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
Appellate Case No. 2012-206987

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

v.

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

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

Petition for Rehearing

Under Rule 221(a) of the South Carolina Appellate Court Rules, Appellant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Janssen") petitions for rehearing of the Court's opinion in *State of South Carolina* ex rel. *Alan Wilson, in his capacity as Attorney General of the State of South Carolina v. Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica, Inc., and/or Janssen, L.P.*, Op. No. 27502 (S.C. Sup. Ct. filed February 25, 2015) (Shearouse Adv. Sh. No. 8 at 31).

I.
INTRODUCTION

The Court's decision upholds an unprecedented award of $136 million in civil penalties for alleged conduct for which the Court acknowledges there was no proof of harm or even a likelihood of harm. The decision penalizes Janssen over $101 million because Janssen allegedly did not have a sufficient basis to represent, during the November 2003-July 2004 period in issue, that its breakthrough antipsychotic drug Risperdal causes less weight gain and has lower diabetes risk than other atypical antipsychotics like Zyprexa, Risperdal's leading competitor. Yet even the State's experts unequivocally admitted that Janssen's premise is now well-recognized and accepted to be true—Zyprexa causes substantially more weight gain and carries greater diabetes risk than Risperdal. The Court's decision nowhere acknowledges this undisputed fact.

The decision also penalizes Janssen over $34.5 million for including cautionary information about the long-known risk of hyperprolactinemia in the "Precautions" section of Risperdal's FDA-approved labeling rather than the "Warnings" section. But the FDA approved that placement, and the State did not allege that new risk information prompting a duty to move the information to the "Warnings" section emerged between the time of approval and the filing of the State's complaint in April 2007. Further, the Court affirms

this penalty amount despite the lack of any evidence that the intended audience for the drug label—physicians—was in any way misled by it.

The $136 million penalty is the highest civil penalty in the history of South Carolina, but is based on an interpretation of the South Carolina Unfair Trade Practices Act ("SCUTPA") that disregards the State Legislature's express directive that SCUTPA standards for deceptive and unfair trade practices be guided by nationally applicable federal standards administered under the FTC Act. By overlooking or misapprehending the Legislature's mandate, the Court subjected businesses operating in South Carolina to more stringent state-law standards that diverged from not only federal interpretations of the FTC Act, but also from the decisions of courts in the many other states that have likewise sought consistency with the FTC Act.

Rehearing is warranted on this and multiple other grounds. As detailed below, the Court's opinion overlooks or misapprehends facts and arguments critical to both its liability and its penalty determinations. Janssen therefore respectfully requests that the Court grant its petition for rehearing.

II.
SUMMARY OF ARGUMENT

Rehearing is warranted because the Court overlooked or misapprehended matters of fact and law that change the outcome in this case, including but not limited to the five matters set forth below.[1]

First, the Court overlooked or misapprehended the Legislature's directive that it apply the standards adopted by the Federal Trade Commission to assess whether chal-

[1] Janssen incorporates by reference its appellate arguments on the issues in their entirety and in no way waives any such arguments.

lenged conduct is deceptive or unfair. SCUTPA specifically directs the Court to look to standards adopted by the FTC for guidance. S.C. Code Ann. § 39-5-20(b) ("[T]he courts will be guided by the interpretations given by the Federal Trade Commission and the Federal Courts to § 5(a)(1) of the Federal Trade Commission Act ...."). Under those statutorily-applicable standards, the State was required to prove a tendency to deceive physicians or, for unfairness, a likelihood of substantial injury to consumers that was not reasonably avoidable. Yet the Court recognized that "[t]he risks associated with atypical antipsychotics were becoming well known by the late 1990s" and that evidence of the risks was "pervasive" by the early 2000s, "underscor[ing] Janssen's point that the community of prescribing physicians was well aware of the Risperdal risks." Op. No. 27502 at 58 n.22. And the Court acknowledged that the State had not proven that the "Dear Doctor Letter" ("DDL") or the Risperdal label caused any injury, and further that the evidence showed they were unlikely to do so. *Id.* at 53, 67. Under the FTC interpretations applicable by virtue of S.C. Code Ann. § 39-5-20(b), the verdicts on both the labeling and the DDL claims should be set aside.

