THE STATE OF SOUTH CAROLINA
In the Supreme Court

APPEAL FROM SPARTANBURG COUNTY
Court of Common Pleas

Roger L. Couch, Circuit Court Judge

Case No. 2007-CP-42-1438

State of South Carolina ex. rel. Alan Wilson in his capacity as Attorney General of the State of South Carolina,.....

Respondent,

v.

Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica, Inc., and/or Janssen, L.P., and Johnson & Johnson, Inc.,.....

Defendants,

Of whom Ortho-McNeil-Janssen Pharmaceuticals, Inc. is....

Appellant.

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11. Did the trial court err in denying Janssen's Motion for Judgment Notwithstanding the Verdict, or in the Alternative, for a New Trial and Janssen's Motion to Alter or Amend the Judgment and/or for a New Trial, and should the trial court's Penalty Order be vacated, because the jury verdict and the Penalty Order violated Janssen's rights under the First Amendment to the United States Constitution?

STATEMENT OF THE CASE

This appeal involves one of the largest judgments in the history of South Carolina. After a two-week trial, a Spartanburg County jury found that Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Janssen")[1] was liable for "unfair or deceptive acts or practices" involving Janssen's atypical antipsychotic medicine, Risperdal®. The trial court then awarded the Plaintiff, the State of South Carolina, more than $327 million in civil penalties.

On April 23, 2007, the Attorney General of South Carolina, on behalf of the State of South Carolina, initiated this action through private counsel, asserting various tort claims, violations of the Medicaid Fraud Act, and violations of the South Carolina Unfair Trade Practices Act ("SCUTPA") against Janssen and Johnson & Johnson. On December 30, 2009, the State filed a First Amended Complaint, which dropped all claims except for the SCUTPA claim and sought a permanent injunction and civil penalties. Then, on March 19, 2010, the State filed a Second Amended Complaint, the complaint on which the case was tried. (Compl., R. _.)

In the Second Amended Complaint, the State again asserted only a SCUTPA claim, but now sought only civil penalties. Although the Second Amended Complaint contained only one count, the State asserted two separate claims. First, the State alleged that from 1994 through 2007, the Risperdal package insert, which was at all times approved and required by the U.S. Food and Drug Administration ("FDA"), violated SCUTPA because it failed to "warn" of various risks that might be associated with

[1] On June 22, 2011, Ortho-McNeil-Janssen Pharmaceuticals, Inc. changed its name to Janssen Pharmaceuticals, Inc.

Risperdal treatment (the "package insert claim"). (Compl. ¶¶ 13, 43, 54-60 R. _.) Second, the State alleged that a November 10, 2003 letter to healthcare providers, transmitting a newly revised Risperdal package insert, or label, also violated SCUPTA (the "November 2003 mailing claim"). (Compl. ¶¶ 13, 46-49, 54-60 R. _.) The November 10, 2003 letter (the "November 2003 letter") discussed the relative incidence of metabolic side effects associated with antipsychotic treatment.

Trial commenced on March 7, 2011. At trial, the State relied on the testimony of eighteen witnesses, thirteen of whom appeared via relatively brief video depositions. The State's two primary live witnesses were experts, Dr. William Wirshing, a medical expert, and Dr. Laura Plunkett, a regulatory expert. The State did not call any medical professionals who work or prescribe Risperdal within the State of South Carolina.

Janssen presented the testimony of eleven witnesses, including three via video depositions. Janssen's witnesses included former Janssen medical, legal, and marketing personnel; two physicians, the current director and a former director of the South Carolina Department of Mental Health; and experts in internal medicine, epidemiology, the development of new medicines, the filing of new drug applications, FDA regulatory matters, the treatment of schizophrenia, the safety and efficacy of antipsychotic medicines, and clinical trials and studies involving antipsychotic medicines.

At the close of the State's case and again at the close of all the evidence, the trial court denied Janssen's motions for directed verdict. (Tr. 1382:19-1417:18, 1780:16-1783:20, 2450:2-2467:1, 2467:15-2473:25, R. _.) At the close of all the evidence, the trial court granted a directed verdict in favor of the State on Janssen's statute of limitations defense. (Tr. 2470:4-2473:25, R. _.) After deliberation, the jury returned a

verdict finding that Janssen had engaged in willful violations of SCUTPA as to the Risperdal package insert and the November 2003 mailing. (Verdict Form, R. _.) The jury found no violation by Johnson & Johnson. (*Id.*)[2] On June 3, 2011, after briefing and a two-day hearing on penalties, the trial judge issued a Penalty Order awarding the State $327,073,700 in civil penalties, including $152,849,700 based on the Risperdal package insert claim and $174,224,000 based on the November 2003 mailing claim. (June 3, 2011 Penalty Order at 16-17, R. _.)

The trial court denied Janssen's Motion for Judgment Notwithstanding the Verdict or, in the Alternative, a New Trial and Janssen's Motion to Alter or Amend the Judgment and/or for a New Trial on December 20, 2011. (Dec. 20, 2011 Order Denying Def.'s Mot. for Judgment Notwithstanding the Verdict or, in the Alternative, for a New Trial; Dec. 20, 2011 Order Denying Def.'s Mot. to Alter or Amend the Judgment and/or for a New Trial, R. _.) This appeal followed, and on February 27, 2012, this Court granted the State's unopposed Motion to Transfer Case and Certify the Case for Review by the Supreme Court.

STATEMENT OF THE FACTS

Risperdal, the medicine at issue in this litigation, is a prescription medicine approved as safe and effective by the FDA. Risperdal belongs to a class of medicines known as "atypical" or "second generation" antipsychotics. (Tr. 382:20-383:12, R. _.) The FDA first approved Risperdal in December 1993, as safe and effective for the "management of the manifestations of psychotic disorders." In April 2002, that initial

[2] Johnson & Johnson, the other defendant in the trial court action, erroneously named in all pleadings as Johnson and Johnson, Inc., is not a party to this appeal.

approved indication was changed to "treatment of schizophrenia." Subsequently, the FDA repeatedly approved Risperdal for the treatment of a variety of other serious mental health conditions in adults, adolescents, and children. (Tr. 2021:20-2022:14, R. _.)

I. THE FDA-APPROVED RISPERDAL PACKAGE INSERT.

As with all FDA-approved medicines, Risperdal has an FDA-approved package insert, or label, which includes, among other things, directions for use and information regarding certain side effects that may be associated with Risperdal treatment. The FDA approved the initial version of the package insert in December 1993 and has, over the years, repeatedly approved revised versions. The FDA required that Janssen use verbatim each version of the package insert that it approved. (Tr. 911:2-6, 1997:6-25, 2021:24-2023:12, 2033:6-14; R. _; Exs. P571, D841, D843, D3180, R. _.)

Janssen continuously studied and monitored Risperdal's efficacy and safety, before and after the initial approval by the FDA. (Tr. 357:18-360:6, 384:13-386:23, 1449:15-22, R. _.) Among other things, these studies examined the incidence of certain conditions that may be associated with Risperdal treatment, including metabolic-related side effects, which include weight gain, diabetes, hyperglycemia, and related illnesses; and hyperprolactinemia, a hormonal imbalance. (Tr. 1431:19-1432:8, 1777:19-1778:12, R. _.) Some of these studies looked at Risperdal's efficacy and safety when compared to other antipsychotics. (*E.g.*, Tr. 1653:4-6, R. _.)

At trial, the State asserted that the FDA-approved Risperdal package insert was deceptive or unfair because it did not adequately warn of certain risks of metabolic side

effects that might be associated with Risperdal treatment.[3] Specifically, the State contended that additional warnings about metabolic risks should have been added to the package insert, or that information about the risks should have been included in the "warnings" section of the package insert, rather than in the "precautions" or "adverse reactions" sections. As support for its claim, the State focused on three "studies" of metabolic side effects: (1) RIS-USA-113, a weight gain study whose preliminary or "topline" results were reported in September 1999, and which was impacted by a mix-up in the study medicines; (2) a "crude data pull" from an insurance claims database, by a company known as ERI, submitted to Janssen in the summer of 2000 in anticipation of an epidemiological study of antipsychotic medicines and diabetes risk; and (3) RIS-USA-275, a study of the glucoregulatory effects of Risperdal and another atypical antipsychotic, whose internal clinical study report was completed in January 2004, which was submitted to the FDA in August 2004 and was published in 2008. (Tr. 1678:3-5, 1711:21-1712:10, R. _.) The State contended that the results of these "studies" should have been disclosed or should have been disclosed sooner. The State, however, did not present any evidence that any such disclosure would have changed any scientific conclusions about the risks, or relative risks, of Risperdal. Moreover, the State did not present any evidence that the FDA would have required, or even approved, any change to the package insert "warnings" based on any of the three studies.

[3] The State also offered testimony about the risks associated with "alpha toxicity," including the possibility of an increased risk of mortality in the elderly. But, in their closing statements, the State's counsel did not argue that liability should be based on inadequate disclosure of "alpha toxicity" or mortality risks.

II. THE NOVEMBER 2003 MAILING.

The State also took issue with Janssen's response to the FDA's September 2003 request for a class-wide warning regarding hyperglycemia and diabetes. In September of 2003, the FDA's Division of Neuropharmacological Drug Products ("DNDP") requested that all manufacturers of atypical antipsychotics add a uniform class-wide warning to the package inserts of their respective medicines regarding the risks of hyperglycemia and diabetes associated with atypical antipsychotic treatment. (Tr. 1495:5-1497:5, 1840:21-1845:13, R. _; Ex. D3175, R. _.) Janssen took the position that a uniform class-wide warning was not appropriate, because the available scientific and medical evidence demonstrated that the risks of metabolic-related side effects associated with Risperdal treatment were lower than the risks associated with some other second-generation antipsychotics. (Tr. 1497:6-1504:19, 1846:20-21, R. _.) Accordingly, Janssen wrote to the FDA suggesting further review, a discussion of the evidence and proposed warning, and modifications to the proposed warning. (Tr. 1776:1-6, 1846:22-1852:22, R. _; Ex. D3140, R._.) As a result of this dialogue, the FDA modified the proposed warning and deleted the following sentence: "The available data are insufficient to provide reliable estimates of differences in hyperglycemia-related adverse event risk among the marketed atypical antipsychotics." (Tr. 1776:1-6, 1863:20-1865:24, 1903:11-1905:2, R. _.) By November 2003, within three months of the FDA's initial request, the discussions regarding the language in the new warning had been completed, and the FDA approved an amended Risperdal package insert with the modified warning. (Tr. 1505:5-7, 1863:20-1865:24, 1903:11-1905:2, R. _; Ex. D3180, R. _.)

On November 10, 2003, Janssen mailed the revised Risperdal package insert to healthcare providers, with a cover letter notifying them of the label changes. (Ex. D351,

R. _; Tr. 1505:8-14, 1862:10-1863:9, R. _.) The cover letter explained the FDA's request for the new warning. (Ex. D351, R. _.) The letter also communicated Janssen's view that "[a]lthough confirmatory research is still needed, a body of evidence from published peer-reviewed epidemiology research suggests that RISPERDAL is not associated with an increased risk of diabetes when compared to untreated patients or patients treated with conventional antipsychotics." (*Id.* (footnotes omitted).) The letter further explained that "[e]vidence also suggests that RISPERDAL is associated with a lower risk of diabetes than some other studied atypical antipsychotics." (*Id.*) As support for those statements, the letter cited to all of the published, peer-reviewed epidemiology studies available at that time concerning antipsychotics and metabolic-related side effects. (*Id.*; Tr. 1507:7-1509:3, R. _.)

Subsequently, on November 21, 2003, DNDP asked Janssen to distribute a "Dear Healthcare Professional letter" informing healthcare providers of the change to the FDA-approved Risperdal package insert. (Ex. D3180, R. _.) On November 26, 2003, Janssen sent DNDP a copy of the November 2003 mailing, informing DNDP that it had already voluntarily mailed a letter to healthcare providers (the November 2003 letter) notifying them of the change and enclosing a copy of the revised Risperdal package insert. (Tr. 1871:12-1872:1, 2036:1-2037:12, R. _; Ex. D3179, R. _.) Nearly five months later, on April 19, 2004, Janssen received a "warning letter" from the FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") asserting that Janssen's November 2003 mailing was "false or misleading in violation of Sections 502(a) and 201(n) of the Federal Food, Drug, and Cosmetic Act." (Ex. P232, R. _; Tr. 1871:12-1872:12, R. _.) Janssen responded in writing, reiterating the scientific support for its

position. (Tr. 2031:4-21, R. _; Ex. P1731, R. _.) Nevertheless, Janssen voluntarily agreed to discontinue using the November 2003 mailing and to issue a new Dear Healthcare Provider letter. (Tr. 1872:22-1876:4, 2031:22-2032:2, R. _.) This "corrective" letter, mailed in July 2004, did not admit any wrongdoing or disavow the earlier statements about the scientific evidence. (Tr. 1523:1-1524:6, 2032:3-10, R. _; Ex. D0442, R. _.) Instead, it acknowledged and summarized Janssen's communications with DDMAC and reproduced the revised FDA-approved Risperdal package insert. (Tr. 1874:18-1876:4, R. _; Ex. D0442, R. _.) After Janssen issued the July 2004 letter, DDMAC closed the matter without further action. (Tr. 1525:12-16, 1526:10-1527:10, 1877:4-12; R. _; Ex. D6253.)

III. THE STATE'S CASE.

A focus of the State's case at trial was whether Janssen "broke" FDA rules and regulations. As to the State's package insert claim, its primary evidence was purported non-disclosures to the FDA, specifically RIS-USA-113 and ERI. The key evidence for the State's November 2003 mailing claim was the April 2004 DDMAC letter, with its statement that the cover letter associated with the mailing was "false or misleading" in violation of federal law. (Ex. P0232, R. _.) The State also relied on two other DDMAC letters, one sent in 1994, discussing promotional materials that were prepared for use at the time of the Risperdal "launch," and the other sent in 1999, taking issue with a promotional effort involving physicians' use of Risperdal to treat elderly patients. (Exs. P1027, P200, R. _.)

The State's experts took issue with the adequacy of the warnings in the package insert, and with the propriety of the statements in the November 2003 letter. The State, however, did not call any South Carolina physicians as witnesses, and there was no

evidence that either the package insert or the mailing had any impact on South Carolina physicians or their patients. In particular, there was no evidence that any South Carolina physician was deceived or was likely to be deceived by the statements in the package insert or the November 2003 letter. There was no evidence that any patient suffered any injury as a result of anything that Janssen did or said. And there was no evidence that anyone, including the State, suffered any monetary loss.

Affirmative evidence that there was no impact, including the results of a survey of South Carolina physicians, was offered by Janssen but was excluded, in part because the State's lawyers questioned the survey methodology, and in part because the trial court considered the evidence irrelevant. Evidence from scientific studies post-dating the November 2003 letter also was excluded as irrelevant. And evidence that the FDA, in 2007 and 2010, had reached the conclusion that there were, indeed, differences in the metabolic risks of the various second generation antipsychotics, as Janssen had said in the November 2003 letter, also was excluded on relevancy grounds.

