IN THE SUPREME COURT OF MISSISSIPPI

NO. 2015-CA-01369-SCT

JOHNSON & JOHNSON, INC. AND ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC.

v.

BRENDA FORTENBERRY, AS THE CONSERVATOR OF THE ESTATE OF PERSON OF LOUISE TAYLOR

DATE OF JUDGMENT:	01/27/2015
TRIAL JUDGE:	HON. LAMAR PICKARD
TRIAL COURT ATTORNEYS:	TIMOTHY W. PORTER PATRICK MALOUF JOHN TIMOTHY GIVENS DANIEL J. McGLYNN PAUL V. CASSISA, JR. ADAM JULIUS SPICER DONNA BROWN JACOBS JENNIFER A. HAWKS-BLAND KIMBERLY NELSON HOWLAND DAVID LOREN STRANGE, JR. CHRISTY D. JONES CHAD ROBERTS HUTCHINSON
COURT FROM WHICH APPEALED:	COPIAH COUNTY CIRCUIT COURT
ATTORNEYS FOR APPELLANTS:	KATHLEEN ELIZABETH CARRINGTON DONNA BROWN JACOBS PAUL V. CASSISA, JR. ADAM JULIUS SPICER CHRISTY D. JONES
ATTORNEYS FOR APPELLEE:	DAVID NEIL McCARTY TIMOTHY W. PORTER JOHN TIMOTHY GIVENS PATRICK MALOUF
NATURE OF THE CASE:	CIVIL - PERSONAL INJURY

DISPOSITION: ON DIRECT APPEAL: REVERSED AND RENDERED IN PART; REVERSED AND REMANDED IN PART. ON CROSS-APPEAL: AFFIRMED - 10/19/2017

MOTION FOR REHEARING FILED:
MANDATE ISSUED:

BEFORE RANDOLPH, P.J., COLEMAN AND MAXWELL, JJ.

COLEMAN, JUSTICE, FOR THE COURT:

¶1. The subject of the present products liability lawsuit is Risperdal, an antipsychotic medication approved by the Federal Food and Drug Administration on December 29, 1993, as a safe and effective prescription drug for the management of the manifestation of psychotic disorders. We hold that, as a matter of law, the Risperdal in question contained an adequate warning; we reverse and render the statutory inadequate warning judgment. We further hold that, as more fully set forth below, various errors in the jury instructions require reversal of the plaintiff's verdict that sounded in negligent misrepresentation, and we reverse and remand the negligent misrepresentation claim. We also address other, nondispositive issues that might arise again upon retrial.

¶2. Louise Taylor began suffering psychotic episodes when she was seventy-one years old, in early 1998. From March 1998 to January 2001, Psychiatrist Richard Rhoden prescribed Risperdal to Taylor for the treatment of her recurrent psychotic manifestations. In February 2001, Taylor developed tardive dyskinesia, a movement disorder caused by antipsychotic medications. Tardive dyskinesia is a syndrome of potentially irreversible, involuntary, dyskinetic movements in patients treated with antipsychotic drugs. Tardive dyskinesia is a type or subcategory of extrapyramidal symptoms, which is a general category

of movement disorders that may result from neuroleptic exposure to antipsychotics.

¶3. On August 6, 2002, Taylor[1] filed a complaint against Ortho-McNeil Janssen Pharmaceuticals, the manufacturer, seller, and distributer of Risperdal, and its parent company Johnson & Johnson (collectively "Janssen"), claiming that Risperdal caused her to develop tardive dyskinesia. Taylor also named her treating physician, Dr. Richard Rhoden, as a defendant in her complaint. Taylor settled her claims against Dr. Rhoden prior to trial. The case went to trial on November 7, 2014. On November 14, 2014, the jury, in a nine to three decision, found that Taylor was harmed by Risperdal due to: (1) Janssen's "failure to provide adequate warnings/instructions" and (2) Janssen's "negligent marketing/misrepresentation." The jury awarded Taylor $650,000 in actual economic damages and $1.3 million in noneconomic damages, for a total damages award of $1,950,000.

¶4. Janssen appeals, raising the following issues:

> I. Is Janssen entitled to judgment as a matter of law on Taylor's failure-to-warn claim because there was no evidence of any alleged inadequacy in the Risperdal warning because Janssen warned of the risk of Tardive Dyskinesia; and there was no evidence that any alleged inadequacy in the Risperdal warning proximately caused Taylor's Tardive Dyskinesia?
>
> II. Is Janssen entitled to judgment as a matter of law on Taylor's negligent misrepresentation claim because Taylor failed to offer proof that Taylor's prescribing physician, Dr. Rhoden, received any specific misrepresentation from Janssen, much less that Dr. Rhoden relied on

[1] Brenda Fortenberry, as conservator of Louise Taylor, was substituted as the plaintiff. For clarity, the Court refers to the plaintiff as Taylor throughout the opinion. Fortenberry actually is Taylor's niece, but she was raised by Taylor and refers to Taylor as her mother.

any alleged misrepresentation in prescribing Risperdal to Taylor?

III. Is Janssen alternatively entitled to a new trial because the trial court's substantive jury instructions were improper?

IV. Is Janssen alternatively entitled to a new trial because economic damages should not have gone to the jury, as there was no proof connecting Taylor's Tardive Dyskinesia, the only condition allegedly caused by Risperdal, to the need for twenty-four-hour attendant care – the only economic damages Taylor sought?

V. Is Janssen alternatively entitled to a remittitur of the economic damage award because it is not supported by evidence?

VI. Is Janssen alternatively entitled to a new trial because Taylor's counsel used inflammatory, highly offensive, and improper argument during closing?

¶5. Taylor cross appeals, raising the following issue:

VII. Did the evidence warrant a punitive damages proceeding?

FACTS AND PROCEDURAL HISTORY

¶6. In early 1998, Taylor began suffering psychotic episodes featured by paranoia, delusions, and hallucinations. One morning, Taylor prevented her daughter Fortenberry from leaving their house to go to work by physically blocking the door because she believed there were people outside her house trying to do Fortenberry harm. Taylor believed what she saw and heard really was there despite Fortenberry's assurances otherwise. Due to the episode, Fortenberry took Taylor to a local physician, who referred Taylor to Charter Hospital, an inpatient behavioral health facility. Taylor was admitted to Charter Hospital and diagnosed with "severe depression with a single psychotic episode." While a patient at Charter Hospital, caregivers prescribed Taylor Haldol (generic: Haloperidol), a "first generation" or

"typical" antipsychotic medication. Taylor received treatment for a number of weeks at Charter Hospital, and on March 3, 1998, she was discharged and was referred to Dr. Rhoden for further treatment.

¶7. On March 23, 1998, Taylor first saw Dr. Rhoden. Dr. Rhoden continued Taylor's Haldol prescription for her previously existing psychosis. Dr. Rhoden did not observe Taylor exhibiting extrapyramidal symptoms during the visit. At the next visit, on June 4, 1998, Dr. Rhoden discontinued Haldol and prescribed Seroquel (generic: quetiapine), a "second generation" or "atypical" antipsychotic medication. Dr. Rhoden explained that he changed medications because he believed Seroquel would help Taylor's insomnia. Dr. Rhoden also explained that Seroquel was "one of the newer types of [antipsychotics,]" and he "was trying to change people from the older type antipsychotics to the newer atypical type." Dr. Rhoden provided Taylor and Fortenberry with the material side effects of Seroquel. Dr. Rhoden testified that the material side effects he believed he would have discussed included "the different types of EPS which could be either temporary, or in some cases long term movement or pulling or different kinds of muscle abnormalities that could occur."

¶8. At the next visit on July 20, 1998, Dr. Rhoden continued the prescription for Seroquel and noted that Taylor "has a mouth twitch some since stopping Haldol[.]" On September 17, 1998, Dr. Rhoden noted that Taylor's "mouth twitching is better[.]" Dr. Rhoden also noted that Taylor was doing well with the current treatment and continued the prescription for Seroquel.

¶9. On November 19, 1998, Taylor was hospitalized at Hardy Wilson Memorial Hospital

following a suicide attempt by taking sixty Seroquel pills and some Prozac pills, which also had been prescribed for her. Taylor was diagnosed with "major depression, recurrent with psychosis[.]" On December 10, 1998, Taylor was discharged with the need for constant supervision until her next appointment scheduled for December 15, 1998, with Region 8 Mental Health. Following the discharge, Fortenberry left her job to care for Taylor twenty-four hours a day because of Taylor's severe depression and psychosis.

¶10. On March 18, 1999, Taylor returned to Dr. Rhoden for her next visit. Dr. Rhoden recognized that Taylor "was on Seroquel and at some point, she was worse and had to be hospitalized[,]" so he discontinued the Seroquel. In an effort to "try something different[,]" Dr. Rhoden prescribed Risperdal (generic: risperidone), a "second generation" or "atypical" antipsychotic, to Taylor. Dr. Rhoden first started Taylor on Risperdal at one to two milligrams at nine p.m. as directed. Dr. Rhoden's record confirmed that "side effects [were] given inc[luding] T.D. [and] EPS." Dr. Rhoden testified that he informed both Taylor and Fortenberry of the risk of tardive dyskinesia and extrapyramidal symptoms during the visit. Dr. Rhoden explained that he would have told Taylor and Fortenberry: "[R]emember that this medicine, as in all medicines in this class, can produce certain movement problems or pulling or muscle problems that can develop that can be short term. It can be treated, but sometimes they can't be; they can be long term."

