IN THE SUPREME COURT OF MISSISSIPPI

NO. 2002-CA-00736-SCT

JANSSEN PHARMACEUTICA, INC. AND JOHNSON & JOHNSON

v.

ROBERT BAILEY, ROSIE LEE BELL, BARBARA BISHOP, CONNIE COLEMAN, MARTHA EVANS, MACY B. JOHNSTON, BY AND THROUGH HER NATURAL PARENTS AND NEXT FRIENDS, MILTON JOHNSTON, TRACY JOHNSTON, MAURICE LANDERS, ELSIE QUEEN, JANIS WHITE AND MARY WILLIAMS

DATE OF JUDGMENT:	09/29/2001
TRIAL JUDGE:	HON. LAMAR PICKARD
COURT FROM WHICH APPEALED:	CLAIBORNE COUNTY CIRCUIT COURT
ATTORNEYS FOR APPELLANTS:	DONNA BROWN JACOBS CHRISTY D. JONES KARI LOUISE FOSTER JOHN C. HENEGAN ROBERT L. JOHNSON, III WALTER ESTES DELLINGER RICHARD B. GOETZ CHARLES C. LIFLAND ANITA K. MODAK-TRURAN
ATTORNEYS FOR APPELLEES:	JAMES D. SHANNON ELISE BERRY MUNN KELLEY MITCHELL BERRY LONNIE D. BAILEY JAMES E. UPSHAW MARK C. CARROLL RENEE C. HARRISON EDWARD BLACKMON, JR. T. MARK SLEDGE JAMES B. GRENFELL
NATURE OF THE CASE:	CIVIL - PERSONAL INJURY
DISPOSITION:	REVERSED AND REMANDED - 05/13/2004
MOTION FOR REHEARING FILED:	

MANDATE ISSUED:

EN BANC.

CARLSON, JUSTICE, FOR THE COURT:

¶1. This case involves the prescription medication Propulsid, which is used to treat gastroesophageal reflux disease. On July 6, 2000, 155 plaintiffs filed this action against Janssen Pharmaceutica and Johnson & Johnson (hereinafter collectively "Janssen") in Jefferson County Circuit Court, alleging injuries caused by Propulsid. The plaintiffs also sued local pharmacies, McDaniel Pharmacy and Bankston Rexall, but the trial court directed verdicts in their favor when the plaintiffs failed to introduce evidence against the pharmacies at trial. The Appellees in this case (hereinafter "Plaintiffs") include ten of those original 155 plaintiffs who were designated as a "trial group" by Plaintiffs' counsel.

¶2. Venue was transferred from Jefferson County to Claiborne County, and trial commenced on September 4, 2001, with the Hon. Lamar Pickard, presiding. The Plaintiffs asserted two claims: (1) that defendants had inadequately warned of Propulsid's potential side effects, and (2) that defendants had negligently misrepresented Propulsid's benefits. At the close of the trial, the trial court granted Janssen a directed verdict on the misrepresentation claims because the Plaintiffs offered no proof that they nor they physicians relied on any misrepresentation made by Janssen. The jury awarded compensatory damages of $10 million per plaintiff ($100 million total). The trial court directed a verdict for Janssen on the Plaintiffs' punitive damages claims. Janssen's post-trial motion for a remittitur was granted, and the trial court reduced the total amount of damages to $48 million. On March 28, 2002, the trial court entered a Final Judgment pursuant to Miss. R. Civ. P. 54(b). Janssen

has now perfected this appeal before this Court. Because of our recent decision in ***Janssen Pharmaceutica, Inc., v. Armond***, 866 So.2d 1092 (Miss. 2004), our mandated course of action today is clear.[1]

FACTS AND PROCEEDINGS IN THE TRIAL COURT

Background:

¶3. Propulsid is a prescription medication used to treat gastroesophageal reflux disease (GERD), the abnormal backflow of stomach acids into the esophagus. GERD's main symptom is heartburn caused by acid irritating the esophagus, but its sufferers often experience chest pain, cough and nocturnal asthma attacks. Chronic GERD can cause esophageal ulcers, scarring of the esophageal lining and constriction of the esophageal pathway. GERD may also damage the vocal chords, lungs and even the teeth. Left untreated, GERD can lead to esophageal cancer in both children and adults.

¶4. Propulsid, which is also known by its chemical name "cisapride", is a prokinetic[2] agent causing it to work differently from other treatments for GERD. While other medications only treat acid and do not block backflow, Propulsid, a motility drug, works by tightening the opening between the esophagus and the stomach increasing the rate at which both the esophagus and stomach move food through the body.

¶5. Janssen Pharmaceutica, Inc., a New Jersey and Belgium-based drug company owned by the New Jersey-based Johnson & Johnson, developed Propulsid in Europe in the 1980s.

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[1] ***Armond*** was decided on February 19, 2004, and inasmuch as no motion for rehearing was filed, the mandate issued on March 11, 2004.

[2] "Pro" meaning for and "kinetic" meaning stimulus. A drug used to stimulate the stomach to prevent reflux from coming back into the stomach.

In 1988, after eight years of research, European regulators approved Propulsid as a prescription medication for GERD and other motility disorders in both adults and children.

¶6. Propulsid first became available in the United States in 1983 in an investigational program approved by the U.S. Food and Drug Administration (FDA), which exclusively regulates the availability of prescription drugs under the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*. In July 1993, after more clinical trials, the FDA approved Propulsid as a "safe and effective" treatment for the symptomatic relief of nocturnal heartburn due to GERD in adults. *See id.* §§ 355(d), 393(b)(2)(B).

¶7. By law, the labeling of every prescription drug must include a package insert listing known side effects. 21 C.F.R. §§ 201.56-201.57 (2002). The FDA must approve the content of such inserts, which communicate to prescribing physicians the essential information about the medication's benefits and risks. When new side effects come to light, the FDA may require the manufacturer to revise the package inserts. ***Id.*** § 201.57(e). For significant revisions, the FDA may also require manufactures to disseminate "Dear Doctor" letters giving prompt and particularized notice of the new information. 21 U.S.C. § 355(e); 21 C.F.R. § 200.5.

¶8. Propulsid's initial U.S. package insert was issued in July 1993. After reviewing a 1992 report issued by two clinicians in the British Medical Journal which stated that seven patients under treatment with Propulsid had experienced tachycardia[3] which ended when the patients discontinued the drug but in three instances reappeared when they restarted the drug, the

[3]Tachycardia refers to a racing heartbeat.

FDA concluded that although the risk of adverse heart events appeared "very low", Janssen was required to disclose these events in their initial U.S. labeling. The "ADVERSE REACTIONS" section of the 1993 package insert accordingly included a statement disclosing the known risk.

¶9. In 1994 Janssen received reports that two patients taking Propulsid in conjunction with high doses of the anti-fungal medicine ketoconazole had experienced a rare but potentially serious heart arrhythmia known as "torsades de pointes."[4] After reporting these events to the FDA, Janssen initiated a study of possible interactions between Propulsid and ketoconazole. The study confirmed that ketoconazole inhibited production of the liver enzymes that break down and eliminate Propulsid from the body, increasing the drug's normal concentration in the body as much as eight-fold. The study also suggested that in some patients, this interaction could lengthen the patient's QT-interval, or the time it takes the heart to reset itself between beats as measured on an EKG.

¶10. After reviewing this information and other post-marketing reports of adverse cardiac events with the FDA, Janssen issued a new package insert and a "Dear Doctor" letter in February 1995 which warned that in rare cases, patients taking Propulsid had experienced "serious cardiac arrhythmias, including ventricular arrhythmias and torsades de pointes associated with QT prolongation." The new FDA-approved labeling contraindicated use of Propulsid with ketoconazole and other drugs that Janssen believed would likely exhibit similar interactions.

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[4]Torsades de pointes is a very rapid and uneven beating of the ventricles, the lower chambers of the heart. If the ventricles cannot effectively fill with blood, the patient may suffer a sudden drop in circulation.

¶11. The "WARNINGS" section and a revised "ADVERSE REACTIONS" section noted that "most" of the reported events had involved patients who took "multiple other medications and had preexisting cardiac disease or risk factors for arrhythmias." The "WARNINGS" section also stated that some of the events had involved patients with no known cardiac histories. A revised "PRECAUTIONS" section advised that physicians should carefully weigh the benefits against the risks before prescribing Propulsid to patients with preexisting risk factors for QT prolongation.

¶12. In October 1995, Janssen again revised the package insert to expand the list of potentially interactive drugs. Janssen also reported in the "WARNINGS" and "ADVERSE REACTIONS" sections that some rare cardiac events associated with Propulsid had been fatal. This warning was emphasized in a separate "Boxed Warning" printed at the top of the package insert. Janssen also mailed out "Dear Doctor" letters highlighting the revised and expanded warnings.

¶13. In March 1998, Janssen and the FDA again reviewed recent adverse reports about Propulsid, and it was agreed that Janssen would issue a new package insert which reinforced and expanded previous warnings. The new FDA-approved labeling, which was issued in June 1998, carried an expanded "Boxed Warning" that contraindicated Propulsid, not only for patients taking potentially interactive drugs, but also for patients otherwise predisposed to QT prolongation, taking other QT prolonging drugs or having conditions potentially predisposing them to arrhythmias. The package insert similarly expanded the warnings found in the "CONTRAINDICATIONS," "WARNINGS" and "PRECAUTIONS" sections and further advised that because of the risk of serious ventricular arrhythmias, physicians should

administer Propulsid only after other therapies had failed. These changes were also highlighted in a "Dear Doctor" letter mailed to over 800,000 physicians and pharmacists.

¶14. In June 1999, Janssen issued another "Dear Doctor" letter revising the package insert to contraindicate Propulsid for patients with family histories of congenital long QT syndrome and those with clinically significant bradycardia.[5] At the FDA's request, another "Dear Doctor" letter was issued in January 2000 which revised the package insert advising physicians not to prescribe Propulsid to any patient whose QT interval exceeded 450 milliseconds.

¶15. In March 2000 after further consultation with the FDA, Janssen announced its decision to make Propulsid available only through an investigational limited access program. Because many physicians continued to prescribe Propulsid in contraindicated situations, Janssen and the FDA determined that a limited access program for patients who had exhausted other treatment options and did not have contraindicated risk factors would be the most effective way to ensure appropriate use.

Plaintiffs:

¶16. At the time of trial, Martha Evans was a sixty-six-year-old resident of Okolona, Chickasaw County, Mississippi. Evans retired from nursing in February 1995 at the age of sixty-two. In August 1999, Evans's family physician, Dr. Roger Ratliffe, noticed she was beginning to lose weight. Dr. Ratliffe referred Evans to Dr. Alan Greenwald in Amory. Dr. Greenwald prescribed Propulsid for Evans on December 7, 1999, after performing an upper

[5]Bradycardia refers to a relatively slow heartbeat.

and lower GI. At her follow-up visit, Dr. Greenwald increased her dosage of Propulsid from 10 milligrams three times a day to 20 milligrams three times a day.

¶17. Dr. Greenwald performed a colonoscopy on Evans on February 15, 2000, in which he detected premature heartbeats and recommended as a precaution that Evans discontinue Propulsid. Evans began having chest pains and shortness of breath later that night. An EKG the next day revealed that she had suffered from a heart attack. She was admitted to the intensive care unit at Gilmore Memorial Hospital in Amory and was transferred two days later to North Mississippi Medical Center. A heart catherization was performed, but no blockage was found.

¶18. Mrs. Evans suffered another heart attack in April 2000. She was hospitalized again at NMMC where she received a temporary pacemaker and then a defibrillator. Although Mrs. Evans had no further heart problems, she continued to regularly visit her cardiologist, Dr. Karl Crossen.