The jury returned a verdict against Janssen, finding that Janssen engaged in "unfair or deceptive acts or practices" both "in its label (package insert)" and "in the dear doctor letter of November 10, 2003." The jury was not asked to, and did not, differentiate between deceptive and unfair acts or practices, and the jury was not asked to, and did not, identify which of the many versions of the Risperdal package insert were deceptive or unfair or in what way the insert was deceptive or unfair.

Ultimately, after a penalty hearing, the trial court ordered Janssen to pay more than $327 million in penalties.

ARGUMENT

For several different reasons, the State's claims were barred, and should never have been submitted to the jury. As an initial matter, the State's package insert claim was preempted by federal law and was barred by SCUTPA's "regulated activity exemption." The State's November 2003 mailing claim also was preempted by federal law. Moreover, both of the State's claims were barred by SCUTPA's three-year statute of limitations. Additionally, the State failed to demonstrate, as required by SCUPTA, that either the FDA-approved Risperdal package insert or the November 2003 mailing had a tendency to deceive, was likely to deceive, or was likely to cause substantial injury – there was no evidence that the statements had any impact, affected any decisions, or caused any loss. Finally, the State did not prove, by clear and convincing evidence, as required by the First Amendment, that Janssen knew that the statements in the package insert or the letter were false or made the statements with reckless disregard as to their truth or falsity. For any of these reasons, the trial court should have entered judgment for Janssen on the State's claims, and this Court should reverse the trial court and enter judgment for Janssen.

Other errors in the trial court's rulings alternatively lead to the conclusion that the trial court must be reversed and a new trial ordered. First, the trial court did not allow Janssen to introduce affirmative evidence that neither the package insert nor the mailing were deceptive. The trial court also erred in admitting three letters from DDMAC – hearsay statements that did not fall within the "public records" exception to the South Carolina hearsay rule and that were, in any event, unfairly prejudicial. The trial court allowed the State's counsel to suggest to the jury that it should punish Janssen for its size and success. The trial court failed to instruct the jury regarding the findings it had to

make under First Amendment precedent. And the trial court committed further error by giving an erroneous jury instruction on the State's unfairness claim, and in using a non-specific and unfair verdict form.

Finally, the trial court also committed reversible error in assessing more than $327 million in penalties against Janssen, in a case in which there was no proof of actual deception, no claim of injury, and no contention that the State or anyone else lost money. The trial court did not have statutory authority to assess penalties for "violations" not found by the jury, and it abused its discretion, in multiple ways, when determining the penalty amounts. The penalty award also was constitutionally infirm because it violated Janssen's rights under the First Amendment. Finally, the penalties assessed against Janssen were grossly excessive, violating Janssen's rights under the Excessive Fines and Due Process Clauses of the South Carolina and United States Constitutions.

I. THE TRIAL COURT ERRED IN NOT ENTERING JUDGMENT FOR JANSSEN AS TO THE STATE'S PACKAGE INSERT CLAIM.

At trial, the State asserted that because the FDA-approved Risperdal package insert did not provide adequate warnings as to the risks of hyperglycemia, diabetes, weight gain, and hyperprolactinemia that may be associated with Risperdal treatment, Janssen's use of the FDA-approved package insert in South Carolina was either unfair or deceptive and, therefore, violative of SCUTPA. The jury found generally that some portion of some version of the FDA-approved package insert violated SCUTPA, either because it was unfair or deceptive, and the trial court subsequently imposed more than $150 million in penalties for this claim. The State's claim as to the package insert, however, was barred both by the principle of federal preemption and by SCUTPA's regulated activity exemption.

A. The State's Package Insert Claim Was Preempted by Federal Law.

The jury found that the warnings in the FDA-approved Risperdal package insert were, in some unspecified respect, inadequate. The trial court then awarded more than $150 million in penalties based on Janssen's use, in South Carolina, of the FDA-approved Risperdal package insert. Thus, South Carolina was allowed to impose its own views as to what should be included in a package insert for an FDA-approved medicine, and to penalize Janssen for using the package insert that the FDA had approved for use throughout the United States. Allowing any one state to "regulate" prescription drug labeling in this fashion stands as a formidable obstacle to the "nationwide uniformity" that is a primary purpose of the federal prescription drug labeling laws. For that reason, the Attorney General's claims for penalties, based on the supposed inadequacy of the federally approved package insert, was preempted by federal law.

Federal preemption is grounded in the Supremacy Clause, which establishes that federal law "shall be the supreme Law of the Land . . . [the] Laws of any State to the Contrary notwithstanding." U.S. Const., art. IV. Under federal preemption, where state and federal law conflict, state law must yield. *PLIVA, Inc. v. Mensing*, __ U.S. __, 131 S. Ct. 2567, 2577 (2011); *City of Cayce v. Norfolk S. Ry. Co.*, 391 S.C. 395, 400, 706 S.E.2d 6, 8 (2011) ("[S]tate law that conflicts with federal law is 'without effect.'" (quoting *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992)).

One manner in which a claim brought under state law can be preempted by federal law is when "the state law actually conflicts with the federal law, such that compliance with both is impossible, or the state law hinders the accomplishment of the federal law's purpose." *State v. 192 Coin-Operated Video Game Machs.*, 338 S.C. 176, 186, 525 S.E.2d 872, 877 (2000) (citing *Michigan Canners & Freezers Ass'n v. Agric.*

Mktg. & Bargaining Bd., 467 U.S. 461, 469 (1984)). When a state law hinders the accomplishment of the purposes and objectives of a federal statute, the federal preemption is referred to as "obstacle" preemption. *See AT&T Mobility LLC v. Concepcion*, __ U.S. __, 131 S. Ct. 1740, 1753 (2011) (citing *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).[4]

The FDCA and its implementing regulations govern a pharmaceutical manufacturer's use of the package insert for an FDA-approved prescription medicine such as Risperdal. *See, e.g.*, 21 U.S.C. § 352; 21 C.F.R. §§ 201.1-201.59. Further, ensuring uniformity of prescription drug labeling throughout the United States is one of the principal purposes of the FDCA and the FDA's prescription drug labeling regulations. *See* Proposed Labeling for Oral Aspirin-Containing Drug Prods., 50 Fed. Reg. 51,400, 51,403 (Dec. 17, 1985) (codified at 21 CFR Part 201) ("FDA has a well-established policy of promoting uniformity in the area of labeling.").

The jury in this case generally found, based on the State's arguments at trial, that the FDA-approved Risperdal package insert should have had more or different warnings regarding certain of the side effects that may be associated with Risperdal treatment, or that the package insert should have displayed some of these warnings more prominently or in different sections of the package insert. (Verdict Form, R. _.) There may well be state attorneys general and juries in other states with different views about the warnings that should have appeared in the Risperdal package insert, or about the placement of those warnings within the package insert. The imposition of different labeling

[4] Janssen does not make an "impossibility" preemption argument.

requirements in different states, enforced by the imposition of massive penalties, however, is entirely inconsistent with the congressional purpose of ensuring nationwide uniformity.

The State's claim based on the FDA-approved Risperdal package insert, therefore, represents an unmistakable obstacle to the uniformity and effectiveness of the federal regulation of prescription drug labeling nationwide, and the claim is preempted by federal law. Other courts have reached that conclusion in similar cases. *See, e.g., Prohias v. AstraZeneca Pharm., L.P.*, 958 So. 2d 1054 (Fla. Dist. Ct. App. 2007) (stating that claim that FDA-approved drug label violated Florida Deceptive and Unfair Trade Practices Act conflicted with federal law and therefore was preempted); *see also, e.g., Cytyc Corp. v. Neuromedical Sys., Inc.*, 12 F. Supp. 2d 296, 301 (S.D.N.Y. 1998) (holding, for false advertising claims, that "representations by [defendant] that comport substantively with statements approved as accurate by the FDA cannot supply the basis for [plaintiff's] claims"); *Am. Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 144-45 (S.D.N.Y. 1987) ("In unfair competition actions under state statutory or common law, it has been consistently ruled that compliance with FDA warning requirements is a complete defense . . . .").

There is nothing in *Wyeth v. Levine*, 555 U.S. 555 (2009), on which the State relied below, that suggests that the State's claim here would not be preempted. In *Wyeth*, the plaintiff received a direct injection of an anti-nausea medication that resulted in gangrene and the eventual amputation of her arm. She then sued Wyeth, claiming that it knew but failed to warn that this method of administering the medicine was more dangerous than other methods. The United States Supreme Court first rejected Wyeth's

impossibility preemption defense and concluded that it was possible for Wyeth to comply with the FDA's regulation and with the demands of the state tort suit because Wyeth could have proactively strengthened its label and sought the FDA's approval after the fact. *Id.* at 573. Then, the Court held that under the specific facts presented in *Wyeth*, individual personal injury product liability suits like Ms. Levine's did not obstruct the purposes and objectives of federal drug labeling regulations. *See id.* at 581 ("In short, Wyeth has not persuaded us that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling.").

There is, however, a vast difference between the "obstructive" impact of individual personal injury actions, such as the *Wyeth* action, and actions, such as this one, brought by a state attorney general challenging the use, in his state, of an FDA-approved package insert. *Wyeth* did not hold that attempts by state attorneys general to penalize pharmaceutical manufacturers for the use of an FDA-approved package insert would not be preempted. Indeed, the *Wyeth* Court specifically "recognize[d] that some state-law claims might well frustrate the achievement of congressional objectives." *Id.* at 581. Moreover, when concluding that Ms. Levine's state-law tort claim was not preempted, the *Wyeth* Court relied on the fact that Congress was familiar with state-law personal injury actions, but did not expressly preempt them when amending the FDCA. *See id.* at 574-75. There is, however, no similar indication that Congress did not intend to preclude state attorneys general from requiring that federally approved package inserts be modified before they can be used in their states, or from seeking enormous penalties based on a manufacturer's use of an FDA-approved package insert. Until very recently, no state had attempted to do what South Carolina has tried to do here. In short, a suit

brought by a state seeking to engage in "regulation by penalization" is neither considered nor controlled by *Wyeth*.

Additionally, to the extent the State's package insert claim was based on the contention that Janssen misrepresented or withheld information from the FDA, that claim also is preempted by federal law. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001) ("Given this analytical framework, we hold that the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by federal law."); *see also id.* at 347 ("Policing fraud against federal agencies is hardly 'a field which the States have traditionally occupied.'" (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947))). The State seemed to advance such a claim. In his closing statement, for example, the State's counsel referred to RIS-USA-113 and ERI and said, "The issue isn't about what they sent to the FDA. It's, of course, what they hid, what they didn't send to the FDA. That's what this case is about." (Tr. 2531:23-25, R. _.)

For all these reasons, the State's package insert claim was preempted by federal law. This Court should reverse the trial court and enter judgment in favor of Janssen on the claim.

B. SCUTPA's Regulated Activity Exemption Barred the State's Package Insert Claim.

The State's claim based on the Risperdal package insert also was barred by SCUTPA's regulated activity exemption. This exemption, set forth in South Carolina Code § 39-5-40(a), provides that SCUTPA does not apply to "[a]ctions or transactions permitted under laws administered by any regulatory body or officer acting under statutory authority of this State or the United States or actions or transactions permitted by any other South Carolina State law."

The purpose of the regulated activity exemption is to remove from SCUTPA's purview allegedly unfair or deceptive acts or practices that are "allowed or authorized by regulatory agencies or other statutes." *Ward v. Dick Dyer & Assocs., Inc.*, 304 S.C. 152, 155, 403 S.E.2d 310, 312 (1991). "The purpose of the exemption is to insure that a business is not subjected to a lawsuit under the Act when it does something required by law, or does something that would otherwise be a violation of the Act, but which is allowed under other statutes or regulations." *Id.* at 156, 403 S.E.2d at 312 (quoting *Skinner v. Steele*, 730 S.W.2d 335, 337 (Tenn. Ct. App. 1987)).[5]

Janssen's use of the FDA-approved Risperdal package insert falls directly within the SCUTPA regulated activity exemption. The package insert has been continuously regulated and approved by the FDA. The FDA first approved the package insert in 1993, and re-approved it numerous times – including in April 2002, November 2003, December 2003, October 2006, and August 2007. (Tr. 911:3-6, 2021:24-2023:12, 2033:6-14, R. _, Ex. D3180, R. _.) Each time, the FDA *authorized* the use of the approved package insert. And each time, the FDA *required* that Janssen use the package insert exactly as approved. (*See, e.g.*, Ex. P571 ("Accompanying this letter (ATTACHMENT 1) is the verbatim text of the labeling under which RISPERDAL® may be marketed."); Ex. D841 ("The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert)."); Ex. D3180 ("The final printed labeling (FPL) must be identical to the

[5] In *InMed Diagnostic Services, L.L.C. v. MedQuest Associates, Inc.*, 358 S.C. 270, 277, 594 S.E.2d 552, 555 (Ct. App. 2005), the Court of Appeals explained that SCUTPA's regulated activity exemption "is based on the concept that the legislature has determined certain matters are appropriate for resolution by administrative agencies with particular expertise, rather than by the general jurisdiction of a trial court." There is no better example of a case appropriate for resolution by an administrative agency with particular expertise than this case, which implicates the complex federal regulatory scheme, administered by the FDA, governing the content of package inserts for FDA-approved prescription medicines.

submitted labeling (text for the package insert – submitted November 6, 2003)."); Ex. D843 ("The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert)."). As Janssen's use of the Risperdal package insert falls within the statutory exemption as explained by *Ward* – it is both regulated and authorized by the FDA and the FDCA – the State's package insert claim was barred by the regulated activity exemption, and the trial court erred in denying Janssen's Motion for Judgment Notwithstanding the Verdict or, in the Alternative, for a New Trial on this ground.

A finding that the FDA's approval of the Risperdal package insert triggers SCUTPA's regulated activity exemption would comport with other courts' treatment of this issue. Other courts have found that the FDA's approval of package inserts for FDA-approved prescription medicines bars analogous consumer protection act claims. *See, e.g., DePriest v. AstraZeneca Pharm., L.P.*, 351 S.W.3d 168, 177-78 (Ark. 2009) (concluding that because allegedly false marketing statements were supported by FDA-approved labeling and were permitted under laws administered by FDA, they were exempt from Arkansas Deceptive Trade Practices Act); *Prohias*, 958 So. 2d at 1056 (holding that because conduct complained of – promotion and advertising activity – was supported by FDA-approved labeling and thus "specifically permitted" by federal law, conduct was exempt from Florida Deceptive and Unfair Trade Practices Act); *see also, e.g., Money v. Bristol-Myers Squibb Co.*, No. 07-cv-1100, 2009 WL 5216987, at *6 (D.N.J. Dec. 30, 2009) (stating that if supposedly deceptive drug marketing materials were in compliance with FDA regulations, regulated activity exemption would apply to plaintiff's consumer protection act claim); *Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1228, 1234 (S.D. Fla. 2007) (concluding that "because the claims made by Pfizer in the post-

July 2004 advertisements were implicitly authorized by the FDA [by its approval of the package insert], the claims in the advertisements fall within the safe harbor provisions of the Florida and Massachusetts consumer fraud acts").