¶11. Risperdal, along with all other antipsychotic medications on the market, were required to carry the Food and Drug Administration approved class label warning for tardive dyskinesia. The Food and Drug Administration utilizes a class label for the purpose of

informing the physician that the medication carries the potential risk for the same particular adverse events as all the other medications in the same class. The pertinent portions of the Food and Drug Administration approved class label included in the Risperdal label during the time period that Dr. Rhoden prescribed Risperdal to Taylor provided:

RISPERDAL™

(Risperidone tablets)

> RISPERDAL™ (risperidone) is an antipsychotic agent belonging to a new chemical class, the benzisoxazole derivatives.
> . . . .
>
> RISPERDAL™ (risperidone) is indicated for the management of the manifestations of psychotic disorders.
>
> . . . .
>
> **WARNINGS**
>
> **Tardive Dyskinesia**
>
> A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with antipsychotic drugs. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to rely upon prevalence estimates to predict, at the inception of antipsychotic treatment, which patients are likely to develop the syndrome. Whether antipsychotic drug products differ in their potential to cause Tardive Dyskinesia is unknown.
>
> The risk of developing Tardive Dyskinesia and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic drugs administered to the patient increase. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses.
>
> There is no known treatment for established cases of Tardive Dyskinesia, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn. Antipsychotic treatment, itself, however, may

> suppress (or partially suppress) the signs and symptoms of the syndrome and thereby may possibly mask the underlying process. The effect that symptomatic suppression has upon the long-term course of the syndrome is unknown.
>
> Given these considerations, RISPERDAL™ (risperidone) should be prescribed in a manner that is most likely to minimize the occurrence of Tardive Dyskinesia. Chronic antipsychotic treatment should generally be reserved for patients who suffer from a chronic illness that (1) is known to respond to antipsychotic drugs, and (2) for whom alternative, equally effective, but potentially less harmful treatments are not available or appropriate. In patients who do require chronic treatment, the smallest dose and the shortest duration of treatment producing a satisfactory clinical response should be sought. The need for continued treatment should be reassessed periodically.
>
> If signs and symptoms of Tardive Dyskinesia appear in a patient on RISPERDAL™, drug discontinuation should be considered. However, some patients may require treatment with RISPERDAL™ despite the presence of the syndrome.

¶12. Dr. Rhoden was aware that all antipsychotics, including Risperdal, had been associated with tardive dyskinesia. Dr. Rhoden, who had prescribed Risperdal since the early 1990s, had familiarized himself with the Risperdal label before prescribing it. Dr. Rhoden verified that the label's language regarding tardive dyskinesia was consistent with his understanding of tardive dyskinesia and its association with Risperdal.

¶13. Dr. Rhoden continued to treat Taylor with Risperdal and on May 6, 1999, Dr. Rhoden increased Taylor's dosage to three milligrams per day. On November 10, 1999, Dr. Rhoden noted that, "psychiatrically [Taylor] is more bright and stable than ever." On January 10, 2000, Dr. Rhoden noted: "reviewed again side effects of Rx esp. Risperdal" including, "T.D." and "EPS[.]" Dr. Rhoden also noted "no significant problems" of the side effects, tardive dyskinesia and extrapyramidal symptoms. On May 1, 2000, Dr. Rhoden noted "no

EPS[,]" and increased Risperdal to four milligrams. On November 6, 2000, Dr. Rhoden noted "no EPS[.]" On January 24, 2001, Dr. Rhoden noted that Taylor had "developed an oral dyskinesia which I had previously warned her and her daughter about." In response, Dr. Rhoden decreased the dosage of Risperdal and restarted Taylor on Seroquel.

¶14. On February 21, 2001, Taylor visited with Dr. Rhoden for the last time. Dr. Rhoden noted that since the previous month's visit, Taylor "has been having trouble w[ith her] tongue moving around inside and darting outside of her mouth since changing from the Risperdal to the new medication – Seroquel– to the point of being unable to wear dentures." Dr. Rhoden noted that Taylor's chief concern was the cause of the involuntary movement of her tongue. Dr. Rhoden noted that Taylor was "clearer psychiatrically, not dizzy – is pleased [with] this even though her oral dyskinesia has increased as above – most likely rebound effect after Risperdal [decreased] – I again reminded her and her daughter of T.D. and [associated] risk factors (age, gender . . .) – [t]hey want to continue [prescription] and try to [treat] side effects[.]" It was apparent to Dr. Rhoden that Taylor had developed tardive dyskinesia as of the February 21, 2001, visit.

¶15. Taylor has since been treated by dozens of other physicians and has continuously needed an antipsychotic medication for the treatment of her severe psychosis. At the time of trial, Taylor was on Seroquel.

¶16. Dr. Richard Trosch, a neurologist specializing in movement disorders, testified for Taylor. Dr. Trosch explained that all tardive dyskinesia is caused by antipsychotic medications or neuroleptics by definition. Dr. Trosch opined that Taylor's exposure to

Risperdal over a period of nearly three years had caused her tardive dyskinesia. Dr. Trosch opined that, with regard to extrapyramidal symptoms and tardive dyskinesia, the safest antipsychotics are Seroquel and Clozaril (generic: Clozapine). Dr. Trosch opined that had Taylor been prescribed Seroquel or Clozaril, rather than Risperdal, it would be "very unlikely" that she would have developed tardive dyskinesia.

DISCUSSION

I. Whether Janssen is entitled to judgment as matter of law on Taylor's failure to warn claim.

¶17. Janssen argues that the trial court erred by denying its motion for a judgment notwithstanding the verdict. Specifically, Janssen argues that Taylor's failure to warn claim fails as a matter of law because she failed to present evidence of any inadequacy in the Risperdal warning. Alternatively, Janssen argues that there was no evidence that any inadequacy in the Risperdal warning caused Taylor's tardive dyskinesia.

¶18. "The standard of review for the denial of a motion for a judgment notwithstanding the verdict (JNOV) is de novo." ***United Servs. Auto. Ass'n (USSA) v. Lisanby***, 47 So. 3d 1172, 1176 (¶ 8) (Miss. 2010). "A motion for JNOV is a challenge to the legal sufficiency of the evidence, and this Court will affirm the denial of a JNOV if there is substantial evidence to support the verdict." ***Id***. The Court considers the evidence in the light most favorable to the appellee, giving that party the benefit of all favorable inferences that may be reasonably drawn from the evidence. ***Id***. "In essence, judgments as a matter of law present both the trial court and the appellate court with the same question – whether the evidence, as applied to the elements of a party's case, is either so indisputable, or so deficient, that the necessity of

a trier of fact has been obviated." ***Id***.

¶19. Under the Mississippi Products Liability Act, "[a] manufacturer is liable under a failure-to-warn theory if the product 'failed to contain adequate warnings,' the inadequate warnings 'rendered the product unreasonably dangerous to the user or consumer,' and the inadequate warning 'proximately caused the damages for which recovery is sought.'" ***Union Carbide Corp. v. Nix, Jr.***, 142 So. 3d 374, 385 (¶ 18) (Miss. 2014) (quoting Miss. Code Ann § 11-1-63(a)(i)-(iii)).

¶20. A drug manufacturer has a duty adequately to warn the prescribing physician of any known adverse effects which might result from the use of its prescription drugs. ***Wyeth Labs., Inc. v. Fortenberry***, 530 So. 2d 688, 691 (Miss. 1988) (citing ***Swayze v. McNeil Laboratories, Inc***., 807 F.2d 464 (5th Cir. 1987). The Court has explained:

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

Janssen Pharmaceutica, Inc. v. Bailey, 878 So. 2d 31, 57 (¶ 122) (Miss. 2004) (quoting ***Fortenberry***, 530 So. 2d at 691 (internal quotations and citations omitted)).

¶21. Under the learned intermediary 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." ***Bailey***, 878 So. 2d at 58 (¶ 124). "If there is no physician in the role of 'learned intermediary' then the drug manufacturer has a duty to adequately warn the consumer." ***Fortenberry***, 530 So.

2d 688 at 692.

¶22. "By law, the labeling of every prescription drug must include a package insert listing known side effects." ***Bailey***, 878 So. 2d at 36 (¶ 7) (citing 21 C.F.R. §§ 201.56-201.57). "The [Food and Drug Administration] must approve the content of such inserts, which communicate to prescribing physicians the essential information about the medication's benefits and risks." ***Id***. "An adequate warning is one reasonable under the circumstances." ***Id***. at 55 (¶ 109). "To be reasonable, the warning should neither understate nor overstate the known risks associated with the use of a particular product." ***Id***. In some cases, a package insert may be sufficient for the warning to be adequate as a matter of law. ***Id***. at 55 (¶ 110).

¶23. The Court also has held that "[t]he issue of a warning's adequacy is factual and usually will be resolved by the trier of fact." ***Fortenberry***, 530 So. 2d at 692. The adequacy of a warning addressed to the medical community may fall into the category of issues requiring expert testimony because prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. ***Id***. "Where the adequacy of the warning is not obvious to the ordinary layperson it is necessary to have expert testimony[.]" ***Id***.

¶24. In ***Fortenberry***, Billy Joe Fortenberry suffered paralysis after receiving a flu vaccine manufactured by Wyeth Laboratories and administered by his local physician, Dr. T.L. Moore. ***Id***. at 689. Fortenberry eventually was diagnosed with transverse myelitis, which is closely related, in etiology and pathology, to Guillain-Barre syndrome. ***Id***. Fortenberry filed a complaint against Wyeth and Dr. Moore for failure to warn. ***Id***. The vaccine package contained an insert for the prescribing physician warning of possible adverse reactions,

including Guillain-Barre syndrome. ***Id***. Dr. Moore testified that he had received and read the package insert and kept abreast of recent medical literature. ***Id***. Dr. Moore also testified that he believed the risk to be minimal and remote. ***Id***. Therefore, Dr. Moore believed a warning to his patients would scare them and was not required. ***Id***.

¶25. The Court determined it was clear from the record that Fortenberry was in the group of "healthy adults" for whom the vaccine was not recommended. ***Id***. at 692. The vaccine was recommended for those "who are at increased risk of adverse consequences from infections of the lower respiratory tract." ***Id***. at 692-93. The package insert went on to warn physicians that, although the connection between the vaccine and Guillain-Barre syndrome was not clear, persons considering the vaccine "should be made aware of the benefits and possible risks, including [Guillain-Barre syndrome], of administration." ***Id***. at 693. Dr. Moore testified that he kept abreast of the medical literature and did not believe there was a sufficient connection between the vaccine and Guillain-Barre syndrome to warrant a warning. ***Id***. Therefore, Dr. Moore decided to give no warning to Fortenberry. ***Id***. The Court held that the warning on the package insert was adequate as a matter of law and reversed and rendered judgment in favor of Wyeth. ***Id***. at 691, 693.

¶26. Here, the Risperdal label unequivocally communicated the risk of tardive dyskinesia associated with the use of all antipsychotic drugs, including Risperdal. The label provided that tardive dyskinesia "may develop in patients treated with antipsychotic drugs." The label also provided: "[w]hether antipsychotic drug products differ in their potential to cause Tardive Dyskinesia is unknown." Dr. Rhoden, who was not designated as an expert,

specifically testified that he considered the language of the Risperdal label adequate to warn him of the risk of tardive dyskinesia in Risperdal users at the time he prescribed it to Taylor.