¶19. Mrs. Evans's family physician had been treating her for high blood pressure and arthritis since 1990. She was also diagnosed with sarcoidosis in 1990 or 1991, which is an incurable immunological disease which affects the body's organs. Initially Evans's skin and lungs were affected by sarcoidosis which, in turn, affected her breathing. Mrs. Evans had also been diagnosed with interstitial lung disease, an enlarged heart and Schatzki's Ring, a condition related to her acid reflux.

¶20. Dr. Greenwald testified that he could not state that Propulsid caused Evans's injuries. He also testified that on the day of Evans's colonoscopy, Fleet's phosphorous soda could

have caused an electrolyte shift. He also testified that he noticed irregular heart beats before the procedure.

¶21. Dr. Karl Crossen, the doctor who inserted Evans's defibrillator, testified that Evans was not on Propulsid while she was under his care. He testified that she should have been off of Propulsid the four days prior to her colonoscopy pursuant to her prescription; therefore, the drug should have been out of her system. Dr. Crossen testified that Propulsid did not cause Evans's arrhythmias or any of her other problems.

¶22. The trial judge did not remit any of Evans's damages; therefore, she was awarded $10 million.

¶23. Macy Beth Johnston was three years old at the time of the trial. Johnston lived with her family in Greenville, Washington County, Mississippi. She was first prescribed Propulsid for her reflux on October 2, 1997, when she was seven days old by Dr. Nathan Bradford. The Propulsid immediately helped with her reflux. Upon her discharge from Delta Regional Medical Center ("DRMC") in Greenville, Johnston was required to wear an apnea monitor which sounded alarms both when Johnston stopped breathing and when her heart rate exceeded 200 beats per minute. Johnston was admitted to DRMC again on October 22, 1997, due to frequent episodes of tachycardia. Dr. Bradford discontinued Johnston's Propulsid when she was discharged on October, 23, 1997, with a diagnosis of "supraventricular tachycardia related to cisapride." She was also prescribed flecainide, an anti-arrhythmia medication, to control her rapid heartbeats.

¶24. Johnston was hospitalized again at the University of Mississippi Medical Center in Jackson on October 27, 1997, because her apnea alarm continued to sound. Dr. Ted Sigrest

performed an EKG which did not show any heart rhythm disturbances. Dr. Sigrest put Johnston back on Propulsid the day before he discharged her from UMC.

¶25. On May 13, 1998, Johnston collapsed at home and was taken to the ER. Her EKG showed a QT level of 568.[6] Dr. Bradford diagnosed Johnston with atrial flutter with rapid conduction. Flecainide was also discontinued after toxic levels were found in her system.

¶26. On June 7, 1998, Johnston was taken to the ER again after collapsing. Dr. Bradford diagnosed her with torticollis.[7] Johnston was taken off Propulsid in June 1998 after her reflux improved. As of September 1999, Johnston was no longer taking any heart medication.

¶27. Dr. Nathan Bradford testified that he did not believe Johnston's arrhythmias were characteristic of those associated with Propulsid. Dr. Bradford further testified that Johnston did not suffer from any heart damage. He stated that he discontinued Johnston's use of Propulsid because of what he had heard about it in regards to potential heart problems. He testified that he did not attribute any of Johnston's current conditions to Propulsid.

¶28. Dr. David Braden testified that the Flecainide which was given to Johnston in May 1998 possibly caused her arrhythmias. There was evidence that there was a toxic level in her system. He also testified that there was no permanent injury and there was no future injury. Dr. Paul Parker testified that Propulsid did not cause Johnston's supraventricular tachycardia

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[6]This was Johnston's only elevated QT interval.

[7]Also known as "wryneck." This condition caused by muscle spasms causes the neck to twist resulting in an abnormal carrying of the head.

or any other injury. Dr. Parker also testified that her reflux improved considerably with the use of Propulsid.

¶29. After the trial judge's remittitur, Johnston was awarded $7.5 million.

¶30. At the time of trial, Barbara Bishop was a seventy-eight-year-old resident of Cleveland, Bolivar County, Mississippi. She retired from nursing in 1982. Beginning in 1946, Bishop suffered from ulcers, female problems, an abdominal aneurism and high blood pressure. She also smoked for forty years. Before using Propulsid, Bishop was diagnosed with hardening of the arteries, aortic arteriosclerosis and arteriosclerotic heart and vascular disease.

¶31. In 1996 Bishop was prescribed Propulsid by Dr. Barry Sullivan for nighttime heartburn as a result of GERD. In August 1998, Bishop was hospitalized with stroke symptoms. She testified that her cardiologist, Dr. James Crosthwait, informed her that she had suffered two heart attacks and two strokes. While she was hospitalized, Bishop was diagnosed with an abdominal aortic aneurism which was repaired in October 1998. Dr. Sullivan discontinued Bishop's Propulsid use in 2000 after learning of her heart problems.

¶32. Dr. Charles O'Mara, a vascular surgeon who performed carotid artery surgery on Bishop in 1998, testified that Bishop had a significant 50% blockage in her carotid artery. He also testified that he was not aware of a connection with Bishop's problems and her Propulsid use. He determined the cause of her blockage to be atherosclerosis, a cholesterol related deposition of fibrous materials, cholesterol and calcium inside the arteries.

¶33. After the trial judge's remittitur, Bishop was awarded $5.5 million.

¶34. At the time of trial, Janis White was a fifty-eight-year-old resident of Fayette, Jefferson County, Mississippi. Although she retired in 1989, she continued to work part time at a beauty salon. White was prescribed Propulsid by Dr. Yoshinobu Namihira in May 1997 for indigestion and heartburn. Dr. Namihira also diagnosed her with ulcers and reflux. She continued using Propulsid until early 2000 when Dr. Leslie England suggested she discontinue its use due to her fluttering heart. White claims to have suffered from heart palpitations and an increased level of anxiety since beginning her prescription of Propulsid. She also testified that her blood pressure has gotten worse since taking Propulsid.

¶35. White previously suffered from problems with her nerves in 1974 and 1985. Although she testified that she was again having problems with her nerves, at the time of trial she was not taking medications for these problems. In 1973 she complained of dizziness and fatigue and was diagnosed with vascular hypertension of her left eye. She had suffered from high blood pressure since the 1980s. In 1981 she was diagnosed with hypertensive cardiovascular disease. In 1985 she had an abnormal EKG which showed a ventricular block.

¶36. In the 1990s, White complained of chest pain related to indigestion. She also complained of dizziness, vomiting and heart flutters and was prescribed nitroglycerin. In August 1996 she was diagnosed by Dr. Shanti Pandey with chronic obstructive pulmonary disease, a progressive, irreversible breathing condition. She complained of not being able to breath, so she was given an inhaler. However, she testified she thought the inhaler was for her cold. She is presently seeing a cardiologist, Dr. Aamer Shabbir, who was referred by Dr. Bills. On August 4, 2000, Dr. Shabbir conducted an EKG which was normal.

¶37. Dr. Yoshinobu Namihira, a board certified gastroenterologist, testified that White never complained of symptoms related to Propulsid while she was under his care. He further testified that he took White off Propulsid when she was on Bioxin and Diflucan pursuant to the interactions listed on the labels. Dr. Aamer Shabbir, White's cardiologist who was referred by Dr. Bills, testified that White's congestive heart failure was caused by hypertension or coronary artery disease, not Propulsid.

¶38. After the trial judge's remittitur, White was awarded $2.5 million.

¶39. At the time of trial, Robert Bailey was a seventy-nine-year-old resident of Lorman, Jefferson County, Mississippi. He was medically discharged from the Army due to nerves in approximately 1963. Bailey suffered a heart attack in the early 1960s. He still suffered from heart trouble and had been diagnosed as schizophrenic. Bailey also suffered from shortness of breath, chest pain and blackouts before he took Propulsid, but he claimed his symptoms got worse after taking Propulsid.

¶40. Bailey was first prescribed Propulsid in 1995 by Dr. Johnny Bills. He was also prescribed Propulsid by Dr. Willie McArthur and the VA Hospital. However, he only had three prescriptions filled. He filed this lawsuit after reading about the effects of Propulsid in the newspapers and hearing about it on the news. Bailey admitted that Propulsid did not cause his problems, but that it only made them worse.

¶41. Bailey had suffered from high blood pressure since 1981. He had suffered from shortness of breath and chest pain for twenty to thirty years. He had complained of fainting and dizziness for the past fifteen years. He was diagnosed with an enlarged heart and irregular heart beats twenty years ago. In 1961 Bailey was diagnosed with a gastric ulcer. In

1963 Bailey was diagnosed with anxiety. He had been disabled for thirty-eight years. In 1991 Bailey had prostrate surgery.

¶42. Bailey had three heart attacks prior to taking Propulsid. He was a smoker for fifteen years, and heart problems and hypertension run in his family. He had been on numerous medications for the past forty years. Bailey testified that he saw a heart specialist at the VA. In 1995 he had two normal EKGs with normal QT intervals. He stopped taking Propulsid because he did not think it was working. He had not had any heart attacks since he stopped taking Propulsid. Dr. Randolph Tillman, a board certified internist and gastroenterologist, testified that he did not believe Propulsid caused Bailey's problems.

¶43. After the trial judge's remittitur, Bailey was awarded $ 2.5 million.

¶44. At the time of trial, Elsie Queen was a sixty-year-old resident of Fayette, Jefferson County, Mississippi. Queen retired in 1987 after she became disabled. In 1987 she began having problems getting around. She also suffered from shortness of breath, heart and chest pains, diabetes and dizziness. She was told by her doctors to exercise and lose weight. She was first prescribed Propulsid in April 1996 by Dr. Namihira. She testified that Propulsid worked in the beginning. She stopped taking Propulsid in 1999 after her condition continued to worsen. She contended that Propulsid had caused her to suffer from shortness of breath, dizziness, depression, diabetes, prolonged QT intervals. She constantly wore an oxygen mask and was also confined to a wheelchair.

¶45. In 1964 Queen suffered from high blood pressure and chest pains. In 1988 it was determined that she had 98% blockage in her arteries. She was diagnosed with coronary artery disease, high cholesterol, and was told she must lose weight. In July 1988 she had

quadruple bypass surgery. In 1991 she was hospitalized for shortness of breath and chest pain. She had been using an inhaler since the 1980s. In 1992 she was hospitalized again and was fitted for a C-pack, which is a mask worn during sleep to aid with sleep apnea. In 1994 she was hospitalized because she could not breath. She was placed on a ventilator in ICU for a couple of weeks. She was also diagnosed with irregular heartbeats and eventually congestive heart failure. She was also hospitalized for her heart in 1996, 1997 and 1999. Her cardiologist was Dr. Malcolm Taylor. Queen remained on numerous medications for all her ailments.

¶46. Dr. Yoshinobu Namihira testified that Queen never told him Propulsid caused any of her injuries. Dr. Namihira also testified that Queen improved with Propulsid. The last time Dr. Namihira saw Queen was June 1997. She had cancelled several appointments since then. Dr. Alphonse Reed, a board certified internist, testified that Queen had serious problems prior to her use of Propulsid. He also testified that Queen never complained to him about symptoms related to Propulsid.

¶47. Dr. Willie McArthur,[8] a family physician, testified that because of Queen's heart disease prior to Propulsid, she should never have been put on Propulsid to begin with. However, he did not learn of these warnings until 2000 because he testified that he did not make it a practice to read "Dear Doctor" letters or updated package inserts.

¶48. After the trial judge's remittitur, Queen was awarded $4 million.

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[8]Dr. McArthur uses 420 as a normal QT level when most other doctors use 440-450 as normal. Janssen advised physicians to use 450 as a normal QT level.