Second, the Court misapprehended the impact of its statute of limitations holding on the viability of the labeling claim under SCUTPA's regulated activity exemption. The Court rejected Janssen's argument that the regulated activity exemption barred imposition of SCUTPA penalties for alleged inadequacies in Risperdal's FDA-approved label, holding that FDA regulations authorize and require manufacturers to strengthen the warnings in drug labels through the "changes being effected" (CBE) process "as new risks and side effects are discovered." Op. No. 27502 at 35-36 (citation omitted). But the Court did not evaluate whether the CBE process would have allowed Janssen to revise the Risperdal

label to correct any alleged deficiency that *continued into the limitations period.* By January 24, 2004, Janssen had already updated the Warnings section of Risperdal's label to include explicit warnings about the risks of diabetes and cerebrovascular adverse events (CVAE). The State alleged the label to be deficient during the limitations period *only* because information about hyperprolactinemia risk continued to appear under Precautions rather than Warnings. But to show that the CBE process was available to change the placement of that information, the State would have had to show that new or different information about the hyperprolactinemia risk emerged *after* the FDA approved its placement in the Precautions section. The State made no such showing as to hyperprolactinemia risk, and the regulated activity exemption therefore bars its claim.

Third, in the alternative, the Court should vacate the jury verdict on the labeling claim and remand it for a new trial. Much of the State's trial presentation focused on diabetes risk. But diabetes risk was added to the Warning section of Risperdal's label in October 2003, R. 3129, three months before the limitations period began. Likewise, CVAE risk was added to the Warnings section in April 2003, nine months before the limitations period began. The Court did not consider the impact of the trial court's erroneous statute of limitations holding on the jury, which was not instructed to limit its verdict to conduct occurring after January 24, 2004. The trial court improperly allowed the jury to base its verdict entirely on conduct barred by the statute of limitations. This requires, at a minimum, a new trial.

Fourth, the Court overlooked record evidence when it applied the statute of limitations to the penalty imposed by the trial court on the labeling claim. The trial court's penalty calculation was based on the number of Risperdal sample boxes distributed in

South Carolina from 1998 through the date of the Complaint, April 23, 2007. Because "it was error [for the trial court] to award the State civil penalties for violations in connection with the labeling claim outside the statute of limitations," Op. No. 27502 at 60, the Court found it necessary to determine the number of sample boxes distributed during the limitations period. But the Court's attempt to estimate that number using a per-visit average computed from the 1998-April 2007 total greatly overstates the true number of sample boxes distributed during the limitations period. Evidence overlooked by the Court establishes that the *actual* number of sample boxes distributed during the limitations period was 117,007 less than what the Court estimated, and the Court's calculation therefore overstated the penalty on the labeling claim by $11,700,700.

Fifth, when it upheld the trial court's determination on the DDL claim that all 36,372 Risperdal "presentation sales calls" made on South Carolina healthcare providers between November 10, 2003 and July 21, 2004 were separate SCUTPA violations, the Court overlooked the absence of record evidence supporting its decision, and in particular, the lack of evidence about what happened during *any* of the sales calls, let alone all 36,372 of them. The trial record contains nothing to support the imposition of penalties for those sales calls, yet the Court's opinion upholds $72,744,000 in penalties, endorsing an unprecedented penalty award based on speculation.

III.
STANDARD OF REVIEW

The purpose of a petition for rehearing "is to aid the court in deciding correctly a case heard by it." *Arnold v. Carolina Power & Light Co.*, 168 S.C. 163, 172, 167 S.E. 234, 238 (S.C. 1933). Where, as here, the existing record does not support the decision, a petition for rehearing is appropriate. *See, e.g., Ashley II of Charleston, L.L.C. v. PCS Ni-*