In the trial court, the State argued that the FDCA does not "permit" the use of a package insert that does not contain "updated" warnings. Janssen, it said, had a "duty to update" the package insert, to add warnings about weight gain, diabetes, and hyperprolactinemia. Because Janssen did not update the package insert, the State asserted the package insert was deceptive or unfair. There is, however, no "duty to update" exception to the regulated activity exemption. The exemption is triggered by the approval of the regulatory agency, and its "permission" to use the approved package insert. *See* S.C. Code Ann. § 39-5-40(a).

In any event, the FDA's *repeated* approval of the Risperdal package insert *without* the warnings the State would have required establishes that Janssen did not violate any duty to update prior to the reapproval. For each time the FDA reapproved the Risperdal package insert without the State's proposed warnings, it necessarily found that, as of the time of the reapproval, the package insert was not, to that point in time, "false or misleading" in any way. *See, e.g.*, 21 C.F.R. §§ 201.1-201.59. Any duty to update, then, is irrelevant, given the specific factual context of this case.

Moreover, there was no proof at trial that a "duty to update" ever was triggered. The State's medical expert, Dr. Wirshing, and its regulatory expert, Dr. Plunkett, both testified that, in their view, the package insert was inadequate from the very first day it was used – i.e., that the FDA had approved a package insert that should have contained more or different warnings. (Tr. 564:13-18, 638:24-639:1, 639:19-22, 824:9-21, 825:11-

15, R. _.) Neither Dr. Wirshing nor Dr. Plunkett identified any newly acquired evidence that would have triggered Janssen's duty to update under the regulations. For example, although there was a great deal of discussion about RIS-USA-113 and ERI at trial, neither of the State's experts testified that RIS-USA-113 would have changed their views or anyone else's view about the risks associated with Risperdal treatment, relative to the risks associated with treatment with other antipsychotics. Similarly, neither expert testified that the preliminary ERI report would have prompted any medical professional to form a new view about weight gain or diabetes risk. Notably, Dr. Plunkett, the State's expert on regulatory matters, did not testify that the FDA would have allowed Janssen to add a diabetes warning based on either RIS-USA-113 or ERI.[6]

Accordingly, the Court should reverse the trial court and enter judgment in Janssen's favor on the State's package-insert claim.

[6] A package insert "must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established." 21 C.F.R. § 201.57(c)(6)(i). The word "causal" was inserted before the word "association" by an amendment effective June 30, 2006. Janssen's regulatory expert, Sheldon Bradshaw, former Chief Counsel of the FDA, was prepared to testify that there was a longstanding requirement that there be evidence of a "causal association," albeit not a proven causal relationship – i.e., that the post-June 30, 2006 version of the regulation was merely a codification of the FDA's prior practice. The State, however, told the trial court that the regulation did not change until 2008, and objected to the testimony as irrelevant, because the State's claim was not based on any use of the package insert after 2007. Taking the State at its word, the trial court refused to allow any evidence that the regulation was, in fact, amended effective June 30, 2006; struck the references in Mr. Bradshaw's testimony to "causal association"; and refused to allow Mr. Bradshaw to testify that the FDA had, since 1982, required a showing of a "causal association." (Tr. 2007:5-2021:14, R. _.) In the State's closing statement, counsel exploited these erroneous rulings. (Tr. 2543:16-20, R. _ ("They brought you their private lawyer, the political appointee, Mr. Bradshaw, who I would suggest to you was spinning so much on the stand and playing so fast and loose that Judge Couch actually struck from the record a couple of his answers.").) The trial court denied Janssen's request for a corrective instruction regarding the testimony of Mr. Bradshaw that had been stricken. (Tr. 2641:18-2642:10, R. _.)

II. THE TRIAL COURT ERRED IN NOT ENTERING JUDGMENT FOR JANSSEN AS TO THE STATE'S NOVEMBER 2003 MAILING CLAIM BECAUSE THE CLAIM WAS PREEMPTED BY FEDERAL LAW.

For its evidence that the November 2003 letter was deceptive or otherwise improper, the State relied almost exclusively on the statement in the April 2004 DDMAC warning letter that "DDMAC has concluded that the DHCP letter [the November 2003 letter] is false or misleading *in violation of Sections 502(a) and 201(n) of the Federal Food, Drug, and Cosmetic Act.*" (Ex. P232 (emphasis added).) As it was presented at trial, then, the State's claim that Janssen's November 2003 mailing to healthcare providers was either deceptive or unfair, and therefore violative of SCUPTA, was based entirely on Janssen's purported violation of federal law.

The State repeatedly asked its expert witnesses to agree with the statements – particularly the statement that Janssen's November 2003 mailing was "false or misleading" – in the 2004 DDMAC letter. For example, the State's counsel elicited the following testimony from Dr. Wirshing:

> Q: . . . Doctor, do you agree with the FDA's assessment that Janssen's November 10th, 2003, letter was false and misleading?
>
> A. Absolutely, it was. In my opinion, it was designed to distinguish themselves from, from the class label, which is an absolute distinction to what the FDA wanted. They wanted a class label.

(Tr. 497:23-498:4, R. _.) Dr. Plunkett gave similar testimony:

> Q. And what does the FDA say about that letter?
>
> A. I believe that they say that it's false and misleading and failed to disclose important information.
>
> Q. It says Janssen's letter creates a serious public health issue also, right?
>
> A. Yes, that's correct.

Q. Now, Doctor, as an expert in the FDA regulations, do you agree with how the FDA interpreted its regulations in this case?

A. Absolutely, yes.

(Tr. 750:8-17, R. _.)

The State also called a former Janssen sales representative, and the State's counsel pressed her to "defer" to the conclusions in the 2004 DDMAC letter:

Q. Well, let me ask you this. If the FDA said it was, if it was false and misleading, will you defer to the FDA here today in front of this jury in Spartanburg County?

A. I would. But this is the package insert change. We were informing the customer and the doctor of what was going on. It was a package insert change.

Q. And all I'm asking you is, is, will you defer to the FDA in regards to Paragraph 4 and if they say it was misleading, you'll have to – you would defer to them, right?

A. Absolutely.

Q. Okay. Cause it's for them to decide?

A. It is for them to decide.

(Tr. 1168:15-1169:2, R. _.)

Similarly, the State stressed the conclusions of the 2004 DDMAC letter in its cross-examination of Janssen's witnesses. The State, for example, elicited the following from Dr. Ramy Mahmoud, who signed the November 2003 letter:

Q. Did you take this [the 2004 DDMAC letter] seriously when you got it?

A. Yes.

Q. Did you feel bad?

A. Yes, I was concerned, because I didn't know how they could of come to this conclusion.

Q. Well, I mean FDA said that your letter was false, right?

A. Right.

Q. Opposite of true, right?

A. DDMAC concluded that the letter was false or misleading, yes.

Q. In other words, what DDMAC is saying to you is that the information you're providing the doctors in your Dear Doctor letter is a lie, right?

A. They concluded that the letter was false or misleading.

(Tr. 1634:5-19, R. _.)

When examining defense witness Michael Chester, the State again reached for the 2004 DDMAC letter:

Q. All right. And, and your opinion is that it wasn't false and misleading?

A. Correct.

Q. You just disagree with the FDA?

A. Correct.

(Tr. 1975:25-1976:4, R. _.) Finally, in an effort to discredit a Janssen scientific expert, the State confronted him with the 2004 DDMAC letter:

Q. And you're aware that DDMAC and the FDA take the position that the opinion you gave to this jury is wrong, right?

A. I don't believe that that's correct. I think that DDMAC is the regulatory piece of FDA which comments on whether or not pieces of communications have, have been part of the approved label.

Q. Okay. We'll make this real easy. You said the letter was true. The FDA concluded that the letter is false or misleading. Do you see that?

A. I see what it says there.

(Tr. 2412:17-2413:3, R. _.)

Further, the State's closing arguments confirmed that the State's November 2003 mailing claim was based on the purported violations of the FDCA identified in the 2004 DDMAC letter:

> The question for you that you will have to answer as to each one of these two Defendants, was that November 10th, 2003, Dear Doctor Letter, which was admittedly disseminated all across South Carolina, there's no question about that, was it unfair and deceptive?
>
> . . . .
>
> We know that the FDA thought so. Remember the warning letter?
>
> . . . .
>
> We know the FDA thinks their letter was unfair and deceptive.

(Tr. 2541:22-2548:1, R. _.)

Clearly, the November 2003 mailing claim presented to the jury was nothing more than a claim based on Janssen's purported violation of the FDCA. Such a claim, however, is precluded by federal law, which provides that state law, including state consumer protection law, may not be used to enforce the FDCA, and explicitly prohibits claims like the one brought by the State here. *See* 21 U.S.C. § 337(a) (stating that "proceedings for the enforcement, or to restrain violations, of this chapter [of the FDCA] shall be by and in the name of the United States"). As the U.S. Supreme Court has explained, Section 337(a) "leaves no doubt that" the federal government has the exclusive authority to "file suit for noncompliance" with the FDCA. *Buckman*, 531 U.S. at 349 n.4; *see also Mut. Pharm. Co. v. Watson Pharm., Inc.*, No. CV 09-5700, 2009 WL 3401117, at *5 (C.D. Cal. Oct. 19, 2009) ("Plaintiffs' contentions concerning the product labels and inserts are even weaker, both because the evidence of confusion is weaker and because disputes concerning the content of those labels and inserts falls even more

squarely within the primary jurisdiction of the FDA."); *Pediamed Pharm., Inc. v. Breckenridge Pharm., Inc.*, 419 F. Supp. 2d 715, 726 n.14 (D. Md. 2006) ("The [FDA] has enforcement power over false and misleading labels. 21 U.S.C. § 352. To the extent that Plaintiff relies solely on the false label argument to find a Lanham Act violation . . . such a claim is essentially a mislabeling claim, which is within the jurisdiction of the FDA and thus would be precluded.").

As the lower court erred in determining that the State's November 2003 mailing claim was not preempted and in denying Janssen's Motion for Judgment Not Withstanding the Verdict or, in the Alternative, for a New Trial on this ground, the trial court should be reversed and judgment entered in favor of Janssen as to the State's November 2003 mailing claim.

III. BOTH OF THE STATE'S CLAIMS WERE BARRED BY THE STATUTE OF LIMITATIONS.

A SCUTPA claim must be filed no more than three years after discovery of the unlawful conduct. S.C. Code Ann. § 39-5-150. Under the discovery rule, "'the three-year clock'" on this statute of limitations "'starts ticking on the date the injured party either knows or should have known by the exercise of reasonable diligence that a cause of action arises from the wrongful conduct.'" *Kimmer v. Wright*, 396 S.C. 53, 719 S.E.2d 265, 268 (Ct. App. 2011) (quoting *Martin v. Companion Healthcare Corp.*, 357 S.C. 570, 575-76, 593 S.E.2d 624, 627 (Ct. App. 2004)); *see also Holly Woods Ass'n of Residence Owners v. Hiller*, 392 S.C. 172, 183, 708 S.E.2d 787, 793 (Ct. App. 2011) (explaining that statute of limitations "'begins to run when the underlying cause of action reasonably ought to have been discovered'" (quoting *Martin*, 357 S.C. at 575, 593 S.E.2d at 627)). Moreover, "South Carolina's statute of limitations requires 'very little to start the clock.'"

Maher v. Tietex Corp., 331 S.C. 371, 380, 500 S.E.2d 204, 208 (Ct. App. 1998) (quoting *Roe v. Doe*, 28 F.3d 404, 407 (4th Cir. 1994)). The State had actual or constructive knowledge of Janssen's allegedly unfair or deceptive conduct before January 24, 2004[7] – more than three years before it filed its original complaint. SCUTPA's statute of limitations therefore bars both of the State's claims.

A. The Trial Court Erred in Not Holding the State's Claims Were Time Barred.

According to the State and its experts, the Risperdal package insert was "inadequate" from the very first day Risperdal was marketed, in 1994, because there were no "warnings" about weight gain, other metabolic effects, and hyperprolactinemia. (Tr. 564:13-18, 638:24-639:1, 639:19-22, 824:9-21, 825:11-15, R. _.) The experts testified that all of the risks that the State now alleges were inadequately disclosed were "predictable," given Risperdal's chemical structure. And, they testified that most of the risks, including the risks of weight gain, hyperglycemia, and hyperprolactinemia, were apparent from the pre-marketing clinical studies of Risperdal. (Tr. 505:23-506:12, 552:1-11, 687:24-689:4, 690:22-691:2, 878:15-879:22, 893:21-894:18, R. _.) Both the chemical structure of Risperdal and the adverse effects observed in those clinical studies were, however, disclosed in the 1994 Risperdal package insert. (Ex. P0643, R. _.) The package insert stated that Risperdal "elevates prolactin levels." (*Id.*; *see also* Tr. 1009:19-25, R. _.) It also reported that clinical studies had revealed "a statistically significantly greater incidence of weight gain for RISPERDAL™ (18%) compared to placebo (9%)." (Ex. P0643, R. _.) And it noted reports about diabetes mellitus. (*Id.*)

[7] A tolling agreement was in place from January 24, 2007 until April 23, 2007, when the State filed this lawsuit.

Moreover, it was obvious that those risks were discussed not in the "Warnings" section of the label, but in the "Precautions" and "Adverse Events" sections. (*Id.*; *see also* Tr. 506:13-508:12, 580:18-23, 613:22-614:3, 870:14-25, R. _.) Any claim that these discussions were in the wrong place, or that the warnings were not sufficiently prominent, was apparent – and discoverable – from the 1994 package insert itself. The three-year statute of limitations on the "package insert" claim thus began to run in 1994, and expired many years before the State filed this lawsuit.

The State's November 2003 mailing claim also is time barred, because the State's claim that the November 2003 letter was "deceptive" or "unfair" was discoverable when the letter was mailed. The letter, which transmitted the new package insert with the diabetes/hyperglycemia warning, discussed "[h]yperglycemia-related adverse events." After noting that "confirmatory research is still needed," it summarized the conclusions then "suggest[ed]" by a certain "body of evidence from published peer-reviewed epidemiology research." (Ex. D0351, R. _.) The support for those conclusions – the entire "body of evidence from published peer-reviewed epidemiology research" on which Janssen relied – was identified and cited in the letter. (*Id.*) Any deception in Janssen's statements about the conclusions suggested by that "body of evidence" could easily have been discovered by the State or by any of the trained medical professionals to whom the letter was addressed[8] simply by looking at the studies to which Janssen pointed them. The three-year statute on the November 2003 mailing claim thus began to run at the time of the 2003 mailing and had expired well before the State filed suit in 2007.

[8] As the State emphasized at trial, the letter was widely disseminated to South Carolina healthcare providers and was publicly available on Janssen's website. (Tr. 1368:6-11, 1628:17-1629:21, R. _.)

B. The Trial Court Further Erred in Not Allowing Janssen to Present Its Statute of Limitations Defense to the Jury.

Because the State's claims were time barred, the trial court should have directed a verdict for Janssen. Instead, it granted the State's Motion for Directed Verdict on the statute of limitations defense, ruling that the jury could not even consider the record evidence about the State's knowledge of the "inadequately disclosed" risks. The trial court erred, for two reasons.

