 (S.D. Ill. 2011).....	27
<i>Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP</i> , No. 08-CV-0179 (SLT) (RER), 2011 U.S. Dist. LEXIS 26857 (E.D.N.Y. Feb. 16, 2011).....	27
<i>In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig.</i> , 257 F.R.D. 315 (D. Mass. 2009).....	27
<i>In re Prempro Prods. Liab. Litig.</i> , 230 F.R.D. 555 (E.D. Ark. 2005)	27
<i>In re Paxil Litig.</i> , 212 F.R.D. 539 (C.D. Cal. 2003)	28
<i>In re Rezulin Prods. Liab. Litig.</i> , 210 F.R.D. 61 (S.D.N.Y. 2002).....	28
<i>Santullo v. Pfizer, Inc.</i> , No. D-0101-CV-200301377, 2005 WL 4255513 (N.M. Dist. Ct. Dec. 9, 2005).....	28

<i>Plubell v. Merck</i> , 289 S.W.3d 707 (Mo. Ct. App. 2009)	28
<i>Wiley v. Adkins</i> , 48 S.W.3d 20 (Ky. 2001)	29
<i>Wiley v. Adkins</i> , No. 1999-SC-0985-D, 2000 WL 34332836 (Ky. filed Sept. 28, 2000).....	29
<i>Cope v. Metropolitan Life Ins. Co.</i> , 696 N.E.2d 1001 (Ohio 1998)	29, 30
<i>Vasquez v. Superior Court</i> , 4 Cal.3d. 800 (1971).....	29, 30
B. The Court Of Appeals Also Properly Declined To Accept Appellant’s Fraud-On-The-Market Theory	31
<i>In re Texas Int’l Secs. Litig.</i> , 114 F.R.D. 33 (W.D. Okla. 1987)	32
<i>Basic Inc. v. Levinson</i> , 485 U.S. 224 (1988).....	32, 33, 34, 35
<i>Heindel v. Pfizer, Inc.</i> , 381 F. Supp. 2d 364 (D.N.J. 2004).....	33, 34, 35
<i>In re Schering-Plough Corp. Intron/Temodar Consumer Class Action</i> , No. 2:06-cv-5774, 2009 WL 2043604 (D.N.J. July 10, 2009)	33, 34
<i>Prohias v. Pfizer, Inc.</i> , 485 F. Supp. 2d 1329 (S.D. Fla. 2007)	33, 34
C. The Court Of Appeals’ Ruling Correctly Focused On Physicians’ Decisions To Prescribe Vioxx	35
<i>Larkin v. Pfizer, Inc.</i> , 153 S.W.3d 758 (Ky. 2004).....	36, 37
<i>Restatement (Third) of Torts: Prods. Liab.</i> § 6(d) (1998)	36
<i>Perez v. Wyeth Labs, Inc.</i> , 734 A.2d 1245 (1999)	37
<i>Beale v. Biomet, Inc.</i> , 492 F. Supp. 2d 1360 (S.D. Fla. 2007).....	37
<i>Colacicco v. Apotex, Inc.</i> , 432 F. Supp. 2d 514 (E.D. Pa. 2006).....	37
<i>Hill v. Searle Labs., Div. of Searle Pharms., Inc.</i> , 884 F.2d 1064 (8th Cir. Ark. 1989)....	38
<i>West v. Searle & Co.</i> , 806 S.W.2d 608 (Ark. 1991)	38
<i>Stephens v. G.D. Searle & Co.</i> , 602 F. Supp. 379 (E.D. Mich. 1985).....	38
<i>Garside v. Osco Drug, Inc.</i> , 764 F. Supp. 208 (D. Mass. 1991).....	38

D. The Court Of Appeals Correctly Concluded That A Class Action Is Not The Superior Method Of Resolving Appellant's Claims.....	38
CR 23.02(c).....	38-39
<i>Zinser v. Accufix Research Inst., Inc.</i> , 253 F.3d 1180 (9th Cir. 2001)	39
<i>In re Light Cigarettes Mktg. Sales Practices Litig.</i> , 271 F.R.D. 402 (D. Me. 2010)	40
<i>Picus v. Wal-Mart Stores, Inc.</i> , 256 F.R.D. 651 (D. Nev. 2009)	40
<i>Iliadis v. Wal-Mart Stores, Inc.</i> , 922 A.2d 710 (N.J. 2007).....	40, 41
KRS 367.220(3)	40
<i>Cohn v. Mass. Mut. Life Ins. Co.</i> , 189 F.R.D. 209 (D. Conn. 1999)	40
<i>Kleinman v. Merck & Co., Inc.</i> , 8 A.3d 851 (N.J. Super. Law Div. 2009).....	41, 42
II. REVERSAL OF THE CIRCUIT COURT'S CLASS CERTIFICATION DECISION SHOULD ALSO BE AFFIRMED ON THE ALTERNATIVE GROUND THAT APPELLANT IS NOT AN ADEQUATE CLASS REPRESENTATIVE.....	42
<i>Minix v. Roberts</i> , 350 S.W.3d 449 (Ky. 2011)	42
<i>J.A.S. v. Bushelman</i> , 342 S.W.3d 850 (Ky. 2011)	42
<i>Trico Cnty Dev. & Pipeline v. Smith</i> , 289 S.W.3d 538 (Ky. 2008).....	42
<i>Greene v. McFarland</i> , 43 S.W.3d 258 (Ky. 2001)	42
<i>Broussard v. Meineke Disc. Muffler Shops, Inc.</i> , 155 F.3d 331 (4th Cir. 1998)	43
<i>Beck v. Maximus, Inc.</i> , 457 F.3d 291 (3d Cir. 2006)	43
<i>Phillips Petroleum Co. v. Shutts</i> , 472 U.S. 797 (1985)	43
<i>Solo v. Bausch & Lomb Inc.</i> , Nos. 2:06-MN-77777-DCN, 2:06-CV-02716-DCN, 2009 U.S. Dist. LEXIS 115029, (D.S.C. Sept. 25, 2009).....	44
<i>Wesley v. Cavalry Invs., LLC</i> , No. 05-3523, 2006 U.S. Dist. LEXIS 69561 (E.D. Pa. Sept. 27, 2006)	44

<i>Randall v. Rolls-Royce Corp.</i> , 637 F.3d 818 (7th Cir. 2011)	44-45
<i>Wal-Mart Stores, Inc. v. Dukes</i> , 131 S. Ct. 2541 (2011)	45
CONCLUSION	45

APPENDIX

Appendix A - <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafety/InformationforPatientsandProviders/ucm106201.pdf> (visited Mar. 7, 2013)

Appendix B - Order, AM-11-09T3 (N.J. Super. App. Div. Oct. 2, 2009) in *Kleinman v. Merck & Co.*, 8 A.3d 851 (N.J. Super. Law Div. 2009), *motion for leave to appeal denied*

Appendix C - Order, No. M-504 (N.J. Jan. 14, 2010) in *Kleinman v. Merck & Co.*, 8 A.3d 851 (N.J. Super. Law Div. 2009), *motion for leave to appeal denied*

COUNTERSTATEMENT OF THE CASE

A. Nature Of The Vioxx Litigation And Appellant's Claims

This case concerns Vioxx (also known as Rofecoxib), a non-steroidal anti-inflammatory drug ("NSAID") developed by Merck and approved by the U.S. Food and Drug Administration ("FDA") in 1999 for the treatment of osteoarthritis pain and other indications. (R. v. 1 at 2, Am. Compl. ¶ 1.) Like other NSAIDs, Vioxx was designed to reduce pain and inflammation by suppressing the expression of the cyclooxygenase, or "COX" enzyme. But unlike traditional NSAIDs, which indiscriminately suppress both forms of the COX enzyme, Vioxx was designed as a "COX-2 selective NSAID[]"; i.e., it suppressed only the COX-2 form – the one associated with pain and inflammation. (R. v. 1 at 3, Am. Compl. ¶ 8.) By sparing the COX-1 enzyme – which mediates the protective lining of the stomach – Vioxx posed a "lower risk of gastrointestinal ulcers and bleeding than other NSAIDs (such as ibuprofen and naproxen)," and Vioxx "is the only NSAID demonstrated to have a lower rate of these side effects." (*Id.*)

Vioxx proved extremely popular. In five years on the market, it was "prescribed to and used by an estimated 84 million patients worldwide." (R. v. 1 at 7, Am. Compl. ¶ 20.) This was so despite publicized concerns that Vioxx might pose a risk of heart attacks. (*See* R. v. 1 at 4, 6, Am. Compl. ¶¶ 11, 18.) As the record in this case demonstrates, even physicians who accepted the possibility of a heart-attack risk while Vioxx was on the market nevertheless found the drug's risk-benefit profile to be favorable for some of their patients in light of the reduced gastrointestinal risks it posed. (*See* R. v. 3 at 376, Dep. of Jayalakshmi Pampati ("Pampati Dep.") 49:5-11.) Nonetheless, on September 30, 2004, Merck voluntarily withdrew Vioxx from the market after it received interim results from a placebo-controlled clinical trial showing that

Vioxx was associated with a risk of heart attacks relative to placebo after 18 months of use. (*See* R. v. 1 at 3, Am. Compl. ¶ 9-10.)

Substantial litigation ensued. (Court of Appeals Opinion Reversing and Remanding (“Op.”) at 2.) The majority of the cases involved claims that Vioxx had caused a heart attack or other personal injury. In 2005, a federal multidistrict proceeding (“the MDL”) was established in federal district court in Louisiana, ultimately comprising thousands of individually filed claims, and additional claims were filed in state courts in a number of jurisdictions. *See generally In re Vioxx Prods. Liab. Litig. (Dier v. Merck & Co.)*, 388 F. App’x 391 (5th Cir. 2010); *Plunkett v. Merck & Co.*, 401 F. Supp. 2d 565, 570-72 (E.D. La. 2005); *In re Vioxx Prods. Liab. Litig.*, 360 F. Supp. 2d 1352, 1354-55 (J.P.M.L. 2005). As the litigation progressed, the FDA continued to analyze the relevant data, and it concluded in a 2005 memorandum that: (1) short-term use of any NSAID, including Vioxx, does not appear to increase cardiovascular (“CV”) risk, with the exception of Bextra, another COX-2 inhibitor, in patients undergoing coronary artery bypass surgery; (2) all NSAIDs, including COX-2 inhibitors like Vioxx as well as traditional NSAIDs (with the possible exception of Naproxen), are associated with similar long-term cardiovascular risk; (3) Vioxx is the only NSAID with a proven reduced risk of gastrointestinal complications when compared to a non-selective NSAID; and (4) there is no evidence to support, and “serious questions about,” the ““COX-2 hypothesis,” which suggests that COX-2 selectivity contributes to increased CV risk.” *See* April 6, 2005 Decision Memorandum at 8, available at <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/>

ucm106201.pdf (visited Mar. 7, 2013) (attached as Appendix A).¹ The 2005 memorandum remains the current position of the FDA.

