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 which ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. is

Appellant.

RESPONDENT'S FINAL BRIEF

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STATEMENT OF ISSUES

1. Did the trial court properly deny Defendant-Appellant's Motion for Judgment Notwithstanding the Verdict, or in the Alternative, for a New Trial by determining that federal law did not preempt the State's Unfair Trade Practices Act claim based on Risperdal's label?
2. Did the trial court properly deny Defendant-Appellant's Motion for Judgment Notwithstanding the Verdict, or in the Alternative, for a New Trial by determining that the South Carolina Unfair Trade Practices Act exemption for legally "permitted" conduct did not bar the State's claim based on Risperdal's label (package insert)?
3. Did the trial court properly deny Defendant-Appellant's Motion for Judgment Notwithstanding the Verdict, or in the Alternative, for a New Trial by determining that federal law did not preempt the State's Unfair Trade Practices Act claim as to the November 2003 Dear Doctor Letter?
4. Did the trial court correctly deny Defendant-Appellant's Motion for Judgment Notwithstanding the Verdict, or in the Alternative, for a New Trial by deciding the State's claims were timely filed; concomitantly, did the trial court properly grant the State's motion for directed verdict as to Janssen's statute of limitations defense at the conclusion of all the evidence?
5. Did the trial court properly deny Defendant-Appellant's Motion for Judgment Notwithstanding the Verdict, or in the Alternative, for a New Trial after determining that the State had submitted sufficient evidence as to the so-called public impact element of its Unfair Trade Practices claims?
6. Did the trial court properly admit certain of the State's evidence over Defendant-Appellant's hearsay and unfair prejudice objections and, therefore, no new trial is warranted?
7. Were the State's opening and closing statements within the appropriate bounds and, therefore, no new trial is warranted?
8. Did the trial court properly deny Defendant-Appellant's Motion for Judgment Notwithstanding the Verdict, or in the Alternative, for a New Trial because the jury was instructed according to South Carolina law and procedure and the verdict form satisfied applicable law?
9. Was the trial court's Penalty Order proper under applicable statutory and abuse of discretion standards?
10. Do the Excessive Fines and Due Process Clauses of the South Carolina and United States Constitutions warrant vacating the trial court's Penalty Order?
11. Did the trial court properly deny Defendant-Appellant's Motion for Judgment Notwithstanding the Verdict, or in the Alternative, for a New Trial, or should the Penalty Order be vacated, where the Penalty Order does not violate Defendant Appellant's First Amendment rights?

STATEMENT OF THE CASE

I. PROCEDURAL HISTORY

The State filed this case against Defendant-Appellant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Janssen" or the "Company") on April 23, 2007. (R. pp. 58–101.) On or about May 22, 2007, Janssen removed the case on the purported basis of federal question jurisdiction. (R. pp. 7681–7688.) On July 10, 2007, United States Senior District Judge Henry M. Herlong, Jr. remanded the case, determining that the federal courts did not have jurisdiction over the case. (R. p. 3.)

On March 19, 2010, the State filed its "live" complaint in the lower court. (R. pp. 102–120.) Prior to trial, the lower court determined that a jury would decide liability under the South Carolina Unfair Trade Practices Act ("SCUTPA"), and the trial judge would assess civil penalties thereunder. (R. p. 7; p. 11.) The lower court denied Janssen's various motions for summary judgment and motions to exclude or limit certain State experts' testimony on February 25, 2011. (R. pp. 8–26.)

The lower court commenced a jury trial on March 7, 2011. (R. pp. 190–192.) The jury returned its unanimous verdict in the State's favor on March 22, 2011. (R. pp. 3030–3031.) 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. (R. p. 1722, line 16–p. 1725, line 20; p. 2365, line 15–p. 2368, line 3.) At the close of all the evidence, the trial court granted the State's motion for directed verdict on statute of limitations grounds. (R. p. 2368, line 4–p. 2371, line 23.)

After dismissing the jury, the lower court separately considered evidence and argument on SCUTPA penalties in a two-day hearing on April 18 and 19, 2011. The

Court's "Penalty Order" issued on June 3, 2011. (R. pp. 27–43.) The lower court awarded a penalty of $300 for each of 509,499 Risperdal sample boxes found to have contained a product label (the prescribing information, also referred to herein as a "package insert") and distributed by Janssen in South Carolina, for a total penalty of $152,849,700.00. (R. pp. 42–43.) The trial court also awarded a penalty of $4000 for each Dear Doctor Letter mailed to South Carolina addresses (7,184) and for each sales call occurring between November 10, 2003 (the Dear Doctor Letter's date (*see infra* p. 4)) and July 21, 2004 (the Correction Letter's date (*see infra* p. 13)) (36,372) for a total penalty of $174,224,000.00. (R. p. 43.) The aggregate penalty assessed against Janssen by the trial court was $327,073,700.00. (*Id.*)

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. (*See* R. pp. 44–49, pp. 50–55.) On January 18, 2012, Janssen filed its Notice of Appeal. On February 27, 2012, this Court granted the State's unopposed Motion to Transfer Case and Certify the Case for Review by this Court. (R. pp. 56–57.)

II. STATE'S SUMMARY OF THE FACTS

This case presents disputes under SCUTPA concerning consumer health, safety, and the marketing and promotion of prescription drugs in this State. The State of South Carolina alleged that Janssen willfully, unfairly, and deceptively misrepresented and failed to disclose the safety risks of its drug Risperdal in promoting and selling Risperdal in South Carolina. The State's SCUTPA claims and the jury's findings have two distinct factual bases.

First, the jury unanimously found that Janssen had willfully engaged in unfair or deceptive acts in the conduct of trade or commerce in South Carolina in relation to a "Dear Doctor Letter" that Janssen disseminated to Risperdal prescribers and others in the State beginning in or about November 2003. (R. pp. 3030–3031.) The Dear Doctor Letter stated, *inter alia*, that Risperdal users were at no increased risk of developing diabetes as compared to persons not taking the drug. (R. p. 3762.) The approved Food & Drug Administration ("FDA") label and Janssen's undisclosed clinical research at the time showed otherwise. *See infra* Part IV.A.

Second, the jury unanimously found that Risperdal's product label (package insert) violated SCUTPA from 1994 to 2007. (R. p. 3031.) The State proved at trial that Janssen willfully omitted Warnings on Risperdal's label as to diabetes/hyperglycemia and hyperprolactinemia safety risks from 1994 to 2007. *See infra* Part IV.A. The State also showed that Janssen—not the FDA—was responsible for the content of the Risperdal label, including all Warnings, at all relevant times. *See infra* Part I.B.1. Moreover, the State showed that Janssen had a legal duty to add or strengthen Warnings to its Risperdal label as soon as it had reasonable evidence of an association between Risperdal and a serious hazard—a causal association need not have been shown. *See id.*

Risperdal and safety hazards

Risperdal (the generic form of which is called "risperidone") is an "atypical" or "second generation" antipsychotic drug that Janssen first began selling throughout the United States, including in South Carolina, in 1994. (R. p. 418, line 24–p. 419, line 2; p. 421, lines 22–23.) Even before 1994, Janssen knew that Risperdal was reasonably associated with a number of serious health risks, including weight gain and related

complications—diabetes mellitus (i.e., "Type II" diabetes) in particular—as well as hyperprolactinemia, a condition of elevated prolactin levels in the body. (R. p. 540, line 19–p. 542, line 12; p. 722, lines 22–24; p. 852, line 4–p. 854, line 22; p. 1322, lines 2–14.) Risperdal is known to cause significantly greater prolactin elevations than any other atypical antipsychotic. (R. p. 856, lines 14–23; p. 1040, lines 15–19.) At no time from 1994 until November 2003 did Janssen put a Warning for diabetes or hyperglycemia (high blood sugar) on Risperdal's label. (R. p. 446, lines 3–7.) Janssen was directed to add such a Warning by the FDA in September 2003. (R. p. 520, lines 22–24.) Also, at no time from 1994 until August 2007 did Janssen include a Warning of hyperprolactinemia risks on Risperdal's label. (R. p. 457, lines 17–19.)

Risperdal faces stiff competition

After its launch in 1994, Risperdal enjoyed huge sales success. (R. p. 338; pp. 872–882; pp. 3552–3675; pp. 3747–3752; pp. 3684–3686; pp. 3720–3727.) Janssen sold $172 million of Risperdal worldwide the first year. (R. p. 338; *see id.* at p. 41.) Risperdal sales increased nearly 600 percent by 2000, topping $1 billion in sales per year for the first time. (R. p. 41.) From there, yearly worldwide sales more than quadrupled to $4.6 billion in 2007. (*Id.*) Internal documents considered by the jury and judge below indicated that Risperdal had a 97 percent gross profit margin. (R. p. 338; p. 880, lines 18–24; p. 1253; p. 3559.)

Despite that success, Risperdal began to face stiff competition from competing drugs in 1996. (R. p. 458, line 17–p. 460, line 17.) That year, Eli Lilly & Company launched its extremely popular antipsychotic drug Zyprexa (also known as "olanzapine"). (R. p. 736, lines 15–16.) A market share war between Janssen and Lilly ensued, which

the State's psychiatric expert witness and former Janssen consultant, Dr. William Wirshing, described as "fierce" and "dramatic." (R. p. 462, lines 9–14.) In Janssen's estimation, Zyprexa caused greater weight gain and carried more diabetes risk than Risperdal. (R. p. 464, line 12–p. 467, line 3.) Janssen began training its sales representatives to promote Risperdal via that message. (*Id.*) According to internal Company documents, sales representatives were trained in 1998 to "Stop the Growth of Zyprexa." (R. p. 474, lines 13–15; p. 476, line 14–p. 477, line 2; p. 479, lines 8–21; p. 3813, p. 3879.) By 2000, the Company sought to exploit and "differentiat[e]" weight gain as "a defensive issue for Zyprexa." (R. p. 810, line 25–p. 812, line 9; p. 3506.) Janssen also claimed that "Zyprexa may be associated with causing Type II diabetes," while Risperdal purportedly was not, and that Zyprexa's association with diabetes "would have significant impact on the medical community" in terms of prescribers' willingness to prescribe Zyprexa. (R. p. 3506; *see id.* at p. 810, line 25–p. 812, line 9.)

Janssen puts Risperdal to the test

In 1997, Janssen commissioned a "gold standard" double-blind, randomized, placebo-controlled clinical trial to establish Risperdal's superiority over Zyprexa as to weight gain and diabetes side effects. (R. p. 504, lines 5–18; p. 3976; p. 3988.) That trial was RIS-USA-113 ("Trial 113"). (R. p. 3976.) Trial 113's "[p]rimary objective" was to "[s]how superiority over [Zyprexa] in the incidence of 7% increase in weight" over the course of a year's treatment. (R. p. 1328, lines 18–23; pp. 3231–3245.) Trial 113 also measured the incidence rate of "New Onset Diabetes"—i.e., patients who did not have diabetes at the start of trial but who developed it during the trial. (R. p. 642, lines 2–7; p. 3976.) No long-term study like Trial 113 had ever been attempted between Risperdal and

Zyprexa (and none was ever commissioned again after Trial 113's results came in). (R. pp. 506–508; pp. 515–518; p. 682, lines 14–22; pp. 1514–1518; pp. 1533–1536; pp. 3764–3776.)

Trial 113's results did not show Risperdal's superiority to Zyprexa on weight gain or diabetes. (R. p. 498, lines 2–6; p. 3233.) The September 1999 results concluded: "There appears to be no difference in the incidence of 7% weight gain [between the Zyprexa and Risperdal] groups." (R. p. 498, lines 2–6; p. 3233.) The results also reported that a greater number (and an equal percentage) of persons taking Risperdal developed diabetes compared to Zyprexa patients. (R. p. 502, line 17–p. 503, line 12; p. 3235.) Janssen did not disclose or publish those results. (R. p. 492, lines 23–25; p. 517, lines 4–5.) The State's expert witness, Dr. Wirshing, who had himself directed one of the trial sites for the first several weeks of Trial 113, had never seen the Trial 113 results until this case was presented to a jury. (R. p. 490, line 17–p. 491, line 1.) It took Janssen ten years from the completion of the study to prepare an internal "Clinical Study Report" or "CSR" for Trial 113, which was also never disclosed outside the Company until trial. (R. p. 679, line 12–p. 680, line 10; p. 683, lines 5–8; p. 3976.) The CSR reconfirmed the 1999 conclusions. (R. p. 1667, line 19–p. 1668, line 21.) The CSR was prepared and surfaced in this litigation only after Risperdal lost its patent protection and could be sold in generic form. (R. p. 1497, lines 3–15.)

At trial in this case, Janssen contended that Trial 113 was a "flawed" or "failed" or "broken" study because nine participants had reportedly taken the wrong drug after the first eight weeks of the study. (R. p. 1388, line 14–p. 1391, line 8.) Yet, the final CSR acknowledged that circumstance and reported that the data, analyzed without those nine

"cross-over" participants, produced the same conclusions—Risperdal and Zyprexa had statistically the same weight gain and diabetes risk after a year of treatment. (R. p. 597, line 22–p. 598, line 7; p. 648, lines 1–11; p. 3991; p. 4013; pp. 4015–4016.)

About 2000, Janssen received the results of a different kind of study—an epidemiological study based upon a review of records of patients treated with antipsychotic medications in a New England insurance database. (R. p. 748, line 25–p. 752, line 23; pp. 3095–3101.) That study was referred to at trial as the "ERI" study. (R. p. 749, lines 1–3.) Comparisons between Zyprexa and Risperdal on the rate of diabetes incidence again did not favor Janssen's drug. (R. p. 750, line 24–p. 752, line 1.) The study showed that Risperdal patients had a higher incidence rate of diabetes than did Zyprexa patients. (*Id.*) Janssen also never published or disclosed ERI's results except in Risperdal litigation. (R. p. 1507, lines 11–18.)

Janssen commissioned yet another epidemiological study, identified at trial as "HECON," the results of which were also known in 2000. (R. pp. 3676–3679.) Like ERI, HECON also surveyed a large managed-care patient database. (*Id.*) A published presentation of the HECON results concluded that "[i]n contrast to . . . [Zyprexa], [Risperdal] was not associated with risk of type II diabetes." (R. p. 757, line 22–p. 758, line 14; pp. 3676–3679.) The published study noted that it was supported by Janssen, and the majority of HECON's authors Janssen either employed or paid as regular consultants. (R. p. 772; p. 1562, line 19–p. 1563, line 19; pp. 3676–3679.)

In short, Janssen decided to publish the one study out of three that returned favorable safety results (HECON). (R. p. 491, lines 2–5; p. 1507, lines 11–18; pp. 3676–3679.) Janssen did not disclose the other two studies, Trial 113 and ERI, outside

Company confines. (R. p. 492, lines 23–25; p. 517, line 11–p. 518, line 13; p. 1507, lines 11–18.)

FDA investigates Risperdal's association with diabetes

In May 2000, the FDA wrote to Janssen informing the Company that it was "evaluating the possibility that atypical antipsychotics may produce disturbances in glucose metabolism" (blood sugar). (R. p. 1089, line 24–p. 1090, line 18; pp. 3087–3088.) Generally, the FDA sought "evidence of new-onset diabetes mellitus, hyperosmolar coma, diabetic ketoacidosis, weight gain, and hyperglycemia" occurring in Risperdal users. (R. p. 510, line 13–p. 512, line 9; pp. 3087–3088.)

Before Janssen's submission responding to the FDA's request, Janssen's internal email correspondence showed that ERI would be ready "in time for inclusion in the FDA response." (R. pp. 3089–3093.) That same email noted that ERI was "looking at crude incidence of diabetes among the use of atypicals." (*Id.*)

In August 2000, Janssen responded to the FDA. (R. pp. 3753–3757, pp. 3764–3776.) The Company acknowledged that the FDA had "requested that Janssen conduct a comprehensive review of all preclinical, clinical and pharmacovigilance data pertaining to the effect of risperidone and disturbances in glucose metabolism." (R. pp. 3753–3757.) But, Trial 113 was not mentioned in Janssen's FDA submission. (R. pp. 3753–3757, pp. 3764–3776.) Janssen denied Trial 113's very existence. In fact, Janssen repeatedly stated in the report that "there were no long term trials with placebo or [Zyprexa]"—despite Trial 113 having been a long-term trial with Zyprexa. (R. pp. 3768–3769.) The Janssen response also did not mention ERI. (*Id.*; p. 3094.) The Company had decided it would now "not include [ERI] in response to FDA" purportedly because

ERI was "only a crude analysis of new-onset diabetes." (R. p. 3094.) Janssen had, however, already acknowledged internally the "crude" nature of the ERI study while Janssen was still awaiting the results. (R. pp. 3089–3093.) And, although Trial 113 and ERI were not mentioned in responding to the FDA, Janssen specifically referenced and discussed the results of the favorable HECON study. (R. p. 3771.)

Janssen's strategy of attempting to differentiate Risperdal from other antipsychotics persisted. (R. p. 3112.) In October 2000, Sally Berry, medical director for psychiatry medical affairs at Janssen, wrote in an email to her colleagues that Janssen must avoid Risperdal being "lumped in to the atypical antipsychotic class for diabetes." (*Id.*) "This is what we need to prevent happening!" (*Id.*) "[W]hen worried about diabetes, we want doctors to prescribe [R]isperdal." (*Id.*) Ms. Berry and her colleagues made no mention of Trial 113 or ERI, studies that showed a significant association between Risperdal and diabetes. (*Id.*)

Ultimately, in a September 13, 2003 letter, the FDA directed that Risperdal's label must bear a Warning for diabetes and hyperglycemia. (R. pp. 3249–3252.) Within three days, Janssen executives began analyzing best case/worst case financial scenarios premised on the success or failure of those negotiations. (R. pp. 3493–3495.) Depending upon whether Janssen "accept[ed]" the FDA's new label or, conversely, convinced the FDA to add a "Precaution" to Risperdal's label while requiring a Warning on all other atypical antipsychotics' labels, the Company projected either a $100 million sales loss (in the former scenario) or a $100 million sales increase (in the latter). (*Id.*) The Company then set out on a "road of submitting data to 'prove' to the FDA differences" between Risperdal, Zyprexa, and the other atypicals. (*Id.*) In the end, however, Janssen was

unable to avoid the FDA's instruction to include a Warning for diabetes/hyperglycemia on Risperdal's label. (R. pp. 3303–3310.)