¶27. Dr. Rhoden testified that he became familiar with Risperdal's package insert before prescribing the medication to his patients. Dr. Rhoden's records and testimony confirm that he understood and appreciated the risk of tardive dyskinesia associated with Risperdal. Dr. Rhoden's awareness also was evident from the medical records in which he repeatedly noted that he specifically had warned Taylor and Fortenberry about the risk of extrapyramidal symptoms and tardive dyskinesia associated with Risperdal. Dr. Rhoden prescribed Risperdal after performing a risk/benefit analysis. Dr. Rhoden testified:

> Q. Doctor, despite th[e label's] language and despite your knowledge about tardive dyskinesia and Risperdal, you made the medical judgment that Risperdal was an appropriate medication for Ms. Taylor?
>
> A. Correct.
>
> Q. And that is even with the knowledge of the risk associated?
>
> A. Correct. Because the benefit was much greater than and the loss of that benefit would be much worse than the risk of the side effects.
>
> Q. . . . . What was your understanding of the benefits of Risperdal for a patient like Ms. Taylor?
>
> A. The benefits would be to decrease or put into remission the psychotic symptoms which are terrible and unremitting and lead to very bad outcomes. And those are much more certain than the risks of possible side effects.
>
> Q. And despite that, you did, nonetheless, warn Ms. Taylor and her daughter, Brenda Fortenberry, of the risk of tardive dyskinesia with Risperdal?
>
> A. Correct.

¶28. Taylor sought to prove that the warning was inadequate by way of Janssen's promotional materials, internal documents, and expert testimony. Dr. William Edwin Fann, an academic psychiatrist and academic physician, testified for Taylor. Dr. Fann testified that the Food and Drug Administration Risperdal class warning label was cookie cutter information and meaningless because it was marketed as "atypical." Dr. Fann testified:

> [Y]ou could go through the PDR, Physicians' Desk Reference, or go through the U.S. Pharmaceutical and Drug Information, and that same information is there on every anti-psychotic. It was required. That doesn't mean as much as it sounds like it means. Because all of this has been gained, that is, not erased but balanced, counter-balanced by saying it's an atypical. To say this drug is as likely to cause tardive dyskinesia as any of the others, but it's a -- you know, those that's what some people would call cookie-cutter information. That's something you're saying about every drug.

¶29. Taylor's attempt to prove her failure to warn claim through Janssen's marketing materials and internal documents expanded the claim beyond the statutory scope of the Products Liability Act. Based on the terms of the Act, enacted in 1993, the only pertinent question is whether the prescription drug label contained adequate warnings or instructions. *See* Miss. Code Ann. § 11-1-63(c)(i)-(ii) (Rev. 2014).

¶30. Although the statutory scope of a failure to warn claim is limited to actual warnings or instructions for a product, the Court has mentioned marketing materials in the prescription drug context. In a pre Products Liability Act case, the Court stated: "Notwithstanding the government regulations in this field, the package insert is a marketing or merchandising procedure to promote sales." ***Thompson v. Carter***, 518 So. 2d 609, 612 (Miss. 1987) (holding that a package insert was admissible in a medical malpractice case). Moreover, the Court stated, "[d]rug manufacturers have had to answer for alleged dilution of warnings by

over-promotion in sales programs." ***Id***.

¶31. In ***Bailey***, a post-Act case, the Court alluded to the association of prescription drug marketing materials in the context of a failure to warn claim. There, the Court reversed and remanded for severance and new trial of the claims of ten plaintiffs based on improper joinder, and the Court discussed pertinent principles of an inadequate warning case against a prescription drug manufacturer. ***Bailey***, 878 So. 2d at 49 (¶ 88). The plaintiffs contended that they had offered sufficient proof to show that, through aggressive marketing and over promotion, the drug manufacturer had nullified the effectiveness of the warnings that it did issue. ***Id***. at 55 (¶ 109). The Court concluded that the issue of whether the Food and Drug Administration approved labeling was adequate, was a question of fact which should be determined by the jury. ***Id***. at 59 (¶ 132). Although the Court mentioned "aggressive marketing and over promotion," the Court's analysis was focused on the actual drug label. *See* ***id***. at 56-59 (¶¶ 108-132).

¶32. The Court does not consider Janssen's marketing materials or internal documents as support of Taylor's failure to warn claim under the Products Liability Act in determining the adequacy of the Risperdal label. Taylor's attempt to support her failure to warn claim with Janssen's marketing materials and internal documents improperly expands the statutory scope of her claim. *See* Miss. Code Ann. § 11-1-63(a)(i)(2) (Rev. 2014) ("The product was defective because it failed to contain adequate warnings or instructions[.]").

¶33. The Risperdal label warned physicians that tardive dyskinesia might develop in patients treated with antipsychotic drugs. The label also warned that whether antipsychotic

drug products differ in their potential to cause tardive dyskinesia was unknown. Under ***Fortenberry***, the Court holds that the Risperdal label warned Dr. Rhoden specifically of the danger of tardive dyskinesia in no uncertain terms and was sufficiently adequate as a matter of law. ***Fortenberry***, 530 So. 2d at 692-93. Because the warning was adequate as a matter of law, we do not reach Taylor's causation argument. We reverse and render judgment in favor of Janssen as to Taylor's failure to warn claim.

II. Whether Janssen is entitled to judgment as a matter of law on Taylor's negligent misrepresentation claim.

¶34. Janssen argues that the trial court erred by denying its motion for judgment as a matter of law because Taylor offered no proof that Janssen had made any specific misrepresentation to Dr. Rhoden, much less that he relied on any alleged misrepresentation in prescribing Risperdal to Taylor. The parties do not dispute whether it is the patient or prescribing physician who must rely on the alleged misrepresentation or omission. As previously discussed, we review the denial of a motion for judgment as a matter of law de novo. ***Lisanby***, 47 So. 3d at 1176 (¶ 8). Janssen and Taylor travel under the theory that the learned intermediary doctrine applies equally in a negligent misrepresentation claim in the prescription drug context.

¶35. "In order to establish a prima facie case of negligent misrepresentation, a plaintiff is required to show: (1) a misrepresentation or omission of a fact; (2) that the representation or omission is material or significant; (3) that the defendant failed to exercise that degree of diligence and expertise the public is entitled to expect of it; (4) that the plaintiff reasonably relied on the defendant's representations; and (5) that the plaintiff suffered damages as a

direct and proximate result of his reasonable reliance." ***Skrmetta v. Bayview Yacht Club, Inc***., 806 So. 2d 1120, 1124 (¶ 13) (Miss. 2002). The first element of misrepresentation must concern a past or present fact, as contrasted with a promise of future conduct. ***Id***.

¶36. Taylor's expert Dr. Fann opined that the incidence of tardive dyskinesia from Risperdal is essentially equivalent with "some of the older anti-psychotics" such as Haldol. Taylor's expert Dr. Trosch opined that Risperdal's pharmacology was more like Haldol than Clozapine, and it would cause a rate of tardive dyskinesia "closer to Haldol and unlike that of [C]lozapine." Dr. Trosch testified that the information was "probably known when [Janssen] did the initial pharmacology studies" prior to the launch of Risperdal.

¶37. Although the Court did not consider promotional materials and internal documents in analyzing whether the warning contained in the Risperdal label was adequate, the evidence becomes relevant in the context of Taylor's negligent misrepresentation claim. Taylor offered evidence by way of Janssen's promotional materials, internal documents, and expert testimony that the warning was diluted by Janssen's promotion of Risperdal in its sales programs.

¶38. On December 21, 1993, the Food and Drug Administration's division of Neuropharmacological Drug Products concluded that Risperdal was safe in use and effective for use if marketed for the management of the manifestations of psychotic disorders and recommended that Janssen's new drug application be approved. However, the Division determined that Janssen's proposed "side by side presentation of data [including adverse reactions suffered by patients] obtained on Risperdal and haloperidol assigned subjects

invites a comparison that leads to the conclusion that Risperdal has been shown to be superior to haloperidol when, in fact, it has not." In the Administration's approval letter dated, December 29, 1993, it stated that, with regard to promotional materials, it "would consider any advertisement or promotional labeling for RISPERDAL false, misleading, or lacking fair balance . . . if there is presentation of data that conveys the impression that risperiodone is superior to haloperidol or any other marketed antipsychotic drug product with regard to safety or effectiveness."

¶39. Janssen's 1995 business plan for Risperdal, one year after the launch of Risperdal, confirmed that the message was received:

> Promotional message monitoring demonstrated the main messages Psychiatrists claim to have received upon launching RISPERDAL were: "side effects, especially EPS, comparable to placebo", "no tardive dyskinesia", "no blood monitoring", "expensive". By May, 1994, total awareness among Psychiatrists was 100%; trial was at 73% and usage was 71%.

The business plan also stated: "During the 1996-7 time frame, RISPERDAL could experience a sustained period of growth as the market realizes the drug's low tardive dyskinesia potential and as outcomes data becomes available." Furthermore, "During this window of opportunity, Janssen can establish RISPERDAL as the 'new gold standard' thereby replacing haloperidol." Taylor offered Janssen's internal emails into evidence from the December 1995 to February 1996 time frame. The email exchange discussed the Food and Drug Administration's denial of the promotion of the comparison of Risperdal to haloperidol. Taylor portrays the email exchange as Janssen disregarding the Food and Drug Administration 's proscription. Janssen employees concluded it needed to address "general

unawareness that Risperdal beat Haldol on positive symptoms." Janssen employees were in favor of entering the "gray area" and "take appropriate risks." No specific decision was made according to the emails; rather, the issue was slated to be discussed at a later time before moving forward.

¶40. Taylor contends that the actions of Janssen following the email exchange shows its defiance to the Food and Drug Administration in its endeavor into the gray area through its submissions of the Food and Drug Administration's division of Drug Marketing, Advertising, and Communications. The division 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 Food and Drug Administration regulations. ***Bailey***, 878 So. 2d at 61 (¶ 139). Janssen's proposed promotional materials submitted to the division in October 1996 included the following statement: "No first-line antipsychotic proven more effective in positive and negative symptoms." Janssen's promotional materials declared that Risperdal had a "[p]roven safety profile." Under the "[p]roven safety profile" heading, the promotional material stated: "No tardive dyskinesia (TD) reported in premarketing clinical trials[,]" and ".4% incidence of TD reported in long-term follow-up trials." Also, "[l]aboratory test results comparable to placebo."