trogen, Inc., 409 S.C. 487, 492 n.4, 763 S.E.2d 19, 21 n.4 (S.C. 2014) ("If, based on the current record, we have misapprehended the scope of PCS's indemnification claim against Ross, we invite a rehearing petition..."); *Arnold*, 168 S.C. at 172, 167 S.E. at 238 (court is "bound by the transcript of record as to the facts of the cause"). Rehearing is also appropriate where the Court misapprehends arguments. *See Kennedy v. S.C. Ret. Sys.*, 349 S.C. 531, 532, 564 S.E.2d 322, 322 (S.C. 2001) ("In order to prevail on a petition for rehearing, appellants must demonstrate the Court overlooked or misapprehended their argument."); Rule 221(a), SCACR (petition shall state the points "supposed to have been overlooked or misapprehended"). These standards are met here.

IV.
ARGUMENT

A. The Court Overlooked FTC Guidance Demonstrating Janssen's Conduct Was Neither Unfair Nor Deceptive

The $136 million penalty is unsustainable because the Court overlooked or misapprehended the Legislative mandate that judicial interpretations of SCUTPA shall be guided by Federal Trade Commission (FTC) interpretations of the Federal Trade Commission Act. In holding that it would be "inappropriate" to look to FTC guidance on issues previously addressed in "[o]ur appellate courts," Op. No. 27502 at 53, the Court overlooked the Legislature's express direction that South Carolina courts maintain a construction of SCUTPA consistent with the ongoing interpretations given by the FTC and the federal courts to § 5(a)(1) of the federal act:

> It is the intent of the legislature that in construing [SCUTPA § 39-5-20(a)] the *courts will be guided* by the interpretations given by the Federal Trade Commission and the Federal Courts to § 5(a)(1) of the Federal Trade Commission Act (15 U.S.C. 45(a)(1)), as from time to time amended.

S.C. Code Ann. § 39-5-20(b) (emphasis added).

As the statutory text makes plain, the South Carolina Legislature intended by this directive to ensure that South Carolina standards for deceptive and unfair trade practices parallel the nationally applicable federal standards administered under the FTC Act. The Legislature could have, if it wished, chosen to subject businesses operating in South Carolina to more stringent state-law standards that did not follow federal interpretations of the FTC Act. Alternatively, it could have left the development of the applicable standards to the discretion of the state courts. But it expressly chose not to do either one of those things. Instead, it mandated that South Carolina courts use the FTC interpretations of the FTC Act as their guide.

Many other state unfair trade practice statutes have similar provisions incorporating FTC standards as the guide for defining unfair or deceptive practices, and the courts of those states have applied those statutes accordingly. *See, e.g., Suminski v. Me. Appliance Warehouse, Inc.*, 602 A.2d 1173, 1174 n.1 (Me. 1992) (following FTC Policy Statement on Unfairness);[2] *Tucker v. Sierra Builders*, 180 S.W.3d 109, 117 (Tenn. 2005) ("Following the mandate of [the TCPA]," the court "use[d] this description of unfairness to guide [its] interpretation of [the TCPA].");[3] *Conn. v. Am. Recycling Techs., Inc.*, 2009

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[2] Maine's Unfair Trade Practices Act has a virtually identical statutory provision to Section 39-5-20(b) of SCUTPA. *See* Me. Rev. Stat. tit. 5, § 207(1) ("It is the intent of the Legislature that in construing this section the courts will be guided by the interpretations given by the Federal Trade Commission and the Federal Courts to Section 45(a)(1) of the Federal Trade Commission Act (15 United States Code 45(a)(1)), as from time to time amended.").

[3] Tennessee's Consumer Protection Act has slightly different wording than that that of Section 39-5-20(b) in SCUTPA. Tenn. Code Ann. § 47-18-115 ("It is the intent of the general assembly that this part shall be interpreted and construed consistently with the interpretations given by the federal trade commission and the federal courts pursuant to § 5(A)(1) of the Federal Trade Commission Act, codified in 15 U.S.C. § 45(a)(1)).").