Janssen's Dear Doctor Letter

Janssen then determined that it would take control of how the message of the new Warning was communicated to prescribers and others. Earlier in 2003, Janssen had communicated another new Risperdal Warning concerning risk of stroke ("cerebrovascular adverse events" or "CAEs") in elderly patients. (R. p. 1526, line 23–p. 1528, line 9.) Through a "dear doctor" letter (also referred to generally as a "DDL," a "Dear Healthcare Provider Communication," and a "DHCP"), Janssen announced the new CAE Warning in very straightforward fashion, quoting the Warning verbatim on the letter's first page. (R. p. 1837, line 24–p. 1838, line 9; pp. 3795–3800.) Immediately thereafter, Janssen saw Risperdal sales plummet in the long-term-care market. (R. p. 3064–3065.) Among the "Lessons Learned" from that experience, Janssen acknowledged internally, was to "[n]ever underestimate the impact of a DDL." (R. p. 3065.)

So, Janssen took a different approach with the diabetes/hyperglycemia Dear Doctor Letter. (R. pp. 3762–3763.) Scott Reines, Senior Vice President for Johnson & Johnson Pharmaceutical Research and Development ("JJPRD"), noted in October 2003 that Lilly sent a dear doctor communication informing prescribers that all the atypicals were now subject to a new "class label" for diabetes and hyperglycemia. (R. p. 3246.) Lilly's letter was thought to carry a positive commercial message for Zyprexa because Zyprexa had been viewed by some as the worst offender among atypicals in causing blood sugar disturbances; now, all the atypicals bore substantially the same

diabetes/hyperglycemia Warning as Zyprexa. (R. pp. 766–768, pp. 844–845, pp. 920–921.) Dr. Reines wrote to Mr. Pruden (who had generated the label change financial projections mentioned above (R. pp. 3493–3495)), commenting: "Lilly's DDL is pretty clever. How much commercial liability would we incur if we sent a similar letter about Risperdal, assuming the FDA is unwilling to communicate [on] the issue?" (R. p. 3246.) Janssen then prepared many drafts of the Dear Doctor Letter to send to Risperdal prescribers and others (e.g., pharmacists) nationally, including in South Carolina. (R. p. 844, line 14–p. 848, line 6; pp. 3788–3789; p. 3790; p. 3791; p. 5430.)

The final Dear Doctor Letter was dated November 10, 2003. The passage at issue in this case stated:

> Hyperglycemia-related adverse events have infrequently been reported in patients receiving RISPERDAL. Although confirmatory research is still needed, a body of evidence . . . suggests that ***RISPERDAL is not associated with an increased risk of diabetes when compared to untreated patients*** or patients treated with conventional antipsychotics. Evidence also suggests that RISPERDAL is associated with a lower risk of diabetes than some other studied atypical antipsychotics.

(R. p. 3762 (emphasis added).) Unlike the CAE letter sent earlier in 2003, the body of this Dear Doctor Letter did not include the text of the new Warning. (*Id.*) The evidence also showed that Janssen trained its sales representatives consistent with the Dear Doctor Letter's message, instructing them that Janssen's double-blind trials showed a "0%" increased diabetes risk for Risperdal compared to placebo. (R. pp. 3157–3196.) Two months later, in January 2004, Janssen officials concluded that "[s]ales impact" had been "minimal to date" after the Dear Doctor Letter was distributed "due to Risperdal [being] viewed as positively differentiated from Zyprexa." (R. p. 3203.)

FDA reprimands Janssen that its Dear Doctor Letter is false and misleading

In April 2004, the FDA issued a "Warning Letter" to Janssen, admonishing it

for—among other infirmities—"false" and "misleading" representations in the Dear Doctor Letter. (R. pp. 3107–3111.) The FDA admonished Janssen that "[t]he healthcare community relies on [dear doctor letters] for accurate and timely information regarding serious risks and associated changes in labeling and the dissemination of this letter at a time critical to educating healthcare providers is a *serious public health issue*." (R. p. 3107 (emphasis added).) The Warning Letter continued: the Dear Doctor Letter "suggests that Risperdal does not increase the risk of diabetes, contradicting the Warning in the revised [label] and minimizing the risks associated with the drug." (R. p. 3109.) The FDA also determined that referenced articles in the Dear Doctor Letter "do not represent the weight of the pertinent scientific evidence" nor did the Letter "accurately describe the results of [those] cited studies." (*Id.*)

Dr. Reines, who had earlier suggested sending the Dear Doctor Letter, reacted negatively to the final version of the Letter after learning of the FDA's Warning Letter. He wrote to another JJPRD employee days after receipt of the Warning Letter, declaring the "warning letter is ugly." (R. p. 3792.) "It's really a black mark for J&J." (*Id.*) He commented that "no competent person would have let [the Dear Doctor Letter] go out" as drafted. (*Id.*) Two months later he wrote to another JJPRD employee, commenting that "[t]here's a lesson in this unfortunate mess – I just hope [the Letter's author/signer] and [Janssen] learned it well." (R. p. 3805.)

Eventually, in July 2004, acceding to FDA demands for the same, Janssen issued a "Correction Letter" to recipients of the Dear Doctor Letter. (R. pp. 3229–3230.) The FDA required the Correction Letter be identified before the salutation, in boxed text, as "IMPORTANT CORRECTION OF DRUG INFORMATION." (R. p. 3229.) Janssen

admitted to recipients of the Correction Letter that it had received the Warning Letter from the FDA concluding that Janssen had "omitted material information about Risperdal, minimized potentially fatal risks, and made misleading claims suggesting superior safety to other atypical antipsychotics without adequate substantiation." (*Id.*)

Even after the diabetes Warning, Risperdal's label remained inadequate

Notwithstanding the diabetes/hyperglycemia Warning in 2003, Risperdal's label did not carry a Warning for hyperprolactinemia until the FDA took action in 2007. Nevertheless, Dr. Ivo Caers, Janssen's "global product leader" for Risperdal, testified that "high prolactin increase" was a well-known Risperdal characteristic within the Company at least since 1994. (R. p. 1320, lines 3–13, p. 1321, lines 4–16.) Further, evidence at trial showed that 18% of Risperdal's sales in the United States was for pediatric use of the drug. (R. p. 1050, lines 8–15; p. 1053, line 7–p. 1054, line 1; pp. 3471–3472.) Dr. Magali Haas, Janssen's clinical leader for the Risperdal pediatric program, acknowledged that "elevated prolactin would be of more concern for a developing . . . child than it would be for a fully formed adult." (R. p. 377, lines 17–21.) Dr. Haas further testified that menstrual-cycle disturbances were experienced in adolescent girls taking Risperdal in clinical trials, and it was not known if those disturbances were permanent. (R. p. 378, lines 3–14.) Dr. Haas also testified that adolescent boys taking Risperdal in clinical trials experienced gynecomastia (abnormal breast enlargement), disturbance of their testosterone system, and their ability to produce semen. (R. p. 379, lines 1–14.) Again, Dr. Haas testified that it was not known if such conditions were irreversible. (R. p. 380, lines 15–16.)

ARGUMENT

"The legislature intended . . . [SCUTPA] to control and eliminate the large scale use of unfair and deceptive trade practices within the state of South Carolina." *Noack Enters., Inc. v. Country Corner Interiors, Inc.*, 290 S.C. 475, 477, 351 S.E.2d 347, 349 (Ct. App. 1986) (citations and internal quotation marks omitted). This case represents the South Carolina Attorney General's efforts to control and eliminate large-scale, unfair, and deceptive prescription drug marketing and promotional practices in this State.

Standard of Review

When reviewing a denial of a motion for judgment notwithstanding the verdict, the appellate court should view the evidence and all reasonable inferences in the light most favorable to the nonmoving party. *Hessenthaler v. Tri-County Sister Help, Inc.*, 365 S.C. 101, 107, 616 S.E.2d 694, 697 (2005). "The trial court can only be reversed by this Court when there is *no* evidence to support the ruling below." *Strange v. S.C. Dep't Highways & Pub. Transp.*, 314 S.C. 427, 430, 445 S.E.2d 439, 440 (1994) (emphasis added). In other words, "[u]nder [this] standard the trial court should not grant JNOV where the evidence yields more than one inference[, and] [a]n appellate court may not overturn the decision of the trial court, under the state standard, if there is *any* evidence to support the trial court's ruling." *Gilliland v. Doe*, 357 S.C. 197, 199, 592 S.E.2d 626, 627 (2004) (emphasis added).

With respect to motions to alter or amend the judgment or for new trial, "a trial judge's order . . . denying a new trial will be upheld unless the order is wholly unsupported by the evidence, or the conclusion reached was controlled by an error of law." *Norton v. Norfolk S. Ry. Co.*, 350 S.C. 473, 478, 567 S.E.2d 851, 854 (2002)

(internal quotation marks omitted). "[R]eview is limited to consideration of whether evidence exists to support the trial court's order." *Id.* at 478–79, 567 S.E.2d at 854. If there was *any* testimony tending to prove allegations of the complaint, the motions were properly refused. *Proctor v. Dep't of Health & Envtl. Control*, 368 S.C. 279, 293, 628 S.E.2d 496, 504 (Ct. App. 2006). "This rule is especially strong in South Carolina where the 'scintilla of evidence rule' is applied." *Id.*

I. THE STATE'S SCUTPA CLAIM BASED ON THE RISPERDAL LABEL IS NOT BARRED BY EITHER FEDERAL OR STATE LAW.

A. The State's Package Insert Claim is not Preempted by Federal Law.

Federal preemption will not lie unless Congress reveals a "clear and manifest purpose" to preempt. *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) ("[T]he purpose of Congress is the ultimate touchstone in *every* pre-emption case." (emphasis added) (citation and internal quotation marks omitted)). Federal preemption of state law is never presumed.[1] *Id.* & n.3. The party advocating federal preemption must prove Congress's clear and manifest purpose to preempt and all other aspects of the affirmative defense. *See Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1087 n.2 (2011).

Because Congress has never included an express preemption provision in the Food, Drug & Cosmetic Act ("FDCA"), *Levine*, 555 U.S. at 574, and because Janssen

[1] Janssen's brief turns this "presumption against preemption" on its head. Janssen apparently contends that congressional *silence* on the issue of whether Congress intended "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," (Appellant's Br. 16), is sufficient to prove Congress's requisite clear and manifest purpose to preempt. But, as the Supreme Court determined in *Wyeth v. Levine*, 555 U.S. 555 (2009), Congress's "silence on the issue, coupled with its certain awareness of the prevalence" of related litigation in state courts, "is powerful evidence that Congress did *not* intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 575 (emphasis added); *see also Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166–67 (1989) ("The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them." (alteration in original) (citation and internal quotation marks omitted)). In short, reliance on congressional silence will not satisfy Janssen's burden here.

does not argue that the FDCA "preempts the field" of drug labeling, Janssen's preemption argument may only succeed if Janssen demonstrates that South Carolina law "actually conflicts" with federal law. *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). An "actual conflict" exists when "it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) (citations and internal quotation marks omitted). Conflict preemption analysis is not, however, a "freewheeling judicial inquiry into whether a state statute is in tension with federal objectives, but an inquiry into whether the ordinary meanings of state and federal law conflict." *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 459 (2005) (Thomas, J., concurring in the judgment in part and dissenting in part) (citation and internal quotation marks omitted). As Janssen cannot show that federal and South Carolina law actually conflict here, the Court should reject Janssen's federal preemption arguments.

1. Janssen Cannot Show that Compliance with South Carolina Law Poses an Obstacle to Congressional Objectives.

Far from the "unmistakable obstacle" that Janssen contends SCUTPA enforcement poses to congressional objectives here (Appellant's Br. at 15), SCUTPA instead furthers the FDCA's "high purpose" of "protect[ing] consumers." *Kordel v. United States*, 335 U.S. 345, 349 (1948). Congress, emphasizing consumer safety as a paramount goal, established in the FDCA that:

- Introduction of any "misbranded" drug would be "prohibited," 21 U.S.C. § 331(a);
- A drug label would be "misbranded" if "false or misleading in any particular," *id.* § 352(a); and
- Drug labeling would be "misbranded" if it lacked "adequate warnings . . .

against unsafe dosage or methods or duration of administration or application," *id.* § 352(f).

For its part, South Carolina law deems unlawful "deceptive" or "unfair" acts or practices in the conduct of "any trade or commerce." S.C. Code Ann. § 39-5-20(a). Accordingly, if a drug label is "false or misleading in any particular," it is considered "misbranded" under federal law, *see* 21 U.S.C. § 321(f), but it may also be "deceptive" or "unfair" under SCUTPA, *see* S.C. Code Ann. § 39-5-20(a). The federal and state statutory schemes are thus not in conflict with one another; they are parallel.

In *Wyeth v. Levine*, 555 U.S. 555 (2009), the United States Supreme Court recently acknowledged and reaffirmed this long-standing cooperative federalism regime. *Id.* at 581. There, the Vermont Supreme Court had upheld a jury verdict finding that the drug manufacturer defendant failed to adequately warn of certain of its drug's inherent dangers, notwithstanding the drug maker's continual use of a label containing FDA-approved Warnings. *Id.* at 563. Reviewing the decision, the Supreme Court flatly rejected the manufacturer's contention that "[o]nce the FDA has approved a drug's label, a state-law verdict may not deem the label inadequate." *Id.* at 573–74. "The most glaring problem with [that] argument," stated the High Court, "is that all evidence of Congress'[s] purposes is to the contrary." *Id.* at 574.

More specifically, the Supreme Court discerned that Congress's purpose in enacting the FDCA was "to bolster"—not supplant—"consumer protection against harmful products."[2] *Id.* Congress, having never enacted *any* federal consumer protection

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[2] States like South Carolina are "vested with the responsibility of protecting the health, safety, and welfare of [their] citizens," and have "great latitude" when carrying out that responsibility. *United Haulers Ass'n v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 342 (2007). That important public interest in preserving state government enforcement action in the health and safety context is even greater

remedy for "unsafe or ineffective" drugs since first approving the FDCA in 1938, evidently "determined that widely available state rights of action . . . appropriate[ly]" protected consumers. *Id.* Congress "may also have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." *Id.* Based in significant part on the foregoing, the Supreme Court held that federal law did not preempt a state law verdict deeming an FDA-approved drug label inadequate.[3]

Janssen counters *Levine* by arguing as self-evident that the decision is restricted to state tort lawsuits. (Appellant's Br. 16.) But, the Supreme Court has repeatedly refused to distinguish between "positive enactments" of state law (like SCUTPA) and common law torts in the federal preemption context. *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 443 (2005); *see Cipollone v. Liggett Group*, 505 U.S. 504, 521–22 (1992) (plurality opinion). Such a limited reading of *Levine* is further undermined by the Supreme Court's recent opinion in *Cuomo v. Clearing House Ass'n*, 557 U.S. 519 (2009). There, the Court readily distinguished between "administrative oversight" of banks as federal powers exclusive to the Office of Comptroller of the Currency under the National Bank Act, as compared to the New York Attorney General's enforcement of state banking laws, which the Court determined were not substantively preempted by federal law. *Id.* at 2717–18.

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where federal agency inaction or under-enforcement may be particularly prevalent. *See Levine*, 555 U.S. at 578–79 n.11 ("'The [FDA] lacks the resources to accomplish its large and complex mission . . . . There is widespread agreement that resources for post-marketing drug safety work are especially inadequate and that resource limitations have hobbled the agency's ability to improve and expand this essential component of its mission.'" (alteration in original) (citation omitted)).

[3] Further to its fundamental misunderstanding of *Levine*, Janssen cites a number of cases that were abrogated by the Supreme Court's decision there. (*See* Appellant's Br. 15 (citing *Prohias v. AstraZeneca Pharms., L.P.*, 958 So. 2d 1054 (Fla. Dist. Ct. App. 2007); *Cytyc Corp. v. Neuromedical Sys., Inc.*, 12 F. Supp. 2d 296, 301 (S.D.N.Y. 1998); *Am. Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 144-45 (S.D.N.Y. 1987))).

Citing *Levine* as archetypal precedent for balancing ostensibly competing federal and state law enforcement interests, the Supreme Court determined that the permissible overlapping of such interests "echoes many other mixed state/federal regimes in which the Federal Government exercises general oversight while leaving state substantive law in place." *Id.* at 2718.[4]

Finally, although *Levine* "recognize[d] that some state-law claims might well frustrate the achievement of congressional objectives," the Supreme Court referred to claims like that in *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000). *See Levine*, 555 U.S. at 579–81. But, unlike the plaintiff in *Geier*, the State's case does not conflict with or obstruct specific determinations by a federal agency. *Compare Geier*, 529 U.S. at 874–75 (deeming that federal law preempted a state tort lawsuit premised on an automobile manufacturer's failure to install airbags, where federal regulation at that time afforded car makers the clear option not to install airbags), *with Williamson v. Mazda Motor of Am., Inc.*, 131 S. Ct. 1131, 1139–40 (2011) (holding that a tort lawsuit based on failure to install shoulder and lap restraint was not preempted under more recent

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[4] Other courts have likewise declined to distinguish government enforcement actions from private actions in applying *Levine*-like preemption principles. *See, e.g.*, *South Carolina v. AstraZeneca Pharms., LP*, No. 7:09-387-HFF, 2009 U.S. Dist. LEXIS 39174, at *18 (D.S.C. May 5, 2009) (rejecting preemption grounds for federal jurisdiction and granting motion to remand relying on *Levine's* consideration that "[i]f Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history" (quoting 555 U.S. at 574)); *Mississippi v. AstraZeneca Pharms., LP.*, 744 F. Supp. 2d 590, 605 (N.D. Miss. 2010) (same); *see also Pac. Merch. Shipping Ass'n v. Goldstene*, 639 F.3d 1154, 1166–67 (9th Cir. 2011) (sustaining state's clean air regulation as not impliedly preempted by federal maritime law based in part on *Levine*); *People v. Guiamelon*, No. B232188, 2012 Cal. App. LEXIS 469, at *42–44 (Cal. App. Ct. Apr. 24, 2012) (applying *Levine* in Medicaid fraud lawsuit brought by California Attorney General and holding that nothing in either the state or federal anti-kickback statute prevented the defendant from complying with both laws, even where such laws had differing liability standards); *Oregon v. Johnson & Johnson*, No. 3:11-CV-86SI, 2011 U.S. Dist. LEXIS 140734, at *17–18, *20–22 (D. Or. Dec. 7, 2011) (granting motion to remand in Oregon's case against Johnson & Johnson for UTPA violations, relying on *Levine's* reasoning in concluding that Oregon's consumer misrepresentation claims "do not seek to enforce a federal statute, but to vindicate a traditional area of state authority—the protection of consumers from allegedly deceptive trade practices" and emphasizing that, in *Levine*, "[t]he Supreme Court . . . made clear that the FDCA regime leaves ample room for such state causes of action").

federal law, notwithstanding *Geier*). Moreover, in keeping with *Geier*, *Levine* demands that there be "clear evidence" that the FDA considered and rejected a specific stronger Warning for conflict preemption to apply. *Levine*, 555 U.S. at 571; *see id.* at 580–81 & n.14. Janssen presented absolutely no evidence of such FDA consideration and rejection of any proposed, stronger Warnings for diabetes/hyperglycemia or hyperprolactinemia at trial, and it cites none in its brief.