First, the trial court ruled that the statute of limitations did not start to run until the Attorney General himself had notice of the claim. But it is the State that is the party-plaintiff in this lawsuit, and it is actual or constructive notice to the State, not its Attorney General, that triggers the running of the statute. *See Willcox v. Stroup*, 358 B.R. 824, 832-34 (D.S.C. 2006), *aff'd*, 467 F.3d 409 (4th Cir. 2006) (reversing Bankruptcy Court's holding that that a state librarian's knowledge of certain historical documents could not be imputed to the State for purposes of the running of the statute of limitations); *State ex rel. Brady v. Pettinaro Enters.*, 870 A.2d 513, 532 (Del. Ch. 2005) ("I cannot accept the State's strange argument that the . . . limitation period did not start to run until the Attorney General received complaints from consumers.").

Second, the trial court also erroneously found the statute of limitations equitably tolled. In reaching its equitable tolling conclusion, the court relied not only on the lack of notice to the Attorney General's office, but also on the non-disclosure of RIS-USA-113 and other "studies." There was, however, no record evidence that the filing of the State's lawsuit was hindered or delayed by the non-disclosure of those "studies."[9] Indeed, there

[9] When the State finally filed its lawsuit in April 2007, it asserted consumer protection claims that were not based on RIS-USA-113, ERI, or RIS-USA-275.

was no record evidence that anyone was ever misled or deceived by any Janssen conduct. The doctrine of equitable tolling should be sparingly applied, *Hooper v. Ebenezer Senior Services & Rehabilitation Center*, 386 S.C. 108, 687 S.E.2d 29 (2009), and there is no basis for applying it here. At a minimum, Janssen should have been able to present its statute of limitations defense to the jury; the trial court's directed verdict ruling should be reversed.

IV. THE STATE'S CLAIMS FAIL BECAUSE THE STATE DID NOT PROVE THE ESSENTIAL ELEMENT OF "IMPACT."

A. There Was No Evidence the FDA-Approved Risperdal Package Insert or the November 2003 Mailing Had a Tendency to Deceive, Were Likely to Deceive, or Were Likely to Cause Substantial Injury.

The State claimed that the FDA-approved package insert and the November 2003 mailing were deceptive. It thus was required to prove that the package insert and the letter had a "tendency to deceive" or were "likely to deceive." *deBondt v. Carlton Motorcars, Inc.*, 342 S.C. 254, 269, 536 S.E.2d 399, 407 (Ct. App. 2000); *Young v. Century Lincoln-Mercury, Inc.*, 302 S.C. 320, 325, 396 S.E.2d 105, 108 (Ct. App. 1989); *FTC v. Tashman*, 318 F.3d 1273, 1277 (11th Cir. 2003).[10] The State also claimed that the package insert and the mailing were unfair. The State therefore had to prove all of the elements of unfairness – including the essential element of the likelihood of substantial injury that is not reasonably avoidable. FTC Policy Statement on Unfairness, 2 Fed Trade Comm'n App. D-1 (Dec. 17, 1980); *see also* 15 U.S.C. § 45(n).

[10] When construing SCUTPA, South Carolina courts are instructed to look to the interpretations given by the Federal Trade Commission and the federal courts to the Federal Trade Commission Act. S.C. Code Ann. § 39-5-20(b); *Plowman v. Bagnal*, 316 S.C. 283, 287, 450 S.E.2d 36, 38 (1994); *State ex rel. McLeod v. VIP Enters., Inc.*, 286 S.C. 501, 504, 335 S.E.2d 243, 244 (Ct. App. 1985).

Whether an act or a statement has a tendency to deceive, or is likely to deceive, or is likely to cause substantial injury "depends upon the surrounding facts and the impact of the transaction on the marketplace." *deBondt*, 342 S.C. at 269, 536 S.E.2d at 407; *Young*, 302 S.C. at 326, 396 S.E.2d at 108. Consideration of "the surrounding facts and the impact of the transaction on the marketplace," in turn, requires consideration of the knowledge, experience, and sophistication of the relevant audience – i.e., the context in which the statements were made. *See* FTC Policy Statement on Deception, 2 Fed. Trade Comm'n App. D-2 (Oct. 14, 1983). In particular, as the FTC Policy Statement provides, "[A] practice or representation directed to a well-educated group, such as a prescription drug advertisement to doctors, would be judged in light of the knowledge and sophistication of that group." *Id.*

The relevant audience, or marketplace, for the State's SCUTPA claim necessarily is South Carolina physicians because (1) Risperdal can only be obtained by prescription; (2) the package insert is written for physicians; and (3) the November 2003 mailing was sent to physicians. The State, then, had to prove that the Risperdal package insert and the November 2003 mailing had a tendency to deceive, or were likely to deceive, South Carolina physicians. That is, the State had to prove that the challenged statements were likely to have a substantial impact on the prescribing decisions of South Carolina physicians.

The State, however, did not offer any evidence that the challenged statements had any impact on the marketplace. It did not even try to prove that the Risperdal package insert and the November 2003 mailing had a tendency to deceive, or were likely to deceive, South Carolina physicians. The State's experts took the position that the

Risperdal package insert was "inadequate" as to certain risks and that the November 2003 mailing was somehow inherently "deceptive." But they provided no testimony whatsoever about the knowledge, experience, and sophistication of South Carolina physicians, and no testimony as to whether the package insert or the mailing actually deceived or were likely to deceive those physicians. Furthermore, the State did not call any South Carolina physicians to the stand, and the State offered no evidence that the statements in the package insert or the mailing made any difference to the decision making of South Carolina physicians.

The only "impact" evidence in this case was evidence presented by Janssen, and it showed that there was no deception, no likelihood of deception, and no possibility of substantial injury. The parties stipulated that Janssen' expert, Dr. William Wecker, would testify that there was no change in Risperdal's share of prescriptions for antipsychotics filled for South Carolina Medicaid and State Health Plan participants after the November 2003 mailing or after the July 2004 corrective letter. (Tr. 2442:9-2443:20, R. _; Exs. D7008, D7337, D7338, R. _.) The mailing, then, had no impact on the prescribing decisions of South Carolina physicians. And Drs. Robert Bank and Brenda Ratliff, the current and former medical directors of the South Carolina Department of Mental Health, who were called as witnesses by Janssen, made clear that they and their colleagues were well-informed about the risks of Risperdal and other antipsychotics. (Tr. 2057:11-16, 2057:25-2058:3, 2095:6-19, 2097:10-15, R. _.) The trial court recognized this when it summarized their testimony during its ruling on the statute of limitations motions: "All of the individuals who testified on behalf of the Defendant from the State as to what they knew and when they knew it, all of them testified to the

fact that they were aware that atypical antipsychotics, the second generation of drugs, had an issue or a problem involving diabetic adverse events, and that that, that particular fact appears to have been known by the medical community for some period of time before this action was filed." (Tr. 2471:11-18, R. _.) Moreover, none of those "state" medical witnesses "testified that they ever felt at any time that they had been, that facts had been misrepresented by Janssen or that Janssen had committed any type of fraud or made misleading statements in the marketplace." (*Id.* at 2471:19-22, R. _.)

"Likelihood" of deception cannot simply be assumed, and likelihood of substantial injury must be proved. But there was no evidence whatsoever from which the jury could conclude that the package insert or the mailing were likely to deceive, or had a tendency to deceive, the knowledgeable South Carolina medical community, or were likely to cause substantial injury. The State failed to prove a critical element of its claims, and the trial court erred in denying Janssen's Motion for Judgment Not Withstanding the Verdict or, in the Alternative, for a New Trial, which raised the failure to prove "impact."

B. The Trial Court Erred in Excluding Evidence Rebutting "Deception."

Moreover, the trial court improperly excluded Janssen's affirmative evidence that the package insert and the mailing were not deceptive. In response to a pretrial motion by the State, and again at trial, the court excluded survey evidence that tended to show that South Carolina physicians were well informed about the risks of antipsychotics and were not deceived by any statements in the Risperdal package insert or the November 2003 letter. When it ruled on the pretrial motion, the court explained that "Defendant presented no testimony from other experts in this field or any other evidence which would indicate the survey or the methodology used by Dr. Wecker [an expert

statistician], in compiling and analyzing the data, were methods that are usually relied upon by persons compiling data and drawing conclusions therefrom." (Feb. 25, 2011 Order at 11, R. _.) The court further ruled that the survey evidence "would not be relevant" because there is no statutory requirement of proof "that someone be actually deceived or injured in any way." (*Id.*) The court's statements about the nature of Dr. Wecker's analysis are not consistent with the record; the Wecker report, which was submitted to the court, and a Wecker affidavit, explaining the methodology, establish the reliability of the analysis. (D7008, R. _; Ex. A to Defs.' Mem. in Opp'n to Pl.'s Mot. to Exclude Expert Testimony of Dr. William E. Wecker, R. _.) The only challenge to the methodology was contained in the State's briefs and in the oral argument of the State's lawyers; the State did not submit any expert testimony or any affidavits supporting its challenge. The court's statements about the relevancy of the Wecker testimony are simply wrong. Not having to prove "actual" deception of a particular physician does not make the absence of deception irrelevant.

Had Dr. Wecker been allowed to testify, he would have extrapolated from the survey responses of twenty South Carolina physicians randomly selected from the 101 most frequent prescribers of antipsychotics. (Defs.' Offer of Proof for the Expert Testimony of Dr. William E. Wecker, R. _.) When the court questioned Dr. Wecker's methodology and refused to allow him to testify about the survey, Janssen proposed calling the twenty prescribers at trial, to testify about their experiences with Risperdal and other antipsychotics, and the impact of the statements in the package insert and the letter. The court would not allow the testimony, ruling that it would be both irrelevant and cumulative. (Tr. 2167:8-2169:8, R. _.) Evidence that there was no impact, however, is

anything but irrelevant. And the testimony of a representative sample of the South Carolina physicians most familiar with antipsychotics is anything but cumulative. It is, rather, highly probative of the absence of the requisite "impact."

In addition, the trial court erroneously excluded evidence (1) that the statements in the November 2003 letter were, in fact, true; and (2) that the FDA later reversed its position with respect to the appropriateness of a "class-wide" warning, concluding that some antipsychotics had a higher incidence of metabolic-related side effects than others. Specifically, the trial court would not allow Janssen to introduce evidence about post-2004 scientific studies and articles. Nor would the court allow Janssen to introduce the 2007 FDA-approved package insert for Zyprexa and the 2010 FDA-approved package insert for Latuda, both of which demonstrated the FDA had recognized that the relative incidence of metabolic-related side effects differs among the atypical antipsychotics. (Tr. 113:16-22, 1418:21-1419:25, 2425:6-11, R. _; Defs.' Offer of Proof for the Post-2007 FDA-Approved Package Insert for Zyprexa and the Post-2010 FDA-Approved Package Insert for Latuda, R. _.) Proof that the statements in the letter were true obviously is relevant to the likelihood of deception. Truth was not, as the court ruled, irrelevant. And proof that the FDA had concluded that diabetes-related risks were, in fact, different, was obviously relevant in a case in which the principal contention was that the FDA characterized statements in the letter about differential risk as false or misleading.

The exclusion of the Wecker survey, the testimony of the twenty prescribers, and the Zyprexa and Latuda package inserts was reversible error. The Wecker methodology was proper, and there was no evidence that it was not. Moreover, the excluded testimony

and the documentary evidence would have been probative, if not determinative, of the absence of "impact." At the very least, then, this Court should order a new trial at which all relevant evidence will be considered.

V. THE STATE'S OPENING AND CLOSING ARGUMENTS WERE INFLAMMATORY AND UNDULY PREJUDICIAL.

In its opening and closing statements, and throughout the trial, the State made repeated statements designed to inflame and prejudice the jury. It was error for the trial court to allow these statements, which were made over Janssen's objections.[11] *See Branham v. Ford Motor Co.*, 390 S.C. 203, 234, 701 S.E.2d 5, 21 (2010) ("It is improper for counsel to make a 'closing argument to the jury . . . calculated to arouse passion or prejudice.'" (quoting *Gathers v. Harris Teeter Supermarket, Inc.*, 282 S.C. 220, 231, 317 S.E.2d 748, 755 (Ct. App. 1984))).

Here, the State's opening statement repeatedly invited the jury to find Janssen liable because it was a large, profitable corporation. (Tr. 220:1-263:14, R. _.) Counsel referred to Janssen as "a very large company that developed a little pill that brought them huge, huge profits." (Tr. 227:6-7, R. _.) Counsel also showed a slide to the jury that referred to "33 Billion" in projected sales and "97% gross profit margin." (Tr. 238:21-22, R. _.) Additionally, counsel talked about "obscene profit," and said Janssen "did it for the money." (Tr. 226:20-21, 238:9, R. _.) "[T]his case," counsel concluded, "is about Janssen's putting profits over safety." (Tr. 261:14:15, 261:24-25, R. _.)

The State's closing argument sought to invoke these same sentiments, suggesting that the jury impose liability because of Janssen's size and success. (Tr. 2520:3-2555:17,

[11] *See* Tr. 146:10-147:11, R. _ (objection to references to Janssen's profits, net worth, wealth, and sales); Tr. 190:19-22, R. _ (standing objection to references to sales figures, projected sales, and similar matters).

2596:25-2607:15, R. _.) For example, the closing began with the words "Little pill. Big profits." (Tr. 2520:8, R. _.) The State's counsel went on to say, "It isn't about patient safety" and "It's all about the money." (Tr. 2537:17, 19, R. _.) And counsel echoed the opening statement themes by references to "billions and billions of dollars" and putting "profits over safety." (Tr. 2605:21, 2598:7, R. _.) These arguments are comparable to those found to be unduly inflammatory and prejudicial in *Branham*. *Compare* Tr. 261:24-25, 2598:7 ("profits over safety"), *with Branham*, 390 S.C. at 234, 701 S.E.2d at 21-22 ("they chose profits over safety").

In the opening statement, in closing arguments, and throughout the trial,[12] the State pressed its theme – that Janssen was a big, wealthy, out-of-state corporation that put "profits over safety."[13] In fact, in closing argument, the State went so far as to claim the mantle of Scriptural authority, invoking the Bible story of David and Goliath, comparing the State to that story's hero and impliedly likening Janssen to the giant Philistine. (Tr. 2599:6-11.) In sum, over the course of the trial, the State repeatedly sought to unfairly inflame the passion and prejudice of the jury, and the trial court permitted it. This was error and warrants reversal.

[12] *E.g.*, Tr. 1192:10-12, R. _ ("But it's much more important to Johnson & Johnson that it makes money than people's kids are safe and effectively treated, right?"); *see also, e.g.*, Tr. 847:22-25, 1023:17-24, 1272:12-18, 1275:18-1276:14, 2072:3-19, R. _ (invoking the Ten Commandments).

[13] Statements about Janssen's wealth and profits were made in the liability trial, even though the jury would not determine penalties.

VI. THE TRIAL COURT COMMITTED REVERSIBLE ERROR IN ADMITTING THE 1994, 1999, AND 2004 DDMAC LETTERS.

A. The DDMAC Letters Were Inadmissible Hearsay.

The State's key "evidence" that Janssen's November 2003 mailing violated SCUTPA was the 2004 DDMAC letter stating that the November 2003 letter was "false or misleading in violation of Sections 502(a) and 201(n) of the Federal Food, Drug, and Cosmetic Act." (Ex. P232, R. _.) The DDMAC letter, however, is hearsay; it contains out-of-court statements that the State offered to prove the truth of the matter asserted – that the November 2003 letter was "false" or "misleading." *See* Rule 801(c), SCRE. The trial court committed reversible error when it admitted the 2004 DDMAC letter into evidence over Janssen's objections. (*E.g.*, Tr. 168:20-169:12, 495:6-13, R. _.)