¶41. The promotional statements were qualified by footnotes. For example, "Prescribing should be consistent with the need to minimize the risk of tardive dyskinesia; if its signs and symptoms appear, discontinuation of RISPERDAL should be considered." "Doses above 6mg/day were not shown to be more efficacious than lower doses and demonstrated

dose-dependent increase in EPS and other adverse side effects." And "the most common adverse events reported in premarketing clinical trials [included]. . . EPS[, among others.]"

¶42. A separate, undated Janssen promotional piece stated that Risperdal had "[m]inimal EPS at recommended doses" and was "[c]omparable to placebo in special populations ([less than or equal to] 1 mg/day)[.]" The promotional piece also stated: "Percentage of adult patients reporting EPS with RISPERDAL, while dose-dependent, is comparable to placebo at doses [less than or equal to] 6 mg/day and differs significantly from placebo at doses > 6 mg/day. In a study in an elderly population, the risk of EPS was comparable to placebo at doses [less than or equal to] 1 mg/day and differs significantly from placebo at doses [greater than or equal to] 2 mg/day."

¶43. Janssen corporate representative, David Fabbri, confirmed that Janssen's sales representatives use the promotional materials to educate physicians on the products and then the physician ultimately decides what is most appropriate for the patient. Part of the sales representatives' compensation would be based on the number of prescriptions written. Dr. Suzanne Parisian, a physician, regulatory consultant, and former Food and Drug Administration employee, testified for Taylor. Dr. Parisian testified that Janssen's marketing representations left physicians with the mistaken idea that Risperdal's risk of extrapyramidal symptoms was comparable to placebo and that there was no tardive dyskinesia risk.

¶44. Dr. Trosch, a neurologist specializing in movement disorders, testified that in his own practice, he had encountered Janssen sales representatives who told him that Risperdal was

similar or equal to placebo in terms of the risk for extrapyramidal symptoms. Dr. Trosch testified that during the late 1990s and early 2000s, most psychiatrists around the country did not understand the risk of Risperdal causing tardive dyskinesia.

¶45. Dr. Trosch opined that describing Risperdal as "atypical" was "very misleading" because the original intent of the term was meant for "drugs that had very little or no risk of inducing tardive dyskinesia." Dr. Trosch testified that the term "atypical" was originally a scientific term describing Clozapine, which demonstrated a lower risk of extrapyramidal symptoms due to its distinctive properties. Dr. Trosch acknowledged there is no consensus on the definition of the term "atypical" and "[i]f you talk to ten psychiatrists, I think you'll get ten definitions of the word[s] typical and atypical." He explained that the term "atypical" has morphed into a marketing term and lost its meaning because it has been used to describe every new drug released since Clozapine, whether it shared the same properties or not, and even if the new drug is linked to fairly high rates of tardive dyskinesia and extrapyramidal symptoms. Dr. Trosch opined that, based on the pharmacology of Risperdal, it is more like Haldol than Clozapine, and it would cause a rate of tardive dyskinesia "closer to Haldol and unlike that of [C]lozapine."

¶46. Dr. William Edwin Fann, an academic psychiatrist and academic physician, also testified for Taylor. Dr. Fann testified that a "serious misconception" exists in the practice of psychiatry that Risperdal is more closely related to Clozaril than it is to Haldol. Dr. Fann explained that Janssen's marketing phrase for Risperdal that "EPS comparable to placebo" did not accurately describe the propensity for Risperdal to cause EPS and tardive dyskinesia.

Dr. Fann also testified that Risperdal was marketed to him by Janssen sales representatives as "one of the new atypical drugs." Dr. Fann explained: "[I]t was marketed as atypical, and by that, everybody knew that clozapine was the drug that did not cause EPS. And so when you said a drug was atypical, it meant it wasn't going to cause EPS." As previously mentioned, Dr. Fann testified that the Food and Drug Administration Risperdal class warning label was cookie cutter information and meaningless because Risperdal was marketed as "atypical."

¶47. Janssen claims that Taylor made no effort to prove that Dr. Rhoden ever saw any of the Risperdal promotional pieces containing alleged misrepresentations. Janssen faults Taylor for failing to show Dr. Rhoden a single promotional piece during his testimony. In support of its argument, Janssen cites an unreported Texas federal district court order granting a motion in limine stating that under the learned intermediary doctrine, "absent evidence that the physicians were exposed to the [drug manufacturer's advertising and promotional] materials, the [district] court finds that the promotional and advertising materials are not relevant evidence." ***In re Norplant Contraceptive Prod. Liab. Litig.***, 1997 WL 81092, at *1 (E.D. Tex. Feb. 21, 1997). Janssen also cites ***Lea v. Wyeth LLC***, 2011 U.S. Dist. LEXIS 155503 (E.D. Tex Sept. 16, 2011) (unreported), in which the district court granted the drug manufacturer defendant's motion to exclude the marketing practices testimony of the plaintiff's experts because the plaintiff's treating physician testified that he did not rely on the drug manufacturer's promotional materials; instead he threw the materials in the trash. ***Id***. at **6, 13-14.

¶48. In contrast, Dr. Rhoden testified that he recalled several Janssen sales representatives specifically tasked with selling Risperdal. Dr. Rhoden testified that he would "try to accommodate them when they c[a]me by." Although Dr. Rhoden explained they would "only have a minute or two, and they usually, typically, would show some of the literature that they had." Dr. Rhoden received Janssen's marketing messages:

> Q. Do you remember [Risperdal] being marketing as having a better EPS side effect profile than the older drugs?
>
> A. I just remember the information about it, and I assume marketing as well as reading about it – I can't always differentiate because I read journals and things, too – but all the information identified it as atypical and having fewer EPS side effects.

¶49. Dr. Rhoden testified that Risperdal was marketed to him as an "aytpical" neuroleptic. Dr. Rhoden also identified the source of the idea that if the Risperdal dose stayed below six milligrams, the tardive dyskinesia risk would remain low. Dr. Rhoden testified the information derived from professional literature, the Physician's Desk Reference, word of mouth, trials, the Food and Drug Administration, and the drug company's literature. However, Dr. Rhoden testified that "most of the information" he received was "not from the drug company literature." Specifically, Dr. Rhoden testified:

> Q. Where did you derive that information about if you stayed below 6 milligrams, it would remain a low risk of tardive dyskinesia?
>
> A. Most of that was from the professional literature at the time. I mean, it was in the [Physician's Desk Reference], too. It was talked about. There were some trials and things. When they went up to higher doses, there were increases in side effects. I don't remember the exact wording at this point, but that information was pretty omnipresent in both professional literature and the [Food and Drug Administration] and the drug company's literature.

Q. And would that have come in part from the literature that the drug company provided to you?

A. Probably. I just don't know what percentage. I really – most of the information I get is from – is not from the drug company literature.

Q. It would have also come in part from the [Physician's Desk Reference]?

A. In part, yes.

¶50. Dr. Rhoden acknowledged that the dosage information was "omnipresent" in professional literature, the Food and Drug Administration's literature, and Janssen's literature. Dr. Rhoden did not recall any promotional materials or advertisements marketing Risperdal's extrapyramidal symptoms side effect profile as being comparable to placebo. However, at least part of the reason Dr. Rhoden began prescribing Risperdal was because he believed it had a better side effect profile. Dr. Rhoden testified that he makes an "independent judgment and assessment with regard to [his] patients when determining whether or not to prescribe medications," including Risperdal. Dr. Rhoden also testified that, at the time he prescribed Risperdal to Taylor, he understood that the risk for tardive dyskinesia with Risperdal was "materially lower" than the risk with Haldol. Dr. Rhoden testified that, based on his experience at the time he prescribed Risperdal to Taylor, he found the occurrences of tardive dyskinesia and other risks associated with first-generation antipsychotics were lower with Risperdal.

¶51. Dr. Rhoden testified that his decision to prescribe Risperdal to Taylor was a "sound medical decision" at the time he prescribed Risperdal to Taylor. And at the time of trial, Dr. Rhoden testified that he stands by his decision to prescribe Risperdal to Taylor. The only

testimony of Dr. Rhoden implying that his conduct would have been altered came from the following exchange:

> Q. Let me ask you this question: If the information at this time, on 3-18-99, with regard to Risperdal, had been that it had a similar EPS/tardive side effect profile to Haldol, would you have opted for one of the other atypical antipsychotics at that time?
>
> . . .
>
> A. Hypothetical, if it had the same risks as Haldol?
>
> Q. Or similar, yes.
>
> A. Is that what you're asking?
>
> Q. Correct. In other words, if someone had told you that Risperdal may not be truly atypical, that it's probably more like the older neuroleptics and carries an EPS/tardive profile similar to the older neuroleptics, would I be correct that you would have probably opted for one of the other antipsychotics – atypical antipsychotics?
>
> . . .
>
> A. Not if somebody told me that. If I believed that, that it was equal to – essentially equal to Haldol, then I would have probably chosen something else.
>
> Q. Okay. If the manufacturer had not promoted this as an atypical but as a typical neuroleptic, basically, with the same risk profile as the older neuroleptics as a whole, would I be correct that you probably would have gone back to Seroquel, Zyprexa, Abilify, or one of the other atypical medications?
>
> A. Well, no because it was identified professionally in all the literature as being part of atypical. It wouldn't be just from what the manufacturer said.
>
> Q. Right. But if I was – hypothetically, if that were to have been disclosed otherwise, that the literature had indicated that it may not be truly atypical – "it" being Risperdal – is it true that you would have likely

used one of the other atypical neuroleptics?

. . .

A. If hypothetically, the scientific information was that it was not atypical – it was the same as Haldol in side effects – yes, I would have chosen something else.

¶52. Even though Dr. Rhoden seemingly testified that he had no regrets as to prescribing Risperdal to Taylor, his testimony that he "would have chosen something else" if "the scientific information was that it was not atypical – it was the same as Haldol in side effects" created a fact question as to causation.

¶53. Taylor's expert Dr. Trosch testified that Dr. Rhoden's actions and deposition testimony were consistent with Janssen's marketing promotions and concepts. At least part of the reason Dr. Rhoden began prescribing Risperdal was because he believed it had a better side effect profile.