In the final analysis, "[i]f Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history." *Id.* at 574. But, Congress did not do so and Janssen makes no showing whatsoever that, notwithstanding Congress's silence on the matter, compliance with South Carolina law imposes such an "'obstructive' impact," (Appellant's Br. 16), so as to trigger federal preemption. Indeed, where no conflict between federal and South Carolina law exists, there can be no obstacle-based "implied conflict" preemption.

2. Janssen Fails to Show that it is Impossible to Comply with Both South Carolina and Federal Law.

To the extent that Janssen contends that it is impossible to comply with South Carolina law and federal prescription drug labeling requirements, that argument also fails. On many occasions, the Supreme Court has said that federal law preempts state law when "compliance with both federal and state regulations is a *physical impossibility*." *Levine*, 555 U.S. at 589 (emphasis added) (quoting *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963)) (internal quotation marks omitted). But, so long as compliance with federal and state law is theoretically possible, then a preemption ruling is not appropriate. *Levine*, 555 U.S. at 573.

Again, federal drug regulation and SCUTPA are complementary, not in conflict with one another. Moreover, a drug manufacturer is required to add or strengthen Warnings on a drug label—whether or not it first seeks FDA approval—"as soon as there is reasonable evidence of an association of a serious hazard" with the drug. 21 C.F.R. § 201.57(e) (2006). A manufacturer must also update its labeling when information becomes available "that causes the labeling to become inaccurate, false, or misleading." 21 C.F.R. § 201.56(a)(2) ("The labeling must be information and accurate" and not "false or misleading in any particular."). Thus, Janssen could have complied with both federal and state requirements by unilaterally strengthening Risperdal's label. *See Levine*, 555 U.S. at 573.

Furthermore, affirmance of the State's SCUTPA claim would not lead to "different labeling requirements in different states." (Appellant's Br. 13–15.) The State did not seek or obtain an injunction. The State's claims in this case do not restrict or mandate the revision of any Risperdal label—in particular, they do not touch upon any Risperdal label currently in use. Janssen may pay the State's penalties award without changing Risperdal's labeling. In keeping with SCUTPA's purpose, the jury verdict should "discourage . . . unfair or deceptive acts in the conduct of any trade or commerce," but it does not mandate future corrective action. *Taylor v. Medenica*, 331 S.C. 575, 579, 503 S.E.2d 458, 460 (1998); *cf. Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 445 (2005) ("[A]n event, such as a jury verdict, that merely motivates an optional decision is not a requirement."). There can be no doubt, then, that there is no physical impossibility because Janssen can pay the State's judgment and not otherwise alter its conduct. "In sum, the relevant federal law did not give [Janssen] a right that the state-law judgment

took away, and it was possible for [Janssen] to comply with both federal law and the [South Carolina]-law judgment at issue here." *Levine*, 555 U.S. at 593 (Thomas, J., concurring in the judgment).

3. *The State's Claim Does Not Constitute a Prohibited "Fraud-on-the-FDA" Claim Under* Buckman.

Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001), is an express preemption case limited to state law claims for fraud *committed on the FDA*. *Id.* at 347–48, 350–51; *see also id.* at 353 ("[T]he fraud claims exist *solely* by virtue of the FDCA disclosure requirements." (emphasis added)). *Buckman* also recognizes that *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), carved out "state-law causes of action that parallel federal safety requirements." 531 U.S. at 353 (citing 518 U.S. at 495).

Janssen's contentions that the State's claims are barred, at least in part, by *Buckman*-style preemption cannot be credited. The State has shown how SCUTPA parallels federal safety requirements here. *See supra* Part I.A.1. Moreover, the State disclaimed any fraud theories of recovery. Indeed, proof of common law fraud (against the FDA or anyone else) is not required by SCUTPA, which "creates new substantive rights by making conduct unlawful that was not actionable under the common law." *State ex rel. McLeod v. C & L Corp.*, 280 S.C. 519, 525, 313 S.E.2d 334, 338 (Ct. App. 1984). Further, the jury was repeatedly instructed that the case "is not an effort to enforce any federal laws or regulations," and was also charged that it may not consider "the violation of a federal law or regulation [to be] in and of itself . . . a violation of SCUTPA." (R. pp. 2383–2384, pp. 2482–2483, p. 2524.)

Thus, the State did not contend that Janssen violated SCUTPA by failing to disclose to the FDA information such as the results of Trial 113 and ERI. Rather, the

State contended and proved that Janssen violated SCUTPA through unfair and deceptive conduct directed at South Carolina doctors, patients, and the State. As "fraud on the FDA" is simply not a factual or legal basis of the State's SCUTPA claim, *Buckman*-style federal preemption is inapplicable.

B. The State's Claim Based on the Risperdal Package Insert Is Not Exempt from SCUTPA.

Otherwise unfair or deceptive practices are exempt from SCUTPA if they constitute actions or transactions *permitted* under laws administered by a regulatory body or officer acting under statutory authority of the United States. S.C. Code Ann. § 39-5-40(a). Janssen argues that it had "'permission' to use the approved package insert" for Risperdal, (Appellant's Br. 20), and therefore the State's claims are barred under S.C. Code Ann. § 39-5-40(a). Janssen also attempts to revive the "general activity" test as a potential bar to the State's labeling claim. Because Janssen cannot show that its conduct in violation of SCUTPA was "permissible" under federal prescription drug labeling law, and because the "general activity" test has no force or effect here, neither contention has merit.

1. Janssen's Conduct Was Not "Permitted" Under Federal Drug Labeling Law.

Federal prescription drug labeling law mandates that a manufacturer add Warnings to its drug's label "*as soon as* there is reasonable *evidence of an association* of a serious hazard" with the drug, or otherwise update its labeling when information becomes available "that causes the labeling to become inaccurate, false, or misleading." 21 C.F.R. § 201.57(e) (2006) (emphasis added); 21 C.F.R. § 201.56(a)(2) (2006); *see also* 21 C.F.R. § 201.57(e) ("a causal relationship need *not* have been proved") (emphasis added); 21 C.F.R. § 201.56(a)(2) ("The labeling must be information and accurate" and

not "false or misleading in any particular.").

Interpreting these regulations, *Levine* clarified that "it has remained a central premise of federal drug regulation that *the manufacturer bears responsibility* for the content of its label *at all times*." 555 U.S. at 570–71 (emphasis added). A drug company "is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Id.* at 571; *see also id.* at 592–93 (Thomas, J., concurring) ("[T]he FDA's initial approval of a drug is not a guarantee that the drug's label will never need to be changed. And nothing in the text of the statutory or regulatory scheme necessarily insulates [a drug company] from liability under state law simply because the FDA has approved a particular label"). The Supreme Court reached those conclusions notwithstanding recent amendments (after the timeframe at issue in this case) to the FDCA and to FDA regulations.[5] "Indeed, the 'complex and extensive' regulatory history and background relevant to this case . . . undercut the FDA's recent pronouncements of pre-emption, as they reveal the longstanding coexistence of state and federal law and the FDA's traditional recognition of state-law remedies." *Id.* at 580–81.

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[5] That includes the 2008 "final rule" and accompanying preamble that Janssen urged upon the trial court. Obfuscating the key FDA regulation here as it did before the trial court, Janssen asserts that *the State* misrepresented the standard for adding or strengthening a Warning under federal regulations during the relevant time period. (Appellant's Br. 21 n.6.) But, Janssen never offered into evidence Defense Exhibit 6372—21 C.F.R. § 201.57—to support its *counsel's* contention, *after* the close of all evidence, that the trial court should charge and instruct the jury in accordance with the regulatory "change [of] June 2006," inserting the words "causal" before the word "association." (Appellant's Br. 21 n.6 (citing R. pp. 2500–2501); *see also, e.g.*, R. pp. 1952–1955, p. 1957 (trial court explaining that it had no evidence of the regulation with the word "causal association," inviting Janssen's counsel or its expert to "show [the court] . . . where it has that language," and explaining that if Janssen's witness "cannot testify in [such a] fashion, then perhaps the only remedy [the court] has is to exclude his testimony"; in response, Janssen's counsel simply stating he "can't quibble with that").) Instead, Janssen only attempted to introduce an August 22, 2008 "final rule" and the preamble thereto, and elicit related testimony from its "expert," Sheldon Bradshaw. (*See* R. pp. 1933–1935 (preamble), R. pp. 1944–1945 (2008 amendment), R. pp. 1952–1953 (preamble and 2008 amendment).) The trial court rightly denied Janssen's requests for a charge and corrective instruction regarding the *post hoc* applicability of the August 22, 2008 amendment, where the State's claims for penalties terminated in August 2007. Further, the 2008 amendment Janssen urged the trial court to recognize is not retroactive; therefore, Janssen was required to comply with then-existing labeling requirements, as argued by the State.

Here, Janssen fails to explain how it proved that its conduct was "permitted" for purposes of SCUTPA's "safe harbor" exception where the evidence at trial showed that Janssen did not comply with the above federal law. As with the label at issue in *Levine*, Janssen was required to unilaterally add or strengthen Warnings in Risperdal's labeling *any time* there was reasonable evidence of an association between Risperdal consumption and a serious hazard. *See* 21 C.F.R. § 201.57(e) (2006); 555 U.S. at 570–71. Janssen ignored its obligations under federal drug labeling law, however, with respect to serious diabetes/hyperglycemia and hyperprolactinemia side effects. *See supra* pp. 3–14. And, the fact that the FDA had intermittently "approved" Risperdal labels over the years did not absolve Janssen from its obligation. The same facts were present in *Levine*—the FDA had reviewed and approved the drug label at issue there on an ongoing basis. *See* 555 U.S. at 558, 561–62, 569–70, 580–81. But, those intermediate label approvals did not support preemption. *See id.* For those reasons, Janssen cannot be afforded "safe harbor" from SCUTPA's reach.

2. The Overruled "General Activity" Test Does Not Alter the Result.

In *Ward v. Dick Dyer & Associates, Inc.*, 304 S.C. 152, 403 S.E.2d 310 (1991), this Court held that SCUTPA claims are not barred simply because the general activity that is the subject of the claim is regulated by other law. *Id.* at 154–57, 403 S.E.2d at 311–13. This Court explained that the "safe harbor" exception is "intended to avoid conflict between laws, not to exclude from the Act's coverage every activity that is authorized or regulated by another statute or agency." *Id.* at 155–56, 403 S.E.2d at 312; *see also Taylor v. Medenica*, 324 S.C. 200, 218, 479 S.E.2d 35, 44 (1996) (rejecting appellant's argument that unwarranted laboratory tests subject of claim were exempt

because they were regulated by state and federal agencies).[6]

Janssen nevertheless urges application of the defunct "general activity" test, arguing that Risperdal's labeling is exempt under SCUTPA for that additional reason. (Appellant's Br. 18.) But, under *Ward*, the exemption is inapplicable here because Janssen's conduct that violated SCUTPA also violated federal laws and regulations. *See supra* Part I.B.1. *See generally Dema v. Tenet Physician Servs.-Hilton Head, Inc.*, 383 S.C. 115, 123 n.6, 678 S.E.2d 430, 434 n.6 (2009) ("Th[e SCUTPA] exception exempts an entity from liability where its actions are lawful or where 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.' This provision lends no support to [the respondents] because Appellants alleged [they] performed *unauthorized* [medical procedures]." (citation omitted) (quoting *Ward*, 304 S.C. at 155, 403 S.E.2d at 312)). Indeed, as shown above, *see supra* Part I.A.1, here there is no conflict between SCUTPA and federal drug labeling law.

Moreover, *Ward* implicitly rejected the argument urged by Janssen here that it is the State's burden to show that the specific acts at issue are not covered by the

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[6] Janssen also relies on *InMed Diagnostic Servs., L.L.C. v. MedQuest Associates, Inc.*, 358 S.C. 270, 277, 594 S.E.2d 552, 555 (Ct. App. 2004). (*See* Appellant's Br. 18 n.5.) However, *InMed* is substantively distinguishable. There, the plaintiff initiated a SCUTPA action against the defendant for having submitted false information and otherwise misrepresenting information submitted to the South Carolina Department of Health and Environmental Control (DHEC) in an application for a Certificate of Need. *Id.* at 272–74, 594 S.E.2d at 553–54. The South Carolina Court of Appeals barred the SCUTPA claim because "the specific transaction at issue . . . [involved] a process for which DHEC has formulated exacting procedural requirements." *Id.* at 278–79, 594 S.E.2d at 556. In other words, a determination of "[w]hether or not [the defendant] followed these procedures correctly is uniquely within the competency of DHEC," and the agency's responsibility for such matters "could continue beyond granting the approval should it ever become apparent that a violation . . . occurred." *Id.* at 279, 594 S.E.2d at 556. Because the application process was the appropriate means for resolving the dispute, neither a court nor a jury should determine the issue. *See id.* In contrast, the State's case presents the precise consumer protection issues covered by SCUTPA, and there are no alternative "exacting procedural requirements" to otherwise address such claims.

exemption. *See id.* at 155, 403 S.E.2d at 311–12; *see also* S.C. Code Ann. § 39-5-40 ("[T]he burden of proving the exemption from the provisions of this article shall be upon the person claiming the exemption"). At trial, Janssen failed to offer evidence supporting the application of SCUTPA's narrow exemption. And, notwithstanding its generalized, conclusory pleading of its Twelfth Defense, Janssen also failed to plead *specific permitted* actions or transactions within SCUTPA's safe harbor. (*See* R. p. 140.) Janssen cannot now shift the burden to the State to shore up the deficiencies in its pleading and proof.

Lastly, none of the cases Janssen cites are controlling, nor do they support a blanket exemption for an FDA-approved drug label. In fact, in *Money v. Bristol-Myers Squibb Co.*, No. 3:07-cv-1100 (FLW), 2009 U.S. Dist. LEXIS 121094 (D.N.J. Dec. 30, 2009), a federal district court sitting in diversity addressed the scope of an exemption under the Oklahoma Consumer Protection Act (OCPA), Okla. Stat. tit. 15, § 754(2),[7] and rejected the "assertion that the exemption is applicable merely because the promotion and marketing of prescription drugs are generally regulated by the FDA." *Id.* at *21. In doing so, the district court emphasized that only if "the promotional materials that Plaintiff identifies as deceptive were nevertheless in compliance with FDA regulations governing those materials[,] . . . could [it] find the statutory exemption applicable." *Id.* at *20–21. On the other hand, if "Defendants' promotional materials were *not authorized* by the FDA's regulatory scheme in that they were . . . *not in compliance* . . . then the

[7] In contrast to SCUTPA, which uses the word "permitted," S.C. Code Ann. § 39-5-40(a), the exemption language under OCPA states, "Nothing in this Act shall apply to . . . [a]ctions or transactions *regulated* under laws administered by . . . any other regulatory body or officer acting under statutory authority of this state or the United States . . . ." Okla. Stat. tit. 15, § 754(2) (emphasis added), *quoted in Money v. Bristol-Myers Squibb Co.*, No. 3:07-cv-1100 (FLW), 2009 U.S. Dist. LEXIS 121094, at *16 (D.N.J. Dec. 30, 2009).

statutory exemption would be *inapplicable*." *Id.* at *21 (emphasis added). Again, Janssen failed to prove that its Risperdal labeling was in compliance with the FDA's regulatory scheme.

Further, the opinions Janssen cites demonstrate only that advertisements that are consistent with FDA-approved labeling are not actionable under the safe harbor provisions of other states' deceptive trade practices statutes. *See, e.g.*, *Prohias v. Pfizer*, 490 F. Supp. 2d 1228, 1232–33 (S.D. Fla. 2007) ("The plaintiffs allege . . . that Pfizer advertised, contrary to its approved label, that Lipitor reduces the risk of coronary heart disease. Thus, . . . the FDA has not approved Pfizer's advertisements either explicitly or implicitly by approving the statements on its label."). Unlike here and in *Levine*, the plaintiffs in those cases did not assert state law challenges against FDA-approved labels, but instead took for granted that those labels did not violate state or federal law and challenged drug advertisements. *See DePriest v. AstraZeneca Pharms., L.P.*, 351 S.W.3d 168, 177 (Ark. 2009); *Prohias v. AstraZeneca Pharms.*, 958 So. 2d 1054, 1056 (Fla. Dist. Ct. App. 2007). The courts thus concluded that the advertisements involved were permitted under federal law because they were consistent with unchallenged FDA-approved labels. *See Prohias v. Pfizer*, 490 F. Supp. 2d at 1232–36.