In 2007, after significant discovery and 13 personal-injury trials in multiple jurisdictions that resulted in verdicts for both sides, Merck and a negotiating committee of plaintiffs' attorneys announced an agreement to settle much of the personal-injury litigation. See *In re Vioxx Prods. Liab. Litig.*, 574 F. Supp. 2d 606, 608-09 (E.D. La. 2008); *Dier*, 388 F. App'x at 393-94. The agreement created a resolution program and a \$4.85 billion fund that settled personal-injury cases in which plaintiffs claimed that Vioxx caused a heart attack, ischemic stroke, or sudden cardiac death, and it ultimately resolved nearly 50,000 pending claims. *In re Vioxx*, 574 F. Supp. 2d at 608-09; see also *In re Vioxx Prods. Liab. Litig.*, 869 F. Supp. 2d 719, 722 (E.D. La. 2012).²

¹ Kentucky courts may properly take judicial notice of public records "and government documents, including" those "available from reliable sources on the internet." *Polley v. Allen*, 132 S.W.3d 223, 226 (Ky. App. 2004). As a general matter, the FDA website qualifies as a reliable source of information on the internet, and courts routinely "take judicial notice of . . . facts provided on [government] website[s], which are 'not subject to reasonable dispute.'" *Gent v. Cuna Mut. Ins. Soc'y*, 611 F.3d 79, 84 n.5 (1st Cir. 2010) (taking judicial notice of facts taken from website of the Center for Disease Control and Prevention) (internal quotation marks and citation omitted); accord, e.g., *Hardin v. Reliance Trust Co.*, No. 1:04 CV 2079, 2006 U.S. Dist. LEXIS 70818, at *12 (N.D. Ohio Sept. 29, 2006) ("the court may take judicial notice of information at a government agency website") (citation omitted). Merck respectfully requests such notice of the FDA memorandum.

² Appellant also refers to settlements with federal and state governments concerning the promotion of Vioxx, one of which resulted in the payment of a criminal fine, the other of which involved payments in connection with civil claims concerning Medicaid payments for Vioxx. (Appellant's Br. at 7-8.) The former of these settlements involved claims that had nothing to do with the allegations raised in this case – namely, the promotion of Vioxx for rheumatoid arthritis before it was approved for that indication by the FDA in 2002 – a fact that appellant omits from his brief. (See Appellant's Br. Ex. A, at 2.) The latter resolved civil Medicaid claims that included allegations that Merck withheld CV risk information and that were settled with several states, but only after Merck won the first and only trial seeking reimbursement for Medicaid Vioxx expenditures on the merits in a case brought by the State of Louisiana. See generally Findings Of Fact & Conclusions Of Law, ECF Dkt. No. 45,739, *In re Vioxx Prods. Liab. Litig.*, MDL No. 1657, 2:05-md-1657 (E.D. La. June 29, 2010). (Although Merck does not think judicial notice is required for judicial opinions, the appellant argues that decisions of other courts are matters of public record and thus subject to judicial notice. (Appellant's Br. at 7.) If such notice is required, Merck requests such notice of the Louisiana ruling.) Notably, the Louisiana case went to trial only *after* Merck won summary judgment on one of the State's causation theories – specifically, that Merck had misled physicians, resulting in more Vioxx prescriptions. As the court explained, "[e]ach decision by each doctor and each patient was different. The effect that any alleged misrepresentations had on each decision is unique." *In re* (cont'd)

Appellant's claim is different in character from those at issue in the personal-injury cases. He took Vioxx, but he does not contend that he sustained a physical injury, or even that he failed to receive the drug's promised benefits. (*See R. v. 3* at 308, 328, Dep. of James Ratliff ("Ratliff Dep.") 38:17-21, 94:5-11, Mar. 10, 2009 (all portions of depositions or affidavits cited herein were filed as exhibits to Merck's Opposition to Motion for Class Certification, found at *R. v. 2* at 233 to *R. v. 6* at 800).) Instead, he contends that Merck "deceived [him] and the members of the proposed class in violation of the Consumer Protection Act by promoting and/or allowing the sales of Vioxx with the use of unfair, false, misleading or deceptive acts or practices." (*R. v. 1* at 9, Am. Compl. ¶ 30.) Specifically, appellant claims that even though "Merck knew of the potentially harmful side effects of Vioxx since at least 1999," it "undertook to downplay, conceal, obfuscate and mislead physicians and others, including consumers, as to the harmful side effects of the drug, while vigorously promoting the drug's use." (*R. v. 1* at 5, Am. Compl. ¶ 15.) He further claims that as a proximate result of such conduct, he and other Kentucky residents: "(a) purchased and used Vioxx when [they] would not have otherwise done so; (b) suffered economic losses consisting of the cost of purchasing the drug[]; (c) suffered and/or will suffer additional economic losses in complying with the recommended medical consultation and any follow-up procedures [they have] undergone or will undergo; and (d) suffered and will suffer additional economic losses incidental to

(cont'd from previous page)

Vioxx Prods. Liab. Litig., MDL No. 1657, 2010 U.S. Dist. LEXIS 142767, at *23-24 (E.D. La. Mar. 31, 2010). It thus concluded that this theory of relief failed as a matter of law because "[i]t is simply impossible, or close to it, to determine the individual thought process of each of the thousands of doctors and patients involved." *Id.* at *24.

the medical consultation[s] and any related procedures, including lost income and related expenses.” (R. v. 1 at 10, Am. Compl. ¶ 33.)

Based on these allegations, appellant asserts claims for violations of the Kentucky Consumer Protection Act (“KCPA”) (Count I; R. v. 1 at 9-10, Am. Compl. ¶¶ 28-33); fraudulent concealment and/or misrepresentation (Count II; R. v. 1 at 10-11, Am. Compl. ¶¶ 34-38); negligent and/or grossly negligent misrepresentation (Count III; R. v. 1 at 11-12, Am. Compl. ¶¶ 39-44); and unjust enrichment (Count IV; R. v. 1 at 12, Am. Compl. ¶¶ 45-47). Appellant seeks reimbursement for the cost of Vioxx and for a medical examination he supposedly underwent to determine whether Vioxx caused him any long-term CV injury. (*See* R. v. 3 at 315, Ratliff Dep. 52:11-23.)

Discovery has revealed that proof of appellant’s claims – either on his behalf or on behalf of absent class members – would be anything but a “common” endeavor. For starters, appellant does not remember any details of the examination for which he claims reimbursement, including the physician’s name, when the examination occurred, what tests were performed, or even where the examination took place; nor does he have any documentation regarding the examination, such as a receipt. (*See* R. v. 3 at 303, 315-316, Ratliff Dep. 30:2-21, 52:11-53:24.) Indeed, he did not even know he was seeking recovery for such an alleged visit until after a break in his deposition. (*Id.*) All appellant now purports to remember about the visit is that he paid cash (*id.*), and his medical records do not contain any record of – or reference to – this alleged examination.

Discovery has also revealed that proof of causation, reliance and loss would likewise entail complicated and individualized inquiries. Two different physicians prescribed Vioxx to appellant: Drs. K. D. Gibson and Jayalakshmi Pampati. Dr. Gibson

prescribed Celebrex and Vioxx to Mr. Ratliff both for pain relief and for anti-inflammatory purposes. (See R. v. 3 at 347, Dep. of K.D. Gibson (“Gibson Dep.”) 21:17-21, Mar. 10, 2009.) Dr. Gibson testified that determining whether a particular NSAID like Vioxx would work for an individual patient such as appellant was a “trial and error” process, and that “[i]t’s all on an individual basis.” (R. v. 3 at 348-349, Gibson Dep. 22:18-23:1.) Dr. Gibson was aware of the potential CV risks of Vioxx while it was on the market, and if Vioxx were on the market today, he would still prescribe it to some patients. (R. v. 3 at 355-356, Gibson Dep. 37:21-38:1.)

Dr. Pampati has treated appellant since 1995 for, among other things, rheumatoid arthritis. (See R. v. 3 at 361, Pampati Dep. 19:3-14.) Dr. Pampati became aware of the potential CV risks of Vioxx “sometime in the early 2000s,” and this knowledge affected her prescribing decisions for the drug depending on the individual patient’s circumstances. (R. v. 3 at 377-378, Pampati Dep. 50:17-51:8.) Dr. Pampati testified that she still believes COX-2 drugs like Vioxx are safer than traditional NSAIDs for certain patients, and she still prescribes the COX-2 drugs Celebrex and Meloxicam. (See R. v. 3 at 376, Pampati Dep. 49:5-11.) Dr. Pampati would also prescribe Vioxx “to a select group of patients” if the drug were still on the market. (R. v. 3 at 379-380, Pampati Dep. 52:20-53:1.)

Appellant’s own testimony further illustrates the complex and individualized nature of the causation inquiry. When appellant stopped taking Vioxx, he began taking another prescription NSAID – Daypro – *which includes a strong warning about its cardiovascular risks*. (See R. v. 3 at 312, Ratliff Dep. 42:10-14.) At his deposition, appellant admitted that he had never read the Daypro warning label (R. v. 3 at 331,

Ratliff Dep. 128:5-8), calling into question any claim that he would not have taken Vioxx if the warning had been stronger. Appellant has also taken prescription narcotics and other pain relievers such as Oxycontin with no apparent concern about their well-publicized risks. (R. v. 3 at 310-312, Ratliff Dep. 40:19-42:8.)

The record also showed that appellant had no common proof of loss. Merck's expert economist, Dr. Thomas Barocci, explained that when one considers all of the individualized factors relevant to the loss inquiry, there are more than 100,000 different potential profile groups of putative class members that the jury would have to analyze in order to decide whether each member of the class actually suffered an economic loss. (R. v. 3 at 408, Aff. of Thomas A. Barocci, Ph.D. ("Barocci Aff.") ¶ 16, May 20, 2009.) For example, Dr. Barocci and another expert, Dr. Richard deShazo, Professor and Chairman of the Department of Medicine and Professor of Pediatrics at the University of Mississippi Medical Center in Jackson, Mississippi, explained that because traditional NSAIDs are associated with gastrointestinal irritation (*see* R. v. 3 at 396, Aff. of Richard D. deShazo, MD ("deShazo Aff.") ¶ 25, May 14, 2009), putative class members susceptible to gastrointestinal problems might have needed to "take two alternative drugs (e.g., a traditional NSAID in combination with proton-pump inhibitor) to obtain treatment therapeutically equivalent to Vioxx" (R. v. 3 at 406, Barocci Aff. ¶ 13(b); *see also* R. v. 3 at 395, deShazo Aff. ¶ 26), at greater expense (R. v. 3 at 406, Barocci Aff. ¶ 13(b)). Dr. Barocci also explained that many putative class members (like appellant) have insurance policies that cover Vioxx at the same rate as other COX-2 inhibitors and traditional prescription-strength NSAIDs; thus, their co-pays would have remained the same regardless of the alternative therapy used. (*See* R. v. 3 at 406, Barocci Aff. ¶ 13(a).)

Vioxx consumer claims like appellant's have received mixed treatment in other jurisdictions. Although certification was approved in *Plubell v. Merck & Co.*, 289 S.W.3d 707 (Mo. Ct. App. 2009), as appellant stresses in his brief (*see, e.g.*, Appellant's Br. at 8-9, 19-20), the two other jurisdictions that have addressed such claims have rejected class treatment. The California Court of Appeal rejected class treatment of Vioxx consumer-protection claims asserted under the California Consumer Legal Remedies Act, Cal. Civ. Code §§ 1750 et seq., and Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200 et seq., citing facts, like those in the record here, demonstrating that different patients have different needs, making any classwide assessment of causation, reliance and loss impossible. *See In re Vioxx Class Cases*, 180 Cal. App. 4th 116, 127-34 (2009), *petition for review & depublication denied*, No. S179699, 2010 Cal. LEXIS 3194, at *1 (Cal. Mar. 30, 2010). And the trial court overseeing the coordinated Vioxx proceedings in New Jersey state court reached a similar conclusion in *Kleinman v. Merck & Co.*, 8 A.3d 851, 862-63 (N.J. Super. Law Div. 2009), *motion for leave to appeal denied*, Order, AM-11-09T3 (N.J. Super. App. Div. Oct. 2, 2009) (attached as Appendix B), *motion for leave to appeal denied*, Order, No. M-504 (N.J. Jan. 14, 2010) (attached as Appendix C).³

B. Course Of The Proceedings Leading To Appeal

As the Court of Appeals noted, this case has taken “a long and circuitous path.” (Op. at 7.) Appellant contends that this path resulted from “obstructive and abusive litigation techniques” (Appellant's Br. at 12), but his accusation is unsupported. As a

³ Merck respectfully requests judicial notice of the appellate history in *Kleinman*.

reasonable view of the record reveals, both parties have vigorously litigated their positions in good faith.