¶54. Based on the evidence presented at trial, a jury question existed as to whether a material misrepresentation or omission existed in the marketing materials and information provided to Dr. Rhoden, namely, that the tardive dyskinesia risk from Risperdal was low and materially lower than the tardive dyskinesia risk from Haldol. Additionally, a jury question was present as to whether Dr. Rhoden relied on Janssen's alleged misrepresentation or omission. Moreover, a jury question existed as to whether Taylor suffered damages as a direct and proximate result of Dr. Rhoden's alleged reliance.

III. Whether Janssen is entitled to a new trial based on improper jury instructions.

¶55. Alternatively, Janssen argues that the trial court erred by denying its motion for a new

trial. Janssen argues that it is entitled to a new trial because the trial court erred in giving jury instructions P-8, P-12, P-3, and P-18.

¶56. The standard of review for the grant or denial of a motion for a new trial is abuse of discretion. ***Lisanby***, 47 So. 3d at 1176 (¶ 8). "As with motions for JNOV, we review the evidence in the light most favorable to the nonmoving party and will reverse only when, upon review of the entire record, we are left with a firm and definite conviction that the verdict, if allowed to stand, would work a miscarriage of justice."

¶57. A new trial may be granted in a number of circumstances, such as when the jury has been confused by faulty jury instructions. ***Poole ex rel. Wrongful Death Beneficiaries of Poole v. Avara***, 908 So. 2d 716, 726–27 (¶ 25) (Miss. 2005). The trial court possesses considerable discretion regarding jury instructions. ***Young v. Guild***, 7 So. 3d 251, 259 (¶ 23) (Miss. 2009). The trial court may properly refuse instructions if it finds they incorrectly state the law or repeat a theory fairly covered in another instruction or are without proper foundation in the evidence of the case. ***Richardson v. Norfolk S. Ry. Co.***, 923 So. 2d 1002, 1010 (¶ 19) (Miss. 2006). A trial court need not grant duplicative instructions simply to satisfy each party's desire for emphasis. ***Gifford v. Four-Cty. Elec. Power Ass'n***, 615 So. 2d 1166, 1173 (Miss. 1992).

¶58. The Court does not review jury instructions in isolation; rather, they are read as a whole to determine if the jury was properly instructed. ***Shields v. Easterling***, 676 So. 2d 293, 295 (Miss. 1996). "Accordingly, defects in specific instructions do not require reversal where all instructions taken as a whole fairly—although not perfectly—announce the

applicable primary rules of law." ***Id***. However, the Court must find reversible error if the instructions in any given case, when considered together as a whole, do not fairly and adequately instruct the jury. ***Richardson***, 923 So. 2d at 1011 (¶ 19).

A. Jury Instruction P-8 (Instruction No. 12)

¶59. Janssen takes issue with instruction P-8 because it did not identify tardive dyskinesia as the exact "danger" or "dangers" posed by Rispderal. Janssen also claims that the instruction failed to instruct the jury properly on whom the drug manufacturer must warn, *i.e.*, the prescribing physician, not the patient; and failed to require the jury to find an adequate warning would have caused Dr. Rhoden not to prescribe Risperdal to Taylor. We reversed and rendered on Taylor's failure to warn claim, holding that the warning contained in the Risperdal label was adequate as a matter of law. Because P-8 was an attempt to instruct the jury on Taylor's failure to warn claim, the assignment of error is moot.

B. Jury Instruction P-12 (Instruction No. 13)

¶60. Janssen argues that the trial court erred in giving instruction P-12 because "negligent marketing" is not a cognizable claim under Mississippi law.

¶61. Jury Instruction P-12 stated:

> Louise Taylor claims she was harmed by Risperdal manufactured by Defendants in that it was negligently marketed and that Defendants are legally responsible for Louise Taylor's damages. To establish this claim, Louise Taylor must prove all of the following are more likely true than not true:
>
> 1. Defendants manufactured and marketed Risperdal;
>
> 2. Defendants specifically marketed and promoted Risperdal to a demographic of individuals which included Louise Taylor;

3. This demographic was elderly women who did not suffer from schizophrenia;

4. Louise Taylor was within this demographic when she was prescribed Risperdal;

5. Dr. Rhoden relied upon the marketing and promotions of the Defendants in prescribing Risperdal to Louise Taylor;

6. The marketing and promotion done by the Defendants was negligent in that a reasonable manufacturer under the same or similar circumstances would not have marketed and promoted Risperdal in the manner in which it was marketed.

7. Due to the Defendants' negligent marketing and promotion, Louise Taylor was prescribed Risperdal and injured;

8. Defendants' negligent marketing and promotion was the proximate cause of Louise Taylor's damages.

¶62. Taylor argues "the actual claim presented to the jury was one for "'Negligent Marketing/Misrepresentation.'" Taylor continues by arguing that her negligent marketing claim was alleged in her complaint under "Count II: Negligence." The Court is unpersuaded by Taylor's argument. In fact, Taylor's argument sheds light on the confusing nature of the instruction. Taylor alleged "negligent marketing" within a general negligence count in her complaint. Taylor also alleged negligent misrepresentation in an entirely different count. The claims alleged in separate counts are significant due to the now-combined claims, as if they were the same claim with alternative labels through the use of a slash mark.

¶63. Janssen argues that "[a]n exhaustive search of Mississippi case law reveals [that negligent marketing] is not a cognizable claim under Mississippi law." The Court's search revealed that, although the Court has not formally adopted "negligent marketing" as a

cognizable claim, Plaintiffs in ***Janssen Pharmaceutica, Inc. v. Armond***, 866 So. 2d 1092, 1096 (¶ 10) (Miss. 2004), claimed they had been injured in various ways as a result of the prescription medication Propulsid, caused by the drug manufacturer's conduct. In particular, Plaintiffs claimed that the drug manufacturer had "engaged in fraudulent advertising and marketing campaigns" for Propulsid. ***Id***. The Court briefly mentioned "negligence in . . . marketing of the drug" and "negligent marketing and distribution" in the context of a discussion on joinder. ***Id***. at 1099-1100 (¶¶ 27-28).

¶64. Taylor argues that claims for negligent marketing and advertising have been recognized in Mississippi jurisprudence, citing ***Kerr v. Phillip Morris USA, Inc***., 2010 WL 1177311, at *1 (S.D. Miss. Mar. 25, 2010) (not reported), and ***R.J. Reynolds Tobacco Co. v. King***, 921 So. 2d 268, 270 (¶ 2) (Miss. 2005). The Court disagrees and notes that neither opinion coined the term "negligent marketing;" rather, the terms "deceptive marketing" and "deceptive advertising" respectively were used. Deceptive marketing and deceptive advertising cannot be equated to negligent marketing. The term "deceptive" connotes intentional misrepresentation, not negligence.

¶65. Taylor also argues that P-12 "fully and accurately instructed the jury on the elements of negligence found in a marketing/advertising claim." P-12 did not "fully and accurately instruct the jury" because we find no authority identifying the essential elements that constitute a "negligent marketing/advertising claim." Janssen aptly points out that Taylor failed to cite caselaw supporting the instruction in her proposed instructions prior to trial. The Court agrees with Janssen that neither negligent marketing nor negligent advertising has

been recognized as a cognizable claim under Mississippi law outside the scope of a misrepresentation claim.

¶66. Janssen also argues that P-12 did not contain all essential elements of a negligent misrepresentation claim, namely, that the misrepresentation or omission of fact was material or significant, and that Dr. Rhoden relied on the material or significant misrepresentation or omission when he prescribed Risperdal to Taylor. The Court agrees that the trial court erred in giving P-12 without specifying every essential element of a negligent misrepresentation claim. The subject jury instruction omitted essential element of a claim for negligent misrepresentation, specifically, the requirement that the representation or omission was "material or significant." ***Skrmetta***, 806 So. 2d at 1124 (¶ 13). The instruction was fatally defective for failing to include an essential element of a negligent misrepresentation claim. Accordingly, the Court reverses the trial court's judgment and remands for a new trial on Taylor's negligent misrepresentation claim.

C. Jury Instruction P-3 (Instruction No. 8)

¶67. Janssen claims P-3 is a general negligence instruction, which was not a claim made in the case, since Taylor's claims are governed exclusively under the Products Liability Act. However, Janssen conceded on appeal in its reply brief: "Defendants do not dispute that [Taylor] could bring a negligent misrepresentation claim."

¶68. Jury Instruction P-3 stated:

> Negligence is the failure to use reasonable care. Reasonable care is that degree of care which a reasonably careful manufacturer would use under like or similar circumstances. Negligence may either consist of doing something that a reasonably careful manufacturer would not do under like or similar

> circumstances, or in failing to do something that a reasonably careful manufacturer would do under like or similar circumstances.
>
> If you find from a preponderance of the evidence in this case that the Defendants failed to act as reasonably prudent manufacturers under similar circumstances and such actions of Defendants contributed to cause injuries, if any, to Plaintiff, then you are under a sworn duty to return a verdict for the Plaintiff against the Defendants.

¶69. Janssen argues that there cannot be a general negligence claim because Taylor's claims for damage caused by a product are governed exclusively by the Products Liability Act. In support, Janssen relies on ***Palmer v. Volkswagen of America, Inc***., 905 So. 2d 564, 600 (Miss. Ct. App. 2003), *aff'd in part, rev'd in part*, 904 So. 2d 1077 (Miss. 2005) ("[T]he jury was properly instructed on the [the plaintiff's] claim of design defect under the MPLA, and additional negligence instructions would have been redundant."); and ***Jowers v. BOC Group, Inc***., No. 1:08-CV-0036, 2009 WL 995613, at *2 (S.D. Miss. Apr. 14, 2009). In ***Jowers***, the district court stated that "[t]he case law" on the issue of whether the Products Liability Act abrogated common law, product-based claims "has been mixed." ***Id***. at *2. "[A] claim for negligent failure to warn about a product's alleged hazards is still a 'product liability claim,' even though it is premised on a theory of negligence and not strict liability." ***Id***. at *4.