WL 1532330, at *4-5 (Conn. Super. Ct. May 5, 2009) (citing FTC Policy Statement on Deception in interpreting the meaning of "deceptive acts" under Connecticut Unfair Trade Practices Act).[4] Before the decision here, South Carolina courts did so as well. *See Plowman v. Bagnal*, 316 S.C. 283, 287, 450 S.E.2d 36, 38 (S.C. 1994) ("In section 39-5-20(b), the Legislature specifically instructs state courts to be guided by the decisions of the Federal Trade Commission (FTC) and the Federal Courts construing the Federal Trade Commission Act."); *State* ex rel. *McLeod v. VIP Enters., Inc.*, 286 S.C. 501, 504-05, 335 S.E.2d 243, 244-45 (S.C. Ct. App. 1985) (using FTC decisions in enforcement action under SCUTPA).

The Court's misapprehension of the Legislative mandate to interpret SCUTPA in accordance with the FTC's interpretation of the FTC Act warrants rehearing of both the labeling claim and the DDL claim. The Court's decision upholds verdicts and unprecedented penalties on both claims based on definitions of "unfair" or "deceptive" conduct that are contrary to FTC guidance. The trial court told the jury it could find that Janssen engaged in "unfair" conduct if Janssen committed an act that was "offensive to public policy" or "immoral, unethical, or oppressive." Op. No. 27502 at 42 (citations omitted). In contrast, for conduct to be "unfair" under the FTC Act, FTC guidance requires proof that an act is likely to cause substantial injury to consumers which is not reasonably avoidable. *See* Federal Trade Comm'n, Policy Statement on Unfairness (Dec. 17, 1980),

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[4] The Connecticut Act has a virtually identical statutory provision to Section 39-5-20(b) of SCUTPA. *See* Conn. Gen. Stat. Ann. § 42-110b ("It is the intent of the legislature that in construing subsection (a) of this section, the commissioner and the courts of this state shall be guided by interpretations given by the Federal Trade Commission and the federal courts to Section 5(a)(1) of the Federal Trade Commission Act (15 USC 45(a)(1)), as from time to time amended.").

available at https://www.ftc.gov/public-statements/1980/12/ftc-policy-statement-unfairness; *see also* 15 U.S.C. § 45(n) (stating that an act or practice is not "unfair" unless "the act or practice causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition"); Op. No. 27502 at 53 n.19 (noting FTC "unfairness" standard). The jury was further instructed that it could find liability for "deception" if it concluded Janssen engaged in conduct that had a "tendency to deceive." R. 2486. But the FTC instructs that "a practice or representation directed to a well-educated group, such as a prescription drug advertisement to doctors, would be judged in light of the knowledge and sophistication of that group." Federal Trade Comm'n, Policy Statement on Deception (Oct. 14, 1983), *available at* https://www.ftc.gov/public-statements/1983/10/ftc-policy-statement-deception.[5]

On the record here, the failure to instruct the jury consistently with FTC guidance requires at a minimum a new trial. As the Court recognized, the evidence showed that "Risperdal has been an effective drug" for treating life-threatening conditions like schizophrenia. Op. No. 27502 at 42. Although Risperdal, "like virtually all pharmaceutical drugs, has risks and side effects," *id.* at 43, the evidence "tended to support Janssen's thesis that its deceptive conduct had no effect on the community of prescribing physicians, for they knew the truth concerning the risks and side effects associated with Risperdal."

[5] Contrary to the Court's suggestion, *see* Op. No. 27502 at 53, these standards do not require enforcement authorities to prove actual injury or actual deception in order to prevail. As the FTC Guidances state, an "unfair" practices claim may be based on proof that conduct is "likely" to cause substantial injury, and a "deceptive" practices claim may be based on evidence that representations have a "tendency" to deceive considered in light of the knowledge and sophistication of the group to whom they are directed.