Appellant commenced his action shortly after Vioxx was withdrawn, and Merck removed the matter to federal district court. Merck argued that the federal court had jurisdiction because the parties resided in different states and because the amount in controversy – when considering appellant’s claims for punitive damages and attorneys’ fees – exceeded \$75,000. *See* 28 U.S.C. §§ 1332(a), 1441(b). Although appellant suggests that removal was frivolous and part of Merck’s alleged “effort to delay the progress of the litigation” (Appellant’s Br. at 12), the federal district court itself rejected a similar argument despite ordering remand, noting that the jurisdictional question was “fairly close,” *Ratliff v. Merck & Co.*, 359 F. Supp. 2d 571, 578 (E.D. Ky. 2005).

Discovery then proceeded, culminating in a motion for summary judgment filed by Merck and a motion for class certification filed by appellant. Appellant opposed Merck’s summary-judgment motion, which argued that Kentucky law barred product suits in which the plaintiff alleges a risk of harm that he did not sustain; that appellant had not sustained any loss because any alternative drug would have cost the same under his insurance; and that appellant’s KCPA claim failed for lack of privity. The Circuit Court denied the motion.

Merck opposed appellant’s class certification motion on several grounds, including predominance and adequacy. As to predominance, Merck argued that Mr. Ratliff’s causes of action require individualized proof of both loss and causation or reliance, making a classwide trial inappropriate. In particular, Merck argued that because prescription decisions are highly individualized, there would be no way to prove, in one

trial, that Merck's conduct caused or had an effect on every Vioxx prescription in the Commonwealth. Rather, these decisions could only be proven using individualized evidence, making class treatment impossible and thus inferior to individualized proceedings.

As to adequacy, Merck argued that appellant was not an adequate class representative because, *inter alia*: (1) both of the physicians who prescribed Vioxx to appellant would still prescribe the drug if it were available today; (2) appellant's co-pay for Vioxx was the same as what he paid for other pain-relief drugs; and (3) appellant had no information regarding the doctor visit for which he supposedly seeks recovery in this case.

On April 1, 2010, the court granted plaintiff's motion for class certification, adopting verbatim plaintiff's proposed class certification order. (R. v. 6 at 822, Order Certifying Class Action at 1, Apr. 1, 2010.) The order was all of two paragraphs and did not include any substantive analysis of the class certification requirements set forth in CR 23, despite the prevailing view that class certification orders should carefully explain how the plaintiff has proven that the requirements for class certification have been satisfied. *See, e.g., In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 309 (3d Cir. 2008) (trial court must perform "a thorough examination of [whether] the factual and legal allegations" satisfy the prerequisites for class treatment) (internal quotation marks and citation omitted); *Ex parte Mayflower Nat'l Life Ins. Co.*, 771 So. 2d 459, 461-62 (Ala. 2000) (issuing writ of mandamus because "the trial judge failed to demonstrate that he had conducted a 'rigorous analysis' of the evidence and . . . to explain how the evidence supported his conclusion that the requirements of Rule 23 are met"); *see also Dorsey v.*

Bale, 521 S.W.2d 76, 78 (Ky. App. 1975) (“The complaint filed in this lawsuit purports to be a class action; however, the record discloses that the trial court did not make findings to satisfy the prerequisites of CR 23.01 . . .”).

Merck sought relief from the class certification order in the form of a petition for writ of mandamus to the Court of Appeals on May 7, 2010. (2010-CA-000873-OA.) Among other things, Merck challenged the cursory nature of the opinion prepared by plaintiff’s counsel and entered by the trial court – and the Circuit Court’s apparent disregard of the individualized evidence presented by Merck. (*See generally* Mem. Of Law In Supp. Of Merck’s Pet. For Relief In The Nature Of A Writ Of Mandamus Pursuant To CR 76.36 (“Mandamus Pet.”), No. 2010-CA-000873-OA (Ky. App. filed May 6, 2010).) Appellant takes issue with Merck’s bid for relief, arguing that “Kentucky precedent states that Petitions for Writs of Prohibition or Mandamus are not an appropriate means for challenging class certification orders,” citing *Garrard County Board of Education v. Jackson*, 12 S.W.3d 686 (Ky. 2000). (Appellant’s Br. at 13.) But Merck acknowledged *Jackson* in its petition, contending that, despite that decision’s general rejection of mandamus in the class certification context, the opinion contained a footnote that suggested mandamus review might be appropriate in a case of larger magnitude – and in “medical products” cases in particular. (Mandamus Pet. at 8 (quoting *Jackson*, 12 S.W.3d at 690 n.1).) Notably, the Court of Appeals did not disagree with Merck’s suggestion that there may be exceptions to *Jackson*’s general rule; it simply concluded that this case was not one, and it denied Merck’s petition on July 12, 2010. (Order at 6, No. 2010-CA-000873-OA (Ky. App. July 12, 2010).)

Merck appealed to this Court, again highlighting the Circuit Court's terse treatment of the class certification issue and its wholesale adoption of appellant's proposed order, and arguing either that the case fit within the exception contemplated by *Jackson* or else that *Jackson* should be overruled in light of the importance of review of questionable class certification decisions -- as confirmed through the Court's impending adoption of CR 23.06. Appellant defended the Circuit Court, but even as he argued to this Court that the Circuit Court had acted appropriately, he moved that court to adopt an amended class certification order, candidly stating that "Kentucky law [is] clear that class certification orders will be reviewed in accordance with federal decisions," and that, "[u]nder the Federal Rules, a trial court order certifying a class will be vacated if the order fails to define the class and the class claims, issues, or defenses" (R. v. 6 at 858, Pl.'s Mot. To Enter Am. Order Certifying Class ("Mot. to Am.") at 2, Nov. 10, 2010) -- as appellant's adopted order had failed to do.

Merck opposed the motion -- not to "whipsaw[]" the Circuit Court, as asserted without support in appellant's brief (Appellant's Br. at 14) -- but because Merck saw the effort as an attempt to derail important appellate review and because the proposed amended order reached factual findings on the merits in appellant's favor. (See R. v. 6 at 842, Am. Order Certifying Class Action ("Orig. Proposed Am. Order") at 13 (stating that "[a]ll of the potential plaintiffs were victims of Merck's fraud upon the market and are entitled to recovery"); see also generally R. v. 6 at 891-901, Def.'s Opp'n To Pl.'s Mot. To Enter Am. Order Certifying Class.) In addition, as Merck explained, the proposed amended order still fell far short of the rigorous analysis required under CR 23. For example, Mr. Ratliff's proposed amended order purported to identify a number of

supposedly “common” issues related to Merck’s conduct and the proposed class members’ losses that will predominate at a class trial, among them the question “[w]hether members of the class have suffered any economic loss as a result of Merck’s conduct.” (See R. v. 6 at 838, Orig. Proposed Am. Order at 9.) But it did not provide any indication as to how he could prove loss or causation on a classwide basis.

With appeal of the mandamus petition concerning the original certification order still pending in this Court, the trial court held a hearing on whether to adopt the proposed amended order on November 19, 2010. At the hearing, appellant’s counsel urged the court to remove the factual findings about Merck’s conduct, including the statement that all the class members were “victims of Merck’s fraud,” and to enter the order with minor amendments. The trial court denied appellant’s motion to amend the order on December 3, 2010. On December 17, 2010, appellant moved the court to reconsider its ruling, appending a virtually identical version of the proposed amended order that simply added the word “allegedly” to many – but not all – of the statements about Merck’s conduct. (See R. v. 7 at 969, Mot. to Reconsider Order Denying Pl.’s Mot. to Enter Am. Order Certifying Class.) Merck opposed the motion to reconsider (R. v. 7 at 1015-1024), but the trial court granted it on January 27, 2011 (R. v. 8 at 1110). In an apparent error, the trial court then entered the *first* amended order proposed by the plaintiff (i.e., the one concluding that all “potential plaintiffs . . . are entitled to recovery”), not the second. (See R. v. 8 at 1112, Amended Order Certifying Class Action (“Am. Order”) at 13.)

Notably, the Amended Order did not address *the key evidence* Merck presented in opposition to class certification, including:

- Testimony from both of Mr. Ratliff’s prescribing physicians that if Vioxx were on the market today, they would still prescribe it to some patients. (R. v.

3 at 355-356, Gibson Dep. 37:21-38:1; R. v. 3 at 379-380, Pampati Dep. 52:20-53:1.)

- Unrebutted affidavit testimony from Merck's expert economist, Dr. Barocci, explaining that some proposed class members who claim they would have stopped using Vioxx would likely have paid more (in differing amounts) for alternative therapies than they did for Vioxx, while others may have paid less (again in differing amounts), and still others would have seen no price change by switching from Vioxx to an alternative therapy. (R. v. 3 at 404, Barocci Aff. ¶ 12.)
- Unrebutted affidavit testimony from Merck's expert, Dr. deShazo, who prescribed Vioxx, that the decision to prescribe a certain drug is highly patient-specific, depending on "the risks and benefits of a particular drug in the context of an individual patient's medical status and preferences and the specific pharmacology of the drug." (R. v. 3 at 392, deShazo Aff. ¶ 19; see also R. v. 3 at 394-95, deShazo Aff. ¶ 22 (noting that the prescribing decision turns on, *inter alia*, "the presence or absence of co-existing conditions that predispose the individual patient to possible complications or drug allergies").)

Merck noticed an appeal under CR 23.06, which had become effective January 1, 2011. The appeal was held in abeyance pending this Court's consideration of Merck's appeal of the Court of Appeals' denial of its petition for mandamus relief.

On March 24, 2011, this Court affirmed the decision of the Court of Appeals denying Merck's petition. In so ruling, the Court agreed with Merck that "certain special circumstances can exist where a class can be challenged through mandamus" and that *Jackson* had so suggested; it further agreed that Merck had "identified potential shortcomings" in plaintiff's case and the class certification order, including the failure of the circuit court in its initial order to make findings required to satisfy the prerequisites of CR 23.01. (Mem. Op. of the Court at 7-8, Mar. 24, 2011.) But it held that the case did not pose the "unique and extraordinary prejudice" necessary to justify writ review. (*Id.* at 8 (citing *Jackson*, 12 S.W.3d at 691).) The Court concluded by stating, "We presume

that upon rendition of this opinion that review [of Merck's appeal under CR 23.06] will resume." (*Id.* at 11.)