¶70. Taylor relies on ***Elliott v. El Paso Corp***, 181 So. 3d 263 (Miss. 2015), for the proposition that if Taylor "alleges and proves claims against Janssen for fraud, misrepresentation and/or negligent marketing, the MPLA does not apply and common law principles control." Taylor's description of the Court's holding in ***Elliot*** is misleading because the Court did not mention the term "negligent marketing." ***Elliott***, 181 So. 3d at 269

(¶ 19)). The ***Elliott*** Court actually held:

> A negligence claim alleging failure to warn, train, educate, or draft a warning plan about the dangers of odorant fade and the need for gas detectors indeed is a claim based upon products liability, and such a claim must be analyzed under the MPLA. If the plaintiffs in this case had alleged negligence claims against the manufacturer and seller that were unrelated to the odorant's alleged defects—for instance, fraud, misrepresentation, or breach of the implied warranty of merchantability—then the MPLA would not have applied and common-law principles would have controlled. But all of Plaintiffs' negligence or strict-liability claims are based on the damages purportedly caused by alleged defects in the odorant, so we must analyze those claims under the MPLA.

Elliott, 181 So. 3d at 269 (¶ 19).

¶71. The only cognizable claim asserted by Taylor was her negligent misrepresentation claim as discussed *supra*. The first paragraph of P-3 containing the definition of negligence is proper as to Taylor's negligent misrepresentation claim, however, the second paragraph of P-3 is improper because it does not contain all the essential elements of a negligent misrepresentation claim.

D. Jury Instruction P-18 (Instruction No. 14)

¶72. Janssen claims P-18 was confusing and misleading because it asked the jury if it was more likely true than not true that Taylor was harmed by Risperdal due to "failure to provide adequate warnings/instructions" and "negligent marketing/misrepresentation."

¶73. Jury instruction P-18 was the jury verdict form, which provided in pertinent part:

> Do 9 or more of you find it is more likely true than not true Louise Taylor was harmed by Risperdal due to the following:
>
> YES NO
>
> A. Failure to Provide Adequate Warnings/Instructions _____ _____

B. Negligent Marketing/Misrepresentation _____ _____

¶74. The jury answered "yes" to both questions.

¶75. Janssen contends that (1) the case does not concern the adequacy of any instructions regarding Risperdal, and (2) there is no cognizable "negligent marketing" claim under Mississippi law. The Court does not agree with Janssen's first contention because Section 11-1-63(A)(i)(2) clearly provides that a product may be defective "because it failed to contain adequate warnings or instructions." The inclusion of the word "instructions" was not improper. However, the Court agrees with Janssen's second contention. The combination of the claims for "negligent marketing" and "negligent misrepresentation" as if they were the same claim, sharing the same elements, was misleading, confusing, and improper. A negligent marketing or negligent advertising claim is not cognizable under Mississippi law to the extent that it is not part of a claim for negligent misrepresentation.

IV. Whether Jansseen is entitled to a new trial because economic damages should not have gone to the jury, as there was no proof connecting Ms. Taylor's Tardive Dyskinesia, the only condition allegedly caused by Risperdal, to the need for twenty-four-hour attendant care – the only economic damages Plaintiff sought.

¶76. Because the Court reverses and remands for a new trial based on defective jury instructions, the remaining assignments of error are not necessary to the decision. Although the Court need not reach the remaining issues, we address the assignments of error in the event the issues resurface on remand.

¶77. Janssen argues that the trial court erred by allowing the jury to assess economic damages because there was no evidence connecting Taylor's tardive dyskinesia to the need

for twenty-four-hour attendant, past and future care, which were the only economic damages requested by Taylor. As a result, Janssen claims that the trial court erred by denying its motion for new trial. The Court reviews the denial of a motion for a new trial for an abuse of discretion. ***Lisanby***, 47 So. 3d at 1176 (¶ 8). The Court reviews the evidence in the light most favorable to the nonmoving party and will reverse only when, upon review of the entire record, we are left with a firm and definite conviction that the verdict, if allowed to stand, would work a miscarriage of justice. ***Id***.

¶78. In any tort case, identifying and proving the source of the harm that proximately caused a plaintiff's injuries is essential. ***Mississippi Valley Silica Co. v. Reeves***, 141 So. 3d 377, 382 (¶ 15) (Miss. 2014). "Recoverable damages must be reasonably certain in respect to the efficient cause from which they proceed, and the burden is on claimant to show by a preponderance of the evidence that the [defendant] was the wrongful author of that cause." ***Id***. (quoting ***Jackson v. Swinney***, 140 So. 2d 555, 557 (Miss. 1962)).

¶79. In addition to tardive dyskinesia, Taylor suffers from Alzheimer's Disease, dementia, seizures, and recurrent psychosis associated with her mental health problems. Dr. Trosch opined that Taylor's tardive dyskinesia was caused by the use of Risperdal. Dr. Trosch described Taylor's various problems associated with her tardive dyskinesia. Taylor experiences constant movement of her tongue, in and out of her mouth, which caused her to develop an enlarged tongue. Taylor suffers from "tardive oculogyric deviation," which causes her eyes intermittently to "turn up and to the left." Taylor experiences a constant chewing movement with her jaw. Taylor puts her finger in her mouth as a "sensory trick"

to diminish the jaw movement. Taylor experiences loud and irregular respirations, called tardive respirations. Taylor's tardive dyskinesia causes difficulty eating and speaking.

¶80. Taylor's daughter and caretaker, Fortenberry, also testified that Taylor is unable to wear dentures and her condition has made it difficult for her to eat and drink. Fortenberry testified that Taylor cannot eat solid food so she has to puree her food to prevent strangling. Fortenberry explained that she has to use thickener in Taylor's water because Taylor cannot handle regular water. Fortenberry also testified that the tongue movement essentially has caused her to be unable to speak. Taylor's expert, Dr. Fann, opined that Taylor's tardive dyskinesia necessitated future care, and that Taylor's tardive dyskinesia would never improve, and likely it would worsen.

¶81. Dr. Randall Thomas, a psychologist involved in life care planning, projected future care costs for Taylor and prepared a life care plan representing the cost of Taylor's future care and value of past care. Dr. Thomas valued the past care services provided to Taylor by Fortenberry over a fifteen year period at $1,379,700. Dr. Thomas opined that the cost of future, twenty-four-hour care for Taylor would be $118,260 per year. However, Dr. Thomas acknowledged that his calculations were not limited to Taylor's tardive dyskinesia because of her other significant health problems.

> Q. These numbers Mr. Porter wrote here on the chart, you didn't limit the numbers to treatment that Ms. Taylor needs for dyskinesia, did you?
>
> A. It is not limited to any specific medical condition, that's right.
>
> Q. You were not considering what specific treatment she might need for Alzheimer's or dementia or psychosis, were you?

A. The difference in treatment, like medical treatment versus care, like home care, there is nothing in my report that dealt with medical treatment or medications or anything like that.

¶82. Dr. Thomas testified that he did not know how to divide the past and future care solely for tardive dyskinesia:

Q. Sir, the care that you have talked to the jury about today, the past care and the future care as it relates to the need for Ms. Taylor to have someone with her for 24 hours a day, that care is not limited to dyskinesia, is it?

A. I can't say yes or no. I mean, I know she has significant problems, but I don't know – I don't think it is just limited to that. I don't know how to divide that out.

¶83. In closing arguments, Taylor's counsel requested that the jury award $1.3 million for her actual economic damages based on her past and future care. The jury awarded $650,000 in actual economic damages.

¶84. "[I]t is primarily the province of the jury and in a bench trial the judge 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." ***Foster v. Noel***, 715 So. 2d 174, 183 (¶ 56) (Miss. 1998).

¶85. The jury's determination of damages was not unreasonable. The amount of damages awarded shows that the jury took notice of Janssen's argument that it should not be held responsible for any physical or mental problems that were unrelated to Taylor's use of Risperdal and reduced the award for actual economic damages accordingly.

V. Whether Janssen is entitled to a new trial because of Taylor's

counsel's closing statements.

¶86. Janssen argues that it is entitled to a new trial because Taylor's counsel used inflammatory, highly offensive, and improper argument during closing statements. "The standard of review that appellate courts must apply to lawyer misconduct during opening statements or closing arguments is whether the natural and probable effect of the improper argument is to create unjust prejudice against the accused so as to result in a decision influenced by the prejudice so created." ***Sheppard v. State***, 777 So. 2d 659, 661 (¶ 7) (Miss. 2000).

¶87. During closing argument, Taylor's counsel stated: "And one interesting thing about Dr. Rhoden. He remembered one sales rep's name was Kim. And if I were a betting man, I'd bet her blouse was too low and her skirt was too high." Counsel for Janssen immediately objected, arguing that Taylor's counsel's statement was improper, inflammatory, and had no basis in the evidence. The trial court overruled the objection.

¶88. "Attorneys are afforded a wide latitude in arguing their case to the jury, but they are not allowed to employ tactics which are inflammatory, highly prejudicial, or reasonably calculated to unduly influence the jury." ***Moffett v. State***, 156 So. 3d 835, 866–67 (¶ 95) (Miss. 2014). "The test in determining whether a lawyer has made an improper argument which requires reversal is whether the natural and probable effect of the improper argument creates an unjust prejudice against the opposing party resulting in a decision influenced by the prejudice so created." ***Eckman v. Moore***, 876 So. 2d 975, 986 (¶ 38) (Miss. 2004).

¶89. The only evidence related to Kim, a Janssen pharmaceutical sales representative,

derived from Dr. Rhoden's testimony:

> Q. Do you recall who the Janssen rep was – drug rep, anywhere from let's say – specifically to Risperdal, I think they had special representatives?
>
> A. There were several.
>
> Q. Do you recall any names from the '90s?
>
> . . .
>
> A. It's been so long since I've seen a rep. I know one was Kim – the first name. I remember a couple of faces, but that's the only name I recall. I think at one time, I saw a list, several years ago when this first came up, but I don't really –
>
> Q. What do you remember about the marketing or the sales effort by either Kim or any of the Risperdal representatives?
>
> A. My experience – The way I handle representatives, I try to accommodate them when they come by. I don't have a – Also, we only have a minute or two, and they usually, typically, would show some of the literature that they had. They always – It was always presented in a way, you know, "This is a good drug. This is why it's here." The literature usually had both the efficacy and the safety profile. I've always – that's always been emphasized – at least people who see me. And we would talk briefly, a couple of minutes; hopefully, get some samples.