¶49. At the time of trial, Mary Williams was a fifty-two-year-old resident of Fayette, Jefferson County, Mississippi. Williams was prescribed Propulsid by Dr. Namihira in 1995 for "stomach problems." Dr. Namihira diagnosed Williams with gastritis, reflux and hiatal hernia. Williams testified that during her time on Propulsid, she did not complain of dizziness, lightheadedness or heart flutters. She discontinued her Propulsid use in December 1999 after she read an article about it. She thought that the medicine helped at one time, but at trial she stated that she was then not sure if it had really helped her condition. After taking Propulsid, Williams claimed that she felt lightheaded and suffered from heart flutters, chest pains and dizziness.

¶50. In 1989 Williams suffered from chest pains, high blood pressure and reflux esophagitis. In December 1990 she complained of anxiety and was prescribed Xanax. Williams was hospitalized in April 1994 for chest and stomach pains. An EKG was performed which was normal showing a QT interval of 407. She was diagnosed with a stomach infection and indigestion by Dr. McArthur. In March 2000 Williams's QT interval was 455, in June 2000 her QT interval was 504 and in April 2001 her QT interval was 457. Another EKG was performed in June 2000 which was within normal limits.

¶51. Dr. Namihira testified that she never told him Propulsid was causing any of her injuries. Although Williams was improving on Propulsid, Dr. Namihira took her off after the news release regarding EKGs.

¶52. Dr. McArthur, Williams primary care physician, testified that Williams suffered from anxiety and high blood pressure. He prescribed Reglan to treat Williams reflux and

dyspepsia. Dr. McArthur testified that he believed Williams's injuries were caused by Propulsid.

¶53. After the trial judge's remittitur, Williams was awarded $2.5 million.

¶54. At the time of trial, Connie Coleman was a fifty-three-year-old resident of Lorman, Jefferson County, Mississippi. Coleman was prescribed Propulsid in 1994 by Drs. Reed, Headley and Barnes. Coleman stopped taking Propulsid in February 2000 after she saw a report on the local news. Coleman claimed she developed problems only after taking Propulsid. She complained of dizziness, headaches, stomach problems, heart fluttering, gas, constipation, vomiting and anxiety.

¶55. Coleman had never been hospitalized. She had never seen a cardiologist, nor had any of her doctors referred her to a cardiologist. An EKG performed in March 2000 revealed her QT interval to be 450. Coleman testified that she was at the time seeing a psychiatrist due to mental problems caused by her taking all of her medication.

¶56. Dr. David Headley testified that Coleman never complained to him about any symptoms related to her Propulsid use.

¶57. Dr. Willie McArthur, who first began treating Coleman on June 22, 2001, testified that Coleman suffered from prolonged QT intervals. He also stated that her anxiety was not present prior to taking Propulsid. He testified her condition was related to her Propulsid use. Dr. McArthur has not referred her to a cardiologist even though he testified that she had heart problems related to an EKG taken in 2000. He also agreed that a majority of her symptoms were effects of anxiety as found in the PDR.

¶58. After the trial judge's remittitur, Coleman was awarded $2.5 million.

¶59. At the time of trial Rosie Lee Bell was a fifty-one-year-old resident of Lorman, Jefferson County, Mississippi. Bell was prescribed Propulsid in March 1994 by Dr. Reed for heartburn.

¶60. Bell retired in 1994 due to anxiety and nerve problems. She was on disability in 1994 for high blood pressure and diabetes. She suffered from occasional heart flutters, dizziness, mild heartburn and obesity. In April 1994, she was hospitalized for rapid heart beats. Her EKG performed while she was in the hospital showed an elevated QT level. She was hospitalized twice more and was diagnosed with cardiac arrhythmia. In 1996 she was diagnosed with an enlarged heart. In 1998 Dr. Reed took Bell off Propulsid and prescribed Prevacid; however, Dr. Yoshinobu Namihira put her back on Propulsid. In 1999, she had two heart racing episodes. Dr. Namihira took her off Propulsid in May or June of 1999 because he had heard on the local news that Propulsid had been taken off the market.

¶61. In 1971 Bell suffered from anxiety and heart flutters. In 1988 she complained of rapid heart beats twice which were confirmed by an abnormal EKG. She was diagnosed with atrial tachycardia. However, she never saw a cardiologist. In 1994 her disability application, which was completed by Dr. Bills, showed that she suffered from heart palpitations, dizziness, depression, arterial narrowing, rapid heart rate and an enlarged heart. In 2000, Bell had a borderline normal EKG of 452. At the time of trial, Bell was taking numerous medications for blood pressure, high sugar, hot flashes, anxiety.

¶62. Dr. Namihira testified that he never told Bell that her injuries were caused by Propulsid. He discontinued her Propulsid use because her condition had improved to the point to where it was safe to discontinue. He testified that he had never diagnosed Bell with

a prolonged QT interval. Dr. Reed testified that Bell did not suffer from side effects of Propulsid. Dr. Johnny Bills testified that he did not refer Bell to a cardiologist because he was accustomed to dealing with cardiac diseases.

¶63. After the trial judge's remittitur, Bell was awarded $5.5 million.

¶64. At the time of trial, Maurice Landers was a sixty-five-year-old resident of Port Gibson, Claiborne County, Mississippi. Landers retired in 1994 from the Jefferson County Schools. In December 1993 he was prescribed Propulsid by Dr. Namihira for heartburn due to reflux. Although he stated that Propulsid helped some, Landers stopped taking Propulsid in 2000 after Dr. Namihira told him the drug was being taken off the market.

¶65. Landers was diagnosed with diabetes when he was thirty-five years old. He smoked for approximately 30 years, and he suffered from high blood pressure. In 1989 he had bypass surgery performed on his legs. Landers suffered from a stroke in 1993, prior to his being prescribed Propulsid. He complained of dizziness and fatigue after the stroke. In 1996 he complained of shortness of breath to two doctors who could find nothing wrong with his lungs. Landers was diagnosed with congestive heart failure by Dr. Headley who also prescribed him Propulsid. He also stated that he suffered from anxiety. He testified that at least three different doctors prescribed sleeping pills to help him sleep. In 1997 he had a heart attack. Dr. Paul Pierce took him off Propulsid; however, Dr. Namihira put him back on. He did see Dr. Malcolm Taylor, a cardiologist, who said he had congestive heart failure. Dr. Taylor left him on Propulsid.

¶66. Landers heard from a coworker at school that Propulsid was bad, so he attended a meeting put on by lawyers where he was referred to Dr. Bills. Landers testified that

Propulsid most likely did not cause his heart problems; however, he claimed that the media stated Propulsid caused heart attacks.

¶67. Dr. Headley testified that he had been treating Landers since 1985 for diabetes, high blood pressure and related complications. He testified that Landers suffered a stroke in 1993. Dr. Headley testified that Landers never complained that Propulsid caused his problems. Dr. Headley also testified that Landers was not diagnosed by himself, nor by other doctors, with heart problems caused or exacerbated by Propulsid. He referred Landers to a cardiologist who found coronary artery disease and blockages. He did not remember Dr. Pierce recommending Landers being taken off Propulsid; therefore, Dr. Headley continued to prescribe Propulsid to Landers. Dr. Headley testified that neither Landers's motility problems nor his taking Propulsid caused his heart attack.

¶68. Dr. Namihira testified that Landers never complained that Propulsid was the cause of his injuries. From the beginning, Dr. Namihira believed that Landers's diabetes, smoking and weight were significant contributing factors to his gastrointestinal problems. Dr. Namihira prescribed Propulsid to Landers on March 14, 1994, for GERD and gastroparesis. Dr. Namihira testified that Landers did not experience any injuries as a result of Propulsid. He discontinued its use because of the news release regarding EKGs.

¶69. Dr. Charles O'Mara testified that Landers's stroke was not caused by Propulsid, and Propulsid did not cause any of his vascular problems.

¶70. After the trial judge's remittitur, Landers was awarded $5.5 million.

DISCUSSION

¶71. For sake of clarity, the issues will be addressed in the following order. Finding the issue of joinder to be dispositive, we will address that issue first.

I. Joinder

¶72. In issues regarding improper joinder, this Court employs a deferential standard of review. ***Janssen Pharmaceutica, Inc. v. Armond***, 866 So. 2d 1092, 1095 (Miss. 2004). *See also* ***Ill. Cent. R.R. v. Travis***, 808 So.2d 928, 931 (Miss. 2002); ***Donald v. Amoco Prod. Co.***, 735 So.2d 161, 181 (Miss.1999); ***Estate of Jones v. Quinn***, 716 So.2d 624, 626 (Miss. 1998); ***Beech v. Leaf River Prods., Inc.***, 691 So.2d 446 (Miss. 1997); ***Bobby Kitchens, Inc. v. Miss. Ins. Guar. Ass'n***, 560 So.2d 129, 135 (Miss.1989); ***Miss. State Highway Comm'n v. Rogers***, 240 Miss. 529, 128 So.2d 353, 358 (1961).

¶73. In this, the first Propulsid case tried in the country, the trial court allowed the selection of plaintiffs to be determined solely by Plaintiffs' counsel. Janssen objected and moved to sever the trials, or in the alternative, for separate trials. The trial court denied the motions, and this Court denied interlocutory review on August 13, 2001.

¶74. Janssen argues they were denied a fair trial because the trial court improperly required them to defend the dissimilar claims of ten differently situated Plaintiffs in a single trial. The Plaintiffs ranged from one three-year old child to nine adults from the ages of 50 to 79. One Plaintiff began taking Propulsid as early as 1993 while one did not start until 1999. Many of the Plaintiffs had serious preexisting heart conditions or risk factors for heart disease including chest pain, shortness of breath, blackouts, obesity, hypertension, high cholesterol, cardiovascular disease, coronary artery disease, congestive heart failure, enlarged heart,

irregular heart beats, diseased lungs and diabetes. Many also had preexisting psychological disorders including anxiety, nervousness, depression and schizophrenia.

¶75. During the trial the Plaintiffs attributed varying injuries to Propulsid including chest pain, strokes, myocardial infarctions, congestive heart failure, fast heartbeats, slow heartbeats and different types of arrhythmias. Some Plaintiffs claimed that Propulsid only made their preexisting conditions worse; some contended that Propulsid prolonged their QT interval so as to increase the risk of serious arrhythmias; while others claimed that past use of Propulsid had put them at risk for serious injury in the future. All Plaintiffs asserted claims for pain and suffering and/or anxiety.

¶76. The Plaintiffs argue joinder of the ten Plaintiffs was proper and, thus, the trial court did not abuse its discretion. The Plaintiffs argue that Rule 20 gives broad discretion to courts to determine how and when claims are tried. ***First Investors Corp. v. Rayner***, 738 So.2d 228, 238 (Miss. 1999). They cite ***American Bankers Ins. Co. v. Alexander***, 818 So.2d 1078 (Miss. 2001), for the proposition that an appellate court cannot substitute its own view for the findings of a trial court regarding joinder. The Plaintiffs argue a severance was denied by the trial court and was rejected by this Court on petition for interlocutory appeal on August 13, 2001. The trial court found the Plaintiffs' claims arose from the same series of transactions or occurrences and shared common issues of fact and law. See Miss. R. Civ. P. 20. The Plaintiffs also contend that after the verdict in favor of the Plaintiffs, the trial court again denied a motion by Janssen to sever the claims of the ten Plaintiffs. The Plaintiffs further argue there is no evidence which proves the jury was confused throughout the trial by the amount of medical evidence introduced, thus the damages awarded should be

affirmed by this Court. Therefore, this Court should not alter the trial court's exercise of discretion.