C. The Court Of Appeals' Reversal

The appeal did resume, and on February 10, 2012, a unanimous Court of Appeals panel issued a ruling reversing the class certification order and remanding the case to Pike Circuit Court for further proceedings. The court found that "claims of fraudulent misrepresentation and negligent misrepresentation require more individualized proof and, thus, pose particular problems for class certification." (*Op.* at 10.) While the court acknowledged that causation or reliance can be presumed in certain contexts, particularly securities litigation, it went on to state that this "'fraud-on-the-market' approach has never been recognized in this jurisdiction for a fraud or misrepresentation case," and that "*every other jurisdiction* we found which has been confronted with the theory has rejected it outside of the securities litigation context." (*Id.* at 15 (emphasis added).) As such, "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." (*Id.* at 12.) According to the court, "[i]t is exactly this type of individualized proof which generally makes class litigation inappropriate in fraud and misrepresentation cases" (*id.*), and in prescription-drug cases in particular (*see id.* at 13 n.6 (noting that certification is generally "not granted in prescription drug cases because of the individualized inquiries such litigation typically involves")). Indeed, as it noted, the record in this case demonstrates the impossibility of classwide proof because appellant's own physician testified that she would still prescribe

Vioxx if it were still on the market depending upon the needs of individual patients. (*Id.* at 12 n.5.)⁴

In addition – and contrary to appellant’s argument (*see* Appellant’s Br. at 19-21) – the Court of Appeals also concluded that individualized issues precluded certification of plaintiff’s KCPA claim. Although the court acknowledged that “there are fewer obstacles to a class claim proceeding under the KCPA” (Op. at 10) and observed that a Vioxx consumer-protection suit had been certified for class treatment in *Plubell v. Merck & Co.* in Missouri, the court nonetheless concluded that, in this case, “[c]ausation, reliance, and damages are required to be shown on an individual basis,” and that “if the action were tried as a class . . . the case would essentially fragment into a series of amalgamated ‘mini-trials’ on each of these individualized questions” (*id.* at 15 (citation omitted)). In so doing, the court approvingly cited *Kleinman*, 8 A.3d at 862-63 (cited in Op. at 15), in which the court overseeing the New Jersey Vioxx coordinated litigation denied certification of a class of Vioxx users asserting consumer-protection claims under the New Jersey Consumer Fraud Act, N.J. Stat. Ann. §§ 56:8-1 et seq. (“NJCFA”) and claims for unjust enrichment. Like the KCPA and the statute at issue in *Plubell*, the NJCFA requires proof of a loss “as a result of” the defendant’s allegedly unlawful conduct – language that requires a “causal nexus,” but “not reliance,” according to the *Kleinman* court. 8 A.3d at 861. Nonetheless, the *Kleinman* court rejected class certification on the ground that “individualized determination[s] would be required for

⁴ With respect to the unjust enrichment claim, the court found that “since each plaintiff may have had different medical conditions and circumstances at the time they were prescribed the drug, and because each may have experienced different effects from the drug as compared to its risks,” a separate analysis would be required for each class member to determine whether Merck “inequitabl[y]” retained any benefit. (Op. at 16.)

each plaintiff to reveal whether the concealment of the CV risk information had a causal relationship to the patient or doctor's decision whether or not to use or prescribe Vioxx." *Id.* at 862-63. The Court of Appeals' citation to *Kleinman*, along with its broad language of reversal in other parts of its opinion, makes clear that it reversed certification on all claims, including the KCPA. (*See, e.g.*, Op. at 2 ("[W]e reverse the order of the Pike Circuit Court."); *id.* at 16 ("[C]lass certification is inappropriate . . ."); *id.* ("[W]e find that the class cannot be certified . . ."); *id.* ("We reverse and remand to the Pike Circuit Court with instructions for the court to vacate its prior order."))⁵

Appellant theorizes that the Court of Appeals' citation to *Plubell* suggests that it considered the KCPA claim certifiable but was under the misconception that it could not reverse certification only as to some claims.⁶ (Appellant's Br. at 20 (arguing that the Court of Appeals "apparently" believed that certification "could not be separately considered with respect to each claim").) But the context of the opinion makes clear that the Court was merely citing *Plubell* to explain why there are "fewer obstacles to a class claim proceeding under the KCPA" (Op. at 10 (emphasis added)) – not to say that there

⁵ Appellant's suggestion that the Court of Appeals' order did not direct decertification of the KCPA claim fails for the additional reason that, in order to reach such a conclusion, the court would have needed to address Merck's additional argument that appellant is not an adequate class representative. Instead, the Court of Appeals expressly found that it did not "need to address whether Ratliff is an adequate or typical representative for the class" in light of its finding that "the class cannot be certified." (Op. at 16.)

⁶ Appellant poses this theory in his statement of facts but does not actually argue that this holding is a ground for reversal; nor does he argue that the Court of Appeals erred in concluding that his KCPA claim is (like his other claims) not amenable to class treatment. Because appellant has not presented these arguments in his opening brief, and because a "reply brief is not a device for raising new issues which are essential to the success of the appeal," *Catron v. Citizens Union Bank*, 229 S.W.3d 54, at 58-59 (Ky. App. 2006) (citation and internal quotation marks omitted), any challenge to the Court of Appeals' decision on either of these bases should be deemed waived. *See, e.g., Grange Mut. Ins. Co. v. Trude*, 151 S.W.3d 803, 815 (Ky. 2004) (appellant's failure to address an issue in its brief resulted in waiver).

are none. Nowhere does the Court embrace the *Plubell* ruling – it simply cites *Plubell* and *Kleinman* and then adopts the approach of *Kleinman*.⁷

The Court of Appeals also held that the lack of predominance meant that appellant failed Rule 23's superiority requirement: "because these individualized questions would substantially overtake the litigation, and would override any common questions of law or fact concerning Merck's conduct, we find that a class action is not the superior mechanism by which to try" the *Ratliff* case. (*Id.* at 16.) For all of these reasons, it concluded that "the class cannot be certified" and reversed and remanded "with instructions for the [Circuit Court] to vacate its prior order." (*Id.*)

ARGUMENT

Under Kentucky law, class certification is proper only where the plaintiff satisfies the requirements of Rule 23 of the Kentucky Rules of Civil Procedure. *See* CR 23.01, 23.02. In particular, a plaintiff moving to certify a class of individuals seeking monetary damages must prove both that "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); *see also Gevedon v. Purdue Pharma*, 212 F.R.D. 333, 335 (E.D. Ky. 2002) ("a party seeking to certify a class bears the burden of establishing that certification is proper"). (*See also* Op. at 10 (a class may only be certified if "common issues *substantially predominate* over those issues which are individual in

⁷ As appellant notes, after this Court granted review, and just days before filing his brief, appellant filed a motion in the Circuit Court seeking a "Second Amended Order Certifying" his proposed class "only with respect to the KCPA claims" on the theory that such certification would be "consistent with the Court of Appeals' Opinion." (Appellant's Br. at 21.) The Circuit Court has denied that motion in light of the pending appeal. (Order at 1, *Ratliff v. Merck & Co.*, No. 04-CI-01493 (Pike Cir. Ct. Jan. 17, 2013).)

nature”).) In addition, a plaintiff may not represent a class unless he can fairly and adequately protect the interests of absent class members. *See* CR 23.01 (requiring that “the claims or defenses of the representative parties are typical of the claims or defenses of the class, and [that] the representative parties will fairly and adequately protect the interests of the class”).

The law is clear that “Rule 23 does not set forth a mere pleading standard.” *Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 2541, 2551 (2011). Rather, a party seeking certification of a class “must affirmatively demonstrate his compliance with the Rule.” *Id.* Thus, a court presented with a class action proposal must “examin[e] the underlying elements necessary to establish liability for plaintiffs’ claims” and determine whether each element of the plaintiffs’ causes of action “can be proven on a systematic, class-wide basis.” *Blades v. Monsanto Co.*, 400 F.3d 562, 569 (8th Cir. 2005). Such an examination requires a “rigorous analysis” of “all *relevant evidence and arguments* presented by the parties.” *In re Hydrogen Peroxide*, 552 F.3d at 307 (emphasis added); *In re Flash Memory Antitrust Litig.*, No. C 07-0086 SBA, 2010 U.S. Dist. LEXIS 59491, at *39 (N.D. Cal. Mar. 31, 2010) (“[C]ourts are not only ‘at liberty to’ but must ‘consider evidence’” at the class certification stage.) (citation omitted); *In re New Motor Vehicles Canadian Export Antitrust Litig.*, 522 F.3d 6, 17, 25 (1st Cir. 2008) (trial court must “rigorously test[] the evidence submitted by both sides” and “formulate some prediction as to how specific issues will play out” at trial) (internal quotation marks and citation omitted). Even though this inquiry will often “entail some overlap with the

merits of the plaintiff's underlying claim," such overlap is permissible; indeed, it "cannot be helped." *Wal-Mart*, 131 S. Ct. at 2551.⁸

Kentucky applies an abuse-of-discretion standard to class certification orders. *See Sowders v. Atkins*, 646 S.W.2d 344, 347 (Ky. 1983) (applying an abuse-of-discretion standard in affirming the trial court's denial of class certification). "The test for abuse of discretion is whether the trial [court's] decision was arbitrary, unreasonable, unfair, or unsupported by sound legal principles." *Commonwealth v. English*, 993 S.W.2d 941, 945 (Ky. 1999). The standard entails some deference to the decision below, but "slightly less deference than the clear error standard." *CertainTeed Corp. v. Dexter*, 330 S.W.3d 64, 71 (Ky. 2010). And in the class action context specifically, abuse-of-discretion review is not particularly "generous or forgiving." *Vega v. T-Mobile USA, Inc.*, 564 F.3d 1256, 1269 (11th Cir. 2009). In light of the "rigorous analysis" required in deciding class certification, a trial court may not rest on "an all-too-cursory discussion of the relevant facts," "back[] into the requisite findings," or "rely[] on a reviewing court to connect the dots." *Id.* Review should also bear in mind that the burden to prove that the requirements for class certification have been satisfied rests with the plaintiff. *See, e.g., Steering Comm. v. Exxon Mobil Corp.*, 461 F.3d 598, 601 (5th Cir. 2006).

⁸ Appellant and his *amicus* believe that a court may not "consider the merits of the plaintiffs' claims" and suggest that the Court of Appeals transgressed this rule, citing *Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 177 (1974). (*See* Appellant's Br. at 22; *Amicus* Br. at 8.) They are wrong. The U.S. Supreme Court recently clarified in *Wal-Mart v. Dukes* that it is a "mistake[]" to cite *Eisen* for this proposition. 131 S. Ct. at 2552 n.6. According to the *Wal-Mart* decision, *Eisen* only stands for the proposition that a court may not consider the merits at the class certification stage for reasons other than "to determine the propriety of certification." *Id.* *Amicus* suggests that *Wal-Mart*'s pronouncement applies only to the commonality prong of class certification (*see Amicus* Br. at 9), but this argument ignores the language of *Wal-Mart* itself. Indeed, the Supreme Court's footnote clarifying *Eisen*'s dictum explains that "the most common example of [properly] considering a merits question at the Rule 23 stage" may be the application of "Rule 23(b)(3)'s [predominance] requirement" in securities-fraud litigation. 131 S. Ct. at 2552 n.6

Even where review is subject to the abuse-of-discretion standard, this Court reviews “legal rulings *de novo*.” *Commonwealth, Energy & Env’t Cabinet v. Shepherd*, 366 S.W.3d 1, 4 (Ky. 2012). As other jurisdictions have held, the “availability of [a] fraud-on-the-market presumption” – a primary justification for the Circuit Court’s certification order and thus a central issue in this appeal – “is a question of law.” *O’Neil v. Appel*, 165 F.R.D. 479, 497 (W.D. Mich. 1996) (citing *Cammer v. Bloom*, 711 F. Supp. 1264, 1287-93 (D.N.J. 1989)).