II. THE STATE'S SCUTPA CLAIM BASED ON JANSSEN'S DEAR DOCTOR LETTER IS NOT PREEMPTED.

Federal drug regulation includes 'dear doctor' letters as part of a drug's "label." 21 C.F.R. 202.1(*l*)(2) (2006) ("labeling" includes "letters . . . for use by medical practitioners . . . containing drug information supplied by the manufacturer . . . of the drug and which are disseminated by or on behalf of its manufacturer"); *see* 21 U.S.C. § 201(m). Therefore, for all the reasons described above, the State's claim related to

Janssen's Dear Doctor Letter is not preempted. *See supra* Part I. In particular, there is no conflict between federal proscriptions against "false" and "misleading" Dear Doctor Letters ("labeling") and SCUTPA prohibitions against "unfair" or "deceptive" conduct in "trade or commerce." Moreover, and tellingly, Janssen does not argue that the Dear Doctor Letter falls within SCUTPA's "safe harbor" exception, in contrast to Janssen's argument relative to the Risperdal label. *See supra* Part I.B. Thus, Janssen effectively concedes that FDA warnings as to the "false" and "misleading" Dear Doctor Letter run parallel to, and do not conflict with, the jury's SCUTPA violation finding.

Furthermore, like its misguided federal preemption argument, Janssen's characterization of the State's Dear Doctor Letter SCUTPA claim as "based entirely on Janssen's purported violation of federal law" cannot stand.[8] (Appellant's Br. 22.) Notwithstanding the FDA's conclusion in its April 2004 Warning Letter that the Dear Doctor Letter was "false" and "misleading," the State separately proved that the Dear Doctor Letter violated SCUTPA.

At trial, the State first introduced the testimony of Dr. William Wirshing as the State's psychiatrist, antipsychotic drug, and clinical trials expert. Dr. Wirshing testified, *based on his own qualifications and experience*, that Janssen's representations in the

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[8] Unlike in *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001), which Janssen relies on to support its preemption claim, "fraud on the FDA" is not an element of the State's claim for civil penalties under SCUTPA relative to the Dear Doctor Letter, nor does the State's claim arise "solely by virtue of the FDCA disclosure requirements." 531 U.S. at 352–53. Moreover, the State does not attempt to make an end-run around the FDA's authority to remove drugs from the market by seeking to enjoin Janssen from distributing Risperdal without adequate warnings as in *Mutual Pharmaceutical Co. v. Watson Pharmaceutical, Inc.*, No. CV 09-5700 PA (RCx), 2009 U.S. Dist. LEXIS 107880, at *5-6 (C.D. Cal. Oct. 19, 2009), upon which Janssen also relies. Furthermore, although *Pediamed Pharmaceutical, Inc. v. Breckenridge Pharmaceutical, Inc.*, 419 F. Supp. 2d 715 (D. Md. 2006), indicated that any claim that could be characterized as a "misbranding" claim under 21 U.S.C. § 352 "is within the jurisdiction of the FDA and thus would be precluded," that decision antedates and is flatly inconsistent with *Levine*. *Id.* at 726 n.4. If the position set forth in *Pediamed* were the law—which it is not—the claim at issue in *Levine* would have been preempted by federal law.

Dear Doctor Letter were "patently untrue."[9] (R. p. 525, line 22.) **The State introduced those expert opinions *even before the Warning Letter ever came into evidence at trial*.**[10] (R. pp. 524–526.) Thus, Janssen's preemption argument as to the Dear Doctor Letter fails on that basis alone. Plainly, Janssen's self-serving, incomplete excerpts of Dr. Wirshing's testimony do not, in truth, support the contention that Dr. Wirshing relied only upon the Warning Letter in forming his opinions about the Dear Doctor Letter.

Likewise, Dr. Laura Plunkett, the State's pharmacologist, toxicologist, and FDA regulatory expert opined that the Dear Doctor Letter was untrue, deceptive, and unfair. (R. p. 694.) As with Dr. Wirshing, *before* Dr. Plunkett was even shown the Warning Letter, she testified that the Dear Doctor Letter was untrue and misleading based on her expert review of the peer-reviewed epidemiological research, Trial 113, and ERI. (R. pp. 771–772.) Janssen's portrayal of Dr. Plunkett's trial testimony as entirely reliant upon the Warning Letter is, therefore, also contrived.

Additionally, notwithstanding SCUTPA's and federal law's parallel objectives, Janssen's preemption argument fails because the trial court carefully distinguished between violations of federal and state law in charging the jury that:

> [T]his is an action under South Carolina law, the South Carolina Unfair Trade Practices Act. It's not an action that has been brought under federal law or federal regulations, and this is not an effort to enforce any federal laws or regulations.
>
> It's recognized that the actions of the Defendants are sometimes governed by those laws, but this action does not constitute an effort to enforce those federal laws.
>
> What must be shown in this case is a violation of the South Carolina

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[9] *See infra* n.16 and Part IV.A.

[10] The State *subsequently* introduced the April 2004 Warning Letter and asked Dr. Wirshing if the FDA's conclusions matched his own opinions described above. (R. pp. 530–536.)

> Unfair Trade Practices. And there must be a showing that SCUTPA has been violated . . . by the actions of the Defendant in order for there to be a finding for the Plaintiff in this case.
>
> * * *
>
> ***The violation of a federal law or regulation, in and of itself, does not constitute a violation of SCUTPA.***
>
> There must be a showing that, that SCUTPA has been violated by the actions of the defendant in order for there to be a finding for the plaintiff.

(R. pp. 2482–2483, p. 2524 (emphasis added).) It is a "sound presumption" that "jurors are reasonable and generally follow the instructions they are given." *Arnold v. State*, 309 S.C. 157, 166, 420 S.E.2d 834, 838–39 (1992) (Toal, C.J.). The sound presumption here is that the jury followed the trial court's admonitions that violations of federal law may not in and of themselves constitute a SCUTPA violation, and that the jury must focus on evidence of any violation of South Carolina law as opposed to federal law.

Therefore, the State did not attempt to impose SCUTPA liability by virtue of alleged FDCA violations. Instead, the State offered independent, stand-alone proof of deceptive and unfair representations in the Dear Doctor Letter. Further, the jury was specifically cautioned not to conflate State and federal law violations. The federal preemption basis on which Janssen seeks reversal as to the Dear Doctor Letter must fail.

III. THE STATE'S SCUTPA CLAIM WAS NOT TIME-BARRED.

A. The Trial Court Correctly Determined that the State's SCUTPA Claims Were Not Time-Barred by General, Anecdotal Knowledge of Risperdal's Side Effects.

In South Carolina, "[t]he burden of establishing the bar of the statute of limitations rests upon the one interposing it." *Turner v. Milliman*, 381 S.C. 101, 110, 671 S.E.2d 636, 641 (2009). The attendant "discovery rule" runs "from the date the injured party either knows or should know, by the exercise of reasonable diligence, that *a cause*

of action exists for the wrongful conduct" of the defendant.[11] *Epstein v. Brown*, 363 S.C. 372, 376, 610 S.E.2d 816, 818 (2005) (emphasis added). "The date on which discovery should have been made is an objective, not subjective, question," and there exists no duty to discover such information or to otherwise undertake a fishing expedition in an effort to find evidence of the wrongful conduct at issue. *Arant v. Kressler*, 327 S.C. 225, 229, 489 S.E.2d 206, 208 (1997); *see also State v. Von Dohlen*, 322 S.C. 234, 240–41, 471 S.E.2d 689, 693 (1996) (government "has no duty to undertake a fishing expedition . . . to find . . . evidence" of unlawful activity). Furthermore, in order to charge the State with notice of Janssen's wrongdoings by way of "publication," the referenced publications must be of sufficient "widespread publicity and awareness" to place the State on notice of the *particularized harm* that it seeks to redress. *See Hedgepath v. AT&T*, 348 S.C. 340, 349–51, 357–59, 559 S.E.2d 327, 333–34, 337–38 (Ct. App. 2001).

The trial court correctly applied the discovery rule to Janssen's statute of limitations defense and concluded that the State's SCUTPA claim was not time-barred. (R. p. 47.) In doing so, the lower court carefully distinguished the requisite knowledge of the State—in particular the Attorney General's Office[12]—regarding Janssen's unfair or deceptive acts or practices from medical professionals' general knowledge about Risperdal. (R. p. 13, *referenced in* Order, Dec. 20, 2011 (R. p. 47).) Consistent with all relevant South Carolina law, the trial court emphasized that "the essential question . . . is when the State Attorney General's Office would have become aware of 'unfair or deceptive acts or practices' in the Defendants' marketing and labeling [of Risperdal]"—

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[11] Janssen does not contest that South Carolina's discovery rule applies to the State's SCUTPA claims. (*See* Appellant's Br. 26.)

[12] *See* discussion *infra* Part III.B.

not when "the medical community nationally and in this State [would have become] aware" of Risperdal's side effects. (R. p. 13.)

At trial, Janssen never offered proof answering that essential question. General knowledge about Risperdal and/or its side effects—whether by the State, State employees, or State witnesses—is not enough to commence the limitations period. There is no cause of action that arises merely from a drug causing side effects. Without facts concerning the specified incidences of wrongdoing of which the State was aware or should have been aware prior to January 24, 2004 (three years and three months before the filing date),[13] Janssen's argument that the limitations period commenced as early as 1994 must fail. Furthermore, Janssen presented no evidence of "widespread publicity and awareness" of *Janssen's illegal conduct in South Carolina.*

Finally, Janssen speculates that any recipient of the Dear Doctor Letter (including, arguably, the State) knew or should have known that a cause of action arose from Janssen's willful, deceptive, and unfair course of conduct in violation of SCUTPA merely because the recipient allegedly had the ability to review the "published peer-reviewed epidemiology research . . . identified and cited in the letter." (Appellant's Br. 28 (citations and internal quotation marks omitted)). Aside from Janssen's argument being a tacit admission of the Dear Doctor Letter's violation of SCUTPA, there is no evidence the State had notice of the Dear Doctor Letter *at all* before investigating its claims in this lawsuit. In fact, there is no evidence the Dear Doctor Letter was ever received or read by any State official outside of this lawsuit.

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[13] *See* S.C. Code Ann. § 39-5-150 (three-year limitations statute on SCUTPA claims). This lawsuit was filed April 23, 2007. The State and Janssen entered a "tolling agreement" that tolled the statute of limitations for three months commencing January 24, 2007. (R. pp. 7673–7674.)

B. The Trial Court Correctly Granted the State's Motion for a Directed Verdict on Statute of Limitations Because Janssen Failed to Offer *Any* Evidence to Justify Sending the Issue to the Jury.

The Attorney General is the only South Carolina government official who is authorized to bring a claim for civil penalties pursuant to S.C. Code Ann. § 39-5-110(a). Therefore, the requisite actual or constructive knowledge relative to the discovery rule must be that of the Attorney General's Office, and the knowledge of another state agency or employee cannot be imputed to the Attorney General's Office for purposes of starting the limitations period. *See Von Dohlen*, 471 S.E.2d at 693 ("Although information known to . . . agencies may, under certain circumstances, be imputable to the State, the government has no 'affirmative duty to take action to discover information which it does not possess . . . .'"); *see also Midtrust Bank, SSB v. C.W. Haynes & Co.*, 893 F. Supp. 1304, 1316 (D.S.C. 1994) (holding that, although two governmental agencies were divisions of the same department, "the entities operate[d] independently of each other" and it was "unrealistic to charge" one agency with the other agency's "employee's knowledge" (citing *Wyler v. Korean Air Lines Co.*, 928 F.2d 1167, 1171 (D.C. Cir. 1991) ("One . . . agency 'should not be charged with knowledge of what another is doing simply because both are components of the same . . . government.'") (citation omitted)).

Having failed to demonstrate at trial any evidence of the Attorney General's actual or constructive knowledge of Janssen's unlawful conduct, Janssen instead contends that the general knowledge of the "collective" State commences the running of the statute.[14] (*See* Appellant's Br. 29.) Janssen relies upon two inapposite decisions to

[14] The only evidence Janssen presented at trial was the general knowledge of Risperdal's side effects by two State Department of Mental Health prescribers, which, for the reasons amply described herein, was

support its position. *See Willcox v. Stroup*, 358 B.R. 824, 833–34 (D.S.C. 2006) (deeming the *open* and *unabashed* possession and exercise of ownership of State civil war documents by a private party sufficient to put the State on notice of its superior title claim, which the court determined was time-barred); *State ex rel. Brady v. Pettinaro Enters.*, 870 A.2d 513, 532–33 (Del. Ch. 2005) (involving closure of condominium's on-site health club that was both *obvious* and *unconcealed* such that residents and attorney general's office were on inquiry notice of closure prior to alleging DTPA claims). But, the State's claims here involve unfair omissions and deception—not open, unabashed, obvious, and unconcealed conduct.[15]

Thus, Janssen again had no evidence to support its statute of limitations defense, and the trial court properly granted the State's directed verdict motion on that ground.

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wholly insufficient to commence the running of the statute of limitations against the State. (*See* R. pp. 1990–1996 (Dr. Bank); R. pp. 2033–2036, p. 2038 (Dr. Ratliff).)

[15] In any event, even if the trial court might have found that the State tardily filed its Complaint in this lawsuit—which for good reasons it did not—the doctrines of equitable estoppel and/or equitable tolling nevertheless permitted the State to bring its claims. *See Hooper v. Ebenezer Senior Servs. & Rehab. Ctr.*, 386 S.C. 108, 115, 687 S.E.2d 29, 32 (2009) ("South Carolina law provides for tolling of the applicable limitations period . . . [i]n order to serve the ends of justice where technical forfeitures would unjustifiably prevent a trial on the merits" and to otherwise "ensure fundamental practicality and fairness." (alteration in original) (citations and internal quotation marks omitted)); *see also id.* at 116–17, 687 S.E.2d at 33 (emphasizing that the equitable power of the court "is not bound by cast-iron rules but exists to do fairness and is flexible and adaptable to particular exigencies so that relief will be granted when . . . to deny it would permit one party to suffer a gross wrong at the hands of the other" (citations and internal quotation marks omitted)). "[T]he equitable tolling doctrine does not require wrongful conduct on the part of the defendant, such as fraud or misrepresentation." *Id.* Accordingly, the State was not required to show that its Original Complaint was "hindered or delayed," (Appellant's Br. 29), by Janssen's non-disclosure of particular clinical trials or other information relative to Risperdal's side effects, including Trials 113 and ERI, where Janssen's intentionally deceptive conduct was designed to avoid detection. *See* discussion *supra* pp. 3–14. The trial court, likewise, correctly considered that Janssen took affirmative action to conceal possible culpability. The disparity between what Janssen told the prescribers and what its own professionals and experts knew about Risperdal's safety risks justified equitable tolling of the limitations period. (*See* R. p. 2371.) *Cf. Hooper v. Ebenezer Senior Servs. & Rehab. Ctr.*, 377 S.C. 217, 240, 659 S.E.2d 213, 225 (Ct. App. 2008) ("A defendant will be estopped to assert the statute of limitations in bar of a plaintiff's claim when the delay that otherwise would give operation to the statute has been induced by the defendant's conduct."), *rev'd on other grounds*, 386 S.C. 108, 687 S.E.2d 29 (2009).

IV. THE STATE SUFFICIENTLY PROVED PUBLIC IMPACT OF JANSSEN'S VIOLATIVE CONDUCT.

A. The State Proved Public Impact Through Janssen's Conduct's "Capacity or Tendency to Deceive" and Its Potential for Repetition in Accordance with South Carolina Law.

As the court stated in *deBondt v. Carlton Motorcars, Inc.*, 342 S.C. 254, 536 S.E.2d 399 (Ct. App. 2000), "[a] deceptive practice is one which has a *tendency to deceive*." *Id.* at 269, 536 S.E.2d at 407 (emphasis added). "Even a truthful statement may be deceptive if it has the capacity or tendency to deceive." *Id.* SCUTPA's overriding concern is not which person in particular is affected by an unfair or deceptive representation. Rather, SCUTPA focuses on unfairness or deception "in the conduct of any trade or commerce" *that affects the public interest generally.* S.C. Code Ann. § 39-5-20(a); *see also Bessinger v. Food Lion, Inc.*, 305 F. Supp. 2d 574, 582 (D.S.C. 2003) ("[SCUTPA] is not available to redress a private wrong where the public interest is unaffected."); *Noack Enters.*, 290 S.C. at 478, 351 S.E.2d at 349 ("The legislature's intent [was] to limit the application of the [SC]UTPA to only those unfair or deceptive acts or practices in the conduct of trade or commerce *that affect the public interest* . . . .") (emphasis added).

Janssen misconstrues *deBondt* and South Carolina law generally in an attempt to convert the "capacity or tendency to deceive" standard into one that requires proof of actual deception or causation. (*See* Appellant's Br. 32.) More specifically, Janssen seeks to convince this Court that in order to prove a tendency to deceive under SCUTPA, the State must show, for example, that the Dear Doctor Letter and Risperdal label "actually deceived" or were "likely to deceive" South Carolina physicians *and* had "substantial impact" on South Carolina doctors' prescribing habits. (*See id.* at 30–33.)

However, the State was not required to show that Janssen actually misled doctors or that doctors relied on Janssen's representations in order to prevail on the State's SCUTPA claims. Preliminarily—but critically—even setting aside the *deceptiveness* of Janssen's conduct, all the State was required to show to recover penalties under section 39-5-110 is that Janssen willfully committed *unfair* trade practices that affected the public interest. *See* S.C. Code Ann. §§ 39-5-110, 39-5-201. "An unfair trade practice has been defined as a practice which is offensive to public policy or which is immoral, unethical, or oppressive." *Wright v. Craft*, 372 S.C. 1, 23, 640 S.E.2d 486, 500 (Ct. App. 2006); *see also Bessinger*, 305 F. Supp. 2d at 582 (construing SCUTPA—per section 39-5-20(b)—in accordance with the Federal Trade Commission ("FTC") Act, under which courts have determined that a practice is *unfair* when it "offends established public policy and when the practice is immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers"). Thus, Janssen does not (and cannot) contend that the "impact" element of the State's SCUTPA claim based on Janssen's *deceptive conduct* extends to its distinct SCUTPA claim based on the *unfairness* of Janssen's conduct.