¶77. As stated in Miss. R. Civ. P. 20(a), joinder is proper if (1) the claims arise from the same series of transactions or occurrences and (2) the claims share a common issue of law or fact. Pursuant to the February 20, 2004, amendment made to Rule 20, the comment now states that "[t]he phrase 'transaction or occurrence' requires that there be a *distinct litigable event* linking the parties." (emphasis added). However,

> [j]oinder of parties under Rule 20(a) *is not unlimited* . . . . Rule 20(a) imposes two specific requisites to the joinder of parties: (1) a right to relief must be asserted by or against each plaintiff or defendant relating to or arising out of the same transaction, occurrence, or the same series of transactions or occurrences; and, (2) some question of law or fact common to all the parties will arise in the action. *Both of these requirements must be satisfied in order to sustain party joinder under Rule 20(a)*. . . .

Miss. R. Civ. P. 20 cmt. (2003) (emphasis added). In ***Armond,*** *supra*, this Court found that the trial court abused its discretion by joining parties in cases failing to satisfy the two requirements of Rule 20:

> the prescribing of the drug Propulsid by 42 different physicians to 56 different patients did not arise out of the same transaction, occurrence, or series of transactions or occurrences, and that joinder in this case unfairly prejudices the defendants. We hold that this joinder was improper and an abuse of the trial court's discretion. We remand the case for severance of all claims against defendants who have no connection with Appellee Armond. This would include all physicians who have not prescribed Propulsid to Ms. Armond. We also instruct the lower court to transfer the severed cases to those jurisdictions in which each plaintiff could have brought his or her claims without reliance on another of the improperly joined plaintiffs.

866 So. 2d at 1095.

¶78. In determining that joinder was not proper in ***Armond***, this Court easily distinguished ***American Bankers Ins. Co. v. Alexander***, 818 So. 2d 1073 (Miss. 2001), where the plaintiffs were borrowers of money from Fidelity Financial Services. The plaintiffs alleged that Fidelity conspired with American Bankers to purchase force-placed collateral protection insurance for their borrowers at substantially inflated rates, thus allowing Fidelity to receive a kickback on each transaction. The plaintiffs argued that joinder was proper because there was a single master policy covering all plaintiffs. The coverages were exactly the same with the premiums dependent only on the outstanding loan balance at the time. The Court found that there was nothing unique or individual about the defendants' treatment of any of the plaintiffs. ***Id.*** at 1076-77.

¶79. This Court found that joinder of the plaintiffs' claims was proper pursuant to Rule 20 as the claims arose out of the same pattern of conduct, the same type of insurance and the same master policy. All of the claims were similar with the only exception being the actual dollar amount charged on the premiums. ***Id.*** at 1079. Also in ***American Bankers***, each individual claim was too small to justify a separate trial. This Court stated that "we have fashioned our Rules of Civil Procedure to handle cases of this type under Rule 20 and 42." ***Id.*** at 1078. In contrast, personal injury cases such as the current case generally involve much larger damage claims. As previously stated, the jury in the present case awarded each Plaintiff $10 million. In the case sub judice, each plaintiff is unique in that he or she was prescribed Propulsid on a different date, under different labels and by different doctors. Each plaintiff took Propulsid for different lengths of time. The plaintiffs are also alleging a wide range of injuries.

¶80. This Court in ***Armond***, however, in determining that joinder was not proper, relied on ***Grayson v. K-Mart Corp***., 849 F. Supp. 785, 790-91 (N.D. Ga. 1994). ***Grayson*** was an age discrimination case brought by eleven former employees of K-Mart, working in different stores and terminated by different managers. In determining that joinder was improper, the district court held that there was a greater chance that the jury would be biased against the defendant by one plaintiff's unique circumstances than there was of the plaintiffs being prejudiced or inconvenienced by a severance.

¶81. The district court concluded that it would be "intolerable" to present all eleven unique situations and all eleven sets of witness testimony at one trial. Id.

¶82. Therefore, the district court granted the defendant's motion for severance. ***Id.*** at 791. While the motion for severance in ***Grayson*** was properly granted, the motion in the case sub judice was denied. Therefore, the case proceeded to trial, where a jury was asked to listen to ten unique factual situations and ten sets of witness testimony pertinent to those situations. As the district court concluded in ***Grayson***, it was likely that the jury was biased against the defendant by one of those plaintiffs. Therefore, a trial consisting of all ten plaintiffs with their unique medical histories and ten sets of witness testimony should have been, and is intolerable.

¶83. Also in ***Armond***, this Court relied on ***Insolia v. Philip Morris, Inc.***, 186 F.R.D. 547, 549 (W.D. Wis. 1999) where three former smokers and their spouses brought suit against several cigarette manufacturers and trade organizations. The district court held that the "plaintiffs' claims do not arise from the same transaction or series of transactions, as they must in order to satisfy Rule 20." ***Id.*** at 550. The district court determined that each plaintiff was unique

in that they "began smoking at different ages; they bought different brands throughout their years as smokers; and they quit for different reasons and under different circumstances." ***Id.*** The district court also determined that because the case involved five tobacco companies which had manufactured hundreds of brands of cigarettes, it would be difficult for a jury to keep track of all of the medical evidence introduced as it related to each separate plaintiff. ***Id.*** at 551. The district court also stated that "confusion could lead to prejudice." ***Id.***

¶84. Therefore, because each plaintiff's claim arose out of a unique set of facts and circumstances, the district court granted the defendants' motion to sever. ***Id.*** at 548. In the case sub judice, the jury was presented the testimony of 43 witnesses. Several depositions of doctors were either read into the record or were viewed via videotape by the jury. The jury was asked to keep up with prior medical histories, injuries alleged to be related to Propulsid, QT intervals and numerous other medical evidence as it related to ten unique plaintiffs. From the record before us, there can be little doubt that this method of presentation of evidence created unfair prejudice for the defendants by overwhelming the jury with this testimony, thus creating a confusion of the issues.

¶85. As previously stated, the case sub judice was the first Propulsid case tried in this country. Since this trial two other Propulsid cases have been tried to verdict. In both the second and third trials, ***Calvert v. Janssen Pharmaceutica***, No. 26-12108 (Cal. Super. Ct., Napa County, May 9, 2003) and ***In re Propulsid Products Liability Litigation,*** Civil Action No. 00-2577 (E.D. La. March 26, 2003), the juries returned a special verdict that expressly found that Propulsid had not caused the plaintiff's death. In each of these trials there was

a single plaintiff and the jury heard extensive medical evidence concerning the cause of plaintiff's death.

¶86. Following the Court's reasoning in ***Armond***, we find that the trial court improperly joined the suits of these ten plaintiffs. The joinder did not meet the requirements of Miss. R. Civ. P. 20, in that, these actions do not arise out of the same transaction or occurrence. Each Plaintiff's claims arose from individual facts and circumstances. The Plaintiffs were prescribed Propulsid by different physicians in different amounts for different ailments. The Plaintiffs were also prescribed Propulsid at different times, thus falling under different labels and different warnings. The Plaintiffs also presented ten unique medical histories. These Plaintiffs are now alleging a myriad of injuries as a result of this drug.

¶87. Also evident of improper joinder was the identical amounts of damages awarded to each Plaintiff. As stated above, each Plaintiff had unique medical histories and unique injuries which were presented to the jury. Along with those histories and injuries, the Plaintiffs also claimed significantly different medical expenses. These expenses ranged from $0 to $100,116.98. Although there were significant differences in medical expenses, the jury took only two hours after a four week trial to award each Plaintiff $10 million. The following chart summarizes this:

	Claimed Medical Expenses ($)	Jury Verdict ($)	Claimed Medical Expense (Ratio)	Remitted Verdict ($)	Claimed Medical Expenses (Ratio)
Martha Evans	100,116.98	10,000,000	1:100	10,000,000	1:100
Barbara Bishop	27,185.02	10,000,000	1:368	5,500,000	1:202
Macy Beth Johnston	24,501.80	10,000,000	1:408	7,500,000	1:306

	Claimed Medical Expenses ($)	Jury Verdict ($)	Claimed Medical Expense (Ratio)	Remitted Verdict ($)	Claimed Medical Expenses (Ratio)
Elsie Queen	14,898.35	10,000,000	1:671	4,000,000	1:268
Rosie Lee Bell	14,306.00	10,000,000	1:699	5,500,000	1:384
Maurice Landers	9,627.91	10,000,000	1:1,039	5,500,000	1:571
Janis White	1,693.00	10,000,000	1:5,906	2,500,000	1:1,477
Connie Coleman	1.092.00	10,000,000	1:9,158	2,500,000	1:2,289
Mary Williams	535.00	10,000,000	1:18,692	2,500,000	1:4,673
Robert Bailey	0.00	10,000,000	1:10,000,000	2,500,000	1:2,500,000

¶88. In this case, each Plaintiff has his or her own individual combination of facts and evidence surrounding the use of Propulsid. Therefore, there was no single transaction or occurrence connecting all of these Plaintiffs to justify a joinder pursuant to Miss. R. Civ. P. 20. Accordingly, the judgment of the circuit court is reversed, and the case is remanded for severance and new trial of the claims of all ten Plaintiffs.

¶89. Although this Court finds that the issue of joinder is sufficient on its own to merit a reversal in this case, we are compelled to offer further guidance for future Propulsid cases, by addressing the remaining issues which would also require reversal.

II. Venue

¶90. Like the standard of review for improper joinder, this Court uses a deferential standard when reviewing issues of improper venue. ***Armond***, 866 So. 2d at 1095-96. *See also* ***Travis***, 808 So.2d at 931; ***Donald***, 735 So.2d at 181; ***Estate of Jones***, 716 So.2d at 626; ***Beech***, 691 So.2d at 446; ***Bobby Kitchens, Inc.***, 560 So.2d at 135; ***Rogers***, 128 So.2d at 358.

¶91. After determining that the Defendants could not receive a fair trial in Jefferson County, the trial court, sua sponte, transferred the case to neighboring Claiborne County. Janssen argues Claiborne County was not a suitable county in which to transfer this case. Thirty-eight of the 155 original plaintiffs were from Claiborne County. Janssen argues that of the 105 qualified prospective jurors not excused for illness or hardship, over one-half of those jurors had personal relationships with Propulsid Plaintiffs or their counsel. Six prospective jurors were Propulsid plaintiffs themselves, including three of the 155 plaintiffs in this particular case. Many of those remaining as prospective jurors knew one or more Propulsid plaintiffs or had seen negative attorney advertising or news reports about Propulsid. Therefore, Janssen moved to strike the venire and for a change of venue. However, the trial court denied the motions, and this Court denied interlocutory review.

¶92. The Plaintiffs argue Janssen's second request to change venue was untimely. Also Miss. Code Ann. § 11-11-57[9] precluded a second change of venue after venue was first transferred from Jefferson County to Claiborne County. Finally, the Plaintiffs argue Janssen has failed to meet the standards necessary to establish error in the trial court for failing to change venue from Claiborne County.

¶93. In ***Quinn v. Estate of Jones***, 818 So.2d 1148, 1154 (Miss. 2002), this Court held that once venue was changed to its proper venue, pursuant to § 11-11-57, venue could not be changed again. Therefore, the trial court in ***Quinn*** was correct in denying the plaintiffs'

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[9]Miss. Code Ann. § 11-11-57 (1972):

> A civil suit shall not be removed more than once, or in any other manner than as prescribed, and in no case where it shall appear that there has been unnecessary delay or negligence in making the application.

request for a second change of venue. ***Id.*** However, the United States Supreme Court has held that:

> the right to jury trial guarantees. . . a fair trial by a panel of impartial, 'indifferent' jurors. The failure to accord an accused a fair hearing violates even the minimal standards of due process. ***In re Oliver***, 333 U.S. 257, 68 S.Ct. 499, 92 L.Ed. 682 (1948); ***Tumey v. State of Ohio***, 273 U.S. 510, 47 S.Ct. 437, 71 L.Ed. 749 (1927). 'A fair trial in a fair tribunal is a basic requirement of due process.' ***In re Murchison***, 349 U.S. 133, 136, 75 S.Ct. 623, 625, 99 L.Ed. 942 (1955). In the ultimate analysis, only the jury can strip a man of his liberty or his life.