As set forth below, the Court of Appeals correctly held that the Circuit Court abused its discretion in concluding that common issues predominated and that a class action is a superior mode of proceeding. As the Court of Appeals explained – relying on the evidence proffered by Merck but ignored by the Circuit Court – several elements necessary to establish each class member’s claims turn on highly individualized questions of fact. In particular, there is no way to prove with common evidence what effect Merck’s alleged conduct had – if any – on each class member, including whether it would have affected his or her doctor’s decision to prescribe it, and how (if at all) it affected the value of the drug to each class member. These variables preclude a common showing of causation, reliance or loss, and the inherent differences in the class cannot be ignored under the auspices of a fraud-on-the-market fiction that has never been extended to this context in any other jurisdiction. Because proving such claims on an individual basis would quickly devolve into hundreds of thousands of mini-trials, the Court of Appeals also properly concluded that a class action would be an inferior mode of proceeding, notwithstanding the alleged low-value nature of the claims.

The Court of Appeals' order should also be affirmed on an alternative ground equally supported by the record: that appellant is not an adequate representative. The record demonstrates that appellant knows very little about the medical consultation that is supposedly the basis of this suit and has no objective evidence that it ever took place. At a minimum, this deficiency would subject him to a significant defense that likely would not apply with equal force throughout the class.

For each of these reasons, the Court of Appeals decision to reverse the Circuit Court's class certification order should be affirmed.

I. THE COURT OF APPEALS PROPERLY HELD THAT INDIVIDUALIZED ISSUES PRECLUDE CLASS TREATMENT OF ANY OF APPELLANT'S CLAIMS.

The predominance requirement "tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation." *In re Hydrogen Peroxide*, 552 F.3d at 310-11 (internal quotation marks and citation omitted). Although "predominance does not require that each and every possible issue be common to all class members," a class may only be certified if "common issues *substantially predominate* over those issues which are individual in nature." (Op. at 10.) *See also, e.g., Adams v. Fed. Materials Co.*, No. 5:05-CV-90-R, 2006 WL 3772065, at *10 (W.D. Ky. Dec. 19, 2006) (class certification is not appropriate where questions affecting individual class members would "overwhelm commonly decided issues"); *Luna v. Del Monte Fresh Produce (Se.), Inc.*, 354 F. App'x 422, 424 (11th Cir. 2009) (where plaintiffs will have to "introduce a great deal of individualized proof . . . to establish most or all of the elements of their individual claims, such claims" do not satisfy the predominance requirement); *Sandwich Chef of Tex., Inc. v. Reliance Nat'l Indem. Ins. Co.*, 319 F.3d 205, 218, 220 (5th Cir. 2003) ("[t]o

decide whether common issues predominate, the district court must consider how a trial on the merits would be conducted if a class were certified,” including whether “individual issues . . . will be components of” a claim or defense). Similarly, a plaintiff cannot show that a class action is the “superior” mechanism to resolve the putative class members’ claims if a “combined adjudication of class members’ claims would involve individual determinations” on key issues. *See Adams*, 2006 WL 3772065, at *11. “[W]hen the complexities of class action treatment outweigh the benefits of considering common issues in one trial, class action treatment is not the ‘superior’ method of adjudication.” *Zinser v. Accufix Research Inst., Inc.*, 253 F.3d 1180, 1192 (9th Cir. 2001).

Here, the Court of Appeals rightly concluded that predominance and superiority could not be satisfied because “[c]ausation, reliance, and damages” – critical elements of appellant’s claims – “are required to be shown on an individual basis.” (Op. at 12-15.)⁹ In so holding, the Court of Appeals agreed with Merck that “individual proof” will be necessary to show that Merck made misstatements “toward each putative class member or his or her physician through the marketing and sale of Vioxx, that the alleged misrepresentations were received by each putative class member’s physician, that each putative class member’s physician relied on such representations in his or her decision to prescribe Vioxx over another drug, and the amount of any damages suffered by each

⁹ Appellant’s KCPA, fraudulent misrepresentation, and negligent misrepresentation claims (collectively, plaintiff’s “fraud-based claims”) all undisputedly require proof of causation and/or reliance. *See* KRS 367.220(1) (plaintiff must prove an “ascertainable loss of money or property . . . as a result of” a prohibited act) (emphasis added); *Rivermont Inn, Inc. v. Bass Hotels Resorts, Inc.*, 113 S.W.3d 636, 640 (Ky. App. 2003) (fraudulent misrepresentation claim requires, *inter alia*, a showing that plaintiff relied on the alleged misrepresentation); *Ann Taylor, Inc. v. Heritage Ins. Servs., Inc.*, 259 S.W.3d 494, 496 (Ky. App. 2008) (to establish a claim for negligent misrepresentation, plaintiff must establish that defendant negligently made a false statement, that he relied on it, and that the alleged misrepresentation caused him to suffer pecuniary loss).

putative class member.” (*Id.* at 9.)¹⁰ Further, the Court of Appeals correctly held that “a class action is not the superior mechanism by which to try these cases” because “these individualized questions would substantially overtake the litigation and would override any common questions of law or fact concerning Merck’s conduct.” (*Id.* at 16.)

Appellant argues that the Court of Appeals’ decision was in error because: (1) causation and reliance can be proven on a classwide basis in light of Merck’s “uniform” misrepresentations; (2) causation and reliance can also be proven on a classwide basis under a “fraud on the market” theory; (3) the Court of Appeals improperly focused on physicians’ decisions to prescribe the drug, rather than the proposed class members’ decisions to take it; and (4) the Court of Appeals should have concluded that a class action is superior in light of the low-value nature of appellant’s claims. None of these arguments has merit.

A. The Court of Appeals Properly Held That The Causation/Reliance Inquiry Will Turn On Individualized Proof.

Appellant argues that the Court of Appeals’ causation/reliance analysis is erroneous because it ignores that all proposed class members relied *on their doctors* in deciding to take Vioxx. According to appellant, causation and reliance can be proven on a classwide basis in a prescription drug case like this one because “it is indisputable that every class member . . . relied on physicians that were equipped with false and fraudulently distributed information.” (Appellant’s Br. at 28-29.) But as the Court of Appeals correctly recognized, whether a patient relied on his or her doctor is not the

¹⁰ The Court of Appeals also correctly held that resolving appellant’s unjust enrichment claim will require similarly individualized inquiries to determine whether Merck “inequitabl[y]” retained a benefit from each class member in light of his or her “medical conditions,” the “circumstances at the time [he or she was] prescribed the drug,” and what “effects [he or she experienced] from the drug as compared to its risks.” (Op. at 16.)

relevant inquiry for purposes of causation or reliance in a product liability suit. Instead, causation and reliance require a causal link between the allegedly misleading statements made by Merck about its product and each proposed class member's use of the drug. (Op. at 12.) Because Vioxx is available only by prescription from a doctor, causation and reliance turn on whether the proposed class members' doctors' "individually relied upon the false or misleading information disseminated by Merck when prescribing Vioxx to them," a question that cannot be resolved on a classwide basis. (*Id.*)

This conclusion is consistent with two prior decisions rejecting class certification of fraud-based claims arising from the sale of Vioxx, as the Court of Appeals noted. In *Kleinman*, for example, the New Jersey court overseeing the coordinated Vioxx proceedings in that state refused to certify a class of Vioxx plaintiffs asserting claims under the New Jersey Consumer Fraud Act. 8 A.3d 851. In language very similar to that employed by the KCPA, the NJCFA requires a showing that plaintiffs suffered a loss "as a result of" the defendant's allegedly wrongful conduct. N.J. Stat. Ann. § 56:8-19. Applying this language, the court held that even though the New Jersey statute does not require a showing of reliance, "there still must be a 'nexus,'" and "[i]n order to fairly determine if a nexus exists for an individual, numerous factors must be considered that differ from consumer to consumer." *Kleinman*, 8 A.3d at 863. This is so because "[t]he decision of whether to prescribe a medication is made upon a host of individualized factors, including other risk factors plaintiffs possessed and whether other drugs were effective in relieving plaintiffs' pain." *Id.* at 862. As a result, an "individualized determination would be required for each plaintiff to reveal whether the concealment of the CV risk information had a causal relationship to the patient or doctor's decision

whether or not to use or prescribe Vioxx.” *Id.* at 862-863. For example, “[s]ome plaintiffs may have never used another painkiller other than Vioxx,” others “may have used naproxen and numerous other NSAIDs without relief of pain before using Vioxx,” and still others “may have gotten significant pain relief.” *Id.* at 863. For all of these reasons, “[t]he individual proofs required to show a causal nexus preclude a class action.” *Id.*

The California Court of Appeal likewise rejected class certification of Vioxx consumer protection claims based on substantially similar reasoning, concluding that common issues would not predominate with respect to causation and reliance because the decisions to prescribe and take Vioxx would have varied from one patient to the next. *See In re Vioxx Class Cases*, 180 Cal. App. 4th at 133-36 (further holding that questions of injury and loss would also vary because perceptions of Vioxx’s value would turn on each patient’s particular medical needs);¹¹ *cf. also In re Vioxx*, 2010 U.S. Dist. LEXIS 142767, at *23-24, *34-36 (rejecting causation theory in Vioxx suit brought by state attorney general because “[e]ach decision by each doctor and each patient was different,”

¹¹ Appellant’s claims here will also turn on individualized questions of loss. To establish an actual pecuniary loss under Kentucky law, each proposed member of the class must demonstrate that he or she lost money as a result of choosing Vioxx over another medication. *See, e.g., Harman v. Sullivan Univ. Sys., Inc.*, No. 03-738-C, 2005 U.S. Dist. LEXIS 10904, at *17-18 (W.D. Ky. June 6, 2005) (finding that plaintiff could not recover refund of her tuition because “the measure of damages for fraud is the actual pecuniary loss sustained,” and “plaintiff . . . received the benefit of her bargain – graduating from an accredited program and being permitted to take the national examination”) (citing *Sanford Constr. Co. v. S&H Contractors, Inc.*, 443 S.W.2d 227, 239 (Ky. 1969)); KRS 367.220(1) (KCPA plaintiff must suffer “ascertainable loss of money or property”); *Stahl v. St. Elizabeth Med. Ctr.*, 948 S.W.2d 419, 423 (Ky. App. 1997) (“one seeking to recover on the basis of fraud must suffer an actual pecuniary loss”) (internal quotation marks and citation omitted). As Merck explained in its briefing to the Circuit Court, each proposed class member’s ability to make this showing would vary based on whether he or she paid more or less for Vioxx than he or she would have for a comparable medication that met his or her medical needs; whether he or she underwent a medical consultation or diagnostic testing to assess whether he or she was injured by Vioxx; whether he or she paid any money for that consultation; and whether he or she lost wages as a result of attending the consultation. (*See R. v. 2* at 263-66, Def. Merck & Co.’s Opp’n To Pl.’s Mot. For Class Certification (“Class Cert. Opp’n”) at 24-27.) The Circuit Court failed to address any of these factors in its Amended Order. For this reason, too, the Circuit Court’s decision was in error.

and “[t]he effect that any alleged misrepresentations had on each decision is unique,” making it “simply impossible, or close to it, to determine the individual thought process of each of the thousands of doctors and patients involved”).