The 2004 DDMAC letter was not admissible under the narrow public records and reports exception to the hearsay rule, which allows the admission of records setting forth "matters observed pursuant to duty imposed by law as to which matters there was a duty to report" but expressly prohibits the admission of "investigative notes involving opinions, judgments, or conclusions." Rule 803(8)(B), SCRE. The 2004 DDMAC letter does not set forth "matters observed" within the meaning of the exception, was not prepared "pursuant to duty imposed by law," and was not written to satisfy a "duty to report."

As an initial matter, one difference between Federal Rule of Evidence 803(8) and South Carolina Rule of Evidence 803(8) is instructive. Whereas the federal rule allows, in some circumstances, the admission both of "matter[s] observed while under a legal duty to report" and "factual findings from a legally authorized investigation," Fed. R. Evid. 803(8)(A)(ii), (iii), the South Carolina rule does not include within the public

records exception "factual findings from a legally authorized investigation." In this State, such investigative findings are hearsay.

In South Carolina, the only two public records exceptions to the hearsay rule are for internal records of a public agency and – the exception relevant here – for certain "matters observed" by public agencies. *See* Rule 803(8), SCRE. Moreover, "matters observed" has a distinctly narrow application, and pertains to information that is concrete and factual, not interpretive or opinion based. *See State v. Pearson*, 223 S.C. 377, 383, 76 S.E.2d 151, 153-54 (1953) ("a record of a primary fact made by a public officer in the performance of official duty" is admissible, whereas "records of investigations and inquiries conducted . . . involving the exercise of judgment and discretion, expressions of opinion, and making conclusions" are not (quotation marks and citations omitted)).[14]

The 2004 DDMAC letter does not contain the sort of hard factual information that qualifies for the South Carolina "matters observed" hearsay exception. Rather, the letter sets forth DDMAC's analysis and preliminary conclusion that the November 2003 mailing violated the FDCA. For that reason, SCRE 803(8)(B) does not allow for its admission. *Accord Pool v. Wade*, 685 N.E.2d 791, 793 (Ohio Ct. App. 1996) (FDA drug bulletin inadmissible under Ohio equivalent of SCRE 803(8)(B) where it contained evaluative and investigative information); *see also State v. Morris*, 376 S.C. 189, 207, 656 S.E.2d 359, 368 (2008) (public records exception did not apply to bankruptcy examiner's report containing investigative opinions, legal analysis, and potential conclusions).

[14] The Note to Rule 803(8)(B) explains that the "subsection is consistent with prior state practice." *See* Note to Rule 803(8)(B), SCRE (citing *Pearson*, 223 S.C. 377, 76 S.E.2d 151, as one of the cases with which SCRE 803(8)(B) is consistent).

Moreover, a public record is admissible under the "matters observed" exception only when it is prepared pursuant to express statutory direction. *See* Rule 803(8)(B), SCRE. *Compare Pearson*, 223 S.C. at 381-82, 76 S.E.2d at 152-53 (record of prior conviction admissible because state law directed record be made), *with Sandel v. State*, 126 S.C. 1, 119 S.E. 776, 780 (1922) (state board of health report inadmissible where no law required its creation). There is no statutory or regulatory provision within the FDCA or its implementing regulations mandating the preparation or issuance of warning letters. In fact, the FDA's own internal procedures emphasize that it is *not* required to issue warning letters, noting that "FDA is under no legal obligation to warn individuals or firms that they or their products are in violation of the law before taking enforcement action." (Ex. D4337, Ch. 4 *FDA Regulatory Procedures Manual: Advisory Actions* at 4-2 (2010).)

Furthermore, records do not fall under the "matters observed" exception when they have not been generated pursuant to a "duty to report." Rule 803(8)(B), SCRE. The FDA's duty is to *regulate* allegedly false and misleading practices by pharmaceutical manufacturers, at times through the use of enforcement actions. Warning letters are not, however, prerequisites to instituting an enforcement action, and the FDA has no duty to report practices that are allegedly false and misleading by means of a warning letter. (Ex. D4337 at 4-2.) Warning letters are nothing more than "informal and advisory" communications that allow "individuals and firms an opportunity to take voluntary and prompt corrective action" before FDA initiates an enforcement action. (*Id.* at 4-1.) Because the FDA sent the 2004 DDMAC letter without statutory direction and without a duty to report, the letter is not admissible as a public record under SCRE 803(8)(B).

Similarly, the trial court committed reversible error when it admitted, over Janssen's objections, the 1994 DDMAC letter and the 1999 DDMAC letter, out of court statements offered for their truth. (*See* Tr. 693:16-697:20, 1032:17-1037:21, 1172:20-1173:3, R. _.) Neither falls within the public records exception to Rule 803(8)(B), SCRE, because neither letter sets forth "matters observed," and the letters were not prepared pursuant to a duty to report. The letters set forth DDMAC's conclusions that certain promotional materials were "misleading" in a way that violated the FDCA and its implementing regulations; they do not set forth mere factual information. (Exs. P1027, P200, R. _.)

B. Any Probative Value of the DDMAC Letters Was Substantially Outweighed by the Danger of Unfair Prejudice and Misleading the Jury.

The trial court's ruling that the 2004 DDMAC letter was admissible also was reversible error because any claimed probative value of the letter was substantially outweighed by the danger of unfair prejudice and misleading the jury. *See* Rule 403, SCRE ("Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury . . . ."); *Jamison v. Ford Motor Co.*, 373 S.C. 248, 269, 644 S.E.2d 755, 766 (Ct. App. 2007) (affirming trial court's decision to exclude evidence where prejudice outweighed any probative value).

The 2004 DDMAC letter was merely a preliminary letter that was informal and advisory; it was not a final action by the FDA or a final determination that the November 2003 mailing was "false or misleading." (*See* Ex. D4337 at 4-2 ("A Warning Letter is informal and advisory. It communicates the agency's position on a matter, but it does not commit FDA to taking enforcement action. For these reasons, FDA does not consider

Warning Letters to be final agency action on which it can be sued.")); *see also State ex rel. McGraw v. Johnson & Johnson*, 704 S.E.2d 677, 689-90 (W. Va. 2010) (reversing trial court's judgment that was based on same 2004 DDMAC letter at issue here, holding that letter was merely "informal and advisory"); *see also Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 944 (D.C. Cir. 2012) (holding that FDA warning letters compel no action by their recipient, do not constitute final agency action, "[n]or do the letters represent a decision determining rights or obligations, or one from which legal consequences flow"); *Schering-Plough Healthcare Prods. v. Schwarz Pharma, Inc.*, 586 F.3d 500, 508 (7th Cir. 2009) ("We can set aside letters from subordinate officials of the FDA; the letters are not final agency action binding on the district court, as there has been no final agency action, let alone action that has been or could be judicially reviewed.").

Furthermore, the FDCA and its implementing regulations attach a particular meaning to "false or misleading" that relates to noncompliance with federal labeling or promotional regulations. *See, e.g.*, 21 U.S.C. §§ 321(n), 352(a); 21 C.F.R. §§ 201.1-201.59; 202.1. A statement can be "false or misleading" for purposes of a warning letter even if it is not untrue and not deceptive. Thus, for example, the FDA may classify truthful off-label promotion as "false or misleading." DDMAC's use of the term "false or misleading" therefore was bound to confuse the jury about the standards for liability under SCUTPA. Indeed, at trial, the State seemed intent on maximizing that confusion – the State confronted witnesses, over and over, with the "fact" that the FDA said that the November 2003 letter was "false and misleading."

The trial court should not have admitted the 2004 DDMAC letter into evidence. Any probative value that it may have had – and it is not apparent that it had any at all –

was substantially outweighed by the danger that the jury would believe, as it did, that it had already been "officially" determined that the November 2003 letter was "false" or "misleading." And that was extraordinarily prejudicial to Janssen.

For these same reasons, the trial court also committed reversible error when concluding that the any probative value of the 1994 DDMAC letter and the 1999 DDMAC letter was not substantially outweighed by the danger of unfair prejudice or misleading the jury. Like the 2004 letter, the State used the 1994 and 1999 letters as evidence that Janssen repeatedly engaged in false and misleading activities. (*See, e.g.*, Tr. 700:21-701:6, R. _ (State's regulatory expert agreeing that in the 1994 DDMAC letter, the FDA said the "excellent safety profile claim" is "misleading"); *id.* at 1041:14-22, R. _ (State's regulatory expert stating that in the 1999 DDMAC letter, DDMAC made the "exact determination" that materials addressed by the letter were "false, misleading, and/or lacking in fair balance and in violation of the law").) This was undoubtedly confusing and clearly prejudicial; the letters were inadmissible under Rule 403, SCRE.

VII. THE TRIAL COURT'S JURY INSTRUCTIONS REGARDING "UNFAIRNESS" WERE ERRONEOUS, AND THE VERDICT FORM WAS UNFAIRLY NON-SPECIFIC.

The South Carolina Unfair Trade Practices Act addresses both "deceptive" and "unfair" acts and practices. The Act does not define those terms, however. Rather, it directs the courts to the interpretations given the terms by the Federal Trade Commission and the federal courts, when they construe and apply parallel provisions of the Federal Trade Commission Act. S.C. Code Ann. § 39-5-20(b); *Plowman*, 316 S.C. at 287, 450 S.E.2d at 38; *VIP Enters.*, 286 S.C. at 504, 335 S.E.2d at 244.

The FTC's criteria for an "unfairness" finding are set forth in its Policy Statement on Unfairness. First, the challenged act must have caused or be likely to cause

"substantial injury." Second, the act must have violated a well-established public policy. FTC Policy Statement on Unfairness, 2 Fed Trade Comm'n App. D-1. The substantial injury requirement is "primary" and is so important that it has been incorporated into the Federal Trade Commission Act itself, in a section entitled "Definition of unfair acts or practices." 15 U.S.C. § 45(n). That section now provides that the Commission may not declare a practice "unfair" "unless the act or practice causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition." *Id.* As set forth in the Policy Statement, and as codified in the federal statute, the "public policy" element is secondary and limited: "In determining whether an act or practice is unfair, the Commission may consider established public policies as evidence to be considered with all other evidence. Such public policy considerations may not serve as a primary basis for such determination." *Id.*

Janssen requested that the trial court instruct the jury in accordance with the FTC interpretations of the Federal Trade Commission Act's "unfairness" provisions. In particular, Janssen asked that the court instruct the jury on the "substantial injury" element of an "unfairness" claim. Janssen also requested that the court instruct the jury that a finding that the package insert or the mailing "violated public policy" was not in and of itself a basis for a finding of an unfair trade practice, and could not even "be the primary basis" for such a finding. (Defs.' Requested Jury Instructions, Mar. 17, 2011, Requested Instruction No. 19, R. _.)

The trial court, however, refused to give the instruction about "substantial injury" and refused to explain the limited role of "public policy." Instead, the court instructed

the jury that it could return an "unfairness" verdict if it found that Janssen acted "unethically" or if anything Janssen did offended established public policy: "A trade practice or act is an unfair trade practice or act if it offends established public policy or it is immoral, unethical, or oppressive." (Tr. 2626:19-22, 2667:11-13, R. _.) Further, the court refused Janssen's request for a verdict sheet that required separate findings as to "deceptive" and "unfair" trade practices and as to the elements of the two claims. The verdict sheet the court employed asked simply "whether or not [Janssen] engaged in unfair or deceptive acts or practices." (Verdict Form, R. _.) Janssen made appropriate objections to the instructions and the verdict sheet. (Tr. 2513:24-2514:6, 2514:23-2515:2, 2633:2-2642:25, 2645:2-15, R. _.)

Anticipating the court's charge and the one-offense verdict sheet, the State's counsel devoted much of their closing statements to the "unfairness" claim. They invited the jury to return a verdict against Janssen not because it made untrue and deceptive statements to South Carolina physicians, but because the company was "immoral" and "unethical," because it did not "play by the rules," because it did not submit "everything like you're suppose to submit" to the FDA, and because it put "profits over safety." (Tr. 2522:15-16, 20; 2554:24-2555:3, 2598:7, 2606:7-8, R. _.) For example:

- "[The case] wasn't about how many people had developed diabetes, and it was not about whether doctors were deceived."
- "Corporate ethics is an issue that's current. It's affected our nation and South Carolina for the last three or four years. That's what we're talking about in this case. It's not science. It's corporate ethics."
- "Now when you listen to the charge by Judge Couch at the end of this case, see if his charge matches up with this side, the science, or see if his charge matches up against bad behavior, misrepresentation, false claims, breaking the law, and not abiding by the rules, profits over safety."

- "You can't fight a warning going into your label because you think your sales are going to go down."
- "The FDA is an honor system. They don't do any studies, and you submit things to them under the honor system. And when you don't submit everything like you're supposed to submit, then you break that system."
- "[W]hat these questions [on the verdict sheet] really ask are did these Defendants play by the rules?"

(Tr. 2522:15-16, 2549:19-20, 2597:20-21, 2598:3-7, 2598:24-2599:2, 2606:5-8, R. _.)

The jury ultimately answered "Yes" to the question on the verdict sheet as to Janssen, finding that Janssen had "engaged in unfair or deceptive acts or practices." (Verdict Form, R. _.) But the trial court's erroneous and incomplete instructions allowed the jury to answer "Yes" if all that it concluded was that, on at least one occasion, Janssen somehow "broke the [FDA] rules" or was motivated by "profits." Indeed, the liability verdict as to the State's mailing claim may well have been based entirely upon the receipt of the 2004 DDMAC letter, with its assertion that Janssen violated FDA rules. The multiple errors in the charge were compounded by the use of a verdict sheet that did not distinguish between "deceptive" acts and "unfair" acts, and did not require specific findings as to the elements of each of the State's claims. Because the instructions were improper and the verdict sheet unfairly non-specific, the verdict cannot stand.

VIII. THE TRIAL COURT'S EXCESSIVE PENALTY AWARD WAS NOT STATUTORILY AUTHORIZED, WAS AN ABUSE OF DISCRETION, AND VIOLATED THE SOUTH CAROLINA AND UNITED STATES CONSTITUTIONS.

The trial court abused its discretion and violated SCUTPA and the South Carolina and United States Constitutions by imposing staggering, unjustified penalties and by imposing penalties for violations not found by the jury. SCUTPA allows the assessment of civil penalties up to $5,000 per violation. S.C. Code § 39-5-110(a); *Wright v. Craft*,

372 S.C. 1, 23-24, 640 S.E.2d 486, 498 (Ct. App. 2006). That does not mean, however, that any penalty amount up to $5,000 per violation is necessarily factually and legally permissible. The amount of the penalty award is subject to review for abuse of discretion, and the constitutionality of the award and the legal issues associated with the award are subject to *de novo* review. *Mitchell v. Fortis Ins. Co.*, 385 S.C. 570, 583, 686 S.E.2d 176, 183 (2009), *cert. denied*, 130 S. Ct. 1896 (2010). This Court may remit the award to correct a trial court's abuse of discretion or constitutional violations. *Id.* at 593, 686 S.E.2d at 188; *Hollis v. Stonington Dev., LLC*, 394 S.C. 383, 714 S.E.2d 904 (Ct. App. 2011).