Irvin v. Dowd, 366 U.S. 717, 722, 81 S.Ct. 1639, 1642, 6 L.Ed.2d 751 (1961).

¶94. In the present case, the trial court determined that although venue was proper in Jefferson County, Janssen could not receive a fair trial after the venire had been significantly reduced due to poor turnout, the seating of the grand jury first, and various disqualifications. Therefore, venue was changed to neighboring Claiborne County. What this Court must now decide is whether Claiborne County was a proper county to which to change venue.

¶95. Pursuant to Miss. Code Ann. § 11-11-51 (1972):

> When either party to any civil action in the circuit court shall desire to change the venue, he shall present to the court, or the judge of the district, a petition setting forth under oath that he has good reason to believe, and does believe that, from the undue influence of the adverse party, prejudice existing in the public mind, or for some other sufficient cause to be stated in the petition, he cannot obtain a fair and impartial trial in the county where the action is pending. . . .

"While the decisions on change of venue deal primarily and predominantly with criminal cases, a person is also entitled to a fair and impartial trial in a civil case." ***King v. Kelly***, 243 Miss. 160, 172, 137 So.2d 808, 813 (1962).

¶96. In ***Eddins v. State***, 110 Miss. 780, 70 So. 898, 899 (1916), this Court stated that the "right to trial by an impartial jury is guaranteed by the organic law of the state." In ***Magness v. State***, 103 Miss. 30, 60 So. 8, 10 (1912), this Court held:

> The requirement of the law is not satisfied by the mere empanelling [sic] of 12 [jurors] against whom no legal complaint can be made. The defendant is entitled to be tried in a county where a fair proportion of the people qualified for jury service may be used as a venire from which a jury may be secured to try his case fairly and impartially, and uninfluenced by a preponderant sentiment that he should be flung to the lions.

In ***Keeton v. State***, 132 Miss. 732, 96 So. 179, 180 (1923), this Court found that it is not enough that:

> [twelve] unbiased [jurors] may be found in the county to try him. The statute contemplates that the jury shall not only be composed of unbiased and impartial [jurors], but of [jurors] who have not been and will not during the trial be subject to the influence of a popular demand for the defendant's conviction.

And finally in ***Seals v. State***, 208 Miss. 236, 249-50, 44 So.2d 61, 68 (1950), this Court held:

> a fair trial means. . .in addition to the right to be tried by such individual jurors, the right to be tried in an atmosphere in which public opinion is not saturated with bias and hatred and prejudice against the defendant; where jurors do not have to overcome that atmosphere, nor the later silent condemnation of their fellow citizens if they acquit the accused. The ascertainment of impartial justice is, or should be, the supreme object of all courts. It is for this purpose they exist and for which they are maintained. It is the object of the courts, as it has been the dream of the sculptors, to symbolize justice as an innocent maiden balancing in her hands the scales of justice, suspended and poised in the open light of day before the world, blinded to bias and prejudice, but ever awake to do fair and impartial justice.

¶97. Janssen first filed a Motion for Change of Venue Under Miss. Code Ann. § 11-11-51 and for Alternate Relief on May 24, 2001 requesting venue be changed from Jefferson County. Out of the original 155 plaintiffs who filed this lawsuit, 117 were residents of

Jefferson County. Of the ten selected for trial in the present case, six are residents of Jefferson County.[10] In its motion, Janssen listed several circumstances evidencing a preexisting bias against Janssen including: (1) prominent Jefferson County residents, such as the Mayor of Fayette, as plaintiffs in the case, (2) high volume of similar litigation in Jefferson County during the last six years, and (3) negative publicity, including advertising by attorneys, creating negative preexisting conceptions about Propulsid. Also, Rosie Lee Bell is the sister-in-law of Burnell Harris, Circuit Clerk of Jefferson County. Mary Williams is married to Justice Court Judge Windell Williams. Robert Bailey is the father of a Jefferson County constable, Carl Bailey. Maurice Landers, a Claiborne County resident, was the assistant high school principal at Jefferson County High School for 29 years. Janssen listed many other family ties and ties to Propulsid in its motion. Janssen also stated that 760 lawsuits were filed in Jefferson County in 2000. Between 1995 and 2000, 21,012 plaintiffs have sued in Jefferson County.

¶98. As for pretrial publicity, Janssen attached several plaintiffs' depositions to its motion, and these plaintiffs testified that they had heard about the lawsuit "on the television like everybody else." Many plaintiffs testified in these depositions that advertising, not medical injury diagnosed by their doctor, prompted their lawsuit. Janssen argued that Jefferson County was bombarded with attorney advertisements, attorney-organized meetings and plaintiff-propelled gossip. Janssen, therefore, averred that due to this deeply rooted negative message so pervasive in the community, a fair trial could not be had in Jefferson County.

[10]The remaining four Plaintiffs are from Bolivar, Chickasaw, Claiborne and Washington Counties.

The trial court granted a change of venue to Claiborne County, located immediately north of Jefferson County, on July 23, 2001. The record reveals that the trial judge sought no guidance from counsel as to the appropriate county to which to transfer venue.[11]

¶99. Almost immediately after the first transfer of venue from Jefferson County to Claiborne County, Janssen filed another Motion for Change of Venue Under Miss. Code Ann. § 11-11-51 and for Alternate Relief on August 20, 2001. Based on the facts listed in its motion, Janssen urged the trial court to move the trial to a county farther removed geographically from Jefferson County. In its motion, Janssen stated that 38 of the plaintiffs involved in the ***Janssen v. Rankin, et al.***, case resided in Claiborne County. Also, a total of 114 Claiborne County residents had Propulsid cases pending in either Claiborne County or adjacent counties. Several prominent citizens were among the 155 original plaintiffs in this case including a Port Gibson police officer and the wife and daughter of a Claiborne County Supervisor. Other prominent citizens were involved in other pending Propulsid cases such as a former county supervisor, a deputy sheriff, the brother of the Claiborne County Circuit Clerk and the father of a jury commissioner. Robert Bailey is related to the District 4 Election Commissioner for Claiborne County, who was also a plaintiff in the diet drug mass tort litigation. Connie Coleman has two sisters residing in Claiborne County. Maurice

[11]Our experience tells us that after a decision has been made to change venue, the trial court will routinely seek assistance from trial counsel as to the appropriate county to which to change venue. At least one method is to have each attorney independently submit to the trial court in camera a list containing the names of counties (five, for example) to which that attorney (and client) would agree for venue to be transferred. After the trial court conducts an in camera review of the various lists, if there appears one or more counties on which all attorneys/parties agree, the trial court can almost without question be assured of being free from reversible error in transferring venue to that county agreed upon by all attorneys/parties.

Landers is a resident of Claiborne County and has several family members who reside in Claiborne County as well. Janssen set out further family histories throughout its motion. Janssen argued that presently there are nine Propulsid cases pending in the Circuit Courts of Claiborne and Jefferson Counties with 114 plaintiffs residing in Claiborne County. There was also deposition testimony presented that many claimants have "signed up" but have yet to file claims against Janssen.

¶100. In its motion, Janssen stated that Claiborne County residents have been subjected to substantial media coverage for more than a year before this case was transferred to that county concerning litigation against pharmaceutical defendants. In 1999, a Jefferson County jury awarded $150 million to five plaintiffs in a diet drug case. One of the original plaintiffs was the foreperson of that jury. In June 1998, a jury awarded $48 million in the asbestos case. An original plaintiff's brother was a plaintiff in that litigation.

¶101. Janssen argued that because of attorney advertisements, attorney-organized meetings and plaintiff-propelled gossip, Janssen could not receive a fair trial in Claiborne County just as it could not in Jefferson County. On September 5, 2001, the trial court denied Janssen's motion for a change of venue citing that "no voir dire has been conducted with respect to the potential jurors, and at this point there is no basis to assume that there are not an ample number of jurors who would be proper for this case."

¶102. "This Court has previously recognized the ineffectiveness of voir dire in detecting juror bias created by pre-trial publicity. Since jurors are aware that they are supposed to be impartial, they are unlikely to reveal any bias, even if they recognize it in themselves."

Beech v. Leaf River Forest Prods., Inc. 691 So.2d 446, 450 (Miss. 1997) (citing ***Fisher v. State***, 481 So.2d 203, 220-21 (Miss. 1985).

> To say that the media are all-pervasive in this day and age would only be to acknowledge the obvious. Newspapers and news broadcasts shape every community's understanding of itself. Public opinions and attitudes are reflected and affected concurrently. A prosecutor can reveal information and innuendo that could never be admitted in a court of law. Separate crimes which should be tried individually can become inextricably intertwined in print and over the airways. Public outrage can be raised to such a state that a defendant--any defendant--could not receive a fair trial. This is merely a reality of modern life. Recognizing this fact, when faced with a case which has been heavily reported in the news media, our trial courts must be prepared to readily grant a change of venue.

Johnson v. State, 476 So.2d 1195, 1214-15 (Miss. 1985). As a practical matter, trial courts must also look to other circumstances which would include suits against members of prominent, influential families; suits against public officials; and multiple suits, such as mass tort actions. Where these circumstances are present and egregious, the likelihood of extensive media coverage is great.

> When these and similar circumstances exist, particularly in combination, it is incumbent that trial be had in as dispassionate an environment as possible. Judicial efficiency and economy would be better served by a change of venue prior to trial, than by trial, reversal and retrial. Justice would be better served by a fair trial initially.

Johnson, 476 So.2d at 1215 (citing ***Hill v. State***, 72 Miss. 527, 534, 17 So. 375, 377 (1895)).

¶103. From the affidavits and motions submitted by Janssen, it is clear to this Court that while the trial court properly determined that a fair trial could not be had in Jefferson County, the trial court improperly changed venue to Claiborne County, a county almost identical in community make-up to Jefferson County, in so far as community connections with Propulsid litigants. Trial courts must be ever mindful in changing venue from one

county to another. The purpose of changing venue is to ensure a fair venire for all parties free from bias, prejudice and passion. In most cases, this will not be found by moving venue to a county immediately next door to the original county of venue.

¶104. This Court holds that the trial court abused its discretion by improperly changing venue to Claiborne County. The record is replete with evidence that Janssen sufficiently proved bias in the community of Claiborne County. Therefore, although the trial court correctly found that it was proper to change venue from Jefferson County, we find that Claiborne County is not a proper venue in which a fair trial may be conducted. This issue alone merits reversal.

III. Judgment Notwithstanding the Verdict

¶105. The standard of review for a denial of a judgment notwithstanding a verdict (JNOV) is well settled. Pursuant to this standard, this Court will:

> consider the evidence in the light most favorable to the appellee, giving that party the benefit of all favorable inference that may be reasonably drawn from the evidence. If the facts so considered point so overwhelmingly in favor of the appellant that reasonable men could not have arrived at a contrary verdict, [we are] required to reverse and render. On the other hand if there is substantial evidence in support of the verdict, that is, evidence of such quality and weight that reasonable and fair minded jurors in the exercise of impartial judgment might have reached different conclusions, affirmance is required. ***Munford, Inc. v. Fleming***, 597 So.2d 1282, 1284 (Miss.1992) (citing ***Litton Systems, Inc.***, 449 So.2d at 1214.)
>
> The above standards of review, however, are predicated on the fact that the trial judge applied the correct law. Under the standard of review applicable to discretionary matters, this Court first asks if the court below applied the correct legal standard. *See* ***Detroit Marine Engineering v. McRee***, 510 So.2d 462, 467 (Miss.1987). If the trial court "has exercised its discretionary authority against a substantial misperception of the correct legal standards, our customary deference to the trial court is pretermitted, [citations omitted] for the error has become one of law." ***Nationwide Mut. Ins. Co. v. Evans***, 553

> So.2d 1117, 1119 (Miss.1989) (citing ***Burkett v. Burkett***, 537 So.2d 443, 446 (Miss.1989)); ***Southern v. Glenn***, 568 So.2d 281, 284 (Miss.1990); ***Gibson v. Manuel***, 534 So.2d 199, 204 (Miss.1988).