In any event, the State presented ample evidence of the Dear Doctor Letter's unfairness and deception. For example, the State's psychiatrist expert, Dr. William Wirshing, explained in great detail the bases for each of his opinions that the Dear Doctor Letter and the label were deceptive and untrue.[16] The jury also rightly considered

[16] *See, e.g.*, R. pp. 524–525 (Janssen statement that Risperdal has no increased risk of diabetes as compared to untreated patients was untrue because of potential for clinically significant weight gain, which axiomatically increases diabetes risk); R. p. 525 (Janssen's assertion that Risperdal was devoid of diabetes risk was untrue based on Trial 113, which Janssen buried, and other evidence); R. pp. 525–526 (assertion that Risperdal had lower diabetes risk was untrue based on Trial 113); R. pp. 548–549 (Dear Doctor Letter omitted material information and reference list was "far from exhaustive"); R. pp. 550–551 (sales materials characterizing Zyprexa as having diabetes risk and Risperdal as not having that risk were untrue in light of

evidence, *see infra* Part VI, that the FDA found the Dear Doctor Letter "fail[ed] to disclose the addition of information relating to hyperglycemia and diabetes mellitus to the approved product labeling," "minimiz[ed] the risk of hyperglycemia-related adverse events, which . . . is associated with serious adverse events including ketoacidosis, hyperosmolar coma, and death," "fail[ed] to recommend regular glucose control monitoring to identify diabetes mellitus as soon as possible," and "misleadingly claim[ed] that Risperdal is safer than other atypical antipsychotics." (R. pp. 530–542; pp. 3107–3111.) Plainly, the State introduced far more than a "scintilla of evidence" as to the deceptive and unfair nature of the Dear Doctor Letter. *Proctor*, 368 S.C. at 293, 628 S.E.2d at 504; *see Strange*, 314 S.C. at 430, 445 S.E.2d at 440.

The same holds true for Janssen's argument that the Warnings in the Risperdal label were not deceptive. For example, only Janssen had possession of the critical Trial 113 and ERI safety results. Janssen chose to keep those results from public and regulatory view. Hiding those results that showed reasonable association with the serious hazards of diabetes/hyperglycemia and weight gain allowed Janssen to steer clear of adding to or strengthening Risperdal's Warnings—a legal requirement Janssen desperately sought to avoid. *See supra* Part I.B.1.[17] The State's pharmacologist and toxicologist expert, Dr. Plunkett, also explained that Janssen knew about Risperdal's propensity to have greater hyperprolactinemia risk than other antipsychotics, yet Janssen entirely failed to include a Warning to that effect—or any hyperprolactinemia Warning—during the relevant time period. (R. p. 856, line 9–p. 857, line 10; p. 1038, line 19–p.

Trial 113 results); R. pp. 585–586 (assertion that Risperdal has zero percent association with diabetes in double-blind trials was untrue given previously revealed 2.8% diabetes risk and Trial 113 results).

[17] *See also, e.g.*, R. pp. 798–800; p. 814; pp. 878–882; pp. 3112–3114; pp. 3493–3495; pp. 3501–3551; pp. 3552–3675; pp. 3973–3975.

1039, line 21; *see also* R. p. 1320, line 17–p. 1321, line 16 (defense witness Ivo Caers testifying that "high prolactin increase" in Risperdal users was known by Janssen in 1994).) Again, Janssen cannot show that there is no evidence to support the ruling below.

Janssen's further contention that the State did not introduce sufficient evidence for the jury to find that the unfair or deceptive Dear Doctor Letter and label adversely "impact[ed] the marketplace" is also contrary to applicable law. (*See* Appellant's Br. 31–32.) South Carolina law does not require the State to prove "actual" impact, but rather that the alleged unfair or deceptive act or practice had the mere *potential* for repetition. *See Wright*, 372 S.C. at 29, 640 S.E.2d at 501. "The potential for repetition may be demonstrated in either of two ways: (1) by showing the same kind of actions occurred in the past, thus making it likely they will continue to occur absent deterrence; or (2) by showing the company's procedures create a potential for repetition of the unfair and deceptive acts." *Id.* at 30, 640 S.E.2d at 502. "These two ways are not the only means for showing the potential for repetition or public impact, and each case must be evaluated on its own merits . . . ." *Id.*; *accord Crary v. Djebelli*, 329 S.C. 385, 387–88, 496 S.E.2d 21, 23 (1998) ("[A] plaintiff need not allege or prove anything further in relation to the public interest."). The purpose of the "public impact" requirement, as noted, is simply to exempt actions for *private* wrong where the public interest is unaffected. *See Noack Enters.*, 290 S.C. at 477–79, 351 S.E.2d at 349–50. This Court has "expressly reject[ed] any rigid, bright line test that delineates in minute detail exactly what a plaintiff must show to satisfy the potential for repetition/public impact." *Daisy Outdoor Adver. Co. v. Abbott*, 322 S.C. 489, 497, 473 S.E.2d 47, 51 (1996).

Here, the State introduced more than a scintilla of "impact evidence," proving the

repeated dissemination of the Dear Doctor Letter to thousands of South Carolina prescribing physicians. (R. p. 1318; pp. 2181–2196; pp. 2578–2594; pp. 2607–2612; pp. 5441–5442; pp. 5443–5445; pp. 3127–3156.) Janssen's own South Carolina sales representative, Angie Alderman, promoted Risperdal to South Carolina doctors during the relevant time period. (R. p. 1153, lines 12–14.) She admitted that sales representatives showed prescribers the Dear Doctor Letter during sales calls. (R. p. 1153, line 15–p. 1154, line 3.) Ms. Alderman's testimony paralleled documentary evidence regarding sales representatives' training on the rollout of the Dear Doctor Letter. Janssen's internal documents showed that Janssen directed Alderman and other sales representatives to "personally deliver a copy of the [Dear Doctor Letter] to ***every called-on customer***." (R. p. 3170 (emphasis added).) If a physician was unavailable on a particular call, they were instructed to leave the Dear Doctor Letter with an office manager or nurse, but then follow up again "to ensure receipt of [the] letter." (*Id.*) Ms. Alderman confirmed that the training she received for her work in South Carolina was consistent with Janssen's sales representative training nationally (and, necessarily, to others in South Carolina). (R. p. 1155, lines 21–22; p. 1174, line 17–1175, line 14.) She testified that she "present[ed] the information that [Janssen] told [her] to" present. (R. p. 1154, lines 18–19.)

In regard to the Risperdal label, the State proved that over a half-million Risperdal sample boxes were distributed with labeling that the jury found to have violated SCUTPA. (R. p. 1173 (each sample includes a package insert); R. p. 2556, pp. 2570–2578, pp. 2611–2612 (509,499 sample boxes); *see* R. pp. 5439–5440, p. 5835, p. 5836.) Further, Janssen's Senior Product Director for Risperdal, Riley Smith, confirmed that its

sales representatives "certainly leave the package insert *on all sales calls with physicians*, so that information is there for them to read." (R. p. 1213 (emphasis added).) In addition, Ms. Alderman's testimony reconfirmed Janssen's uniform practice of disseminating Risperdal labeling through sample boxes of Risperdal. (R. pp. 1173–1175.)

This Court has determined such evidence is particularly responsive to the public impact requirement of SCUTPA. *See Daisy Outdoor*, 322 S.C. at 494–95, 473 S.E.2d at 50. It has found that evidence of other instances of the alleged deceptive or unfair conduct at issue is "directly relevant to UTPA's public interest requirement" and "[establishes] a potential for repetition of the defendant's unfair and deceptive acts." *Id.* More specifically, the Court held that the potential for repetition requirement is satisfied where the unfair or deceptive communication at issue has been repeated through publication to others, as was Janssen's Dear Doctor Letter and Risperdal labeling. *See Haley Nursery Co. v. Forrest*, 298 S.C. 520, 524, 381 S.E.2d 906, 908–09 (1989).

Finally, in light of the above, it is disingenuous for Janssen to proclaim that "[t]he only 'impact' evidence in this case was offered by Janssen, and it showed that there was no deception, no likelihood of deception, and no possibility of substantial injury." (Appellant's Br. 32–33.) The anecdotal testimony of State Department of Mental Health Drs. Robert Bank and Brenda Ratliff regarding the purported lack of actual impact on *their own* prescribing practices is immaterial to the factfinder's "potential for repetition" determination. *See Wright*, 372 S.C. at 29, 640 S.E.2d at 501. In any event, Drs. Bank and Ratliff were admittedly unaware of Trial 113 and the ERI study. (*See* R. p. 2025, pp. 2045–2048.) Similarly, the calculations of Dr. Wecker, which purportedly show that

there was no change in Risperdal's market share after Janssen sent the Dear Doctor Letter and related Correction Letter, are wholly irrelevant to the question of whether Janssen's deceptive and/or unfair Dear Doctor Letter had the "potential for repetition." *See* additional discussion regarding Dr. Wecker, *infra* Part IV.B.

Thus, the Court should reject Janssen's attempt to sidestep South Carolina law in favor of a self-serving "actual impact" standard cobbled together from select FTC policy statements. The State introduced more than a scintilla of evidence proving that the Dear Doctor Letter and Risperdal's labeling were unfair and/or had a tendency to deceive and impacted the public interest because of their potential for (and actual) repetition.

B. The Trial Court Properly Excluded the Testimony of Dr. William Wecker and Related Unreliable and Prejudicial Defense Evidence.

Under South Carolina law, "[a]ll expert testimony must satisfy the Rule 702 criteria, and that includes the trial court's gatekeeping function in ensuring the proposed expert testimony meets a reliability threshold for the jury's ultimate consideration." *State v. White*, 382 S.C. 265, 270, 676 S.E.2d 684, 686 (2009) (citing S.C.R. Evid. 702). The relevant inquiry cannot focus solely on the reliability of the witness himself but must also assess the reliability of the process by which he derived his opinion. *See State v. Tapp*, 387 S.C. 159, 168, 691 S.E.2d 165, 170 (Ct. App. 2010); *see also id.* at 168 n.7, 691 S.E.2d at 169–70 n.7 (explaining that, in determining admissibility of scientific evidence under the *State v. Jones* standard, 273 S.C. 723, 259 S.E.2d 120 (1979), the trial court may consider these factors: "(1) the publications and peer review of the technique; (2) prior application of the method to the type of evidence involved in the case; (3) the quality control procedures used to ensure reliability; and (4) the consistency of the method with recognized scientific laws and procedures" (citations and internal quotation

marks omitted)). In addition, although South Carolina Rule of Evidence 802 provides that hearsay is generally not admissible, "[a]n expert may base his opinion on hearsay evidence *so long as* it is of a type reasonably relied upon by other experts in the field" and the offering party has demonstrated the same. *State v. Hutto*, 325 S.C. 221, 224, 481 S.E.2d 432, 433 (1997) (emphasis added). When admitting evidence under Rule 702, the Court must also determine if it is relevant and whether its probative value, if any, is outweighed by its prejudicial effect as prescribed by Rule 403. S.C.R. Evid. 402, 403.

Dr. Wecker's "survey," conducted through trial depositions of twenty South Carolina doctors, was so flawed—because of bias created by direct Janssen attorney involvement, leading questions, a skewed target population, and other failings recognized by the trial court—that it could not be deemed reliable and admissible under South Carolina Rule of Evidence 702. (R. pp. 17–19.) As the trial court found, "[t]he group of doctors sampled was taken from the top 101 prescribers of antipsychotics, which resulted in approximately ***90% of the physicians in the State being excluded*** from consideration in the same." (R. p. 17 (emphasis added).) For those same reasons, Dr. Wecker's testimony about the "survey" was inadmissible hearsay. The "survey" was also not based on the type of data reasonably relied upon by experts in the fields of medicine or statistics, and therefore its admission would have violated Rule 703. Admission of Dr. Wecker's testimony about the "survey" would also have unfairly prejudiced the State's case under Rule 403.[18]

Additionally, Dr. Wecker's opinions (and the underlying "data" gleaned from the

[18] The State's Motion to Exclude Dr. Wecker (R. pp. 7837–8092), its Reply in Support of its Motion to Exclude (R. pp. 8483–8524), and the oral hearing on the Motion to Exclude (R. pp. 143–181), incorporated herein by reference, provide more than adequate support for the trial court's rulings to exclude Dr. Wecker's testimony.

purported "survey" conducted by Janssen attorneys during depositions taken for this litigation) were immaterial to SCUTPA's "capacity or tendency to deceive" standard. *deBondt*, 324 S.C. at 269, 536 S.E.2d at 407. Further, and importantly, Janssen does not argue that Dr. Wecker's testimony, his "survey," or the depositions of the twenty doctors that formed the basis for the "survey" were relevant to the State's contention at trial that Janssen violated SCUTPA through "unfair"—as opposed to "deceptive"—conduct.

Relatedly, the trial court properly excluded the deposition testimony of the twenty South Carolina doctors that served as the basis for Dr. Wecker's "survey." Like the "survey," that testimony was inadmissible under Rule 403 because it had no probative value coupled with a significant danger of unfair prejudice given the unrepresentative and unreliable nature of the twenty-doctor, skewed "sample." The deposition testimony of those doctors would also have been cumulative because the trial court had already allowed other doctors to testify that they did not feel that Janssen had disseminated false or misleading information and that they were not misled. (*See* R. pp. 2088–2089.) The doctors' testimony was also irrelevant to the State's claims and burden of proving that Janssen's labeling and communications regarding Risperdal had the "capacity or tendency to deceive" or were unfair.

Lastly, the "Latuda" and Zyprexa prescription drug labels issued post-2007 and -2010 were irrelevant to the jury's consideration of representations made in the Risperdal labeling primarily because they postdated the period for which the State sought penalties. *See, e.g.*, *Bolen v. Strange*, 192 S.C. 284, 292, 6 S.E.2d 466, 469 (1939) (finding evidence regarding defendant's actions occurring after the alleged negligent event were irrelevant); *Najarian v. Charlotte Russe, Inc.*, No. CV 07-501-RGK, 2007 U.S. Dist.

LEXIS 95606, at *7 (C.D. Cal. Aug. 16, 2007) (excluding evidence as irrelevant because it postdated plaintiff's allegations of willful violations of the Fair and Accurate Credit Transactions Act); *Rosentreter v. Munding*, No. 89 C 5691, 1991 U.S. Dist. LEXIS 18121, at *45–46 (N.D. Ill. Dec. 26, 1991) (excluding evidence of written policy as irrelevant because it postdated the events giving rise to dispute). Those other drugs' *post hoc* labels would likewise have confused the jury because they had no relationship with or connection to Risperdal. *See* S.C. R. Evid. 403. Therefore, the trial court did not abuse its discretion by excluding them.

V. THE STATE'S OPENING AND CLOSING REMARKS WERE WITHIN PROPER BOUNDS.

In *Branham v. Ford Motor Co.*, 390 S.C. 203, 701 S.E.2d 5 (2010), this Court stated, "The test for granting a new trial on the basis of improper . . . argument is whether the complaining party was prejudiced to the extent that he or she was denied a fair trial." *Id.* at 235, 701 S.E.2d at 22. There, the plaintiff sought punitive damages and the plaintiff's attorney emphasized inadmissible anecdotes of other, similar incidents during closing argument, urging that the jury punish the defendants not only for the plaintiff's injuries, but also for non-parties' injuries. *Id.* at 234–35, 701 S.E.2d at 21–22; *see also id.* ("[Plaintiff] is here today with a brain injury and six hundred other people, or however many it is, lost their lives, and numerous others have brain injuries or are paralyzed, quadriplegic, have extremely serious injuries. We believe that you should tell Ford Motor Company what you think about this kind of thing."). This Court determined that the plaintiff's attorney's heavy reliance on such non-evidence invited the jury to base its decision on passion rather than reason and that the defendants were thereby denied a fair trial. *See id.*

Branham is Janssen's lone case in support of its demand for a new trial based on the State's opening and closing remarks. But, the trial of this case cannot be likened to *Branham*. The State's counsel did not discuss inadmissible evidence in opening or closing remarks, the State did not seek punitive damages, and the jury did not determine damages or penalties. Further, evidence and argument related to Janssen's projected and actual Risperdal sales and profits were admissible to demonstrate, *inter alia*, that Janssen willfully violated SCUTPA, and that Janssen's violative conduct adversely affected the public interest. (*See* R. p. 248, line 15–p. 251, line 12; p. 252, lines 4–8.) Without more, Janssen is not entitled to a new trial on the basis of the State's opening and closing remarks.

VI. THE DDMAC LETTERS WERE PROPERLY ADMITTED.

Janssen's argument that the FDA Division of Drug Marketing, Advertising, and Communications ("DDMAC") April 2004 Warning Letter, (R. pp. 3107–3111), should have been excluded is without merit. The letter was not hearsay, let alone inadmissible hearsay, and it did not confuse or mislead the jury and was not unfairly prejudicial under Rule 403. The same arguments apply to the 1994, (R. pp. 3397–3405), and 1999, (R. pp. 3102–3107), DDMAC letters, which the trial court also correctly admitted.

First, the DDMAC letters were not hearsay because they were not offered to prove the truth of the matter asserted—i.e., that Janssen's Dear Doctor Letter and the promotional conduct referenced in the 1994 Pre-Marketing Letter and the 1999 Notice of Violation were "false and misleading" as a matter of law. *See* S.C.R. Evid. 801(c). The State did not claim that because the FDA deemed the Dear Doctor Letter false and misleading in the 2004 Warning Letter, the Dear Doctor Letter was therefore "deceptive" or "unfair" as a matter of law under SCUTPA. That ultimate question was for the jury to

determine based upon all the evidence presented, and the jury was so charged. *See supra* Part II.

Whether its conclusions are right or wrong, then, the 2004 Warning Letter was offered only to show that the FDA had undertaken a review of the Dear Doctor Letter, why the FDA engaged in such a review, and the official conclusions that the FDA reached, among other non-hearsay reasons discussed below. "An out of court statement is not hearsay if it is offered for the limited purpose of explaining why a government investigation was undertaken." *State v. Brown*, 317 S.C. 55, 63, 451 S.E.2d 888, 893–94 (1994). Of course, Janssen was free to offer admissible evidence countering those facts and conclusions, and it did so.