The trial court imposed a penalty of $4,000 for each "violation" arising from Janssen's November 2003 mailing: 7,184 letters mailed and 36,372 sales calls in which the trial court erroneously believed the mailing was "published," or shown to a physician. All told, the total penalty assessed was in excess of $327 million. As explained in detail below, this award was far beyond appropriate and was an abuse of discretion. *See Midlands Util. v. S.C. Dep't of Health & Envtl. Control*, 313 S.C. 210, 212, 437 S.E.2d 120, 121 (Ct. App. 1993) ("[E]ach fine must be analyzed individually to determine if it is appropriate under the circumstances.").

A. The Trial Court's Penalty Award Regarding the Package Insert Claim Was Legally and Factually Erroneous.

At the insistence of the State, the trial court chose to impose a penalty for the package insert violation based on the number of Risperdal sample boxes distributed by Janssen to South Carolina physicians from 1994 to 2007. The trial court reasoned that "[e]ach distributed sample clearly contains a copy of the label and would be the most likely source of information for patients who are considering entering into an ongoing

therapy with the drug." (Penalty Order at 16, R. _.) At $300 per sample box, the amount the trial court settled on, the penalty came to $152,849,700. The court's imposition of package insert penalties based on the number of "sample[s] distributed" was impermissible for several reasons, both legal and factual.

First, the trial court erred by basing its package insert penalty award on the failure of the package insert to provide "adequate" warnings to patients. Janssen had no legal duty to warn patients about risks associated with the use of Risperdal; its only duty was to warn physicians, who would then act as learned intermediaries between the pharmaceutical manufacturer and the physicians' patients. *See, e.g., Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1231 (4th Cir. 1984) ("Although the South Carolina Supreme Court has not addressed the issue, we conclude it would adopt the rule, generally accepted and supported by sound policy, restricting the manufacturer's duty to warn to the prescribing physician."). Accordingly, the Risperdal package insert was written for physicians, not patients. *See* Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49,603, 49,604 (Aug. 22, 2008) (codified at 21 CFR Parts 314, 601, and 814) ("FDA's comprehensive scientific evaluation is embodied in the labeling for the product which reflects thorough FDA review of the pertinent scientific evidence and communicates *to health care practitioners* the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively." (emphasis added)); *Morlino v. Med. Ctr.*, 152 N.J. 563, 580, 706 A.2d 721, 729-30 (N.J. 1998) ("Drug manufacturers write explanations and warnings for doctors, not the general public.").

Second, there is no basis in the record for the trial court's apparent conclusion that the Risperdal package insert deceived, or was likely to deceive, patients. There is, for example, no evidence that a patient would think it important that the hyperprolactinemia discussion was in the "precautions" section of the package insert, rather than in the "warnings" section. Indeed, there was no record evidence supporting the trial court's statement that the package inserts distributed with samples "would be the most likely source of information for patients who are considering entering into an ongoing therapy with the drug." (Penalty Order at 16, R. _.) Far more likely is that patients would rely on their physicians and their physicians' recommendations, based on the physicians' experiences with the medicine and knowledge accumulated by them from multiple sources.

Third, the trial court imposed a "package insert" penalty for every sample box distributed to physicians from the first day Risperdal was sold in South Carolina, in 1994, to the day the State filed its original complaint, in 2007. (*Id.*) But the jury was not asked to find, and did not find, that the label was "inadequate" or deceptive for the entire 1994 through 2007 period. At most, the jury found that the Risperdal package insert was "inadequate" in at least one respect, at one point in time. Because the verdict form was non-specific, there is no way of knowing what "inadequacy" prompted the verdict – e.g., whether it related to the absence of a "diabetes" warning from July or August 2000, when the preliminary ERI data were received, to November 2003, when the "diabetes" warning was added; or to the placement within the label of the "hyperprolactinemia" discussion from 1994 to 2007; or simply to the "delay" in adding a diabetes warning in November

2003 after the FDA requested one in September 2003. The trial court's "package insert" penalties award, then, was not, as the statute requires, tied to the jury's liability verdict.

B. The Trial Court's Penalty Award Regarding the November 2003 Mailing Claim Also Was Legally and Factually Erroneous.

The trial court imposed a penalty of $174,224,000 based on the jury's November 2003 mailing verdict. The court assessed $4,000 for every "Dear Health Care Provider" letter mailed to a South Carolina address. The trial court also imposed a $4,000 penalty for each sales visit in South Carolina between November 10, 2003 and July 21, 2004, based on the belief that the letter was published during every sales call. (Penalty Order at 17, R. _.) By imposing penalties on both mailings and sales calls, the trial court was double- and triple-counting the "violations." Moreover, the trial court's finding that there were 36,372 "[s]ales calls where letter published" is not consistent with the record evidence.[15]

As an initial matter, the trial court imposed multiple penalties for what it believed was an effort to mislead the same physician with the same letter. Specifically, the court imposed a penalty for every mailing to a South Carolina physician and then imposed the same penalty again for every sales call during which the letter supposedly was published. The physicians upon whom Janssen's sales representatives called, however, were the

[15] The trial court did not explain its finding that the "appropriate penalty" was "$4,000.00 per violation." *See In re Treatment & Care of Luckabaugh*, 351 S.C. 122, 132, 568 S.E.2d 338, 343 (2002) ("Trial courts, sitting without juries in an action at law, write their findings specially and separately: to allow a reviewing court to determine from the record whether the judgment – and the legal conclusions which underlie it – represent a correct application of the law. The requirement for appropriately detailed findings is thus not a mere formality or a rule of empty ritual; it is designed instead to dispose of the issues raised by the pleadings and to allow the appellate courts to perform their proper function in the judicial system."); *Walterboro Cmty. Hosp., Inc. v. Meacher*, 392 S.C. 479, 485, 709 S.E. 2d 71, 74 (Ct. App. 2011) ("We note that Rule 52(a) of the South Carolina Rules of Civil Procedure requires a trial court to make specific findings of fact so that the parties and the appellate court may determine the basis for the ruling.").

very physicians who had received the letter in the first place. As other courts have held, awarding a penalty for multiple deliveries of the same letter over-counts the violations. *See, e.g.*, *Walnut Creek Manor v. Fair Emp't & Hous. Comm'n*, 814 P.2d 704, 721 (Cal. 1991) ("'[T]he number of violations is to be determined by the number of persons to whom the misrepresentations were made, and not by the number of separately identifiable misrepresentations involved.'" (quoting *People v. Superior Court*, 507 P.2d 1400, 1404 (Cal. 1973))); *State ex rel. Corbin v. United Energy Corp.*, 725 P.2d 752, 759 (Ariz. Ct. App. 1986) (affirming trial court and noting that "[t]he judge ruled that there could be only one violation of the consumer fraud act for each consumer, regardless of the number of misrepresentations made to each consumer").

Additionally, the trial court erroneously assumed that the November 2003 letter was published on every sales call made from November 10, 2003 until July 21, 2004. The undisputed record evidence, however, is that the use of the letter on sales calls was a "one and done" event – i.e., the letter was shown to a physician only once, no matter how many sales calls were made on that physician between November 10, 2003 and July 21, 2004. (Tr. 1143:18-20, 2306:20-2307:16, R. _.)[16] Nonetheless, the trial court awarded penalties not only for the first sales call to each physician, but also for subsequent sales calls, when the letter was not published. Again, penalties were awarded when there were no "violations."

[16] Between November 10, 2003 and July 21, 2004, Janssen sales representatives made Risperdal-related sales calls on 3,149 different South Carolina medical professionals. (Penalty Hr'g Ex. P5 (hard-drive containing all of Janssen's sales call data from 1994 through 2007, from which the 3,149 number can be extracted).) Furthermore, Janssen observes that there were only 12,930 prescribing physicians in South Carolina at that time. (Penalty Hr'g Tr. 107:4-5, R. _.)

C. The Trial Court Misapplied the Relevant Factors When Assessing Penalties.

As a framework for their exercise of discretion in the assessment of penalties for consumer protection act violations, courts frequently use the five-factor test set out in *United States v. Reader's Digest Association*, 662 F.2d 955 (3d Cir. 1981), and consider:

- the good or bad faith of the defendants;
- the injury to the public;
- the desire to eliminate the benefits derived from a violation;
- the necessity of vindicating the authority of a regulatory agency; and
- the defendants' ability to pay.

The trial court properly looked to *Reader's Digest*. But the court misconstrued several of the *Reader's Digest* factors and ignored evidence and precedent as to others.

1. The Trial Court's Finding of "Bad Faith" is Not Supported by the Jury's Verdict or by the Record.

The trial court wrote that Janssen's conduct in connection with the package insert demonstrated "considerable" bad faith. In making this determination, the court assumed that the jury had found that the package insert was "deceptive" because Janssen "hid" the preliminary results of RIS-USA-113 and other "studies" relating to weight gain and diabetes risk. But there was no basis for that assumption. The jury was asked to decide only whether the package insert was deceptive *or* unfair for any reason at any time between 1994 and 2007. The jury verdict may have had nothing to do with weight gain or diabetes risk. It may, for example, have been based on the placement of the hyperprolactinemia discussion in the "precautions" section of the label rather than in the "warnings" section. If so, RIS-USA-113 and the other supposedly hidden studies – the basis for the "bad faith" determination – would be irrelevant. Similarly, the jury verdict

may have been based on the "inadequacy" of the label prior to 1999, when the Topline Results of RIS-USA-113 were first distributed, and a year or more before ERI or any of the other "bad faith" conduct the trial court considered.

The trial court also concluded that Janssen's conduct in connection with the November 2003 mailing "exhibited extreme bad faith." Penalty Order at 10. As in its discussion of the package insert, the court assumed that the jury had found that the letter was "deceptive" rather than "unfair," and that it was deceptive because it suggested that Risperdal had less of a risk of weight gain and diabetes than the antipsychotic Zyprexa. Again, there is no basis for those assumptions. The verdict could have reflected nothing more than the jury's conclusion that the letter was "unfair" because Janssen "broke the rules" when it sent the letter – even if what the letter said was true. Indeed, the trial court took the position, at trial and again in its Penalty Order, that whether the letter was true was irrelevant. (Penalty Order at 5, R. _; Tr. 113:16-22, 2437:6, R. _.) The trial court relied in its Penalty Order on an online article in a philosophy journal in which an academic opined that "[l]ying has nothing to do with truth or falsity." (Penalty Order at 5, R. _.) And the court's penalty calculations were not impacted at all by the uncontradicted evidence that the key statements in the letter – the statements about the relative risks of Risperdal and other atypical antipsychotics – were true.

2. The Trial Court Did Not Engage in an Analysis of the "Injury to the Public" Factor.

Because full disclosure of risk information "is of paramount importance to the health and safety of those using the drugs," the trial court held that "the public interest affected by the actions of these Defendants is enormous." (Penalty Order at 12, R. _.) Whether the "public interest" is implicated by the claim, however, is a different question

from whether there has been "injury to the public." "Impact on the public interest" is an element of liability and requires a showing that the challenged act or practice is something other than a private wrong – e.g., that it is capable of repetition. *See deBondt*, 342 S.C. at 270, 536 S.E.2d at 407. "Injury to the public," by contrast, is a factor to be considered when exercising discretion as to the amount of penalties, and requires an inquiry into the harm that was done by the act or practice. *See Reader's Digest*, 662 F.2d at 967, 969. The trial court did not engage in an analysis of the nature or severity of the "injury to the public."

There is no evidence that any physician was misled, and no evidence that any patient was harmed, by anything in the Risperdal package insert or the November 2003 letter. By contrast, there is ample evidence that the availability of Risperdal substantially benefited the South Carolina public. (Penalty Order at 4, R. _ ("[I]t is acknowledged by all concerned that Risperdal is an excellent drug for the treatment of mental illnesses. It has been a quality of life saver for millions of patients. It allows those who are treated with it to escape many of the effects of their mental illnesses and live a more open and productive life.").)

3. There is No Evidence that Janssen Benefited from the Violations.

The trial court concluded that Janssen must have benefited from the violations because Risperdal's market "share did not suffer as a result of the ever expanding warnings." (Penalty Order at 13, R. _.) In reaching that conclusion, the court assumed that, but for some deception, the market share would have dropped. The court then justified the imposition of enormous penalties by reference to Janssen's "enormous" profits from the sale of Risperdal. The court, however, ignored the undisputed evidence that Risperdal's market share did not drop in response to the July 2004 corrective letter.

The fact that physicians' prescribing patterns did not change even when they were told, in the July 2004 letter, that the FDA considered the November 2003 letter to be "false or misleading" establishes conclusively that the November 2003 letter had no impact at all on Janssen's market share. (*See* Ex. D7337, R. _; Tr. 2442:15-2443:17, R. _.) Similarly, there was no evidence of any impact on market share when diabetes or hyperprolactinemia "warnings" were added to the package insert. (*See* Ex. D7337, R. _.) There was, then, no evidence of "enormous profits" that were "derived from a violation" of SCUTPA. There was no evidence that Janssen benefited from the "violations," as opposed to benefiting from the sale of an effective medicine that helped thousands of South Carolina residents.

4. The Trial Court Erroneously Applied the "Vindication of Agency Authority" Factor.

When exercising their discretion to award penalties, courts properly take into account the need to vindicate the authority of a regulator. Thus, courts commonly impose higher penalties when a defendant has violated a cease and desist order or an injunction, entered at an agency's request, in an earlier enforcement action. The "vindication of agency authority" factor does not apply, however, where there was no agency order or injunction. And it certainly does not apply in every SCUTPA action merely because "it is the responsibility" of the Attorney General's office " to vindicate the public's interest" through enforcement of SCUTPA. (*See* Penalty Order at 14, R. _.)

5. Janssen's "Ability to Pay" Was Not an Issue and Was Improperly Considered.

The trial court focused its attention on Janssen's "ability to pay." Nothing in the case law, however, indicates that this factor is to be used to justify or enhance a penalty award. Rather, the case law teaches that ability to pay is a non-factor unless there is

some assertion by the defendant of an inability to pay. *United States v. Cornerstone Wealth Corp.*, 549 F. Supp. 2d 811, 824 (N.D. Tex. 2008) ("'[A]bility to pay' is not a determinative factor in assessing a [Federal Trade Commission Act] civil penalty."); *United States v. Boston Scientific Corp.*, 253 F. Supp. 2d 85, 101 (D. Mass. 2003) (disposing of ability to pay factor by noting that "BSC [the defendant] does not raise an issue of inability to pay.").