Sperry-New Holland, a Div. of Sperry Corp. v. Prestage, 617 So.2d 248, 252 (Miss. 1993).

The standard of review to be followed when reviewing a motion for a new trial is also well settled.

> This Court applies the abuse of discretion standard of review when determining whether a trial court erred in refusing an additur or a new trial. It is primarily the province of the jury to determine the amount of damages to be awarded and the award will normally not "be set aside unless so unreasonable in amount as to strike mankind at first blush as being beyond all measure, unreasonable in amount and outrageous." The party seeking the additur must prove his injuries, damages, and loss of income. In deciding if the burden has been met, we must look at the evidence in the light most favorable to the party in whose favor the jury decided, granting that party any favorable inferences that may reasonably be drawn therefrom.

Harvey v. Wall, 649 So.2d 184, 187 (Miss. 1995) (citations omitted).

¶106. The Plaintiffs asserted two claims: (1) that the Defendants had inadequately warned of Propulsid's potential side effects, and (2) that the defendants had negligently misrepresented Propulsid's benefits. This second claim did not make it to the jury as the trial court granted Janssen a directed verdict at the close of the evidence. However, Janssen argues this ruling came too late to prevent the Plaintiffs from admitting irrelevant and prejudicial evidence before the jury. Because this case went to the jury solely on the issue of failure to warn and because the Plaintiffs presented no substantial evidence to contradict Janssen's proof that Propulsid's FDA-approved labeling disclosed all potential risks as they became known, Janssen avers that they are entitled to a judgment as a matter of law.

¶107. A motion for JNOV tests the legal sufficiency of the evidence supporting the verdict, not the weight of the evidence. ***Tharp v. Bunge Corp.***, 641 So.2d 20, 23 (Miss. 1994) (citing ***Goodwin v. Derryberry Co.***, 553 So.2d 40, 42 (Miss. 1989); ***Stubblefield v. Jesco, Inc.***, 464 So.2d 47, 54 (Miss. 1984)). *See also* ***Corley v. Evans***, 835 So.2d 30 (Miss. 2003). In asking for a judgment as a matter of law, Janssen is asking this Court to hold that the verdict reached by the jury may not stand. *See* ***Jesco, Inc. v. Whitehead***, 451 So. 2d 706, 713 (Miss. 1984) (Robertson, J., specially concurring).

> Where a motion for j.n.o.v. has been made, the trial court must consider all of the evidence--not just evidence which supports the non-movant's case--in the light most favorable to the party opposed to the motion. The non-movant must also be given the benefit of all favorable inferences that may reasonably be drawn from the evidence. If the facts and inferences so considered point so overwhelmingly in favor of the movant that reasonable men could not have arrived at a contrary verdict, granting the motion is required. On the other hand, if there is substantial evidence opposed to the motion, that is, evidence of such quality and weight that reasonable and fairminded men in the exercise of impartial judgment might reach different conclusions, the motion should be denied and the jury's verdict allowed to stand. See, e.g., ***General Tire and Rubber Co. v. Darnell***, 221 So.2d 104, 105 (Miss. 1969); ***Paymaster Oil Co. v. Mitchell***, 319 So.2d 652, 657 (Miss. 1975); ***City of Jackson v. Locklar***, 431 So.2d 475, 478 (Miss. 1983).

Jesco, Inc., 451 So.2d 713-14. However, because we find that Janssen is not entitled to a judgment as a matter of law, we must utilize the standard of review for a motion for new trial.

> A motion for a new trial falls within a lower standard of review than does that of a judgment notwithstanding the verdict or a directed verdict. A motion for a new trial simply challenges the weight of the evidence. "The Supreme Court will reverse the lower court's denial of a motion for a new trial only if, by doing so, the court abused its discretion." ***Gleeton v. State***, 716 So. 2d 1083, 1088 (Miss. 1998). "We will not order a new trial unless convinced that the verdict is so contrary to the overwhelming weight of the evidence that, to

allow it to stand, would be to sanction an unconscionable injustice." ***Groseclose v. State***, 440 So.2d 297, 300 (Miss.1983).

Sheffield v. State, 749 So.2d 123, 127 (Miss. 1999).

A. Whether Propulsid's FDA-approved Labeling Adequately Warned Plaintiffs' Prescribing Physicians of Potential Side Effects as They Became Known.

¶108. Over a fifteen-day trial, the jury heard testimony from 43 witnesses, including the ten Plaintiffs, nine company witnesses, twelve treating physicians, and eleven medical experts. Janssen argues that the evidence presented sufficiently demonstrated that Propulsid's FDA-approved labels disclosed all potential risks as they became known. All but one of the Plaintiffs' treating physicians testified that they knew about the disclosed risks by keeping current on the labeling changes. However, these physicians weighed the risks and prescribed Propulsid to the patients whom they believed would improve from its benefits. The Plaintiffs' lead witness on adequacy of warnings, Dr. Dennis Bowsher, could cite nothing that Janssen should have warned about but did not. Dr. Bowsher's sole criticism was that Janssen's updates provided too much information for doctors to keep up with.

¶109. The Plaintiffs argue significant evidence was offered to prove that Janssen failed to provide adequate and timely warnings about the potential for Propulsid to cause cardiac arrhythmias. Plaintiffs also contend that sufficient proof was offered to show that through aggressive marketing and over promotion, Janssen nullified the effectiveness of the warnings that they did issue. Finally, Plaintiffs argue that sufficient evidence was offered to prove that Propulsid became a victim of label fatigue, such that it was made clear to the jury that the warnings were never adequate.

¶110. An adequate warning is one reasonable under the circumstances. ***Id.*** *See also* ***Swayze v. McNeil Labs., Inc.***, 807 F.2d 464, 471 (5th Cir. 1987); ***Phelps v. Sherwood Med. Indus.***, 836 F.2d 296, 303 (7th Cir. 1987); ***Plummer v. Lederle Labs.***, 819 F.2d 349, 356 (2d Cir. 1987); ***Brochu v. Ortho Pharmaceutical Corp.***, 642 F.2d 652, 657 (1st Cir. 1981); ***Johnson v. Husky Indust., Inc.***, 536 F.2d 645 (6th Cir. 1976); ***Basko v. Sterling Drug, Inc.***, 416 F.2d 417, 426 (2d Cir. 1969); ***Sterling Drug, Inc. v. Yarrow***, 408 F.2d 978, 992-93 (8th Cir. 1969); ***Graham v. Wyeth Labs.***, 666 F. Supp. 1483, 1498 (D. Kan. 1987); ***Felix v. Hoffman-LaRoche, Inc.***, 513 So.2d 1319, 1320-21 (Fla. Dist. Ct. App.1987); ***Leesley v. West***, 165 Ill.App.3d 135, 518 N.E.2d 758, 761 (1988). "Several cases have held that a package insert may be sufficient for the warning to be adequate as a matter of law." ***Id.*** (citing ***Hurley v. Lederle Labs.***, 651 F. Supp. 993, 1002 (E.D.Tex.1986)). *See also* ***Plummer v. Lederle Labs.***, 819 F.2d 349, 357 (2d Cir. 1987); ***Chambers v. G.D. Searle & Co.***, 441 F. Supp. 377 (D. Md. 1975), *aff'd per curiam,* 567 F.2d 269 (4th Cir. 1977); F. Harper, F. James & O. Gray, *The Law of Torts* § 28.7 nn. 27-29 (2d ed.1986 & Supp.1987).

¶111. In the original 1993 package insert for Propulsid under "ADVERSE REACTIONS," the labeling stated that although rare instances of tachycardia had been reported, "the relationship of Propulsid to the event was not known in these cases."

¶112. This original label pertains to Maurice Landers, who was prescribed Propulsid in December 1993, Rosie Lee Bell, who was prescribed Propulsid in March 1994, and Connie Coleman, who was prescribed Propulsid in 1994. Following the original 1993 package insert for Propulsid, Janssen revised Propulsid's labeling five times. Those revisions were made in February 1995, October 1995, June 1998, June 1999 and January 2000.

¶113. The revisions made to the February 1995 package insert indicated that Propulsid was contraindicated with antifungal drugs, such as Nizoral, Sporanox and Monistat. The labeling warned that although rare cases of cardiac arrhythmias had been reported, most of these patients had preexisting cardiac conditions or were taking multiple other medications which could be contraindicated with Propulsid. Again the labeling advised that a "causal relationship to Propulsid ha[d] not been established."

¶114. This revised label applies to Mary Williams, who was prescribed Propulsid in March 1995, and Robert Bailey, who was prescribed Propulsid in June 1995.

¶115. The revisions made to the October 1995 package insert, set out in a boxed warning, listed further antifungal drugs and other antibiotics which were contraindicated with Propulsid.

¶116. These revisions apply to Elsie Queen, who was prescribed Propulsid in April 1996, Barbara Bishop, who was prescribed Propulsid in June 1996, and Mary Beth Johnston, who was prescribed Propulsid in October 1997.

¶117. In June 1998, Propulsid's labeling was again revised, by way of a boxed warning, to warn that Janssen had received reports of cardiac arrythmias and QT prolongation occurring in patients taking Propulsid. The labeling again listed drugs which were determined to be contraindicated with Propulsid. However, this label indicated that "QT prolongation, torsades de pointes (sometimes with syncope), cardiac arrest and sudden death have been reported in patients taking Propulsid without the mentioned contraindicated drugs." The labeling also suggested that an ECG should be performed prior to any prescription for Propulsid.

¶118. In June 1999 revisions were once again made to Propulsid's labeling and were referenced in a "Dear Doctor" letter. A boxed warning added two new medical conditions to the "CONTRAINDICATIONS" section which were "known family history of congenital QT syndrome" and "clinically significant bradycardia." The labeling also warned against the coadministration of grapefruit juice with Propulsid.

¶119. These revisions apply to Martha Evans who was prescribed Propulsid in December 1999.

¶120. In January 2000, Janssen made its final revisions to Propulsid's labeling before restricting distribution to a limited-access program. A revised BOXED WARNING and additional revisions were added to the package insert of Propulsid and were listed in a "Dear Doctor" letter. Janssen again stated that of the received reports of cardiac arrhythmias, approximately 85% of those cases occurred when patients used Propulsid in conjunction with contraindicated drugs or occurred in patients with known medical conditions which were contraindicated with Propulsid. Janssen again recommended that an ECG should be performed before Propulsid was prescribed to a patient. Also the labeling indicated that Propulsid should not be prescribed in patients whose QT intervals exceeded 450 milliseconds.

¶121. On March 23, 2000, Propulsid sent out another "Dear Doctor" letter informing all physicians that the distribution of Propulsid was going to be restricted to a limited-access program due to the "continue[d] [] inappropriate use in some patients who have contraindicated medical conditions or who use contraindicated medications."

¶122. Janssen argues that the ***Wyeth*** analysis applies to the present case, and therefore, Janssen's warnings were adequate as a matter of law. In ***Wyeth Laboratories, Inc. v. Fortenberry***, 530 So. 2d 688 (Miss. 1988), Billy Joe Fortenberry became seriously ill after receiving a flu vaccine manufactured by Wyeth and administered by Dr. T.L. Moore. ***Id.*** at 689. Fortenberry filed suit against both Wyeth and Moore for failure to warn. The jury found for Fortenberry and against Wyeth in the amount of $200,000. ***Id.*** This Court held, inter alia, that "the drug manufacturer has a duty to adequately warn the prescribing physician of any known adverse effects which might result from use of its prescription drugs." ***Id.*** at 691 (citing ***Swayze v. McNeil Labs., Inc.***, 807 F.2d 464 (5th Cir. 1987)).