Kleinman and *In re Vioxx Class Cases* are representative of the overwhelming majority of decisions rejecting consumer fraud class actions involving pharmaceutical products. See, e.g., *In re St. Jude Med., Inc.*, 522 F.3d 836, 838-40 (8th Cir. 2008) (“resolution of [defendant’s] potential liability to each plaintiff under the consumer fraud statutes will be dominated by individual issues of causation and reliance”); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Relevant Prods. Liab. Litig.*, 275 F.R.D. 270, 277 (S.D. Ill. 2011) (striking fraud-based class allegations in pharmaceutical drug case where court would have to undertake “an assessment of individualized issues pertaining to each class member’s prescriber, including how the doctor balances the risks and benefits of the medicine for that particular patient”); *Sergeants Benevolent Ass’n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, No. 08-CV-0179 (SLT) (RER), 2011 U.S. Dist. LEXIS 26857, at *49 (E.D.N.Y. Feb. 16, 2011) (recommending that class certification be denied in pharmaceutical drug case with respect to, *inter alia*, consumer fraud and unjust enrichment claims given “the individualized nature of the prescription-making process”), *report and recommendation adopted by*, 2011 U.S. Dist. LEXIS 36454 (E.D.N.Y. Mar. 30, 2011); *In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig.*, 257 F.R.D. 315, 331 (D. Mass. 2009) (individualized nature of causation inquiry doomed putative consumer fraud class of Neurontin users); *In re Prempro Prods. Liab. Litig.*, 230 F.R.D. 555, 567 (E.D. Ark. 2005) (denying certification of claims involving hormone replacement therapy; plaintiffs’ consumer fraud claims “require individualized proof”

regarding causation) (internal quotation marks and citation omitted); *In re Paxil Litig.*, 212 F.R.D. 539, 551 (C.D. Cal. 2003) (refusing to certify class of users of prescription anti-depressant Paxil alleging consumer fraud and other claims where causation inquiry would turn on highly individualized evidence); *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 68 (S.D.N.Y. 2002) (“individual questions, particularly but not limited to causation and reliance, overwhelm those common issues”); *Santullo v. Pfizer, Inc.*, No. D-0101-CV-200301377, 2005 WL 4255513, at *6 (N.M. Dist. Ct. Dec. 9, 2005) (denying class certification in part because “individual issues relating to causation, reliance and injury will dominate proceedings”).

Appellant says virtually nothing about this body of law in his brief. Instead, he champions one outlier decision – *Plubell*, 289 S.W.3d 707 – that affirmed class treatment of Vioxx claims. (See Appellant’s Br. at 19-20.) According to appellant, *Plubell* should dictate the ruling here because it involved supposedly similar law and facts. But as set forth above, the allegations and applicable law are just as similar to those at issue in *Kleinman*, which denied class certification. The Court of Appeals was correct to follow *Kleinman* and not *Plubell*. *Plubell* concluded that causation and loss could be shown on a classwide basis because the plaintiffs had alleged that Vioxx was ““worth less than the product they thought they had purchased.”” 289 S.W.3d at 715 (citation omitted). But this conclusory statement ignores the complicated context of prescription drugs, every one of which poses risks and benefits that must be measured against available alternatives – typically, either the use of another drug (which also poses risks and benefits) or nothing at all. Thus, when new risk information is revealed, the calculus may change for some patients, but not others. As the record in this case indicates, for example, doctors would

have continued to prescribe Vioxx to some patients, for whom the drug would have retained all of its value as a pain-reliever that avoided gastrointestinal side effects. Cases like *Kleinman, In re Vioxx Class Cases*, and the vast majority of other consumer protection cases involving prescription drugs account for this reality; *Plubell* does not.¹²

Appellant also relies on cases from “[o]ther jurisdictions” that supposedly “permit a presumption or inference of reliance and causation” where the plaintiff alleges that a common omission was made to all class members. (Appellant’s Br. at 29.) But these cases – *Cope v. Metropolitan Life Insurance Co.*, 696 N.E.2d 1001 (Ohio 1998), and *Vasquez v. Superior Court*, 4 Cal. 3d 800 (1971) (Appellant’s Br. at 29-30) – were not decided under Kentucky law. Moreover, they involved *uniform*, material misstatements made in a business context that the courts in those cases concluded would have been material to all class members.

In *Cope*, for example, the “gravamen of [plaintiffs’] complaint [was] that MetLife engaged in a scheme to collect larger commissions and front-end load charges by intentionally omitting the state-mandated written disclosure warnings when issuing replacement life insurance.” 696 N.E.2d at 1006. According to the court, it could not “imagine a case more suited for class action treatment” because it “involve[ed] the use of form documents, standardized practices and procedures, common omissions spelled out in written contracts, and allegations of a widespread scheme to circumvent statutory and

¹² Even further afield is the reliance by appellant’s *amicus* on *Wiley v. Adkins*, 48 S.W.3d 20 (Ky. 2001). (*Amicus* Br. at 10-12.) The class certification analysis in that decision was all of four sentences, presumably reflecting the undeveloped nature of the argument offered by the appellant. *Wiley*, 48 S.W.3d at 23. Indeed, in his brief in that case, the appellant’s only argument was that the issue of damages was individualized. Br. for Appellant, *Wiley v. Adkins*, No. 1999-SC-0985-D, 2000 WL 34332836, at *9-13 (Ky. filed Sept. 28, 2000). Moreover, the brief all but conceded that liability issues could be certified, *see id.* at *11 (“It is clear from the evidence that any *commonality of interest that the Appellees may have had insofar as liability of the Appellant is concerned* breaks down when we reach the question of damages”) (emphasis added) – which obviously is not the case here – making *Wiley* utterly inapposite.

regulatory disclosure requirements.” *Id.* at 1009. Further, the court found that the “alleged circumstances surrounding each transaction present a common fact situation” because each proposed class member received the exact same information that was uniformly material to their insurance policies. *Id.* Thus, the court concluded that reliance could be presumed as to all class members for class certification purposes. *Id.*

Similarly, in *Vasquez*, the California Supreme Court approved a presumption of reliance in a case involving omissions about a commercial freezer product, but only because the defendants’ sales representatives had “memorized a standard statement containing the representations (which in turn were based on a printed narrative and sales manual)” and “recited [them] by rote to every member of the class.” 4 Cal. 3d at 811-12. According to the court, if a jury were to conclude that these representations were both false and objectively material to the sale of the freezer, then “at least an inference of reliance would arise as to the entire class.” *Id.* at 814.

Appellants’ claims regarding Vioxx are very different because risk information was not disseminated uniformly, and the materiality of the information received by the proposed class members and their physicians differed depending on the medical history and needs of each individual patient. (*See, e.g., R. v. 3* at 387-89, 396-97, *deShazo Aff.* ¶¶ 11, 13-14, 25-26 (noting the various channels through which risk information was distributed and debated and explaining that the risk-benefit calculus for Vioxx would vary individually based on medical history and other factors).) For this reason, the California Court of Appeal expressly refused to apply a presumption of reliance in *In re Vioxx Class Cases*, notwithstanding binding precedent like *Vasquez*. *See* 180 Cal. App. 4th 116. According to the court, any such presumption would be “a vast

oversimplification of the matter,” because different Vioxx users – and their doctors – placed different levels of importance on risk information depending on the user’s particular medical needs. *Id.* at 133. Indeed, “[s]ome patients would still take Vioxx today if it were on the market [and] some physicians would still prescribe it . . . because, for some patients, the benefits outweigh the risks.” *Id.* at 134. The court further recognized that “[f]or those physicians with a distrust of statements made by the pharmaceutical industry, Merck’s statements could not have been material.” *Id.* Thus, “individual issues prevailed over common issues, justifying denial of class certification.” *Id.*

This case is no different. Just as in *In re Vioxx Class Cases*, the evidence in the record makes clear that the proposed class members’ physicians would have made different prescribing decisions if they had been given more information about the risks of Vioxx. Indeed, as the Court of Appeals expressly recognized, appellant’s own physician testified that she would still prescribe Vioxx to certain patients if it were available. (Op. at 12 n.5.) Accordingly, the Court of Appeals correctly held that the causation/reliance inquiry would inevitably “fragment into a series of amalgamated ‘mini-trials’” that would “substantially overtake the litigation.” (*Id.* at 15-16.)

B. The Court Of Appeals Also Properly Declined To Accept Appellant’s Fraud-On-The-Market Theory.

Appellant also argues that: (1) the Court of Appeals incorrectly held that the Circuit’s Court’s predominance ruling was based on the “fraud-on-the-market” theory; and (2) even if the Circuit Court did apply fraud-on-the-market principles, it was justified in doing so. Appellant is wrong on both courts.

As an initial matter, the Court of Appeals correctly concluded that the fraud-on-the-market theory was essential to the Circuit Court's class certification order. (Op. at 14 (quoting R. v. 8 at 1124, Am. Order at 13).) Indeed, the Circuit Court order – which appellant wrote – specifically describes Merck's behavior as “fraud upon the market” and relies on cases that avoid the need for individualized proof by invoking the fraud-on-the-market theory. (See R. v. 8 at 1124, Am. Order at 13 (citing *In re Texas Int'l Secs. Litig.*, 114 F.R.D. 33 (W.D. Okla. 1987)).) Appellant cannot escape the very reasoning used to justify class certification in the order he drafted for the Circuit Court's signature.

Appellant is also wrong that application of the fraud-on-the-market theory would be proper. According to appellant, the Court of Appeals should have extended the rationale of *Basic Inc. v. Levinson*, 485 U.S. 224 (1988), in which the U.S. Supreme Court held that plaintiffs seeking to represent a class of investors may satisfy the reliance requirement of a federal securities-fraud cause of action by proving that the defendant perpetrated a “fraud on the market.” (See Appellant's Br. at 33.) As the Court of Appeals recognized, however, such a “‘fraud-on-the-market’ approach has never been recognized in this jurisdiction for a fraud or misrepresentation case.” (Op. at 15.) Moreover, “*every other jurisdiction*” that has “confronted . . . the theory has rejected it outside of the securities litigation context.” (*Id.* at 15 (emphasis added).)

The Court of Appeals – like “every other jurisdiction” that has considered the question – got it right. As the U.S. Supreme Court explained in *Basic*, fraud on the market turns on the notion “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.” 485 U.S. at 241-42 (internal quotation marks and citation omitted).

That premise makes zero sense here. Appellant and the putative class members did not buy stock; they were prescribed drugs by their doctors. While the fraud-on-the-market theory may have some explanatory force in the securities context, in which “a ‘perfect market’ or ‘efficient market’ is assumed, and adverse information is expected to be quickly absorbed by the market . . . causing the price of the stock or commodity at issue to fluctuate,” such is not the case with drugs. *Heindel v. Pfizer, Inc.*, 381 F. Supp. 2d 364, 380 (D.N.J. 2004). “[T]here is no prescription drug ‘market,’ at least as that term is understood in the securities context,” *id.*, because “the price of prescription drugs [is] fixed by pharmaceutical manufacturers, not the market,” *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 2:06-cv-5774, 2009 WL 2043604, at *21 (D.N.J. July 10, 2009). Thus, “[a]ny perceived price impact attributed to [a drug manufacturer’s misrepresentations] is merely speculative and discounts the impact of important external variables such as the medical judgment of physicians and the preference of patients.” *In re Schering-Plough*, 2009 WL 2043604, at *21; *see also Prohias v. Pfizer, Inc.*, 485 F. Supp. 2d 1329, 1337 (S.D. Fla. 2007) (rejecting fraud-on-the-market theory because it depends on the “faulty premise that the price of Lipitor fluctuates based on the public’s knowledge of Lipitor’s benefits, even though drug prices . . . are fixed by the product’s manufacturer”). As one court bluntly put it, the fraud-on-the-market theory is “patently absurd” as applied to prescription drugs. *Heindel*, 381 F. Supp. 2d at 380 (rejecting the theory in a case involving Vioxx and another drug because “[i]t depends on the totally implausible predicate that, had some adverse information

about side effects derived from” a study about Vioxx “been more widely disseminated, the Plaintiffs would have paid *less* for . . . Vioxx”). For these reasons, the theory has been repeatedly rejected in the drug context whether proffered to prove reliance or causation. *See, e.g., In re Schering-Plough*, 2009 WL 2043604, at *21 (causation) (courts have “consistently rejected this sort of market-based injury as having no application in the context of claims for recovery of the purchase price for prescription drugs”); *Prohias*, 485 F. Supp. 2d at 1337 (causation and reliance); *Heindel*, 381 F. Supp. 2d at 380 (reliance).