Janssen did not argue "inability to pay." The trial court therefore erred in admitting and considering evidence of sales and profits. The court compounded its error by looking to sales and profits that were not relevant. The "worldwide" sales of Risperdal to which the court referred at pages 15 and 16 of the Penalty Order included sales of Risperdal by companies other than Janssen. The "worldwide sales" of Johnson & Johnson and the "operating profits" of the "Pharmaceutical Division" to which the court referred at page 16 of the Penalty Order included sales of Risperdal by companies other than Janssen – i.e., sales by non-parties – and sales of products other than Risperdal. Finally, as explained by Dr. Ivo Caers at trial, but not referenced in the Penalty Order, Janssen's "profit margin" was not "97%." (Tr. 1738:19-25, R. _.)

D. The $327 Million Penalty Violated Janssen's Rights Under the South Carolina and United States Constitutions.

The unprecedented $327 million penalty violated the Excessive Fines and Due Process Clauses of the South Carolina and United States Constitutions. Although these constitutional issues were briefed and argued below, the trial court did not address them in its Penalty Order. Janssen raised these issues again in its Motion to Alter or Amend the Judgment and/or for a New Trial.

1. The $327 Penalty Is Constitutionally Infirm Because It Is Grossly Disproportional.

A fine that is "grossly disproportional to the gravity of a defendant's offense" violates the Excessive Fines Clause of the Eighth Amendment to the U.S. Constitution. U.S. Const. amend. VIII; *United States v. Bajakajian*, 524 U.S. 321, 334 (1998). Here, the constitutionally mandated "proportionality" analysis must take into account, first, the position of the FDA with regard to the challenged statements in the package insert and the November 2003 letter. The FDA has never asserted that a Risperdal package insert was "inadequate." Although the FDA did take issue with certain of the statements in the November 2003 letter, it saw no need for an enforcement action. Instead, it sent an informal warning letter, and it marked its file "closed" when Janssen sent the July 2004 corrective letter. (Ex. D6253, R. _; Tr. 1526:2-1527:10, R. _.) Second, the proportionality analysis must give substantial weight to the fact that the State presented no evidence of actual deception, no evidence of any personal injury, and no evidence of any financial loss. A $327 million penalty in a case such as this – a case involving no federal enforcement action, no deception, no harm, and no loss – surely is grossly disproportional. *See Bajakajian*, 524 U.S. at 339 (relying on the fact that "[t]he harm that respondent caused was also minimal").

Article 1, Section 15 of the South Carolina Constitution is substantially identical to the Excessive Fines Clause of the Eighth Amendment to the U.S. Constitution, and a similar "proportionality" test should be used to determine whether a penalty is excessive. *See Medlock v. One 1985 Jeep Cherokee VIN 1JCWB7828FT129001*, 322 S.C. 127, 470 S.E.2d 373 (1996) (adopting the "instrumentality" test of the federal courts for purposes of South Carolina "excessive fines" analysis); *see also Midlands Util.*, 313 S.C. at 212,

437 S.E.2d at 121 ("[E]ach fine must be analyzed individually to determine if it is appropriate under the circumstances."). Under the State's Constitution, as under the Federal Constitution, then, the $327 million penalty is grossly disproportional to the offense, and therefore impermissible.

2. The $327 Million Penalty Violates Due Process Because It Is Grossly Excessive and Not Tied to Janssen's Purported Wrongdoing in South Carolina.

The Due Process Clauses of the United States and South Carolina constitutions also bar disproportional and unreasonable penalty awards. *See, e.g., State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *Mitchell*, 385 S.C. 570, 686 S.E.2d 176. A grossly excessive penalty award, like the award in this case, "furthers no legitimate purpose and constitutes an arbitrary deprivation of property." *Campbell*, 538 U.S. at 417.

Further, the Due Process Clause requires that penalty awards be tied to the defendant's wrongdoing in South Carolina. *Mitchell*, 385 S.C. at 586, 686 S.E.2d at 184. The trial court, however, based its penalty award on worldwide sales of Risperdal – including sales in other states and other countries and sales by companies other than Janssen. More important, there was no proof of sales made or profits earned because the package insert or the November 2003 mailing was "deceptive." The State did not contend – and did not prove – that even a single physician was misled or even one inappropriate prescription written.

Rather than limiting its consideration to profits derived by Janssen from violations of the South Carolina statute, the trial court focused on the wealth and success of Johnson & Johnson. Thus, in reaching its conclusions as to an appropriate penalty, the court considered the worldwide sales of Johnson & Johnson and the sales and profits of its "Pharmaceutical Division." It acted on the view that "the penalties must have a direct

relationship to those numbers." (Penalty Order at 14, R. _.) Reliance on the sales and profits of Janssen would have been improper, for "[w]ealth cannot justify an otherwise unconstitutional [penalty] award." *Mitchell*, 385 S.C. at 588 n.8, 686 S.E.2d at 185 n.8. The court's reliance on the sales and profits of Johnson & Johnson, rather than Janssen, was inexplicable; the jury had returned a verdict in favor of Johnson & Johnson.

Finally, the trial court should have considered how its $327 million penalty award compared to penalty awards in other consumer protection cases. *Id.* at 592-93, 686 S.E.2d at 187-88. As best Janssen can determine, no other court has ever imposed a penalty, much less a nine-figure penalty, for the "inadequacy" of an FDA-approved package insert. And when courts have imposed penalties for consumer protection act violations, they frequently have settled on penalties that are a small fraction of the amount allowed by statute. In *Reader's Digest*, for example, a case involving a mailing in defiance of a consent order, the penalty was $1,750,000 for 16,100,820 violations, or 11¢ per violation. 662 F.2d at 960 & n.3. In *State ex rel. Medlock v. Nest Egg Society Today, Inc.*, 290 S.C. 124, 348 S.E.2d 381 (Ct. App. 1996), a case involving a pyramid scheme clearly violative of SCUTPA, the trial court imposed a penalty of only $5 per violation. By comparison to similar cases, the penalties in this case are grossly excessive.

The $327 million penalty amount also is grossly excessive when compared to the State's total net cost of slightly more than $23 million for payments made for Risperdal prescriptions through Medicaid and the State Health Plan from 1994 through 2006. (Penalty Hr'g Ex. D6, R. _; Penalty Hr'g Tr. 269:6-19, R. _.)

IX. THE LIABILITY VERDICT AND THE $327 MILLION PENALTY VIOLATED THE FREE SPEECH PROTECTIONS AFFORDED TO JANSSEN UNDER THE FIRST AMENDMENT.

In this case, the State sought to penalize Janssen for (1) the statements it made in the November 2003 letter regarding the conclusions that could be drawn from the scientific evidence relating to the metabolic side effects associated with antipsychotic treatment, and (2) statements in the FDA-approved Risperdal package insert regarding the various risks that may be associated with Risperdal treatment. Regardless of how they are characterized or classified, Janssen's statements are protected by the First Amendment. *See Sorrell v. IMS Health Inc.*, __ U.S. __, 131 S. Ct. 2653, 2659 (2011) ("Speech in aid of pharmaceutical marketing, however, is a form of expression protected by the Free Speech Clause of the First Amendment."); *Snyder v. Phelps*, __ U.S. __, 131 S. Ct. 1207, 1215 (2011) (holding that state law cause of action seeking to impose liability on speech on a matter of public concern must satisfy requirements of First Amendment). The trial court, however, refused to instruct the jury regarding the findings it had to make in order to protect Janssen's First Amendment rights, and it subsequently denied Janssen's Motion for Judgment Notwithstanding the Verdict or, in the Alternative, for a New Trial, which again raised the First Amendment issues. (Tr. 2477:23-2478:15, 2479:10-2480:6, 2507:25-2508:12, 2508:21, 2509:4, 2610:25-2632:19, 2633:18-2634:15, 2645:2-15, R. _.) In doing so, the trial court committed reversible error.

Speech on matters of public concern is protected by the First Amendment. *Snyder*, 131 S. Ct. at 1215. Speech involves a matter of "public concern" if it relates to "any matter of political, social or other concern to the community." *Connick v. Myers*, 461 U.S. 138, 146 (1983); *Parker v. Evening Post Publ'g Co.*, 317 S.C. 236, 452 S.E.2d 640 (Ct. App. 1994). Statements on scientific and medical research – the type of

statements at issue here – are statements on matters of public concern. *See, e.g., Bd. of Trs. of Leland Stanford Jr. Univ. v. Sullivan*, 773 F. Supp. 472, 474 (D.D.C. 1991); *McMillan v. Togus Reg'l Office, Dep't of Veteran Affairs*, 294 F. Supp. 2d 305, 317 (E.D.N.Y. 2003), *aff'd* 120 F. App'x 849 (2d Cir. 2005). Accordingly, they are entitled to the full protection of the First Amendment. And, under First Amendment precedent, the trial court was required to instruct the jury that in order to find Janssen liable, the State had to prove, by clear and convincing evidence, that Janssen believed its statements were false when it made them, or that Janssen made the statements with reckless disregard for whether they were false. *See Illinois ex rel. Madigan v. Telemarketing Assocs.*, 538 U.S. 600, 620 n.10 (2003); *Gertz v. Robert Welch, Inc.*, 418 U.S. 323, 342, 348-50 (1974); *Erickson v. Jones St. Publishers, LLC*, 368 S.C. 444, 467-68, 629 S.E.2d 653, 655-66 (2006).[17]

Even if this Court does not classify Janssen's statements as relating to matters of "public concern," they remain subject to the protections of the First Amendment as "commercial speech," and a reversal still is warranted. *See Sorrell*, 131 S. Ct. at 2659 (making clear that "speech in aid of pharmaceutical marketing" is protected by First Amendment); *id.* at 2667 ("As in previous cases, however, the outcome is the same whether a special commercial speech inquiry or a stricter form of judicial scrutiny is applied."); *id.* at 2653 ("Under a commercial speech inquiry, it is the State's burden to

[17] The First Amendment requires clear and convincing evidence that a challenged statement was made with knowledge that it was false or with reckless disregard for whether it was false in *any* challenge to First Amendment-protected speech regarding matters of public concern. Although this proof requirement is often imposed in defamation cases, it is not an element of a defamation cause of action. Rather, it is a proof requirement designed to ensure that speech worthy of First Amendment protection is not chilled. *See New York Times Co. v. Sullivan*, 376 U.S. 254, 277-78 (1964) (explaining the need for clear and convincing proof of knowing falsehood or reckless disregard by reference to the need to guarantee robust public debate about matters of public concern).

justify its content-based law as consistent with the First Amendment."). The State sought to penalize Janssen because it disagreed with the content of Janssen's statements in the November 2003 letter and the Risperdal package insert. In such circumstances, there must be a heightened judicial scrutiny. As explained in *Sorrell*, "[t]he First Amendment requires heightened scrutiny whenever the government creates a regulation of speech because of disagreement with the message it conveys." 131 S. Ct. at 2664 (quotation marks and citations omitted). The *Sorrell* Court also recognized that "[a] consumer's concern for the free flow of commercial speech often may be far keener than his concern for urgent political dialogue. That reality has great relevance in the fields of medicine and public health, where information can save lives." *Id.* (internal quotation marks and citations omitted).

Additionally, although the State presented no evidence of any impact Janssen's statements actually had on physicians' prescribing decisions, it suggested to the jury that the FDA-approved Risperdal package insert and the November 2003 mailing must have influenced prescribers' decisions and/or led to more prescriptions of Risperdal than otherwise would have been written. (Tr. 2550:18-23, R. _.) The fear that Janssen's speech might have been effective does not remove the speech from the protections of the First Amendment:

> Speech remains protected even when it may "stir people to action," "move them to tears," or "inflict great pain." The more benign and, many would say, beneficial speech of pharmaceutical marketing is also entitled to the protection of the First Amendment. If pharmaceutical marketing affects treatment decisions, it does so because doctors find it persuasive. Absent circumstances far from those presented here, the fear that speech might persuade provides no lawful basis for quieting it.

Id. at 2670 (internal citations omitted); *see also id.* at 2670-71 ("Those who seek to censor or burden free expression often assert that disfavored speech has adverse effects.

But the fear that people would make bad decisions if given truthful information cannot justify content-based burdens on speech." (quotation marks and citations omitted)); *id.* at 2671 ("The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good. . . . These precepts apply with full force when the audience, in this case prescribing physicians, consists of sophisticated and experienced consumers." (quotation marks and citations omitted)); *id.* ("The State may not burden the speech of others in order to tilt public debate in a preferred direction.").[18]

At a minimum, therefore, the trial court had to instruct the jury that in order to find Janssen liable – and subject to penalties – it had to find that Janssen's statements were false or misleading within the meaning of the U.S. Supreme Court's commercial speech cases. In other words, the jury had to find that Janssen's statements were either literally false or actually misleading. *See Sorrell*, 131 S. Ct. at 2672; *Cent. Hudson Gas & Electric Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 564 (1980); *Peel v. Attorney Registration & Disciplinary Comm'n*, 496 U.S. 91, 100-01, 106-07. The trial court's refusal to so instruct the jury, and its subsequent denial of Janssen's Motion for Judgment Notwithstanding the Verdict, or in the Alternative, for a New Trial, which advanced these First Amendment arguments, was reversible error.

[18] The fact that *Sorrell* addressed a prior restraint on speech whereas this case addresses burdens placed on Janssen after its statements were made does not change *Sorrell*'s applicability. *See* 131 S. Ct. at 2664 ("The Court has recognized that the distinction between laws burdening and laws banning speech is but a matter of degree and that the Government's content-based burdens must satisfy the same rigorous scrutiny as its content-based bans. Lawmakers may no more silence unwanted speech by burdening its utterance than by censoring its content." (quotation marks and citations omitted)).

Janssen's First Amendment protections again were violated in the trial court's Penalty Order. The jury was not required to find – and did not find – that Janssen's statements were false, misleading, or deceptive. Therefore, even under the lesser scrutiny that applies to commercial speech, in order to satisfy the requirements of the First Amendment, the penalties imposed on Janssen had to directly and materially advance a substantial state interest and be no more restrictive than reasonably necessary. *Sorrell*, 131 S. Ct. at 2667-68; *Cent. Hudson*, 447 U.S. at 564, 566; *Video Gaming Consultants, Inc. v. S.C. Dep't of Revenue*, 342 S.C. 34, 42, 535 S.E.2d 642, 646 (2000) ("'A governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restrictions will in fact alleviate them to a material degree.'" (quoting *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 188 (1999)). The trial court thus had to make a determination that the imposition of monetary penalties would directly and materially advance a substantial state interest, and that other forms of regulation less restrictive than the assessment of $327 million in penalties – including the provision of non-monetary relief, such as requiring disclaimers or clarifying speech – would be insufficient to satisfy the State's interests. *Sorrell*, 131 S. Ct. at 2667-68; *Cent. Hudson*, 447 U.S. at 564, 566; *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 371 (2002) ("[I]f the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so."). The trial court's failure to make any of these requisite determinations renders the penalty constitutionally infirm, and thus the trial court's Penalty Order must be set aside.

CONCLUSION

For the reasons set forth herein, the trial court should be reversed and judgment should be entered in favor of Janssen. Failing that, the trial court should be reversed and a new trial absolute ordered. Alternatively, the trial court's penalty order should be reversed and vacated.

Respectfully submitted,

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Columbia, South Carolina
March 19, 2012.

THE STATE OF SOUTH CAROLINA
In the Supreme Court

APPEAL FROM SPARTANBURG COUNTY
Court of Common Pleas

Roger L. Couch, Circuit Court Judge

Case No. 2007-CP-42-1438

State of South Carolina ex. rel. Alan Wilson in his capacity as Attorney General of the State of South Carolina,.....