Nor did the State take the position at trial that because the FDA deemed Janssen's promotional conduct referenced in the 1994 Pre-Marketing letter and the 1999 Notice of Violation false and misleading, it was therefore "deceptive" or "unfair" under SCUTPA. Indeed, the State did not contend that those letters violated SCUTPA. Again, whether their conclusions are right or wrong, the 1994 Pre-Marketing letter and the January 1999 Notice of Violation were offered only to show that the FDA had undertaken a review of Janssen's promotional materials, why the FDA engaged in such a review, and the official conclusions that the FDA reached. *See, e.g.*, *State v. Thompson*, 352 S.C. 552, 558–59, 575 S.E.2d 77, 81 (Ct. App. 2003). And, Janssen was free to offer admissible evidence countering those facts and conclusions. As the DDMAC letters were not introduced to prove the truth of the matter asserted, they were not hearsay.

Assuming *arguendo* that the DDMAC letters were hearsay, they fell within the "Public Records and Reports" exception to the hearsay rule. *See* S.C.R. Evid. 803(8).

That exception specifically exempts the "[r]ecords, reports, statements, or data compilations, ***in any form***, of public offices or agencies, setting forth (A) the activities of the office or agency, or (B) *matters observed pursuant to duty imposed by law* as to which matters *there was a duty to report.*" *Id.* (emphasis added); *see also, e.g., State v. Cutro*, 365 S.C. 366, 377, 618 S.E.2d 890, 896 (2005).

Janssen mischaracterizes the DDMAC letters as merely "preliminary conclusion[s]," which it argues are not covered by the Rule 803(8) "matters observed" exception. Yet, to characterize the 2004 Warning Letter as a "preliminary conclusion" is misleading in light of the FDA's conclusions reached therein—"DDMAC *has concluded* that the [Dear Doctor Letter] ***is*** false or misleading in violation of Sections 502(a) and 201(n) of the [FDCA] (21 U.S.C. 352(a) and 321 (n))" (R. p. 3107 (emphasis added)); and "[f]ailure to correct the violations . . . may result in FDA regulatory action, including seizure or injunction, ***without further notice***" (R. p. 3111 (emphasis added).) Additionally, the *Regulatory Procedures Manual*, which Janssen cites, further clarifies that the "Warning Letter was developed ***to correct violations*** *of the statutes or regulations*" and "[its use is] based on the expectation that most individuals and firms will voluntarily ***comply with the law***" as set forth in the Warning Letter. (R. pp. 7080–7081 (emphasis added).)

Likewise, with respect to the 1994 and 1999 DDMAC letters, the FDA reached similar conclusions regarding the "matters observed" therein: "The materials and promotional messages Janssen has disseminated ***contain*** false and/or misleading information about the safety and effectiveness of Risperdal. . . . Accordingly, Janssen *should* ***immediately discontinue*** *the use of all materials that state, suggest, or imply*

false, misleading, or unbalanced claims of the type discussed in this letter." (R. p. 3105 (1999 DDMAC Letter) (emphasis added)); "[DDMAC] offer[s] the following comments: . . . (15) 'excellent safety profile.' 'An outstanding safety profile that offers excellent potential for compliance.' These claims ***are misleading***. The adverse event rates of risperidone *are not consistent* with claims for an outstanding or excellent safety profile." (R. p. 3397, p. 3401 (1994 DDMAC Letter) (emphasis added).)

Additionally, to the extent that Janssen contends that Rule 803(8) does not apply to "information" that is "interpretive or opinion based," (*see* Appellant's Br. 39), the Rule's limitation as to "opinions, judgments, and conclusions" expressly applies only to "investigative *notes*," not to an agency's conclusions as here. S.C.R. Evid. 803(8) (emphasis added). And, Janssen's reliance on *State v. Pearson*, 223 S.C. 377, 76 S.E.2d 151 (1953) is misguided in that *Pearson* actually supports admission of the DDMAC letters. In *Pearson*, this Court observed that:

> Where public officers are under a ***duty to keep a record of transactions which occur in the course of their public service***, the ***official records and writings so made*** by such officers, or under their supervision, are of a public nature and are ***ordinarily admissible in evidence*** as proof of their contents, even though not proved by the person who actually made the entries. Such records are made under such circumstances which afford a sufficient guarantee of trustworthiness to render them admissible as evidence under a well-defined exception to the Hearsay rule.

Id. at 381, 76 S.E.2d at 153 (emphasis added). Janssen may not credibly contend that the DDMAC letters were not issued pursuant to a legal "duty" of the FDA. (*See* Appellant's Br. 40.) Pursuant to the FDCA, 21 U.S.C. § 301 *et seq.*, the FDA has authority to regulate drug marketing. *See* 21 C.F.R. § 202.1 (2006). Under FDA regulatory procedure, "warnings letters are issued by the DDMAC Division Director and receive concurrence from appropriate officials in the Center for Drug Evaluation and Research"

("CDER") for "violations of regulatory significance" which must be "promptly and adequately corrected." *FDA Regulatory Procedures Manual* § 4-1-1 (2008); *CDER Handbook* at 53–54, Warning Letter, *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM198415.pdf (last visited Apr. 30, 2012) ("Warning letters are written communications from FDA, in this case DDMAC, to a company notifying the company that DDMAC considers one or more promotional pieces or practices to be in violation of the law.").

Finally, the letters' admission did not prejudice Janssen under Rule 403. The jury was reasonably able to understand the information in the DDMAC letters, thus distinguishing between liability under SCUTPA as opposed to violation of the FDCA or FDA regulations. The letters were probative of whether Janssen knew or should have known that its alleged conduct was deceptive or unfair and whether Janssen's conduct adversely affected the public interest.[19] The letters were also relevant to and placed in issue by Janssen's "safe harbor" and federal preemption arguments. *See* discussion *supra* Parts I.A–B, II. By way of example, it would have been unfairly prejudicial to the State had Janssen been permitted to contend that it complied with all FDA rules and regulations so as to satisfy its "safe harbor" SCUTPA defense, yet simultaneously exclude the DDMAC letters—evidence indicating Janssen had not so complied. *See supra* Part I.B.

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[19] For example, the 1994 and 1999 DDMAC letters were admissible to show that Janssen's conduct related to the 2003 Dear Doctor Letter had the potential for repetition and, therefore, adversely affected the public interest. *See* discussion *supra* Part IV.A. The letters were admissible to show the potential for repetition because they are probative of similar past conduct and whether Janssen's "procedures create[d] a potential for repetition of the unfair and deceptive acts." *Wright*, 372 S.C. at 30, 640 S.E.2d at 502.

Janssen additionally argues that admission of the DDMAC letters was prejudicial because they are purportedly only "informal and advisory" and do not constitute final agency actions. As noted, there is no requirement under the South Carolina Rules of Evidence that the DDMAC letters be evidence of "final" agency action to come within the hearsay exception in Rule 803(8)(B), so Janssen's argument in that regard is a nonstarter.[20] Moreover, both the State and Janssen presented their positions about the FDA investigations and conclusions described in the DDMAC letters, as well as the meaning of "false," "misleading," and other terms used therein.[21] Both sides also presented expert testimony about those matters, including the accuracy of the conclusions set forth in the DDMAC letters.[22] With that assistance, the jury could understand the information contained in the DDMAC letters and not be misled or confused about standards of liability. Thus, the use of the DDMAC letters at trial did not convey the appearance of presumptive wrongdoing.

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[20] In sharp contrast to these proceedings, all of the cases Janssen cites involved far different circumstances—i.e., where the question of whether *final agency action* had occurred *was decisive*. *See State ex rel. McGraw v. Johnson & Johnson*, 704 S.E.2d 677, 687–90 (W. Va. 2010) (reversing and remanding for new trial the trial court's *summary judgment ruling* that dear doctor letter and promotional material were false and misleading as a matter of law where trial court gave *final effect* to DDMAC's determination in warning letters that statements at issue were false and misleading); *Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 944 (D.C. Cir. 2012) (holding that appellants had *no cause of action under the federal Administrative Procedure Act*, which requires a final agency action as a prerequisite to bringing suit thereunder, because the letters at issue "did not mark the consummation of the FDA's final decisionmaking"); *Schering-Plough Healthcare Prods. v. Schwarz Pharma, Inc.*, 586 F.3d 500, 508 (7th Cir. 2009) (concluding that letters from "subordinate officials of the FDA" were not "final agency action *binding on the district court*" (emphasis added)).

[21] *See, e.g.*, R. pp. 332–338 (opening argument by the State regarding the 2004 Warning Letter and related events); R. p. 2426, p. 2440 (closing argument by the State regarding 1999 Notice of Violation and 2004 Warning Letter); R. pp. 2455–2456 (closing argument by Janssen regarding all three DDMAC letters).

[22] *See, e.g.*, R. pp. 531–552 (testimony of State's expert Dr. Wirshing regarding 2004 Warning Letter); R. pp. 730–733 (testimony of State's expert Dr. Plunkett regarding 1994 Pre-Marketing Letter); R. pp. 1068–1075 (testimony of Dr. Plunkett regarding 1999 Notice of Violation); R. pp. 782–784 (testimony of Dr. Plunkett regarding 2004 Warning Letter); R. pp. 1780–1818, pp. 1919–1922 (testimony of defense witness Michael Chester, J.D. regarding 2004 Warning Letter and related events); R. pp. 1828–1834, pp. 1836–1846, pp. 1907–1915 (cross-examination of Mr. Chester regarding same).

And, in any event, the trial court cured any prejudice arguably suffered by Janssen as to the DDMAC letters through the court's instruction regarding the limited import of violations of federal law and regulations. (R. p. 2524.) *See supra* Part I.A.3.

VII. THE JURY INSTRUCTIONS AND VERDICT FORM WERE PROPER.

Janssen submitted a thirty-instruction request for charge to the trial court together with a sixteen-page verdict form to cover the State's two claims of statutory penalties under SCUTPA. The court reasonably rejected much of Janssen's proposed charge, opting for straightforward, easily understood jury interrogatories. The verdict form tracked SCUTPA's statutory language and relevant South Carolina case law.

Despite opposing authority, Janssen essentially argues that the FTC Policy Statement on Unfairness supersedes this and other South Carolina courts' sound interpretations of SCUTPA. Janssen claims that, consistent with the FTC Policy Statement on Unfairness, the challenged act must have caused or be 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." (Appellant's Br. 43–44.) Additionally, "the act must have violated a well-established public policy." (*Id.*) Under Janssen's misguided reasoning, that greater burden of proof is also required to establish SCUTPA violations under S.C. Code Ann. § 39-5-20(a). (*See id.*) Applying this novel, quasi-common law standard to SCUTPA and the jury verdict, Janssen concludes that the trial court erred in refusing to give Janssen's proposed instruction "about 'substantial injury'" or "to explain the limited role of 'public policy.'" (*Id.* at 44.) However, Janssen's proposed standard is inscrutable and inapplicable.

The State was not required to prove that the Dear Doctor Letter or Risperdal label was "likely to cause substantial injury to consumers" or demonstrate any proof relative to a "substantial injury." (*Id.* at 43–44.) All relevant South Carolina and federal case law makes clear that while "substantial injury" may be probative of "unfairness" under SCUTPA, it is not required to prove a violation thereof. *See, e.g.*, *Wright*, 372 S.C. at 23, 640 S.E.2d at 498 (defining "unfair" (quoting *Wogan v. Kunze*, 366 S.C. 583, 606, 623 S.E.2d 107, 120 (Ct. App. 2005))); *see also Bessinger*, 305 F. Supp. 2d at 582. In fact, notwithstanding Janssen's proposed FTC standard, "substantial injury" is not even required to prove "unfairness" under the FTC Act. *See Spiegel, Inc. v. FTC*, 540 F.2d 287, 293 (7th Cir. 1976) ("A practice is unfair when it offends established policy and when the practice is immoral, unethical, oppressive, unscrupulous ***or*** substantially injurious to consumers." (emphasis added)). Further, in order to demonstrate public impact, the State is not required to demonstrate that public policy was violated. As explained above, *see supra* Part IV.A, the State may show the same kind of actions occurred in the past, thus making it likely they will continue to occur absent deterrence; that the company's procedures create a potential for repetition of the unfair and deceptive acts; or, *any other* evidence demonstrating the potential for repetition. *See Daisy Outdoor*, 322 S.C. at 492, 473 S.E.2d at 49; *see also Wright*, 372 S.C. at 23, 640 S.E.2d at 498; *Wogan*, 366 S.C. at 606, 623 S.E.2d at 120.

The trial court, thus, correctly ruled that it would charge based upon *South Carolina* courts' interpretations of SCUTPA where there was controlling South Carolina precedent, rather than based on FTC cases, policy statements, and the like. *See, e.g.*, *Liberty Mut. Ins. Co. v. Employee Res. Mgmt., Inc.*, 176 F. Supp. 2d 510, 515–16 (D.S.C.

2001) (rejecting defendants' motion to limit plaintiff's SCUTPA action pursuant to S.C. Code Ann. § 39-5-20(b) "to instances of consumer protection or antitrust activity, because the FTC Act . . . is so limited"); *see also Bostick Oil, Co. v. Michelin Tire Corp.*, 702 F.2d 1207, 1220 (4th Cir. 1983). Thus, the trial court properly relied on this Court's interpretation of "unfair" under *South Carolina* consumer protection law in *Gentry v. Yonce*, 337 S.C. 1, 522 S.E.2d 137 (1999). (*See* R. p. 2485, p. 2526.)

Finally, the verdict form was proper. Janssen complains that the trial court erred in rejecting Janssen's proposed verdict sheet requiring separate findings as to "deceptive" and "unfair" and as to all the elements of the State's claims in order to avoid a verdict based solely on Janssen "somehow '[breaking] the [FDA] rules'" or being "motivated by profits" on only "one occasion." (Appellant's Br. 46.) But, Janssen cites no authority suggesting that separate interrogatories must be included for each element of "deception" and "unfairness."[23] In any event, the court did separately address what constituted an "unfair" versus a "deceptive" practice under South Carolina law in its detailed charge. (R. pp. 2485–2486.) With respect to the verdict form, the trial judge has the discretion to determine whether to submit special interrogatories. S.C.R. Civ. P. 49(b); *Constant v. Spartanburg Steel Prods., Inc.*, 316 S.C. 86, 90, 447 S.E.2d 194, 196 (1994); *see* 9 *Moore's Federal Practice* 3D § 49.11[2][a], at 49-16 (1997) ("Rule 49 is a rule of discretionary implementation, solely in the control of the trial judge. No party has a right to the use of a special verdict."); *see also Steele v. Dillard*, 327 S.C. 340, 343, 486 S.E.2d

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[23] As an initial matter, because Janssen has advanced only a "blanket conclusion and provides no authority supporting [its] argument" in this regard, this Court need not consider it. *Colleton County Taxpayers Ass'n v. Sch. Dist.*, 371 S.C. 224, 241, 638 S.E.2d 685, 694 (2006); *see also Glasscock, Inc. v. U.S. Fid. & Guar. Co.*, 348 S.C. 76, 81, 557 S.E.2d 689, 691 (2001) ("South Carolina law clearly states that short, conclusory statements made without supporting authority are deemed abandoned on appeal and therefore not presented for review.").

278, 279-80 (Ct. App. 1997). The Court should reject Janssen's verdict form complaints.

VIII. THE TRIAL COURT'S PENALTY AWARD SHOULD BE UPHELD AS AUTHORIZED AND VALID PURSUANT TO APPLICABLE STATE AND FEDERAL LAW AND WITHIN THE TRIAL COURT'S SOUND DISCRETION.

SCUTPA allows the assessment of civil penalties up to $5,000 *per violation*. S.C. Code Ann. § 39-5-110(a). In South Carolina, there can be "no error of law in imposing a fine within the limits authorized by [SCUTPA]." *C & L Corp.*, 280 S.C. at 528, 313 S.E.2d at 340. "Within those limits, the amount of the fine was a matter for the judge's discretion." *Id.* The party challenging a discretionary ruling of the trial court has the burden of showing a clear abuse of discretion. *Id.* (citing *Watson v. U.S. Rubber Co.*, 260 S.C. 129, 194 S.E.2d 395 (1973)). Further, any constitutional challenge to a SCUTPA penalties award must be decided under a "grossly disproportionate" standard—i.e., the Court may find a violation only if the penalty is "grossly disproportionate to the gravity of defendant's offense." *United States v. Bajakajian*, 524 U.S. 321, 334 (1998); *accord St. Louis, Iron Mt. & S. Ry. Co. v. Williams*, 251 U.S. 63, 67 (1919).

Janssen has not carried its burden here to show that the trial court abused its discretion with respect to the Court's "counting" of violations or assessment of penalties within SCUTPA's permissible range. Janssen likewise fails to demonstrate the unconstitutionality of the penalty award—i.e., that the award is grossly disproportionate to Janssen's bad faith conduct.

A. The Trial Court's Penalty Award as to the Risperdal Label Is Legally and Factually Correct.

The trial court considered "each publication of the Risperdal label (package insert), by way of sample [of Risperdal], to prescribers in the State of South Carolina until April 23, 2007, to be a separate [SCUTPA] violation." (R. p. 42.) The jury found

that Janssen willfully "engaged in unfair or deceptive acts or practices in the conduct of any trade or commerce in its label (package insert)." (R. pp. 3030–3031.) In its discretion, in accordance with the proof at trial and at the penalties phase, the trial court awarded a $300 penalty for each of 509,499 package inserts that were distributed in South Carolina to patients through their physicians from 1994 until April 23, 2007. (R. p. 42.) The total penalty awarded for the label unanimously found by the jury to be unfair and deceptive was $152,849,700. (*Id.*) In its Brief, Janssen attempts to refashion the trial court's Penalty Order to fit its misguided arguments against the labeling penalty. This Court should reject that effort.