Unable to deny that “courts have . . . been hesitant to” adopt a presumption of causation or reliance based on a fraud-on-the-market theory in drug cases, appellant nevertheless argues that such an approach is necessary to “avoid . . . injustice” because it is not feasible for plaintiffs to pursue these small-value claims in individual actions. (Appellant’s Br. at 33-34.) According to appellant, *Basic* adopted a presumption in securities cases precisely to avoid such an injustice, and this Court should do the same. (*Id.* at 33.)

Appellant’s argument misreads *Basic*. Essential to the Supreme Court’s adoption of a presumption in *Basic* was its belief that the presumption was “supported by common sense and probability,” based on how the securities market operates. 485 U.S. at 246-47. Equally important was the Court’s conclusion that individual proof of reliance in the securities context is, in any event, “speculative” because of the “impersonal” nature of the market. *Id.* at 245. Finally, the Supreme Court also emphasized that its ruling was uncontroversial; indeed, “nearly every court” to consider the issue had adopted a similar presumption in securities-fraud cases. *Id.* at 247.

This case is the opposite of *Basic* in nearly every way. Doctors prescribe drugs with known risks (and patients purchase them) every day, based on the patients' individualized medical histories and needs. Moreover, appellant has not proffered any evidence that drug prices fall when new risks are disclosed, and no such evidence exists. *See, e.g., Heindel*, 381 F. Supp. 2d at 380 ("The suggestion . . . that drugs with certain side effects should cost less[] defies both reality and common sense."). Accordingly, adopting a presumption that everyone in the class necessarily relied on Merck's alleged representations would be contrary to "common sense and probability." *Basic*, 485 U.S. at 246-47.

For all of these reasons, the Court of Appeals properly held that the fraud-on-the-market theory has no place in the prescription-drug context, and that the Circuit Court therefore erred in certifying appellant's class based on its application.

C. The Court Of Appeals' Ruling Correctly Focused On Physicians' Decisions To Prescribe Vioxx.

Appellant also incorrectly argues that the Circuit Court's causation/reliance analysis is flawed because it focuses on whether prescribing physicians would have prescribed the drug if more risk information had been released, rather than whether patients would have taken it. According to appellant, the Court of Appeals should not have considered "the *doctors'* thought process" at all in this case because the "learned intermediary doctrine" does not apply, and Merck's duty to warn thus ran to consumers, not doctors. (Appellant's Br. at 34.) Appellant's argument is misplaced.

As a preliminary matter, the Court of Appeals did not base its ruling on the learned-intermediary doctrine. Instead, the Court of Appeals simply recognized that Vioxx is a prescription drug that is only available by prescription, and that the causation

and reliance inquiries in this case will thus necessarily turn on whether each proposed class member's physician was affected by the allegedly "false or misleading information disseminated by Merck when prescribing Vioxx to them." (Op. at 12.)

In any event, appellant's argument that the learned-intermediary doctrine does not apply because Merck allegedly "withheld information from the health care industry" (Appellant's Br. at 34-35) is completely illogical. As this Court made clear in *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758 (Ky. 2004), the learned-intermediary doctrine is "an exception to the general rule that a manufacturer's duty to warn of any risks or dangers inherent in the product runs to the ultimate consumer." *Id.* at 762. Specifically, the doctrine provides that the "obligation of a manufacturer to warn about risks attendant to the use of drugs and medical devices that may be sold only pursuant to a health-care provider's prescription traditionally has required warnings directed to health-care providers and not to patients." *Id.* (quoting *Restatement (Third) of Torts: Prods. Liab.* § 6 (cmt. b) (1998)). By adopting the doctrine, the Court accepted that, in cases alleging a failure to disclose pharmaceutical risk information like this one, the relevant inquiry is whether the manufacturer gave a proper warning to "the health care provider[s] who prescribe[] the drug[]." *Id.* at 770. Nowhere in *Larkin* – or in any of the out-of-state decisions cited by appellant – is there a suggestion that this general rule "identif[ying] the party to be warned" in a pharmaceutical case, *id.*, does not apply where a party alleges that the warning provided was inadequate. Indeed, if that were the case then the doctrine would have no application at all, given that all failure-to-warn claims are necessarily based on a theory that the manufacturer did not provide sufficient information about its product.

Appellant's suggestion that the learned-intermediary doctrine is inapplicable because Merck engaged in direct-to-consumer ("DTC") advertising is also baseless. Appellant relies heavily on *Perez v. Wyeth Laboratories, Inc.*, 734 A.2d 1245 (1999), for the proposition that courts do not apply the learned-intermediary doctrine in cases where a drug manufacturer "makes direct claims to consumers" about its product. (Appellant's Br. at 36.) However, as this Court noted in *Larkin*, this exception for "direct-to-consumer advertised drugs" is "recognized *only* by New Jersey."¹³ 153 S.W.3d at 766 (emphasis added); *see, e.g., Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1376 (S.D. Fla. 2007) ("Since *Perez* was decided, no court – including any Florida court – has recognized the DTC exception to the learned intermediary doctrine, and several courts have expressly rejected the DTC exception."); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 547 n.30 (E.D. Pa. 2006) ("If we reached the merits of the [learned-intermediary-doctrine, or "LID"] issue, any direct-to-consumer [] advertising exception would likely not apply. This is because, in the eight years since *Perez*, the New Jersey Supreme Court case making an exception to the LID for direct-to-consumer advertising, was decided, no state has joined New Jersey."), *rev'd on other grounds*, 129 S. Ct. 1578 (2009). Indeed, none of the cases appellant cites from jurisdictions other than New Jersey actually adopts the DTC exception. Instead, two of his authorities merely recognize a limited exception to the doctrine for contraceptive medications on ground that, in contrast to other drugs, "the treating physician generally does not make an intervening, individualized medical

¹³ Further, the Court noted in *Larkin* that the DTC exception adopted in *Perez* is very limited because New Jersey's codified learned-intermediary rule "include[s] a rebuttable presumption that advertisements that compl[y] with Federal Drug Administration (FDA) regulations provide[e] a sufficient warning" as a matter of law. *Larkin*, 153 S.W.3d at 766 n.2. This rule significantly "narrows the chance of recovery" in a DTC case by "leaving a cause of action equivalent to mere agency review." *Id.* (internal quotation marks and citation omitted).

judgment in the birth control decision.” *Hill v. Searle Labs., Div. of Searle Pharms., Inc.*, 884 F.2d 1064, 1070 (8th Cir. 1989) (Appellant’s Br. at 36),¹⁴ *see also Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379, 381 (E.D. Mich. 1985) (Appellant’s Br. at 36).

Obviously, those cases are irrelevant here. And appellant’s remaining case merely noted that a DTC exception “may” theoretically apply in some prescription-drug cases, but did not analyze or decide the issue because there had been no DTC advertising in that case. *See Garside v. Osco Drug, Inc.*, 764 F. Supp. 208, 211 (D. Mass. 1991) (Appellant’s Br. at 36).

Appellant fails to account for this adverse authority or to advance any reason why Kentucky should depart from the vast majority of other jurisdictions to have considered the issue. For this reason, too, appellant’s attacks on the Court of Appeals’ ruling fail.

D. The Court Of Appeals Correctly Concluded That A Class Action Is Not The Superior Method Of Resolving Appellant’s Claims.

Appellant is also wrong that the Court of Appeals erred in finding that a class action was not the superior method of adjudicating the controversy under CR 23.02(c). (*See* Appellant’s Br. at 37-41.) As the Court of Appeals rightly concluded, resolution of individualized issues would necessitate complex mini-trials for each class member, destroying the intended efficiency of the class device. (Op. at 15.)

Under CR 23.02(c), certification is improper unless the trial court finds “that a class action is superior to other available methods for the fair and efficient adjudication of

¹⁴ *Hill* is no longer good law. In that case, the U.S. Court of Appeals for the Eighth Circuit predicted that the Arkansas Supreme Court would reject the learned-intermediary doctrine in birth-control cases. But when the Arkansas Supreme Court spoke to the issue in a later case, it rejected *Hill*’s prediction and held that the doctrine does apply in such cases. *See West v. Searle & Co.*, 806 S.W.2d 608, 616 (Ark. 1991) (notwithstanding *Hill*, “we are convinced that the stated public policy reasons for the learned intermediary doctrine are present with respect to oral contraceptives”).

the controversy.” As the rule elaborates, “[t]he matters pertinent to the findings include: (i) the interest of members 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; the desirability or undesirability of concentrating the litigation of the claims in the particular forum; the difficulties likely to be encountered in the management of a class action.” C.R. 23.02.

As the Court of Appeals noted, courts in other jurisdictions that have had the opportunity to construe the superiority requirement have concluded that class treatment is inappropriate where “individualized questions would substantially overtake the litigation.” (Op. at 16 (citing *Zinser*, 253 F.3d at 1192, for the proposition that “[w]hen the complexities of class action treatment outweigh the benefits of considering common issues in one trial, class action treatment is not a “superior” method of adjudication”).) That is the case here, in light of the Court of Appeals’ correct determination that “[c]ausation, reliance, and damages are required to be shown on an individual basis.” (Op. at 15.) In order to resolve those central and complicated issues, a class trial would necessarily “fragment into a series of amalgamated ‘mini-trials’ on each.” (*Id.*)

Appellant asserts that the four superiority factors outlined under CR 23.02(c) “each weigh[] in favor of class certification” – including the fourth, addressing “the difficulties likely to be encountered in the management of the class action” – but does not address any one factor particularly. (Appellant’s Br. at 38.) Instead he argues that a class proceeding is superior because the claims are of “relatively small monetary value” and therefore “would not be tried on an individual basis.” (*Id.* at 37-39.) This consideration cannot establish superiority by itself. To the contrary, courts consistently

reject this “small claims” argument where, as here, the need to resolve individualized issues like causation and reliance would render a class trial unmanageable. *See, e.g., In re Light Cigarettes Mktg. Sales Practices Litig.*, 271 F.R.D. 402, 421-22 (D. Me. 2010) (“individual issues of injury, causation, and affirmative defenses” “defeat[ed] the superiority of class treatment”); *Picus v. Wal-Mart Stores, Inc.*, 256 F.R.D. 651, 660 (D. Nev. 2009) (denying class certification even though “each class members’ damages presumably [were] very small” where “the need to determine individual reliance and damages ma[de] manageability of the action difficult” because “the Court would be forced to conduct mini-trials for each class member”). As these courts have explained, even where the plaintiff’s claims are “at the heart of Rule 23(b)(3)’s purpose of ‘vindicat[ing] the claims of consumers and other groups of people whose individual claims would be too small to warrant litigation,’” class treatment is not a superior resolution mechanism where the class proceedings would be plagued with individualized inquiries. *See Light Cigarettes*, 271 F.R.D. at 421-22 (citation omitted).¹⁵