> The general rule is "that where prescription drugs are concerned, a manufacturer's duty to warn only extends to physicians and not to laymen." ***Swayze***, 807 F.2d at 470. "If the language of the warning is adequate then the drug manufacturer ordinarily is freed from liability." ***Swayze***, 807 F.2d at 469. The "learned intermediary" doctrine is the basis for this rule.

Wyeth, 530 So.2d at 691. This Court also held that the "issue of a warning's adequacy is factual and usually will be resolved by the trier of fact." ***Id.*** at 692 (citations omitted).

¶123. As detailed above, Janssen's package inserts warned since February 1995 that patients taking Propulsid have, in rare cases, experienced "serious cardiac arrhythmias, including ventricular arrhythmias and torsades de pointes associated with QT prolongation." The 1995 labeling stated that most of these patients had been receiving multiple other medications and had preexisting cardiac disease or other risk factors for arrhythmias, but made clear as well that some had not. The labeling also cautioned physicians to weigh the potential benefits and risks of administering Propulsid to patients with any "conditions associated with QT prolongation." Janssen contends that pursuant to ***Wyeth***, the FDA-approved labeling fairly

disclosed what was known about Propulsid's potential adverse effects and properly called on prescribing physicians to exercise medical judgment as learned intermediaries.

¶124. The Plaintiffs argue that while ***Wyeth*** may be instructive in the present case, it is not determinative to the issue as to adequacy of warning. The Plaintiffs state that ***Wyeth*** holds the adequacy of a warning is factual and will be determined by a jury. 530 So. 2d 692. To aid in addressing such a complex issue, it may be necessary to rely on the testimony of expert witnesses. ***Id.*** The Plaintiffs contend the record is replete with expert testimony about the inadequacy of the warnings. The Plaintiffs also argue the package inserts were not "reasonable under the circumstances." The Plaintiffs contend that because every package insert issued after June 1998 contained the phrase "the preceding lists of drugs are not comprehensive," the warnings lacked sufficient clarity and specificity to rise to the level of adequacy required by law.

> Under Mississippi law, a product may be unreasonably dangerous if the manufacturer fails to warn of a non-obvious risk associated with the normal use of the product. When the product in question is a prescription drug, Mississippi follows the learned intermediary doctrine. Under this doctrine, the manufacturer's failure to warn the patient of the product's risks does not render the product defective or unreasonably dangerous so long as the manufacturer adequately warns the learned intermediary.

Thomas v. Hoffman-LaRoche, Inc., 949 F.2d 806, 811 (5th Cir. 1992) (citing ***Wyeth***, 530 So. 2d at 691-96). The Plaintiffs bear the burden of establishing that Propulsid was the cause of their injuries and that "an adequate warning would have convinced the treating physician not to prescribe the product for the [P]laintiff[s]." ***Id.*** (citations omitted). As previously stated, ***Wyeth*** requires a manufacturer to give a reasonable warning. 530 So. 2d at 692. "To

be reasonable, the warning should neither understate nor overstate the known risks associated with the use of a particular product." ***Thomas***, 949 F.2d at 815.

¶125. Both sides presented expert witness testimony as to the adequacy of warnings. The Plaintiffs' own expert, Dr. Bowsher, testified that he knew of nothing else Janssen could have done to make their labeling more adequate, except to make them less frequent. However, if the warnings were less frequent Janssen would not be advising physicians of potential risks as they became known to Janssen. Other physicians testifying for the Plaintiffs admitted that they never bothered to read the updated labels or "Dear Doctor" letters because their family practices kept them too busy to keep abreast of the changes in the drugs which they were prescribing.

¶126. Dr. McArthur testified that all of the patients had symptoms related to Propulsid. He stated that he did not remember receiving "Dear Doctor" letters, changes in labeling or sales representatives advising him of those changes. He testified that he very rarely reads package inserts because the font is too small. He also testified that he probably would not have read the "Dear Doctor" letter if he had gotten one. He read the original label in 1994, but he never read another label. He found out on his own in 2000 about the revised labels and immediately stopped prescribing Propulsid. He testified that in his expert opinion the patients suffered from prolonged QT intervals even after they were taken off of Propulsid.

¶127. Dr. O'Brien, the Plaintiffs' psychologist, consistently found that all of the Plaintiffs suffered from anxiety related to Propulsid. However, he has now turned the Plaintiffs over to their local physicians so that they might treat the Plaintiffs' anxiety. Dr. Bills testified he

never received a "Dear Doctor" letter. He read the label in 1996. He stopped prescribing in 1998; however, he would refill his patients' already existing prescriptions.

¶128. The experts offered by Janssen all read the labels but testified that they weighed the risks on a case-by-case basis. At trial Dr. Namihira testified that he received enough information from Janssen regarding the package inserts and labeling updates. Dr. Namihira testified that he still believes that Propulsid is a safe and effective treatment. He discontinued its use because of a news release regarding EKGs. Even after Dr. Namihira became aware of the label revising Propulsid to be contraindicative for people with congestive heart failure, he testified that his main concern was still to treat people for gastrointestinal diseases.

¶129. Dr. Greenwald testified that Propulsid was a safe and effective treatment. He was aware of the warnings and he considered the information he received from Janssen sufficient. Dr. Reed testified that he was made aware of all changes made by Janssen. He testified that he still believes Propulsid is a safe medication, and he thinks he should be allowed to prescribe it to his patients. Dr. Bradford testified that he still considers Propulsid to be a safe and effective medication.

¶130. Dr. Tillman testified that he was made aware by Janssen of all the potential side effects and the drug interactions. However, once patients stop taking Propulsid, they are no longer at risk because Propulsid leaves the system within 3-4 days. Dr. Braden testified that the labels and the "Dear Doctor" letters were specific about side effects and were adequate.

¶131. Dr. Parker testified that he was extraordinarily impressed with the safety of Propulsid. He also testified that Propulsid is extremely effective and no other drug compares. Dr. Braden testified that Propulsid only causes prolonged QT intervals when given with other

medications and in extreme excess. Dr. Braden also confided that he still takes Propulsid. He testified that Propulsid is very safe if used in the correct dosage. He further testified that he has never had a patient to have a problem with Propulsid, nor has he seen a prolonged QT related to Propulsid. He testified that Janssen's labeling erred on the side of gross overstatement based on the studies that he has read.

¶132. In addressing the issue of whether the FDA-approved labeling was adequate, the Plaintiffs are correct in that this is a question of fact which should be determined by the jury. However, as this Court held in ***Wyeth***, we must still determine if there was sufficient evidence presented by the Plaintiffs proving Propulsid was the cause of their injuries.

B. Whether Plaintiffs Failed to Present Legally Competent or Sufficient Evidence That Propulsid Actually Caused Their Injuries.

¶133. As to medical causation, the Plaintiffs argue competent expert testimony was offered by qualified witnesses to show that the Plaintiffs were injured by Propulsid. Dr. Bowsher testified for the Plaintiffs as to medical causation, stating that in "relatively rare" cases, Propulsid may produce heart-related side effects, as disclosed in Propulsid's labeling. Because Dr. Bowsher never examined any plaintiff in this case, he could not testify that any plaintiff in this case experienced such a side effect. The only two prescribing physicians who believed that Propulsid caused the Plaintiffs any heart injuries were the Plaintiffs' non-specialist experts, Drs. McArthur and Bills, who are both family physicians and are not board certified in gastroenterology or internal medicine.

¶134. Janssen argues Drs. McArthur, Bills, Ramsey and O'Brien, two local family physicians, an internist and a psychologist, respectively, were not qualified to provide expert

testimony on whether Propulsid caused any of the Plaintiffs' injuries, nor did their testimony meet the requirements for scientific testimony sufficient to sustain a verdict. These were also the doctors hired by the Plaintiffs' attorneys to examine all plaintiffs who signed up with the Propulsid lawsuit. Janssen argues their testimony was "conclusory, speculative and argumentative in the extreme." Janssen further argues that the "failure to rule out obvious and likely causes before settling on a rare and highly improbable one violates all generally accepted scientific and medical principles and cannot support a rational finding of causation."

¶135. The recent case of ***APAC-Mississippi, Inc. v. Goodman***, 803 So. 2d 1177 (Miss. 2002), offers guidance to this issue. In ***Goodman***, this Court recognized that:

> "[U]nder the guidelines of the Mississippi Rules of Evidence Rule 702, the trial judge serves as a 'gatekeeper' in ruling on the admissibility of expert testimony. The Supreme Court of Mississippi has advised that '[t]he facts upon which the expert bases his opinion must permit reasonably accurate conclusions as distinguished from mere guess or conjecture.'" ***Watkins v. U-Haul Int'l, Inc.***, 770 So.2d 970, 974 (Miss. Ct. App. 2000) (citing ***Hickox v. Holleman***, 502 So.2d 626, 638 (Miss. 1987)). The facts relied upon "must afford a 'reasonably accurate basis' for the expert's conclusion." ***Fielder v. Magnolia Beverage Co.***, 757 So.2d 925, 937 (Miss.1999).[12]

Goodman, 803 So. 2d at 1185. As part of this "gatekeeper" role, this Court has instructed trial judges to examine the reliability of expert opinion, and we have also recognized our own authority to do the same on appeal.

> The sufficiency of foundational facts or evidence on which to base an opinion is a question of law. ***Gulf Ins. Co. v. Provine***, 321 So.2d 311, 314

[12]This Court amended Miss.R.Evid. 702, effective May 29, 2003, to address the amendment to Fed.R.Evid. 702 which was adopted in response to ***Daubert v. Merrell Dow Pharmaceuticals, Inc.***, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993).

> (Miss.1975). These facts must afford a "reasonably accurate basis" for the expert's conclusion. [***Id.***] Expert testimony must be consistent with scientific principles "as established by the laws of physics or mechanics." ***Id.*** The scientific principles underlying an expert's opinion must be generally accepted by practitioners in the expert's field. ***May v. State***, 524 So.2d 957, 963 (Miss.1988); M.R.E. 702, Comment.

Materials Transp. Co. v. Newman, 656 So.2d 1199, 1203-04 (Miss. 1995).

¶136. This Court has continually insisted that it must be "scientifically established that due investigation and study in conformity with techniques and practices generally accepted within the field will produce a valid opinion" before an opinion based on "those techniques and practices" will be considered for admission in a Mississippi Court. ***T.K. Stanley, Inc. v. Cason***, 614 So. 2d 942, 951 (Miss. 1992). Therefore, if a particular expert's methods ignore or conflict with the "techniques and practices generally accepted within the field," that expert's opinion should not be considered valid or competent for admission in court.

¶137. When considering a motion for a new trial, the trial judge should consider and weigh a number of factors. Among these are:

> (1) Has the search for the true facts proceeded as far as it reasonably may under the peculiar facts and circumstances of the case?
> (2) To what extent would it be unfair to the party in whose favor the verdict was returned in effect to give that party's adversary a second bite at the apple?
> (3) Considering the evidence, is there a substantial basis for believing that the jury disregarded their oaths and failed to follow the instructions of the Court in reaching its verdict? Put another way, is it substantially apparent that the jury's verdict is the product of passion, prejudice or any other arbitrary factor?
> (4) Assuming arguendo that the verdict is unjust (by reference to the underlying facts of the transaction or occurrence, the complete truth of which we will never know), what is the impact of that "injustice" upon the party against whom the verdict has been returned?
> (5) If a new trial is ordered, will the party in whose favor the verdict has been returned be deprived of some fair advantage he enjoyed in the first trial?
> (6) Are there any other factors present, peculiar to the particular case or the parties, that would render just or unjust the grant or denial of a new trial?