¶90. Other than Dr. Rhoden's mere identification of Kim during his testimony, no mention of Kim was made at trial. Janssen correctly points out that no evidence of Kim's appearance or even gender was offered at trial. Janssen argues that the purpose of Taylor's counsel's statements was not to assist the jurors in evaluating the evidence, but rather to excite their passions and prejudices by suggesting that Janssen's female sales representatives dressed provocatively to increase Risperdal sales. Janssen claims that the inflammatory nature of Taylor's counsel's statement undoubtedly had a harmful influence on the jury, particularly

coupled with Taylor's negligent marketing claim. Taylor responds that nothing in her counsel's closing argument broached the broad latitude afforded to attorneys in summing up a case, and nothing rose to the level of reversal.

¶91. The wide latitude afforded to counsel in statements to the jury was set out by the Court in ***Nelms & Blum Co. v. Fink***, 131 So. 817, 820 (Miss. 1930). "[Counsel] may comment upon any facts introduced in evidence. [Counsel] may draw whatever deductions seem to him [or her] proper from these facts, so long as he [or she] does not use violent and abusive language, and even in many cases invectives may be justified and even called for[.]" ***Id***. "[Counsel's] function is to draw conclusions and inferences from evidence on behalf of his [or her] client in whatever way he [or she] deems proper, so long as he [or she] does not become abusive and go outside the confines of the record." ***Id***. The Court elaborated on counsel's wide latitude.

> [Counsel] may give wing to his [or her] wit and play to his [or her] imagination so long as he [or she] does not imagine fact not in evidence, which the court does not take judicial knowledge of, or does not go out of the record for the facts not in evidence. As to the facts in evidence, [counsel] may array them in such figures and form and clothe them with such ideas and conclusions as he [or she] can conjure up in his [or her] mind for the best interest of his [or her] cause. [Counsel] cannot, however, state facts which are not in evidence, and which the court does not judicially know, in aid of his [or her] evidence. Neither can [counsel] appeal to the prejudices of men by injecting prejudices not contained in some source of the evidence.

Fink, 131 So. at 821.

¶92. "While an attorney making a closing argument may not make remarks which are unfairly calculated to arouse passion or prejudice, and while we do not condone appeals to sectional prejudices of the jury, the control of such argument is left largely to the discretion

of the trial judge, who is in a much better position to observe and determine what is improper." ***James W. Sessums Timber Co. v. McDaniel***, 635 So. 2d 875, 882 (Miss. 1994). "In general, parties may comment upon any facts introduced into evidence, and may draw whatever deductions and inferences that seem proper from the facts." ***Moffett v. State***, 156 So. 3d 835, 858 (¶ 63) (Miss. 2014).

¶93. Taylor argues that counsel did not represent that Kim's hypothetical appearance was a fact; rather, counsel merely stated "if [he] were a betting man, [he'd] bet" that was the case. Regardless of the way counsel framed the statement, his statement was inappropriate. The Court cannot contemplate any purpose for counsel's inference from Kim's mere identification other than that it was unfairly calculated to arouse passion or prejudice. "The [trial court] is in the best position to weigh the consequences of the objectionable argument, and unless serious and irreparable damage has been done, admonish the jury then and there to disregard the improper comment." ***Johnson v. State***, 477 So. 2d 196, 210 (Miss. 1985). Based on the record before the Court, the trial court should have sustained the objection as unsupported by the evidence adduced at trial, admonished the jury, and instructed it to disregard the improper comment.

VI. Whether the evidence warranted a punitive damages proceeding.

¶94. Taylor cross appeals, arguing that the trial court abused its discretion by refusing to allow the trial to proceed to a punitive damages phase in light of the expert testimony and Janssen's internal documents introduced into evidence at trial.

¶95. "As a general rule, exemplary or punitive damages are 'added damages' and are in

addition to the actual or compensatory damages due because of an injury or wrong." ***Summers ex rel. Dawson v. St. Andrew's Episcopal Sch., Inc***., 759 So. 2d 1203, 1215 (¶ 52) (Miss. 2000). "The kind of wrongs to which punitive damages are applicable are those which, besides the violation of a right or the actual damages sustained, import insult, fraud, or oppression and not merely injuries but injuries inflicted in the spirit of wanton disregard for the rights of others." ***Id***. "In order to warrant the recovery of punitive damages, there must enter into the injury some element of aggression or some coloring of insult, malice or gross negligence, evincing ruthless disregard for the rights of others, so as to take the case out of the ordinary rule." ***Id***.

¶96. "When deciding whether to submit the issue of punitive damages to a trier of fact, the trial court looks at the totality of the circumstances, as revealed in the record, to determine if a reasonable, hypothetical trier of fact could find either malice or gross neglect/reckless disregard." ***Bradfield v. Schwartz***, 936 So. 2d 931, 936 (¶ 15) (Miss. 2006). The trial court's decision on whether a case warrants punitive damages to be considered by the jury is reviewed by the Court for an abuse of discretion. ***Id***.

¶97. After the jury returned its verdict in favor of Taylor and awarded her compensatory damages, Taylor requested that the trial court consider proceeding to the punitive damages phase of the trial. The trial court refused Taylor's request: "I just don't believe this is a punitive case. I don't see this being a case that would require jury consideration of punitive damages. I may be right or I may be wrong. That's my opinion, though." The trial court then excused the jury and stated:

> Let the record reflect the jury has been excused. I do want to make it clear, for the record, that Mr. Porter has requested a punitive damage hearing before this jury, and I acknowledged his request to do so. However, the [trial] [c]ourt has found that this is not a case that would be appropriate for the determination of punitive damages, and I have overruled his request. Without question, there is an objection to that, Mr. Porter. In any event, that's the [trial] [c]ourt's ruling.

¶98. Taylor argues that, according to ***Bradfield***, once compensatory damages have been determined, the trial court automatically should have proceeded to the punitive damages phase of the trial. The Court specifically has rejected the proposition that the trial court automatically must submit the issue of punitive damages to the jury for determination. ***Causey v. Sanders***, 998 So. 2d 393, 407 (¶ 45) (Miss. 2008) (noting that the use of the word "automatically" in ***Bradfield*** has been "misconstrued."). The Court explained the procedure for when and if a jury should consider punitive damages:

> If the jury awards compensatory damages, then an evidentiary hearing is conducted in the presence of the jury. At the close of this second phase of the trial, via an appropriate motion for a directed verdict, the judge, as gatekeeper, then ultimately decides whether the issue of punitive damages should be submitted to the trier-of-fact (jury). If the judge, from the record, should determine, as a matter of law, that the jury should not be allowed to consider the issue of punitive damages, a directed verdict shall be entered in favor of the defendant on the issue of punitive damages, and the case will end. If, on the other hand, the judge should allow the issue of punitive damages to be considered by the jury, then the jury, upon being properly instructed by the judge on the punitive damages issue, may decide to award punitive damages, and if so, in what amount, or the jury may decide not to award punitive damages.

Causey, 988 So. 2d at 407 (¶ 45) (quoting ***Bradfield***, 936 So. 2d at 939 (¶ 23)).

¶99. The ***Causey*** Court emphasized: "The decision in ***Bradfield*** does not stand for the proposition that the trial court should automatically submit the issue of punitive damages to

the jury for determination, but only that the trial judge should commence an evidentiary hearing before the jury on the issue of punitive damages, and at the conclusion of this evidentiary hearing in the second phase, the trial court has available all of the traditional options for determining whether or not the punitive-damages issue should be submitted to the jury." ***Id***. (emphasis added).

¶100. Taylor argues that "in light of the ample evidence heard by the jury" of Janssen's marketing and conduct, the issue should have been submitted to the jury for the consideration of punitive damages. The only additional evidence identified by Taylor that could have been considered during the punitive damages phase was "Janssen's indictment by the federal government for the misleading labeling of Risperdal." However, Janssen pleaded guilty to only a certain portion of the indictment covering conduct between March 3, 2002, and December 31, 2003. The trial court excluded evidence of the indictment and guilty plea during trial as irrelevant because it found that "all of the acts covered by the guilty plea were acts that occurred after the time period" that Taylor was prescribed Risperdal. Thus, the trial court had before it all the necessary information to make a determination of whether "under the totality of the circumstances and in light of defendant's aggregate conduct, that a reasonable, hypothetical juror could have identified either malice or gross disregard to the rights of others." *See* ***Causey***, 988 So. 2d at 408 (¶ 49).

¶101. Taylor claims the trial court's "bare ruling" constituted an abuse of discretion, citing ***Tricon Metals & Services, Inc. v. Topp***, 516 So. 2d 236, 239 (Miss. 1987) ("Where, however, a case is hotly contested and the facts greatly in dispute and where there is any

complexity involved therein, failure to make findings of ultimate fact and conclusions of law will generally be regarded as an abuse of discretion."). "In other words, in cases of any complexity, tried upon the facts without a jury, the Court generally should find the facts specially and state its conclusions of law thereon." ***Id***. at 239. ***Topp*** is inapplicable because the case sub judice was not tried upon facts without a jury." *See* ***id***. Even if ***Topp*** did apply, the trial court made a specific finding "that this is not a case that would be appropriate for the determination of punitive damages[,]" based on the record before it.

¶102. "[T]he trial court judge should initially determine whether to submit punitive damages to the jury, and in making this determination, the trial court must review all of the evidence before submitting the issue of punitive damages to the jury." ***Choctaw Maid Farms, Inc. v. Hailey***, 822 So. 2d 911, 923 (¶ 50) (Miss. 2002). "Clearly, the trial court is the gatekeeper for the issue of whether punitive damages, in cases involving both intentional and non-intentional torts, should be submitted and considered by a jury." ***Doe ex rel. Doe v. Salvation Army***, 835 So. 2d 76, 79 (¶ 6) (Miss. 2003). Here, the trial court acted properly as the gatekeeper by determining initially whether to submit punitive damages to the jury, and in making its determination, considering all the evidence submitted at trial. *See* ***id***. The trial court's decision did not constitute an abuse of discretion.

CONCLUSION

¶103. The Risperdal warning was adequate as a matter of law. As such, the Court reverses and renders judgment in favor of Janssen as to Taylor's failure to warn claim.

¶104. The Court reverses and remands for a new trial as to Taylor's negligent

misrepresentation claim based on fatally defective jury instructions, which omitted essential elements of the negligent misrepresentation claim. The Court also holds that the negligent marketing and negligent advertising claims are not cognizable under Mississippi law to the extent that they are not part of a claim for misrepresentation. Finally, even though the Court reverses and remands for a new trial based on fatally defective jury instructions, the Court holds that the remaining issues are without merit except for the improper statement made during closing argument, which the jury should have been instructed to disregard.