First, the trial court's award does not overlook or run contrary to the learned intermediary doctrine, as Janssen mistakenly contends. (*See* Appellant's Br. 48.) The Penalty Order's statement that "the label . . . would be the most likely source of information for patients who are considering entering into ongoing therapy with the drug," (R. p. 42), does not signify that the patient's prescriber is *excluded* from conveying the information contained in the label to the patient. In any event, there can be no disagreement that the *purpose* of prescription drug labeling, whether directed at physicians or patients, is to provide the essential "information needed for the safe and effective use of the drug" *ultimately by the patient*. 21 C.F.R. § 201.56(a)(1) (2006); *see id.* § 201.57(a)(10) (labeling must contain "information . . . critical to safe use of the drug" by the patient "and measures that can be taken to prevent or mitigate harm"). Thus, the Penalty Order recognizes that it is "likely" that patients "would rely on their physicians and their physicians' recommendations . . . and knowledge" based on information contained in the package insert included with every sample of Risperdal

distributed in South Carolina. (Appellant's Br. 48.) That determination was consistent with the record testimony.[24]

Second, for reasons shown above, Janssen's contention that the Risperdal label did not deceive or was unlikely to deceive patients is without merit. (*See* Appellant's Br. 49.) Whether there was "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," (*id.*), ignores the foundational legal premise that the State was not required to prove actual deception or reliance. *See supra* Part IV.A. Moreover, Janssen's attempt to characterize this case as a dispute over the *placement* of information purportedly "already" contained in the label ignores critical Warnings that were entirely omitted from the label during the relevant time period. *See supra* Part IV.A. Lastly, the State's expert witnesses repeatedly and expansively distinguished the critical, primary importance of the label's Warnings section as compared to posterior, less weighty subsections. (R. p. 438, line 1–p. 440, line 7; p. 539, lines 4–9; p. 544, lines 21–22; p. 705, lines 10–23; p. 708, line 22–p. 712, line 16.)

Third, Janssen's complaint about the general verdict form ignores the evidence and the jury's verdict, as discussed above. *See supra* Part VII. Janssen contends that

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[24] R. p. 434, lines 4–6 (Dr. Wirshing: "Q: And do you read and rely on product labels like this in your practice? A: Yes, to, to a certain degree. Absolutely."); R. p. 546, lines 8–24 (Dr. Wirshing: ("Q: Doctor, what role does the warning section play in determining which drug you're [going to] use in patients on atypical antipsychotics? A: . . . . [These drugs] distinguish themselves on toxic, toxic profile. So, you pick the drugs based on their specific toxic profile. So, that really becomes the paramount issue. Trying to select a particular patient to a drug, you really select toxicities. That's what you're doing. Q: So, whether there's a warning or not on a drug can have a significant effect on your prescribing decision, right? A: Oh, absolutely.") R. p. 701, lines 5–8 (Dr. Plunkett: "Q: And is the ultimate purpose of drug labeling so that patients can use drugs safely? A: Yes, so physicians can prescribe drugs and patients can use them safely."); R. p. 375, lines 1–4 (Janssen scientist Dr. Magali Haas: "Q. Do you expect to know material safety information about drugs if you treat a patient? A. I can read the package insert to find out what is known about the compound.")).

"[b]ecause the verdict form was non-specific, there is no way of knowing what 'inadequacy' prompted the verdict." (Appellant's Br. 49.) But, Janssen overlooks the State's evidence that the label was deceptive or unfair throughout the time period from 1994 to 2007. *See supra* pp. 3–14, Part IV.A. Therefore, viewing the evidence and its reasonable inferences in the light most favorable to the State, it simply cannot be said that the trial court's Penalty Order is wholly unsupported by the evidence that the label violated SCUTPA throughout the relevant time period. *See, e.g.*, *Norton*, 350 S.C. at 478–79, 567 S.E.2d at 854. The trial court, in its sound discretion, tied the package insert penalties award to the jury's liability verdict as to all Risperdal sample package inserts during the relevant time period.

B. The Trial Court's Dear Doctor Letter Penalty Award Is Also Legally and Factually Correct.

The trial court also awarded a total of $174,224,000 for the jury's finding that Janssen's November 2003 Dear Doctor Letter was unfair or deceptive. (R. p. 43.) The award assesses $4,000 for every Dear Doctor Letter mailed to a South Carolina address and for each sales call visit occurring between November 10, 2003 (the Letter's date) and July 21, 2004 (the Correction Letter's date). Janssen's arguments that the trial court's count of violations is in error must be rejected for at least the following reasons.

First, the failure to disclose relevant information is actionable under SCUTPA. *See York v. Conway Ford, Inc.*, 325 S.C. 170, 172–73, 480 S.E.2d 726, 727–28 (1997); *Ward*, 304 S.C. at 157, 403 S.E.2d at 313; *Inman v. Ken Hyatt Chrysler Plymouth, Inc.*, 294 S.C. 240, 242–43, 363 S.E.2d 691, 692 (1988). Janssen ignores the facts and law by overlooking its own failure to *disclose the truth* concerning unfair and deceptive misrepresentations in the Dear Doctor Letter while continuing to call upon South

Carolina doctors and promote Risperdal to them—which Janssen does not dispute. (*See* Appellant's Br. 47, 50.) It is also uncontested that Janssen promoted Risperdal to South Carolina doctors some 36,372 times while the Dear Doctor Letter was in circulation from November 2003 to July 2004. (R. p. 43.) There is no evidence that Janssen attempted to disclose the truth about the unfair or deceptive message in the Dear Doctor Letter until July 2004, after it was directed to do so by the FDA.

Further, Ms. Alderman's and other sales representatives' training materials concerning the Dear Doctor Letter prove that sales representatives were trained to promote Risperdal at the time as having "0%" diabetes risk, a marketing message consistent with the unfair and deceptive language in the Dear Doctor Letter itself. (R. p. 3164.) Lastly, it is undisputed that although Janssen received the FDA's Warning Letter in April 2004, demanding that Janssen correct the false, misleading, and misrepresentative statements in the Dear Doctor Letter, it waited three additional months (until July 2004) to distribute the Correction Letter to South Carolina prescribers and others—all the while continuing to promote Risperdal consistent with the Dear Doctor Letter. (R. pp. 778–789; pp. 1155–1156; pp. 3107–3111; pp. 3247–3248; pp. 3792–3794.)

Second, in relying on inapposite California and Arizona law discussing the legislative intent of those states' legislatures, Janssen disregards SCUTPA's express language permitting the trial court to assess a civil penalty "not exceeding five thousand dollars *per violation*." S.C. Code Ann. § 39-5-110(a) (emphasis added). The Court should be mindful of the purpose behind SCUTPA and its statutory penalties: "The purpose of the UTPA is to discourage unfair methods of competition and unfair or

deceptive acts in the conduct of *any trade or commerce*." *Taylor*, 331 S.C. at 579, 503 S.E.2d at 460 (emphasis added). It follows that the South Carolina General Assembly would seek to "avoid[] a situation in which the statutory penalty would be regarded by potential violators of [the Act] as nothing more than an acceptable cost of violation rather than as a deterrence to violation," just as the United States Supreme Court divined to be Congress's intent relative to the FTC Act. *United States v. ITT Cont'l Baking Co.*, 420 U.S. 223, 232 (1975), *cited in United States v. Reader's Digest Ass'n, Inc.*, 662 F.2d 955, 966–67 (3d Cir. 1981); *see also* S.C. Code Ann. § 39-5-20(b).

Thus, it is not enough for the trial court to have merely counted each mailed copy of the Dear Doctor Letter alone and assess penalties thereon. It is uncontested that Janssen mailed 7,184 Dear Doctor Letters to South Carolina recipients. (Appellant's Br. 47.) It is also uncontroverted that Janssen continued to follow up with personal presentations of the Dear Doctor Letter and its unfair and deceptive marketing message to South Carolina prescribers and their office personnel throughout the relevant time period.[25] Ms. Alderman admitted that sales representatives showed prescribers the Dear Doctor Letter during sales calls. *See* discussion *supra* p. 41. This testimony confirmed documentary evidence regarding sales representatives' training on the rollout of the Dear Doctor Letter. *See supra* p. 41. Plainly, the trial court recognized that a simple count of the mailed Dear Doctor Letters would be incomplete and an inadequate "discourage[ment of] unfair methods of competition and unfair or deceptive acts in the conduct of any trade

[25] The Court should note there is no record evidence (and Janssen cites none in its Brief) supporting the contention that the "physicians upon whom Janssen's sales representatives called . . . were the very physicians who had received the letter [by mail] in the first place." (Appellant's Br. 50–51.)

or commerce." *Taylor*, 331 S.C. at 579, 503 S.E.2d at 460.[26]

C. The Trial Court Faithfully Applied the *Reader's Digest* Factors.

As guidance for its penalty award, the trial court considered and soundly applied each of the factors set forth in *United States v. Reader's Digest Ass'n*, 662 F.2d 955 (3d Cir. 1981), notwithstanding Janssen's contentions.

1. The Jury Verdict and the Record Below Support the Trial Court's Finding of Bad Faith.

Janssen essentially contends that the trial court's finding of "bad faith," in applying the *Reader's Digest* factors, is based on a faulty assumption because it cannot be determined whether the jury considered the nondisclosure of Trial 113 and "other 'studies' relating to weight gain and diabetes risk" to be the basis for the jury's finding. (*See* Appellant's Br. 20.)

As a preliminary matter, the jury found that Janssen's conduct was "willful," meaning that Janssen knew or should have known that its conduct violated SCUTPA. *See* S.C. Code Ann. § 39-5-110(c). "Bad faith" has been defined under South Carolina law as "[t]he opposite of good faith, generally implying or involving actual or constructive fraud, or a design to deceive or mislead another, . . . not promoted by an honest mistake as to one's rights or duties, but by some sinister motive." *Estate of Carr*

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[26] Janssen relegates to a footnote its complaint that the trial court "did not explain its finding that the 'appropriate penalty' was '$4,000.00 per violation.'" (Appellant's Br. 50 n.15.) Perhaps Janssen's overemphasis on *In re Treatment & Care of Luckabaugh*, 351 S.C. 122, 568 S.E.2d 338 (2002), caused it to overlook the Court's more recent pronouncements as to South Carolina Rule of Civil Procedure 52(a), declaring the Rule to be "directorial in nature" and requiring only that the trial court "substantially compl[y]" with it. *Mathis v. Brown & Brown of S.C., Inc.*, 389 S.C. 299, 320, 698 S.E.2d 773, 784 (2010); *accord Dixon v. Besco Eng'g, Inc.*, 320 S.C. 174, 179, 463 S.E.2d 636, 639 (Ct. App. 1995) ("Rule 52(a), SCRCP, is directory; noncompliance alone does not invalidate the judgment . . . ."). Moreover, as stated above, "[w]ithin [the] limits [defined by SCUTPA], the amount of the fine was a matter of the judge's discretion." *C & L Corp.*, 280 S.C. at 528, 313 S.E.2d at 340. Therefore, the trial court was free to award the full penalty for all violations supporting the jury's verdict; but in the trial court's sound discretion, it decided that the evidence supported a lower penalty based on particular conduct, as described in the Penalty Order. (*See* R. pp. 27–43.)

v. Circle S Enters., 379 S.C. 31, 43, 664 S.E.2d 83, 88–89 (Ct. App. 2008). Certainly it is not a tremendous leap from the jury's finding of "willful" SCUTPA violations to the trial court's determination that Janssen acted in "bad faith" under the *Reader's Digest* test.

Further, Janssen's questioning the rationale behind the jury's verdict and, concomitantly, the Penalty Order is again resolved by reference to the evidence and South Carolina law. The trial court rightly found that Janssen's hiding the results of Trial 113 and other studies related to weight gain and diabetes risk reasonably supported the jury's verdict as to the Risperdal label. The trial court also had within its purview reasonable evidence supporting Janssen's knowing failure to include Warnings in its label concerning hyperprolactinemia risks during the entire relevant time period, 1994to 2007. *See supra* pp. 3–14 & Part I.B.

The same analysis applies to the Dear Doctor Letter, the evidence surrounding which the trial court found reasonably to support the verdict. The thrust of Janssen's argument concerning the Dear Doctor Letter is that it was "true"—at least technically or scientifically. (Appellant's Br. 53.) But, as the trial court correctly observed, not all the so-called "science"—the eight studies cited in the Dear Doctor Letter—"support[ed] the premise of the letter itself," despite the Dear Doctor Letter's representations otherwise. (R. p. 35; p. 683, line 19–p. 684, line 6; p. 1035, line 19–p. 1036, line 5; p. 1557, lines 4–16; p. 1565, lines 9–23.) More importantly, Janssen carefully avoids discussion of the most egregious language in the Dear Doctor Letter—i.e., that evidence shows that Risperdal is *not* associated with *any* increased risk of diabetes when compared to "untreated patients." *See supra* pp. 11–14. The State's expert, Dr. Wirshing, testified that the statement was "patently untrue." (R. p. 524, line 20–p. 525, line 22.) Further,

the trial court correctly recognized that Janssen issued the Dear Doctor Letter at the same time "the FDA was requiring . . . a warning concerning the dangers of [Risperdal and other antipsychotic drugs] and their increased risk of diabetes." (R. p. 35.) The trial court found that the Dear Doctor Letter's declaration of 'no diabetes risk' as compared to untreated patients—at the same time the FDA was requiring a diabetes Warning on Risperdal's label—together with other evidence "indicate[d] a conscious effort by the company to 'spin' the message, driven by marketing considerations, about Risperdal." (*Id.*) For those and other reasons, the trial court correctly found the "actions of the Company in regards to [the Dear Doctor Letter] exhibited extreme bad faith." (*Id.*)

2. *The Trial Court Correctly Found Evidence of Impact on the Public Interest.*

As discussed above, Janssen argues that because the State failed to prove that "anyone in South Carolina was harmed" by the Dear Doctor Letter or the Risperdal label, the Court was constrained to assess either a negligible penalty or no penalty at all. (*See* R. p. 2728.) Again, that argument is fundamentally contrary to controlling law. *State ex rel. McLeod v. Brown*, 278 S.C. 281, 285, 294 S.E.2d 781, 783 (1982) ("The trial court's second ground for dismissal was the State's alleged . . . inability to demonstrate . . . harm or damage to any citizen. [But, that] is [not] a prerequisite to an action under the Unfair Trade Practices Act."). *Cf. Williams*, 251 U.S. at 66–67 (holding that state penalties provisions addressing "public wrongs" ***need not be "confined or proportioned to [actual] loss or damages***" (emphasis added)). *See* discussion *infra* Part VIII.D. The trial court properly found sufficient evidence of impact on the public interest and awarded penalties designed to deter future, similar SCUTPA violations. *See supra* Part IV.A.

3. *Janssen Benefited from the SCUTPA Violations Because It Avoided the Market Share Losses It Feared as a Result of the 2003 Label Change.*

Janssen argues that, because the evidence purportedly showed that there was no impact on Janssen's market share as a result of the Correction Letter, there was no evidence of any benefit to Janssen by and through its deception. (Appellant's Br. 54–55.) But, that reasoning ignores the trial court's finding that "[i]t is clear . . . that if the aim of [Janssen's] actions . . . was to *protect* the market share of Risperdal[,] ***then it succeeded.***" (R. p. 39 (emphasis added).) And, the evidence demonstrated precisely that. One of the very first things Janssen did after it received word of the class warning from the FDA in 2003 was to measure the financial impact of various scenarios—outright compliance with the FDA labeling request, some modification of the class label, or avoidance of the class label altogether. *See supra* pp. 10–11. Ultimately, Janssen executives considered their strategy a success because the "[s]ales impact [was] minimal . . . due to Risperdal [being] viewed as positively differentiated from Zyprexa" after transmission of the Dear Doctor Letter. *See supra* p. 12.

In any event, the trial court was correct that its aim was "to penalize the actions of the Defendant[] and . . . not . . . to award damages based upon any measure of damages or ill-gotten gains." (R. p. 39.) Janssen's attempts to tie the penalties to some measure of unjust enrichment or other profits as a way to nullify the penalties are futile.

4. *The Penalty Award Vindicates the Authority of the South Carolina Attorney General to Enforce SCUTPA.*

Janssen contends, without citing any support, that this factor "does not apply . . .

where there was no agency order or injunction."[27] (Appellant's Br. 55.) Remarkably, Janssen further contends that the factor "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." (*Id.*) Janssen clearly gives very little credence to the General Assembly's legislative purpose behind SCUTPA. *See supra* pp. 60–61. Aside from the contention not being sufficiently briefed, the Court should reject Janssen's derogation of SCUTPA and the Attorney General's authority.

5. The Issue of Janssen's "Ability to Pay" Is Resolved.

Janssen contends that the trial court need not have considered Janssen's ability to pay because that factor only comes into play if the defendant argues an "inability to pay." (Appellant's Br. 55–56.) Whether or not that is true, Janssen does not argue an inability to pay—and therefore concedes an ability to pay the penalties award. That factor is, therefore, resolved in the State's favor. Both parties agree that Janssen has the ability to pay the penalties award.

D. The Penalty Award Is Neither Unconstitutionally Excessive Nor Violative of Janssen's Due Process Rights.

As something of an afterthought relegated to a handful of paragraphs at the back of its brief, Janssen contends the penalty award violates the Excessive Fines and Due Process Clauses of the South Carolina and United States Constitutions. The Court should give no weight to either contention.