Jesco, Inc., 451 So.2d at 715-16. Applying these factors to the case at bar, we find it was an abuse of discretion that the trial judge did not grant Janssen's motion for a new trial. We find that the verdict was "so contrary to the overwhelming weight of the evidence that to allow it to stand would sanction an unconscionable injustice [on] this Court." ***Baker v. State***, 802 So.2d 77, 81 (Miss. 2001) (quoting ***Dudley v. State***, 719 So.2d 180, 182 (Miss. 1998)). Therefore, a new trial is granted.

¶138. The medical testimony provided by the Plaintiffs failed to address and account for the innumerable preexisting conditions and other causative factors which are much more likely than Propulsid to have caused Plaintiffs' symptoms. The defense experts in numerous specialties uniformly testified that Plaintiffs' heart-related symptoms were typical of their preexisting conditions. As stated previously, there is a "substantial basis" to believe that the damages awarded by the jury were based entirely on passion and prejudice. Therefore, we find that this issue alone merits a new trial.

IV. Improper Arguments

¶139. The Plaintiffs based their negligent misrepresentation claim, which was not allowed to be submitted to the jury, on objections to certain Janssen promotional materials by the FDA's division of Drug Marketing, Advertising and Communications (DDMAC). DDMAC reviews marketing materials for approved drugs and may request modifications or withdrawal of any materials it may consider false and misleading within the meaning of FDA regulations. *See* 21 C.F.R. §§ 5.109 & 202.1. Between 1993 and 2000, DDMAC reviewed and approved over 300 sales brochures, medical journal advertisements and other promotional materials for Propulsid. However, on four occasions DDMAC requested that

Janssen modify or withdraw certain materials. Janssen promptly modified or withdrew the materials in accordance with DDMAC's requests.

¶140. Before trial, Janssen moved for summary judgment on the Plaintiffs' misrepresentation claim arguing that neither the Plaintiffs nor their prescribing physicians relied on any allegedly misleading materials. Janssen also objected to the admission of the DDMAC correspondence. The trial court denied the motions and overruled the objections. However, after the defense rested, the trial court granted Janssen's motion for directed verdict on the misrepresentation claim due to the Plaintiffs' failure to offer any proof of reliance.

¶141. After the trial court directed a verdict for the defendants on the Plaintiffs' misrepresentation claim, the trial court denied a motion by the defendants which would preclude the plaintiffs from referring to marketing materials and DDMAC correspondence relevant only to that dismissed claim. Only two plaintiffs were prescribed Propulsid off-label, Martha Evans for motility-related bloating and Macy Beth Johnston for pediatric GERD. Therefore, Janssen argues the Plaintiffs were allowed improper closing arguments which appealed to the bias and prejudice of the jury.

¶142. Although the only issue before the jury was inadequacy of warnings, counsel for Plaintiffs continuously argued throughout closing arguments that the campaign Janssen developed to promote Propulsid was false and misleading. While the DDMAC correspondence may have been relevant to prove failure to warn to a certain extent, the trial court specifically ruled, in granting the defendants' motion for directed verdict, that the

Plaintiffs failed to prove that the prescribing physicians relied on any alleged misrepresentations.

¶143. In the closing arguments by Plaintiffs' counsel, countless references were made to "false and misleading promotional activities," "lying and cheating about promoting," accusations made by the FDA that Janssen was "lying and cheating" and "promoting their drugs with lies." Finally, to further prejudice the jury, Plaintiffs' counsel suggested that the jury should "send a message" to Janssen and Johnson & Johnson by basing the amount of damages solely on the finances of these two defendants. Although the Plaintiffs submitted no quantifiable damages apart from the medical bills discussed in Section I, each plaintiff simply demanded $20 million:

> It's time that they be made to pay for that vow that they made that they didn't keep. $20 million for each now. There is a line for each of my clients. . . . You just keep going down this line, and for each plaintiff, write in $20 million for each one. Johnson & Johnson and Janssen will then understand that when you damage individuals. . .that even in Claiborne County, Mississippi, you have to pay.

Essentially, Plaintiffs' counsel was making a punitive damages argument for intentional fraud when the only issue before the jury was a compensatory damages claim for negligent failure to warn. Such statements made by counsel were intended to inflame and prejudice the jury. In awarding each Plaintiff $10 million across the board, the jury responded to this inflammatory and improper argument.

¶144. We have "condemn[ed] the use of inflammatory language calculated to mislead the jury and which has no relation to the issues of fact which are being presented to the jury for determination." ***Miss. State Highway Comm'n v. Hall*** 252 Miss. 863, 877, 174 So.2d 488,

493-94 (1965). "The only legitimate purpose of the argument of counsel in a jury case is to assist the jurors in evaluating the evidence and in understanding the law and in applying it to the facts. Appeals to passion and prejudice are always improper and should never be allowed." ***Shell Oil Co. v. Pou***, 204 So.2d 155, 157 (Miss. 1967). Therefore, this issue alone merits reversal.

V. Parent Company Liability

¶145. Janssen argues that the jury was improperly allowed to impose liability not only on Janssen Pharmaceutica, but also on its parent corporation Johnson & Johnson. Janssen contends that because Johnson & Johnson neither manufactured nor sold Propulsid in Mississippi, the jury was precluded from finding any direct liability under Mississippi law. See Miss. Code Ann. § 11-1-63; ***Scordino v. Hopeman Bros. Inc.***, 662 So. 2d 640, 643 (Miss. 1995). Janssen argues that because Johnson & Johnson was not a link in the chain of distribution between Propulsid's manufacture and the Plaintiffs' use of it, Johnson & Johnson had no duty to warn the Plaintiffs.

¶146. The Plaintiffs argue that at trial they proved Johnson & Johnson played an integral part in the marketing of Propulsid. Johnson & Johnson's purpose was to increase the sales of Propulsid, thus increasing revenue for Johnson & Johnson. Janssen's field sales representatives were paid by Johnson and Johnson. Johnson & Johnson was also heavily involved in the science surrounding Propulsid.

¶147. The trial court found that there was sufficient evidence to submit the issue of Johnson and Johnson's direct liability to the jury. The trial court held that sufficient evidence was submitted that Johnson and Johnson "actively participated in the marketing and the plan with

respect to Propulsid that was sold and marketed and manufactured. . . ." The trial court also found that, with respect to the issue concerning piercing the corporate veil, sufficient evidence was introduced so that a question of fact was raised for the jury.

¶148. This Court has held:

> Our institutional role mandates substantial deference to the jury's findings of fact and to the trial judge's determination whether a jury issue was tendered. When a verdict is challenged via appeal from denial of a motion for j.n.o.v., we have before us the same record the trial judge had. We see the testimony the trial judge heard. We do not, however, observe the manner and demeanor of the witnesses. We do not smell the smoke of the battle. Cf. ***Culbreath v. Johnson***, 427 So.2d 705, 708 (Miss.1983). The trial judge's determination whether, under the standards articulated above, a jury issue has been presented, must per force be given great respect here.

City of Jackson v. Locklar, 431 So.2d 475, 478-79 (Miss. 1983). Therefore, this Court finds that in the present case the trial court did not err in submitting Johnson & Johnson's liability to the jury.

¶149. Because this Court is reversing this case and remanding it to the trial court for severance and for new trials, we will not discuss the issues of remittiturs, compensatory damages or punitive damages.

CONCLUSION

¶150. This is a case of first impression for this Court as this was the first Propulsid case in the country to be completed through trial and a jury verdict. As already apparent from this Court's docket, there is no doubt that many more will soon follow in Mississippi. However, this Court has previously held that it is improper to join groups of Plaintiffs whose claims do not arise out of the same transaction or occurrence. Because each Plaintiff has his or her own very unique set of facts and circumstances to be presented at trial, this Court cannot find

that the claims of these ten Plaintiffs arise out of the same transaction or occurrence. Therefore, the judgment of the circuit court is reversed, and this case is remanded for severance, transfer to appropriate venue and new trial of the claims of all ten Plaintiffs, and for any other necessary proceedings consistent with this opinion.

¶151. **REVERSED AND REMANDED.**

SMITH, C.J., WALLER AND COBB, P.JJ., AND DICKINSON, J., CONCUR. GRAVES, J., CONCURS IN RESULT ONLY. EASLEY, J., DISSENTS WITH SEPARATE WRITTEN OPINION. DIAZ AND RANDOLPH, JJ., NOT PARTICIPATING.

EASLEY, JUSTICE, DISSENTING

¶152. I dissent from the majority's ruling today. The majority's decision follows on the heels of our recent decision, ***Janssen Pharmaceutica, Inc. v. Armond***, 866 So.2d 1092 (Miss. 2004), in which I joined Justice Graves's specially concurring opinion.

¶153. In ***Armond***, Justice Graves advocated the adoption of a class action rule instead of relying upon Rule 20. In this case, as well as ***Armond***, the majority provides little guidance in this new course of proceeding. The majority is quick to hold that the Propulsid claims do not arise out of the same transaction or occurrence, thus failing to meet the requirements of Rule 20. However, litigants, their lawyers, and the trial courts are left without a clue as to how to proceed in cases. ***Armond*** was reversed and remanded because the claims did not arise out of the same transactions or occurrence and their joinder prejudiced the defendants. ***Id.*** at 1095 (¶7). Specifically, the Court reversed the trial court ruling and remanded the case for severance of any defendant with no connection to Armond, including doctors that did not prescribe Propulsid to Armond. ***Id***.

¶154. The Court in ***Armond*** referred to "mature" and "immature" torts. ***Id***. at 1099 (¶¶ 25-26). Asbestos suits which have been present for "decades" are considered a "mature" tort and thus more amenable to aggregation. ***Id***. at (¶ 25). On the other hand, in ***Armond***, this Court classified Propulsid claims as "immature" torts since "scientific, legal, and factual issues related to "immature torts" are novel and unsettled." ***Id***. at (¶26). Mass joinder is not considered to be appropriate until there have been enough trials and the "contours" of different claims are more readily known in the litigation. ***Id***. (citing ***In re Bristol-Myers Squibb Co.***, 975 S.W.2d 601, 603 (Tex. 1998)).

¶155. The Court's holding in ***Armond*** and today's decision in the case sub judice leave a number of unanswered questions. First, when does an immature tort mature? Even if it becomes a "mature" tort will the law have then so evolved as to make it impractical to return this tort to the realm of Rule 20 joinder? Second, is the proper course for the legal system simply to venture down the path of forcing multiple cases into multiple counties? Are we not creating yet another problem with numerous separate filings all over the state and potential back logs in the trial courts by not allowing joinder in certain cases? Are we subjecting defendants to increased costs in defending numerous lawsuits filed in various locations? The taxpayers will ultimately bear the burden of the increased litigation and increased filings in our court system. The court system will become rapidly clogged with yet more cases slowing the legal process further and increasing the burden on court staff and further straining the limited budget of our court system. Thirdly, where does a litigant stand in future cases, especially if his individual claim is relatively small, and therefore the economics of the matter would deter cases and deprive litigants of any recourse.

¶156. As this decision leaves too many questions unanswered, I must respectfully dissent. M.R.C.P. 20 is intended to streamline cases and promote judicial economy. ***Armond*** and this case create further problems which will ultimately impact Mississippi by clogging our court systems, strain our judicial staff and resources, and place an added cost burden on the taxpayer by increasing the litigation and subsequent court costs. In my opinion, this Court needs to take a more thorough look at this troubling situation, consider setting up a special committee to address the situation and seriously consider and investigate the alternative of implementing class actions in Mississippi, possibly following the federal court model set out in F.R.C.P. 23.