¶105. ON DIRECT APPEAL: REVERSED AND RENDERED IN PART; REVERSED AND REMANDED IN PART. ON CROSS-APPEAL: AFFIRMED.

WALLER, C.J., RANDOLPH, P.J., MAXWELL, BEAM, CHAMBERLIN AND ISHEE, JJ., CONCUR. KITCHENS, P.J., CONCURS IN PART AND DISSENTS IN PART WITH SEPARATE WRITTEN OPINION JOINED BY KING, J.

KITCHENS, PRESIDING JUSTICE, CONCURRING IN PART AND DISSENTING IN PART:

¶106. I agree with the majority that reversal and remand of Louise Taylor's negligent misrepresentation claim is appropriate. But despite substantial evidence adduced at trial in support of Taylor's claim that the warning label on the Risperdal was inadequate and that the warning's inadequacy proximately caused Taylor's tardive dyskinesia, the majority impermissibly substitutes its judgment for that of the jury. Accordingly, I respectfully dissent.

¶107. In reviewing a judgment as a matter of law, this Court is presented with the same question asked of the trial court: "'whether the evidence, as applied to the elements of a party's case, is either so indisputable, or so deficient, that the necessity of a trier of fact has been obviated.'" ***State v. Murphy***, 202 So. 3d 1243, 1251-52 (Miss. 2016) (quoting ***White***

v. Stewman, 932 So. 2d 27, 32 (Miss. 2006)). The nonmoving party "'must be given the benefit of all favorable inferences that may reasonably be drawn from the evidence.'" ***Smith v. Union Carbide Corp.***, 200 So. 3d 1035, 1041 (Miss. 2016) (***Smith II***) (quoting ***Smith v. Union Carbide Corp.***, 130 So. 3d 66, 68 (Miss. 2013) (***Smith I***)). The Court continued:

> "If the facts and inferences so considered point so overwhelmingly in favor of the movant that reasonable [jurors] 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 [jurors] in the exercise of impartial judgment might reach different conclusions, the motion should be denied and the jury's verdict allowed to stand*."

Smith II, 200 So. 3d at 1041 (quoting ***Smith I***, 130 So. 3d at 68) (emphasis in ***Smith II***).

¶108. Despite the jury's having determined otherwise, the majority concludes that "the Risperdal label warned Dr. Rhoden specifically of the danger of tardive dyskinesia in no uncertain terms and was sufficiently adequate as a matter of law." Maj. Op. at ¶ 33. Dr. Edwin Fann, an academic psychiatrist and physician who had published "the book on tardive dyskinesia" and was tendered and accepted "as an expert in the area of therapeutic, geriatric psychiatry, pharmacology, and medicine," testified on behalf of Taylor. On cross-examination of Dr. Fann, defense counsel read the Risperdal warning labels. When counsel asked whether Haloperidol, Haldol, or Seroquel also were associated with tardive dyskinesia, Dr. Fann responded that "it's got the same package insert warnings that you read out for Risperdal. Those package inserts are required by the FDA and were recommended by the U.S. Pharmacopeia committee that every anti-psychotic have that. That's how – that's what you just read out. You can read that for any anti-psychotic." On redirect, Dr. Fann was asked

to clarify his comment made in response to defense counsel's questioning about anti-psychotic drug labeling:

> [Y]ou could go through the PDR, *Physicians' Desk Reference*, or go through the U.S. Pharmaceutical and Drug Information, and that same information is there on every anti-psychotic. It was required. That doesn't mean as much as it sounds like it means. Because all of this has been gained, that is, not erased but balanced, counter-balanced by saying it's an atypical. To say this drug is as likely to cause tardive dyskinesia as any of the others, but it's a – you know, that's what some people would call cookie-cutter information. That's something you're saying about every drug.

Dr. Fann continued: "What opposing counsel read about Risperdal is in every antipsychotic, so it's meaningless in that."

¶109. And while the "learned intermediary doctrine" may insulate the pharmaceutical company from liability if adequate warnings were provided the physician, the question of adequacy of FDA-approved labeling "is a question of fact which should be determined by the jury." ***Janssen Pharmaceutica, Inc. v. Bailey***, 878 So. 2d 31, 57, 59 (Miss. 2004). Dr. Fann's testimony alone renders a judgment notwithstanding the verdict (JNOV) unwarranted. Reasonable and fairminded jurors in the exercise of impartial judgment could have heard Dr. Fann's testimony and concluded that the Risperdal warnings, which Dr. Fann described as "meaningless," "cookie-cutter information" which appeared on every antipsychotic drug, were inadequate to warn Dr. Richard Rhoden of the severity of the risk of tardive dyskinesia associated with Risperdal.

¶110. The majority then opines that Taylor's use of "Janssen's marketing materials and internal documents expanded the claim beyond the statutory scope of the Product[] Liability

Act" and that,"[b]ased on the terms of the Act,[2] enacted in 1993, the only pertinent question is whether the prescription drug label contained adequate warnings or instructions." Maj. Op. at ¶ 29. With respect, I disagree with the majority's interpretation of Mississippi Code Section 11-1-63(a).

¶111. The majority correctly observes that this Court has held that "[n]otwithstanding the government regulations in this field, the package insert is a marketing or merchandising procedure to promote sales." ***Thompson v. Carter***, 518 So. 2d 609, 612 (Miss. 1987). And the majority does mention this Court's holding in ***Bailey*** that the adequacy of FDA-approved labeling is a question of fact to be decided by the jury. ***Bailey***, 878 So. 2d at 59. But the majority then writes, "[a]lthough the Court mentioned 'aggressive marketing and over

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[2]Mississippi Code Section 11-1-63 provides, in pertinent part, the following:

> (a) The manufacturer, designer or seller of the product shall not be liable if the claimant does not prove by the preponderance of the evidence that at the time the product left the control of the manufacturer, designer or seller:
>
> (i) . . .
>
> 2. The product was defective because it failed to contain adequate warnings or instructions . . .
>
> . . . ; and
>
> (ii) The defective condition rendered the product unreasonably dangerous to the user or consumer; and
>
> (iii) The defective and unreasonably dangerous condition of the product proximately caused the damages for which recovery is sought.

Miss. Code Ann. § 11-1-63(a) (Rev. 2014).

promotion,' the Court's analysis was focused on the actual drug label." Maj. Op. at ¶ 31 (citing ***Bailey***, 878 So. 2d at 56-59). I disagree that ***Bailey*** stands for the proposition for which the majority cites it: that this Court "does not consider . . . marketing materials . . . as support of . . . [a] failure-to-warn claim under the Product[] Liability Act . . . ." Maj. Op. at ¶ 32.

¶112. On the contrary, the Court, having been presented, in part, with the argument 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," ruled that adequacy of labeling presented a fact question for the jury. ***Bailey***, 878 So. 2d at 55, 59. Expert testimony was adduced in the ***Bailey*** trial regarding the adequacy of warnings. "[P]hysicians 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." ***Id.*** at 58. One plaintiff's expert, Dr. McArthur, testified that he read the original label in 1994, that he never received "Dear Doctor" letters advising him of side-effect changes, that he "probably would not have read the 'Dear Doctor' letter if he had gotten one," and that "he rarely reads package inserts because the font is too small." ***Id.*** The experts for Janssen testified that Janssen provided adequate information about side effects through labeling, package inserts, and "Dear Doctor" letters. ***Id.*** at 58-59.

¶113. The ***Bailey*** Court did consider package inserts, which this Court has described as "a marketing or merchandising procedure to promote sales," and other materials in deeming the

question of adequacy of warnings to be one for the jury's consideration. *See* ***Bailey***, 878 So. 2d at 58-59; ***Thompson***, 518 So. 2d at 612. The question of fact for the jury in this context thus becomes whether the warnings were rendered inadequate by over-promotion of Risperdal.

¶114. Even assuming Dr. Fann's testimony that the Risperdal warning label, on its face, adequately warned Dr. Rhoden of the risk of tardive dyskinesia associated with Risperdal, reasonable and fair-minded jurors in the exercise of impartial judgment nevertheless could have believed that Dr. Rhoden's view that the benefits of Risperdal outweighed any possible deleterious side effects in Taylor's case was influenced by the promotional materials which told him that Risperdal was comparable side-effect-wise to other similar drugs.

¶115. Dr. Suzanne Parisian, who was tendered and accepted as an FDA expert and as a medical doctor and testified on behalf of Taylor, said that Janssen aggressively marketed Risperdal as a comparable medication to Haldol or other antipsychotics and informed physicians that the side effects were "comparable to placebo, and that there's no tardive dyskinesia risk." Dr. Richard Trosch also testified on behalf of Taylor, having been tendered and accepted as an expert in the field of medicine, specializing in neurology. Dr. Trosch testified that he "heard repeatedly that people are under the impression – psychiatrists are under the impression that [Risperdal] would not or could not or have very little or no risk of [tardive dyskinesia]." Dr. Trosch opined that Risperdal caused Taylor's tardive dyskinesia. And Dr. Rhoden, Taylor's treating physician, stated in his deposition, which was read to the jury, that he believed the side-effect risks of Risperdal were lower than the side-effect risks

associated with other antipsychotic medications. Dr. Rhoden was asked "if someone had told you that Risperdal may not be truly atypical, that it's probably more like the older neuroleptics and carries an EPS/tardive profile similar to the older neuroleptics, would I be correct that you would have probably opted for one of the other antipsychotics . . . ?" He replied "[n]ot if somebody told me that. If I believed that, that it was equal to–essentially equal to Haldol, then I would have probably chosen something else."

¶116. Reasonable and fair-minded jurors in the exercise of impartial judgment could have believed that Janssen's marketing campaign rendered the Risperdal warnings inadequate by failing adequately to inform Dr. Rhoden, the learned intermediary, of the substantial tardive-dyskinesia risk associated with Risperdal. Based on Dr. Rhoden's testimony that, had he been properly warned with regard to the substantial tardive-dyskinesia risk associated with Risperdal, he would not have prescribed it, reasonable and fair-minded jurors in the exercise of impartial judgment could have determined that the failure to warn Dr. Rhoden, the learned intermediary, proximately caused Taylor's tardive dyskinesia. Accordingly, because Taylor presented substantial evidence in opposition to the motion for JNOV, the trial court's denial was proper and I would decline to disturb the jury's verdict on appeal.

KING, J., JOINS THIS OPINION.