Appellant’s primary authority, *Iliadis v. Wal-Mart Stores, Inc.*, 922 A.2d 710 (N.J. 2007) (Appellant’s Br. at 39-40), also cited by the trial court (R. v. 8 at 1126, Am. Order at 15), is not to the contrary. There, the New Jersey Supreme Court held that the lower court erred in denying certification of a class of aggrieved employees who claimed that the defendant denied them rest and meal breaks and forced them to work off the

¹⁵ In any event, although the small size of any loss suffered might deter suits by many members of the proposed class, the cost of litigation will not be an insurmountable obstacle to those who wish to pursue claims, given the availability of attorneys’ fees under the KCPA. *See* KRS 367.220(3) (“In any action brought by a person under [the KCPA], the court may award, to the prevailing party, in addition to the relief provided in this section, reasonable attorney’s fees and costs.”); *see also Cohn v. Mass. Mut. Life Ins. Co.*, 189 F.R.D. 209, 218-19 (D. Conn. 1999) (rejecting “small value” argument where attorneys’ fees were available under the Connecticut Unfair Trade Practices Act and the consumer protection statutes of many other states).

clock. *Iliadis*, 922 A.2d at 713. In so holding, the court noted that “class actions are often the superior form of adjudication when the claims of the individual class members are small,” but recognized that the putative class members could submit their individual claims to the Wage Collection Division of the Department of Labor pursuant to the New Jersey Wage and Hour Law. *Id.* at 725-26 (internal quotation marks and citation omitted). Thus, its determination of superiority centered on a comparison between class treatment in state court or individual adjudication in an administrative forum. *Id.* Ultimately, it held the “administrative structure to be an inferior forum” for a number of reasons, including its “arduous” framework, its “procedures that favor parties with greater resources and litigation experience,” and its “two-year statute of limitations” which could bar numerous potential class members from pursuing their claims. *Id.* at 726. It was in light of these considerations – completely irrelevant here – that the court found that class treatment was the superior method of resolving their claims. *Id.*

In cases more analogous to this one, courts have refused to follow *Iliadis* because individualized issues presented serious obstacles to a manageable class trial. *See, e.g., Kleinman*, 8 A.3d at 864-65. Most notably, the *Kleinman* court acknowledged *Iliadis*’s observation that the failure to grant class certification “may sound a ‘death knell’” for claims of putative class members where their claims are small. *Id.* at 864. Nonetheless, the court held that it could not “find that a class action [was] a superior form of resolution.” *Id.* at 865. As it explained, “[e]stablishing a ‘causal nexus’ examination would require individualized inquiries into the plaintiffs’ histories and backgrounds.” *Id.* This “lack of predominance create[d] manageability issues,” which prevented the court

from finding that a class action was a superior mechanism for adjudication of plaintiffs' Vioxx claims. *Id.*

For these reasons too, the Court of Appeals correctly found that class treatment of appellant's claims would be improper.

II. REVERSAL OF THE CIRCUIT COURT'S CLASS CERTIFICATION DECISION SHOULD ALSO BE AFFIRMED ON THE ALTERNATIVE GROUND THAT APPELLANT IS NOT AN ADEQUATE CLASS REPRESENTATIVE.

Even if the Court of Appeals committed any error in its analysis, the Court should still reverse the Circuit Court's class certification decision because appellant is an inadequate class representative. It is well within this Court's discretion to affirm the Court of Appeals "upon different grounds" from those stated in its order. *Minix v. Roberts*, 350 S.W.3d 449, 450 (Ky. 2011) (affirming dismissal of Appellant's petition "upon different grounds" from those stated by the Court of Appeals); *see also J.A.S. v. Bushelman*, 342 S.W.3d 850, 854 (Ky. 2011) ("Although, we affirm the Court of Appeals['] [denial of Appellant's writ], we do so upon different grounds."); *Trico Cnty. Dev. & Pipeline v. Smith*, 289 S.W.3d 538, 539 (Ky. 2008) ("We affirm although our reasoning differs from that of the Court of Appeals"); *Greene v. McFarland*, 43 S.W.3d 258, 259 (Ky. 2001) (similar). Thus, the fact that the Court of Appeals held that it "did not need to address whether [appellant] is an adequate or typical representative of the class" in light of its predominance/superiority ruling (Op. at 16), does not prohibit this Court from affirming the Court of Appeals' order because the adequacy requirement is not met.

The law is well settled that a proposed class representative is inadequate if his claims suffer from unique weaknesses that compromise the representative's ability to

fairly act as a surrogate for absent class members. *See Broussard v. Meineke Disc. Muffler Shops, Inc.*, 155 F.3d 331, 338 (4th Cir. 1998). This is so because “[a] class representative should not be permitted to impose . . . a disadvantage on the [absent] class” members that they would not face if they were to try their claims individually. *Beck v. Maximus, Inc.*, 457 F.3d 291, 297 (3d Cir. 2006) (internal quotation marks and citation omitted). While appellant suggests that Merck’s concerns regarding the absent class members’ right to fair representation should be “viewed skeptically” (Appellant’s Br. at 41), the U.S. Supreme Court has recognized that defendants have a legitimate interest in challenging the adequacy of a proposed class representative in order to ensure that absent class members cannot later attack any classwide verdict in favor of the defendants on this ground. *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 805 (1985). Accordingly, Merck has the right to demand that a proposed class representative be so typical of the absent class members that he can fairly stand in their place to litigate their claims.

Here, the Circuit Court’s Amended Order concluded that appellant is an adequate class representative because he “possesses the same interests, has suffered the same injuries, [and] seeks the same economic redress” as the class members who were directed “to see their physicians for consultation regarding their use of” Vioxx and “incurred expenses related to these consultations.” (R. v. 8 at 1123-24, Am. Order at 12-13.) But this conclusion does not consider any of the evidence that Merck put before the Circuit Court on adequacy.

As Merck explained in its briefing below, appellant seeks to represent all Kentucky residents who obtained a medical consultation when Vioxx was withdrawn from the market (or still intend to seek one more than eight years later). But Mr. Ratliff:

- Did not know his lawsuit involved a claim for an alleged medical consultation the first time he was asked about it at his deposition (*see* R. v. 3 at 304, 307, Ratliff Dep. 32:16-17; 36:14-18), and only testified that he was seeking such relief after a break in the deposition (R. v. 3 at 315, Ratliff Dep. 52:11-23);
- Could not provide any details about the examination, including the name of the doctor who supposedly examined him, what tests were performed, where the tests allegedly took place, or when the examination occurred (*see* R. v. 3 at 304, 315-16, Ratliff Dep. 30:2-21; 52:24-53:24); and
- Has no receipts from the supposed examination, which he claims he paid for in cash (R. v. 3 at 316, Ratliff Dep. 53:13-19).

The Circuit Court's Amended Order utterly ignores the fact that Mr. Ratliff cannot possibly prove such a claim to a jury – rendering him a highly inadequate class representative. *See Solo v. Bausch & Lomb Inc.*, MDL No. 1785, Nos. 2:06-MN-77777-DCN, 2:06-CV-02716-DCN, 2009 U.S. Dist. LEXIS 115029, at *19-22 (D.S.C. Sept. 25, 2009) (denying class certification where proposed class representative offered “inconsistent testimony” about her claimed purchase and discard of allegedly defective contact lens solution, raising questions about whether she was even a member of the proposed class); *see also Wesley v. Cavalry Invs., LLC*, No. 05-3523, 2006 U.S. Dist. LEXIS 69561, at *20 (E.D. Pa. Sept. 27, 2006) (finding that proposed representative was inadequate because “it is unclear whether she even falls within the class as defined”).

Appellant argues that any issues concerning his credibility or the merit of his particular claims are irrelevant to the adequacy inquiry because the Court must assume that his substantive allegations are true and that his claims have merit at the class certification stage. (Appellant's Br. at 42.) But it is well recognized that class “[c]ertification and merits cannot always be separated,” especially when evaluating whether the named plaintiff can fairly represent the absent class members. *Randall v. Rolls-Royce Corp.*, 637 F.3d 818, 821 (7th Cir. 2011) (affirming denial of class

certification on adequacy grounds). After all, “named plaintiffs who are subject to a defense that would not defeat unnamed class members are not adequate class representatives, and adequacy of representation is one of the requirements for class certification.” *Id.* at 824. Accordingly, a court will often have to delve into the merits of the named plaintiff’s allegations to determine whether his claims are “significantly weaker than those of some (perhaps many) other class members.” *Id.*¹⁶

That is precisely the case here. Even a cursory review of the facts underlying appellant’s claims reveals that his case is subject to substantial weaknesses that would make it manifestly unfair for him to stand in the place of the absent class members. Indeed, it is hard to imagine a better example of such an unfit class representative than someone who seeks to recover for a medical consultation, even though he does not know the name of the doctor he supposedly saw or the address of the facility where the consultation supposedly took place and has no receipt or medical records documenting the alleged visit. It would be unfair both to Merck and to the putative class members to allow appellant to stand in the place of Vioxx users throughout the Commonwealth, whose claims will rise and fall on Mr. Ratliff’s ability to prove that he lost money as a result of paying for a medical consultation after Vioxx was withdrawn. For this reason too, the Court of Appeals ruling should not be disturbed.

CONCLUSION

For the foregoing reasons, the Court of Appeals decision should be affirmed.

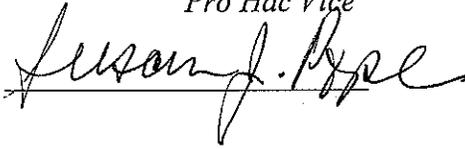
¹⁶ As noted previously, the Supreme Court made clear in *Wal-Mart* that a court must consider the merits to the extent they overlap with class certification requirements. 131 S. Ct. at 2552 n.6; *see also supra* note 8.

Respectfully submitted,

SUSAN J. POPE
FROST BROWN TODD LLC
250 W. Main Street, Suite 2800
Lexington, KY 40507-1749
(859) 231-0000
Counsel for Appellee

JOHN H. BEISNER
JESSICA DAVIDSON MILLER
SKADDEN, ARPS, SLATE, MEAGHER
& FLOM LLP
1440 New York Avenue, NW
Washington, DC 20005
(202) 371-7000
Of Counsel for Appellee
Pro Hac Vice

BY:

A handwritten signature in cursive script that reads "Susan J. Pope". The signature is written over a horizontal line.

APPENDIX LIST

Appendix A - <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafety/InformationforPatientsandProviders/ucm106201.pdf> (visited Mar. 7, 2013)

Appendix B - Order, AM-11-09T3 (N.J. Super. App. Div. Oct. 2, 2009) in *Kleinman v. Merck & Co.*, 8 A.3d 851 (N.J. Super. Law Div. 2009), *motion for leave to appeal denied*

Appendix C - Order, No. M-504 (N.J. Jan. 14, 2010) in *Kleinman v. Merck & Co.*, 8 A.3d 851 (N.J. Super. Law Div. 2009), *motion for leave to appeal denied*

LEXLibrary 0106603.0529378 558935vvvvv1