With respect to the Excessive Fines Clause, the Court may find a violation only if the penalty is "*grossly* disproportional to the gravity of a defendant's offense." *Bajakajian*, 524 U.S. at 334 (emphasis added). "Because the standard is whether the fine

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[27] The argument is waived. *See supra* note 23.

is 'grossly disproportional,' the fine need only bear some relationship to the offense's gravity; this is not a proportionality inquiry." *United States ex rel. Tyson v. Amerigroup Ill., Inc.*, 488 F. Supp. 2d 719, 744 (N.D. Ill. 2007). Such an inquiry must recognize both that "judgments about the appropriate punishment for an offense ***belong in the first place to the legislature***" and that "any judicial determination regarding the gravity of a particular . . . offense will be inherently imprecise." *Bajakajian*, 524 U.S. at 334–36 (emphasis added). Legislative determinations regarding the assessment of civil penalties "represent the collective opinion of the . . . people as to what is and what is not excessive." *United States v. 817 N.E. 29th Drive*, 175 F.3d 1304, 1309 (11th Cir. 1999). Accordingly, the Court should factor into its analysis the maximum penalty prescribed by the General Assembly. *See United States v. Mackby*, 339 F.3d 1013, 1019 (9th Cir. 2003). Thus, "[c]ivil penalty awards in which the amount of the award is less than the statutory maximum do not run afoul of the Excessive Fines Clause." *United States v. Mackby*, 221 F. Supp. 2d 1106, 1110 (N.D. Cal. 2002) (and cases cited therein).[28]

Similarly, with respect to the Due Process Clause, the United States Supreme Court's well-settled precedent establishes that statutory penalties designed to address

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[28] *See 817 N.E. 29th Drive*, 175 F.3d at 1309 (observing that if the penalty assessed is within the range of fines prescribed by the legislature, "a strong presumption arises" that the penalty is constitutional); *Pharaon v. Fed. Reserve Sys.*, 135 F.3d 148, 156 (D.C. Cir. 1998) (holding that a $37 million penalty did not violate the Excessive Fines Clause because the penalty was "well below the statutory maximum [of $111.5 million]"); *United States v. Emerson*, 107 F.3d 77, 79 (1st Cir. 1997) (holding that "a fine one-half the size of that permitted by the relevant statute, assessing $5,000 for each of [defendant's] thirty-seven admitted violations rather than the statutory maximum of $10,000 per violation . . . though substantial, is constitutionally permissible"). Additionally, courts considering excessive fines challenges have expressly rejected any "no harm, no foul" argument—i.e., that there is no evidence of actual damages or injury—particularly in cases related to healthcare issues and public expenditures. *See, e.g., United States ex rel. Hobbs v. Medquest Assocs., Inc.*, No. 3:06-01169, 2011 U.S. Dist. LEXIS 126569, at *14 (M.D. Tenn. Oct. 21, 2011) (quoting *Mackby*, 339 F.3d at 1019). Therefore, any absence of demonstrated government loss or harm is not controlling. *Id.*; *see United States ex rel. Shutt v. Cmty. Home & Health Care Servs., Inc.*, 305 F. App'x 358, 361 (9th Cir. 2008) ("Given the seriousness of the offense . . . and the need to deter difficult-to-detect fraudulent [activity], Congress's decision to impose a penalty [under the federal False Claims Act] that may sometimes substantially exceed actual damages is not unreasonable.").

"public wrongs" need not be "confined or proportioned to [actual] loss or damages[;] as it is imposed as a punishment for the violation of public law, the Legislature may adjust its amount to the *public wrong* rather than the *private injury*." *Williams*, 251 U.S. at 66 (emphasis added). In *Williams*, the Supreme Court held:

> When [a statute] is considered with due regard for the interests of the public, the numberless opportunities for committing the offense, and the need for securing uniform adherence to [the law], ***we think it cannot be said to be so severe and oppressive as to be wholly disproportionate to the offense or obviously unreasonable***.

Id. at 67 (emphasis added). Accordingly, with respect to the statute at issue in *Williams* (a fixed penalty of $50 to $300 for each passenger overcharge in violation of lawfully prescribed railroad passenger rates), the Court recognized that "[w]hen the penalty is contrasted with the overcharge possible in any instance it of course seems large, but as we have said, its validity is not to be tested in that way." *Id.* This Court follows the *Williams* rule. *Shipman v. DuPre*, 222 S.C. 475, 483, 73 S.E.2d 716, 719 (1952) (affirming trial court's decision based on *Williams*, stating "[t]he amount of the forfeiture considered in light of the business transacted during a year cannot be considered so excessive or unreasonable as to violate due process when taken along with all of the other considerations upon which the legislative discretion may rest"); *see Moore v. Timmerman*, 276 S.C. 104, 108, 276 S.E.2d 290, 292–93 (1981) (relying on *Shipman* to hold that forfeiture statute at issue did not violate constitutional rights).[29]

Here, the trial court awarded four-fifths of the maximum allowable penalty attributable to the Dear Doctor Letter. (R. p. 43.) The lower court limited the penalty

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[29] Other courts' recent decisions likewise reaffirm the *Williams* rule. *See, e.g., Zomba Enters. v. Panorama Records, Inc.*, 491 F.3d 574, 587–88 (6th Cir. 2007); *Follman v. Village Squire, Inc.*, 542 F. Supp. 2d 816, 821–23 (N.D. Ill. 2007); *Arrez v. Kelly Servs., Inc.*, 522 F. Supp. 2d 997, 1008 (N.D. Ill. 2007); *Texas v. Am. Blast Fax, Inc.*, 121 F. Supp. 2d 1085, 1090–91 (W.D. Tex. 2000).

allocable to the Risperdal label to six percent of the maximum. Given the strength of the State's case—unquestionably demonstrating Janssen's unfair and deceptive conduct relative to the undisclosed dangers of Risperdal use and the concomitant health and welfare of South Carolinians, *see supra* pp. 3–14, as well as the "public impact" of Janssen's repeated violations, with literally hundreds of thousands of opportunities for Janssen to have brought its conduct into compliance with controlling law, *see supra* Part IV.A, it cannot be credibly argued that the penalty award is grossly disproportionate to the offense. *See Bajakajian*, 524 U.S. at 334. Nor may the penalty award be deemed "so excessive or unreasonable as to violate due process"—notwithstanding any absence of proof of the State's actual losses or damages—given the requisite deference to the legislature in fixing penalties to address public wrongs. *See Shipman*, 222 S.C. at 483, 73 S.E.2d at 719; *see also Williams*, 251 U.S. at 66–67. *Cf. Bajakajian*, 524 U.S. at 334–36.

Janssen also claims that no other court has ever imposed a penalty, much less a nine-figure penalty, based on the "inadequacy" of an FDA-approved label. Janssen overlooks that a Louisiana court has imposed an eight-figure penalty against Janssen for its conduct related to the Dear Doctor Letter *alone*. *See Caldwell ex rel. State of La. v. Janssen Pharm., Inc.*, No. 11-1184, 81 So. 3d 1012, 2011 La. App. Unpub. LEXIS 717, at *2–3 (La. Ct. App. Nov. 23, 2011). In addition, an Arkansas court has more recently imposed a $1.2 billion penalty against Janssen for its conduct related to the Dear Doctor Letter and Risperdal's label. *See* Katie Thomas, *J.&J. Fined $1.2 Billion in Drug Case*, N.Y. Times, Apr. 12, 2012, at B1.

Janssen's reliance on punitive damages cases in support of its due process contentions should be discounted. (Appellant's Br. 58–59 (citing *Mitchell v. Fortis Ins.*

Co., 385 S.C. 570, 686 S.E.2d 176 (2009) (relying on *BMW v. Gore*, 517 U.S. 559 (1996)) and *State Farm Mutual Auto Insurance Co. v. Campbell*, 538 U.S. 408 (2003))). The applicability of those cases and their punitive damages analyses and holdings is at best suspect because none of those cases account for the aforementioned deference to the legislature mandated by *Shipman* and *Williams*. Because such cases were "designed essentially to constrain the otherwise 'unregulated and arbitrary use of judicial power' inherent in punitive damages awards, their holdings are 'not implicated by [the Legislature's] carefully crafted and reasonably constrained' statutory damages regime." *Verizon Cal. Inc. v. OnlineNIC, Inc.*, No. C-08-2832-JF, 2009 U.S. Dist. LEXIS 84235, at *22 (N.D. Cal. Aug. 25, 2009) (citation omitted); *see Zomba Enters.*, 491 F.3d at 587 ("We know of no case invalidating such an award of statutory damages under *Gore* . . . ."); *Lowry's Reports, Inc. v. Legg Mason, Inc.*, 302 F. Supp. 2d 455, 459 (D. Md. 2004); *see also Amerigroup Ill.*, 488 F. Supp. 2d at 744 ("[T]he Due Process Clause does not apply to statutory damages").[30] The policy implications of *Campbell*, *Gore*, and *Mitchell* and those cases' related aims of reining in otherwise unfettered, jury-determined punitive damage awards are simply not present here.

Finally, the State reiterates that the Court should avoid a situation where Janssen considers the penalty nothing more than the cost of doing business in South Carolina. The penalty must instead deter violations of South Carolina law by Janssen and others. As shown, the trial court's penalty award satisfies but does not exceed that requirement.

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[30] Furthermore, Janssen's argument that the trial court improperly considered worldwide sales of Risperdal and profit information as reported in the annual report of Janssen's parent, Johnson & Johnson, should be discounted. The lower court considered such information only with respect to Janssen's "ability to pay" under the *Reader's Digest* factors, *see* discussion *supra* Part VIII.C.5, which Janssen has repeatedly argued is not in issue before both the trial court and this Court. (*See* R. pp. 40–42.) Thus, there is no error—and certainly no reversible error—with respect to the trial court's consideration of that evidence.

IX. THE LIABILITY VERDICT AGAINST JANSSEN AND CONCOMITANT SCUTPA PENALTIES DO NOT VIOLATE JANSSEN'S FIRST AMENDMENT FREE SPEECH PROTECTIONS.

It is fundamental to free speech jurisprudence that "[t]he government may ban forms of communication more likely to deceive the public than inform it, or commercial speech related to illegal activity." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 563–64 (1980)) (internal citations omitted); *see also Johnson v. Collins Entm't Co.*, 349 S.C. 613, 624, 564 S.E.2d 653, 659 (2002) ("For commercial speech to come within th[e First Amendment], it must at least concern lawful activity and not be misleading." (alteration in original) (quoting *Central Hudson* and *Video Gaming Consultants v. S.C. Dep't of Revenue*, 324 S.C. 34, 40, 535 S.E.2d 642, 645 (2000)) (internal quotation marks omitted)).

Here, the jury found that Janssen's false and misleading label and Dear Doctor Letter constituted deceptive and/or unfair conduct under SCUTPA. Janssen nevertheless contends such "speech" is entitled to First Amendment protections. Janssen seeks to avoid *Central Hudson*'s formidable barrier to its free speech contentions by wrongly arguing that the State was required to prove "actual malice" by "clear and convincing evidence" with respect to the false statements and representations supporting the State's SCUTPA claim. As opposed to "commercial speech," Janssen primarily asserts its Risperdal label and Dear Doctor Letter constitute "matters of public concern" entitled to heightened First Amendment protections.

A fatal flaw in Janssen's novel but ill-conceived argument is that not a single case cited by Janssen addresses—much less answers—the question of whether a promotional letter to doctors about Risperdal (the Dear Doctor Letter) and a commercial prescription drug label constitute "matters of public concern." (*See* Appellant's Br. 60–61 (citing,

inter alia, *Snyder v. Phelps*, 131 S. Ct. 1207, 1213–14 (2011) (involving picketing by church members at dead soldier's funeral); *Illinois ex rel. Madigan v. Telemarketing Assocs., Inc.*, 538 U.S. 600, 606 (2003) (limiting free speech protections attributable to charitable solicitation, which otherwise enjoys full First Amendment protections, in certain fraud cases); *Connick v. Myers*, 461 U.S. 138, 150 (1983) (involving an employee who was terminated for unprotected private speech and addressing the "particularized balancing" attributable to punishing government employees for speech at work))).

Janssen additionally cites two cases for the proposition that statements on scientific and medical research are matters of public concern. However, both of those cases are also inapposite. *Board of Trustees of Leland Stanford Jr. University v. Sullivan*, 773 F. Supp. 472 (D.D.C. 1991), addressed the issue of "the extent to which the government may curtail speech of a recipient of a government grant." *Id.* at 473. More specifically, *Sullivan* involved a prior restraint on speech set forth in a confidentiality clause requiring researchers to obtain government approval before publishing or otherwise publicly disseminating preliminary research results. *Id.* at 473–74. *McMillan v. Togus Regional Office, Department of Veteran Affairs*, 294 F. Supp. 2d 305 (E.D.N.Y. 2003), *aff'd* 120 F. App'x 849 (2d Cir. 2005), involved a plaintiff who sought declaratory judgment that the National Academy of Sciences and Institute of Medicine failed to adequately review scientific evidence concerning the association between herbicide Agent Orange exposure and illnesses among Vietnam veterans when conducting a study required by the Agent Orange Act. *Id.* at 306, 317. In stark contrast to the State's case, neither of those cases involved allegations of unfair or deceptive conduct, let alone illegal activity.

Furthermore, *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011), the case on which Janssen primarily relies, does not remotely touch upon false, misleading, deceptive, or unfair commercial speech and attendant First Amendment protections. *See id.* at 2672. *Sorrell* involved a state law that attempted to regulate the type of prescriber-identifiable information, such as pharmacy records, that a drug manufacturer could obtain and use for marketing purposes. *Id.* at 2659. Critically, the state in *Sorrell* "***never contend[ed]" that the marketing activity in question was "false or misleading within the meaning of [the Supreme Court's] First Amendment precedents***." *Id.* at 2672 (emphasis added). Nor did the state assert that the challenged provision would "prevent false or misleading speech." *Id.* Unmistakably, *Sorrell* has no bearing on the deceptiveness or unfairness of drug manufacturers' "commercial speech." Therefore, the decision side-stepped the applicable exception to First Amendment protections recognized in *Central Hudson*, *Video Gaming Consultants*, and similar cases.

Unlike Janssen's cited cases, the State here does not attempt to dictate how scientific or medical research should be conducted or stifle the sharing of medically related information as in *Sullivan* and *McMillan*. Nor does the State attempt to control what information drug manufacturers can obtain about doctors' prescribing habits and its use in marketing as in *Sorrell*. None of the cases Janssen cites will assist the Court in deciding the threshold matter of whether "public concern" First Amendment protections even apply here—and they do not.

Nor will they guide the Court in deciding whether an "actual malice" standard applies to Janssen's "speech" because none of the aforementioned cases adopted an "actual malice" standard of proof. The "actual malice" cases Janssen does cite—*New*

York Times v. Sullivan, 376 U.S. 254 (1964), and *Gertz v. Robert Welch, Inc.*, 418 U.S. 323 (1974), among others—are plainly inapt. All are media-related defamation and/or libel cases discussing the extent to which the *New York Times* "actual malice" standard applies, if at all, before finding liability. *See, e.g.*, *Gertz*, 418 U.S. at 346 ("We hold that, so long as they do not impose liability without fault, the States may define for themselves the appropriate standard of liability *for a publisher or broadcaster of defamatory falsehood injurious to a private individual.*" (emphasis added)); *Parker v. Evening Post Publ'g Co.*, 317 S.C. 236, 243, 452 S.E.2d 640, 644 (1994) ("[A] public official may recover damages for defamatory statements relating to his official conduct only if he proves . . . actual malice."). Janssen never explains how those media-related defamation cases fit any claim before this Court.

Thus, Janssen has not identified *any court* in *any jurisdiction* that has applied a broad "matter of public concern" First Amendment free speech guarantee, or a "clear and convincing" *New York Times* "actual malice" burden of proof, in *any action*—much less any SCUTPA action—concerning pharmaceutical companies' communications with prescribers in support of a for-profit prescription drug, such as the Dear Doctor Letter and Risperdal label here. The Court should reject Janssen's argument based on the sheer absence of authority for its application in this case.

CONCLUSION

For all the foregoing reasons, the State of South Carolina *ex rel.* Alan Wilson asks that the Court AFFIRM the trial court below.

Respectfully submitted,

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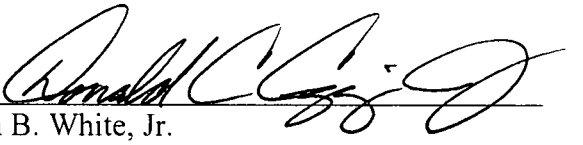
By: 
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Date: November 8, 2012
Columbia, South Carolina

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S.C. Supreme Court

CERTIFICATE OF COUNSEL

This is to certify that the Respondent's Final Brief complies with the South Carolina Appellate Court Rule 211(b).

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November 8, 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,

vs.

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

Of Whom Ortho-McNeil-Janssen Pharmaceuticals, Inc., is ..... Appellant.

PROOF OF DELIVERY

This is to certify that on the 8th day of November, 2012, the undersigned, litigation paralegal, Rose Fagan, for Harrison, White, Smith & Coggins, P.C., served copies of the **RESPONDENT'S FINAL BRIEF** by depositing a copy of the same into the United States Mail, postage pre-paid and in the correct amount to the following:

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Harrison, White, Smith & Coggins, P.C.

SWORN to before me this 8th day of November, 2012.

(SEAL)
NOTARY PUBLIC FOR SOUTH CAROLINA

My Commission Expires: MY COMMISSION EXPIRES JUNE 16TH, 2017

THE STATE OF SOUTH CAROLINA
In the Supreme Court

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vs.

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Of Whom Ortho-McNeil-Janssen Pharmaceuticals, Inc., is ..... Appellant.

AFFIDAVIT OF HAND DELIVERY

This is to certify that on the 8th day of November, 2012, the undersigned served a copy of the **RESPONDENT'S FINAL BRIEF** by hand delivering to the following:

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Lauren Deptula

SWORN to before me this 8
day of November, 2012.
Jennifer Gamble (SEAL)
NOTARY PUBLIC FOR SOUTH CAROLINA
My Commission Expires: 8/28/2016

THE STATE OF SOUTH CAROLINA
In the Supreme Court

APPEAL FROM SPARTANBURG COUNTY
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vs.

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

Of Whom Ortho-McNeil-Janssen Pharmaceuticals, Inc., is.....Appellant.

AFFIDAVIT OF HAND DELIVERY

This is to certify that on the 8th day of November, 2012, the undersigned served three (3) copies of the **RESPONDENT'S FINAL BRIEF** by hand delivering to the following:

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November 8, 2012

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The South Carolina Supreme Court
1231 Gervais Street
Columbia, SC 29211

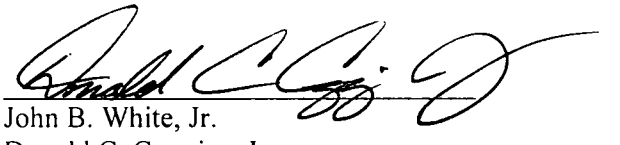
Re: State of South Carolina vs. Ortho-McNeil-Janssen Pharmaceuticals, Inc., et al
2007-CP-42-1438

Dear Mr. Shearouse:

I am enclosing an original and fourteen (14) copies of the Respondents' Final Brief, together with the Certificate of Counsel. I am also enclosing an Affidavit showing proof of service on opposing counsel.

Please do not hesitate to contact me if you should have any questions or require any further information.

Sincerely,
Harrison, White, Smith & Coggins, P.C.



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