Respondent,

v.

Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica, Inc., and/or Janssen, L.P., and Johnson & Johnson, Inc., ...

Defendants,

Of whom Ortho-McNeil-Janssen Pharmaceuticals, Inc. is....

Appellant.

PROOF OF SERVICE

I, the undersigned Administrative Assistant of the law offices of Nelson Mullins Riley & Scarborough LLP, attorneys for Appellant, do hereby certify that I have served all counsel in this action with a copy of the pleading(s) hereinbelow specified by mailing a copy of the same by United States Mail, postage prepaid, to the follow address(es):

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March 19, 2012

THE STATE OF SOUTH CAROLINA
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Respondent,

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Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica, Inc., and/or Janssen, L.P., and Johnson & Johnson, Inc., ...

Defendants,

Of whom Ortho-McNeil-Janssen Pharmaceuticals, Inc. is....

Appellant.

APPELLANT'S DESIGNATION OF MATTER
FOR THE RECORD ON APPEAL

Pursuant to Rule 209, SCACR, Appellant Ortho-Mc-Neil-Janssen Pharmaceuticals, Inc. designates the following material for inclusion in the record on appeal. Undersigned counsel certifies, pursuant to Rule 209(c), SCACR, that the designation contains no matter which is irrelevant to the appeal:

ORDERS

1. Order regarding Defendant's Motions for Summary Judgment and Parties' Motions *in Limine*, February 25, 2011

2. Penalty Order, June 3, 2011

3. Order Denying Defendant's Motion for Judgment Notwithstanding the Verdict or, in the Alternative, for a New Trial, December 20, 2011

4. Order Denying Defendant's Motion to Alter or Amend the Judgment and/or for a New Trial, December 20, 2011

JURY INSTRUCTIONS, VERDICT FORM, and VERDICT

5. Defendants' Requested Preliminary Jury Instructions and Memorandum of Law in Support Thereof, March 7, 2011

6. Defendants' Requested Jury Instructions, March 17, 2011

7. Plaintiff The State of South Carolina's Proposed Requests for Charge and Proposed Form of Verdict, March 17, 2011

8. Plaintiff The State of South Carolina's Request for Charge No. 1 on Elements of SCUTPA Claim; Plaintiff's Amended Request for Charge No. 6 on Statute of Limitations; Plaintiff's Request for Charge No. 7 regarding Striking/Rejecting Certain Testimony; Plaintiff's Request for Charge No. 8 regarding Drug Company Labeling; and Plaintiff's Amended Proposed Form of Verdict, March 18, 2011

9. Defendants' Requested Verdict Sheet, March 18, 2011

10. Defendants' Objections to Plaintiff's Proposed Requests for Charge and Proposed Verdict Sheet and Defendants' Request for Corrective Instruction, March 20, 2011

11. Verdicts as to Johnson & Johnson, Inc. and Ortho-McNeil-Janssen Pharmaceutica, Inc., f/k/a Janssen Pharmaceutica, Inc., and/or Janssen L.P., March 22, 2011

PLEADINGS

12. Complaint, April 23, 2007

13. Amended Complaint, December 30, 2009

14. Second Amended Complaint, March 19, 2010

15. Defendants' Answer to Plaintiff's Second Amended Civil Action Complaint, April 12, 2010

TRANSCRIPTS

16. Trial Transcript, March 7, 2011 through March 22, 2011 excerpts: 1-8, 97-184, 186-191, 220-263, 356-362, 382-387, 394-650, 665-931, 935-1057, 1129, 1140-1144, 1167-1169, 1172-1173, 1177, 1192, 1232-1236, 1272-1276, 1367-1368,

1380-1420, 1422, 1430-1655, 1659-1783, 1803-1804, 1823-1865, 1870-1878, 1897-1907, 1969-1976, 1986-2047, 2049-2126, 2165-2177, 2184, 2191-2212, 2217-2231, 2241-2250, 2279-2290, 2296-2308, 2321-2415, 2421-2427, 2436-2437, 2442-2446, 2450-2556, 2596-2607, 2610-2679

17. Penalty Hearing Transcript, April 18, 2011 through April 19, 2011: 1-364

EXHIBITS

Plaintiff's Trial Exhibits

18. P0200 – Letter from L. Stockbridge to T. McIntyre, dated January 5, 1999

19. P0232 – Letter from T. Abrams to A. Shetty, dated April 19, 2004

20. P0280 – August 2008 Risperdal Package Insert

21. P0571 – Letter from R. Temple to R. Wasserman, dated December 29, 1993

22. P0631 – 1997 Physicians' Desk Reference for Risperdal

23. P0640 – 2006 Physicians' Desk Reference for Risperdal

24. P0641 – March 2003 Risperdal Package Insert

25. P0643 – 1994 Risperdal Package Insert

26. P0648 – July 1998 Risperdal Package Insert

27. P0649 – May 1999 Risperdal Package Insert

28. P0653 – December 2000 Risperdal Package Insert

29. P0656 – Revised July 2002 Risperdal Package Insert

30. P0657 – March 2003 Risperdal Package Insert

31. P0661 – December 2003 Risperdal Package Insert

32. P0662 – February 2005 Risperdal Package Insert

33. P0665 – October 2006 Risperdal Package Insert

34. P1027 – Letter from S. Danese to R. Wasserman, dated February 9, 1994

35. P1224 – October 2001 Risperdal Package Insert

36. P1731 – Letter from D. Ohye to T. Abrams, dated April 28, 2004

37. P2049 – September 1996 Risperdal Package Insert

38. P2061 – April 1995 Risperdal Package Insert

Plaintiff's Penalty Hearing Exhibits

39. P1 – Letter from S. Pugh to D. Coggins, dated April 13, 2011

40. P5 – Hard Drive containing sales call data produced by Defendants

41. P16 – South Carolina Department of Labor, Licensing and Regulation 2003-2004 Annual Report

42. P21 – Plaintiff's Calculations for Potential Violation Numbers

43. P2720 – Sample Quantity Data Summary

44. P2722 – Number of Sales Calls when Samples Left

Defendants' Trial Exhibits

45. D0351 – Letter from Janssen Pharmaceutica Inc. to Healthcare Providers with Risperdal Package Insert, dated November 10, 2003

46. D0352 – Wirshing, et al., J Clin Psychiatry 2002; 63:856-865, "The Effects of Novel Antipsychotics on Glucose and Lipid Levels"

47. D0442 – Letter from Janssen Pharmaceutica Inc. to Health Care Providers, dated July 21, 2004

48. D0498 – August 2007 Risperdal Package Insert

49. D0807 – Volume 1 of the 2000 Submission to FDA

50. D0821 – Volume 15 of the 2000 Submission to FDA

51. D0841 – Letter from R. Katz to E. Brann, dated March 3, 2002

52. D0843 – Letter from R. Katz to M. Zoschg, Dated December 4, 2003

53. D0919 –Letter from S. Merchant to R. Katz, dated March 29, 2004

54. D3097 – Letter from R. Katz to V. Wagner-Weber, dated May 1, 2000

55. D3131 – Letter from R. Katz to V. Wagner-Weber, dated July 2, 1999

56. D3140 – Letter from E. Brann to R. Katz, dated September 24, 2003

57. D3175 – Letter from R. Katz to C. McGowan, dated September 11, 2003

58. D3179 – Letter from S. Merchant to R. Katz, dated November 26, 2003

59. D3180 – Letter from R. Katz to S. Merchant, dated November 21, 2003

60. D4188 – Yood, M.U., et al. The Incidence of Diabetes in Atypical Antipsychotic Users Differs According to Agent – Results from a Multisite Epidemiologic Study

61. D4337 – Chapter 4 of the 2004 Version of the FDA's Regulatory Procedures Manual

62. D5274 – Form FDA 2253, submitted July 30, 1998 with submitted materials

63. D5350 – Form FDA 2253, submitted March 24, 2000 with submitted materials

64. D5360 – Form FDA 2253, submitted May 19, 2000 with submitted materials

65. D5380 – Form FDA 2253, submitted January 19, 2001 with submitted materials

66. D6086 – April 5, 2003 Diabetes Expert Panel Executive Summary: Antipsychotics and Diabetes/Glucose Metabolism

67. D6211 – Letter from S. Merchant to R. Katz, dated April 18, 2002

68. D6253 – Letter from M. Brony to D. Ohye, dated October 14, 2004

69. D6284 – Draft of November 10, 2003 letter from Janssen Pharmaceutica Inc. to Healthcare Providers

70. D6294 – Letter from Eli Lilly and Company to Doctors, dated October 6, 2003

71. D6305 – E-mail from I. Caers to G. Neil and others, dated September 16, 2003

72. D6366 – Promotional Review Committee Copy Approval For November 10, 2003 Mailing

73. D7008 – Expert Report of William E. Wecker, Ph.D., dated December 3, 2010 (referred to in trial transcript as "Def. Exh. A")

74. D7174 – Chart of South Carolina Department of Health and Human Services Drug Utilization Review Program – Patient Drug History Profile

75. D7185 – "Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes," The Journal of Clinical and Applied Research and Education Diabetes Care, 27:2 (2004); 596-601

76. D7186 – SC-DMH Laboratory Monitoring Guidelines for Antipsychotic Medications

77. D7252 – Undated, draft letter from W. Murray Yarbrough

78. D7262 – Wirshing, et al., "Risperidone-Associated New-Onset Diabetes" Biol Psychiatry 2001; 50:148-149

79. D7276 – List of South Carolina recipients of November 2003 Mailing

80. D7281 – Advertisement -01-RS-782R

81. D7294 – IND 31,931 Risperidone Tablets Annual Report July 1, 1998 – June 30, 1999

82. D7336 – W. Murray Yarbrough letter to T. Engles, dated September 19, 2002

83. D7337 – South Carolina Medicaid & SHP Claims Data, June 2003 – October 2004 (referred to in trial transcript as "Def. Exh. B")

84. D7338 – South Carolina Medicaid & SHP Claims Data, November 2004 – December 2005 (referred to in trial transcript as "Def. Exh. C")

Defendant's Penalty Hearing Exhibits

85. D1 – "Second-Generation (Atypical) Antipsychotics and Metabolic Effects: A Comprehensive Literature Review," John W. Newcomer

86. D2 – 2007 Zyprexa Package Insert (Offer of proof; not admitted into evidence)

87. D3 – 2009 Zyprexa Package Insert (Offer of proof; not admitted into evidence)

88. D4 – 2010 Latuda Package Insert (Offer of proof; not admitted into evidence)

89. D5 – South Carolina Fee for Service, State Health Plan, and HMO Claims Data – Antipsychotic Prescriptions by Month

90. D6 – Calculation of Net Cost of Risperdal to the State (Columns 1-7 admitted)

91. D7 – Janssen Compilation of Rebates to South Carolina

Court's Exhibits

92. C-1 – Note from Juror

93. C-2 – Federal Regulations

94. C-3 – Objections to Openings

95. C-4 – Offer of Proof

96. C-5 – Charge by the Court

97. C-6 – Question from the Jury

98. C-7 – Question from the Jury

MISCELLANEOUS AND OTHER MOTIONS

99. Plaintiff The State of South Carolina's Motion to Exclude the Testimony of Certain Risperdal Prescribers at Trial, July 2, 2010

100. Defendants' Motion *in Limine* and Memorandum of Law in Support Thereof to Preclude the Introduction into Evidence of the April 19, 2004 DDMAC Letter and Any Evidence of or Reference to the Letter at Trial, January 7, 2011

101. Plaintiff The State of South Carolina's Motion to Exclude the Expert Testimony of Dr. William E. Wecker, January 13, 2011

102. Defendants' Memorandum of Law in Opposition to Plaintiff's Motion to Exclude the Testimony of Certain Risperdal Prescribers at Trial, January 20, 2011

103. Defendants' Memorandum of Law in Opposition to Plaintiff's Motion to Exclude the Expert Testimony of Dr. William E. Wecker, January 21, 2011

104. Defendants' Objections to Plaintiff's Opening Statement, March 8, 2011

105. Defendant's Motion for a Directed Verdict and Memorandum of Law in Support Thereof, March 14, 2011

106. Defendants' Reply in Support of Motion for a Directed Verdict, March 15, 2011

107. Defendants' Offer of Proof for the Expert Testimony of Dr. William E. Wecker, March 21, 2011

108. Defendants' Offer of Proof for the Post-2007 FDA-Approved Package Insert for Zyprexa and the 2010 FDA-Approved Package Insert for Latuda, March 21, 2011

109. Defendants' Renewed Motion for a Direct Verdict and Memorandum of Law in Support Thereof, March 21, 2011

110. Plaintiff The State of South Carolina's Motion for a Directed Verdict as to Defendants' Eighth Affirmative Defense on Statute of Limitations, March 21, 2011

111. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc.'s Motion for Judgment Notwithstanding the Verdict or, in the Alternative, for a New Trial, April 1, 2011

112. Janssen's Penalty Hearing Brief, April 15, 2011

113. Defendant's Offer of Proof for the Testimony of Prescriber Physicians; and Robert L. Bank, M.D., and Brenda Ratliff, M.D., April 18, 2011

114. Defendant Ortho-McNeil Janssen Pharmaceuticals, Inc.'s Post-Penalty Hearing Brief, May 3, 2011

115. Reply Memorandum of Law in Support of Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc.'s Motion for Judgment Notwithstanding the Verdict or, in the Alternative, for a New Trial, May 3, 2011

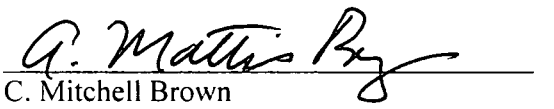
116. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc.'s Motion to Alter or Amend the Judgment and/or for a New Trial, June 13, 2011

117. Memorandum of Law in Support of Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc.'s Motion to Alter or Amend the Judgment and/or for a New Trial, June 13, 2011

118. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc.'s Reply in Support of its Motion to Alter or Amend the Judgment and/or for a New Trial, July 15, 2011

119. Appellant Ortho-McNeil-Janssen Pharmaceuticals, Inc.'s Notice of Appeal, January 18, 2012

NELSON MULLINS RILEY & SCARBOROUGH LLP

By: 

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March 19, 2012

THE STATE OF SOUTH CAROLINA
In the Supreme Court

APPEAL FROM SPARTANBURG COUNTY
Court of Common Pleas

Roger L. Couch, Circuit Court Judge

Case No. 2007-CP-42-1438

State of South Carolina ex. rel. Alan Wilson in his capacity as Attorney General of the State of South Carolina,.....

Respondent,

v.

Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica, Inc., and/or Janssen, L.P., and Johnson & Johnson, Inc.,.....

Defendants,

Of whom Ortho-McNeil-Janssen Pharmaceuticals, Inc. is....

Appellant.

PROOF OF SERVICE

I, the undersigned Administrative Assistant of the law offices of Nelson Mullins Riley & Scarborough LLP, attorneys for Appellant, do hereby certify that I have served all counsel in this action with a copy of the pleading(s) hereinbelow specified by mailing a copy of the same by United States Mail, postage prepaid, to the follow address(es):

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