Op. No. 27502 at 50. "The risks associated with atypical antipsychotics . . . were becoming well known by the late 1990s," *id.* at 58, and "[b]y all accounts, in the early 2000s, evidence of the risks was pervasive." *Id.* As the Court recognized, this evidence "underscores Janssen's point that the community of prescribing physicians was well aware of the Risperdal risks, and Janssen's resulting contention that the allegedly deceptive practices had little or no effect on the practice and frequency of prescribing Risperdal." *Id.* at 58-59 n.22. The Court's suggestion that the November 2003 DDL nevertheless helped Janssen "maintain[] its superior market share ...," Op. No. 27502 at 46, overlooks undisputed record evidence demonstrating the contrary. If the Court's suggestion were accurate, Janssen's market share would have fallen after the July 2004 corrective letter. But an analysis of actual sales, to which the State stipulated, shows that Risperdal sales neither increased relative to Zyprexa after the DDL *nor decreased relative to Zyprexa after the July 2004 corrective letter.* R. 2340-41, 7366. Given this evidence, a properly instructed jury would have concluded that the challenged conduct had no tendency to deceive prescribing physicians and no likelihood of causing substantial injury to consumers.

Further, the Court's opinion overlooks or misapprehends other record evidence that reinforces that conclusion. In its recitation of the facts, the Court focuses on Janssen's continuing effort to distinguish Risperdal's weight gain and diabetes risk from that of its primary competitor, Zyprexa, after Zyprexa's manufacturer sent a letter to doctors suggesting that the FDA's newly instituted class diabetes warning meant the diabetes risks for all atypical antipsychotics were the same. The Court's opinion places great emphasis on preliminary data in Janssen's possession from a clinical trial and an insurance database that did not detect a difference in risk with Zyprexa. *Id.* at 38. But there are

many reasons why data may not reveal a difference that in fact exists, as the record here concerning those preliminary data demonstrates.[6] More important are the express admissions of the State's own experts that, based on the totality of what is known about Risperdal and Zyprexa, Zyprexa does in fact cause significantly more weight gain than Risperdal and carries a concomitantly higher risk of diabetes. R. 653 (Wirshing: Zyprexa causes twice as much weight gain as Risperdal); R. 1016 (Plunkett: "Zyprexa has a greater risk of producing weight gain and diabetes"); R. 525 (Wirshing: "[I]f you cause an increase in weight gain, you will cause an increase in diabetic risk ...").

Indeed, evidence offered by Janssen but wrongly excluded at trial establishes that since 2007, the FDA itself has recognized that Zyprexa carries higher diabetes risk by requiring its labeling to carry a stronger diabetes warning than Risperdal's labeling. R. 7496. The Court's opinion states that Janssen failed to preserve its claim that exclusion of this evidence was error because Janssen's "offer of proof came too late," Op. No. 27502 at 49 & n.16. But this misapprehends what occurred at trial. Janssen satisfied the requirement to make "a proffer of testimony ... to preserve the issue of whether [the evidence] was properly excluded by the trial court," *State v. King*, 623 S.E.2d 865, 868 (S.C. Ct. App. 2005), by proffering the excluded Zyprexa label before the end of Janssen's case. R. 2323. South Carolina law requires nothing more to preserve the issue for appeal. *See* Rule 103(a)(2), SCRE. The wrongly excluded Zyprexa label shows, like the admissions of the State's experts, that Janssen's marketing message that Risperdal carried low-

[6] *See* R. 1374-90 (explaining reliability issues with RIS-113 data); R. 1397 (explaining reliability issues with ERI data). The Court's opinion appears to accept the preliminary RIS-113results and ERI data as if they were reliable, overlooking that the State's experts never so testified and Janssen's experts affirmatively testified they were not.

er diabetes risk than its principal competitor Zyprexa was in fact fundamentally true, and this too is powerful evidence that a properly instructed jury would have concluded that the challenged conduct was unlikely either to deceive physicians or harm consumers.

In its recitation of the facts, the Court also places great emphasis on the April 2004 DDMAC warning letter, which criticized Janssen's November 2003 DDL.[7] But this overlooks and misapprehends that DDMAC does not apply the FTC standards for unfair or deceptive conduct when reviewing and responding to what it deems to be promotional communications by drug manufacturers subject to FDA regulation. Instead, DDMAC applies a regulatory standard which treats as "false or misleading" communications that the FDA deems to depart from its approved labeling. *See* 21 U.S.C. §§ 352(a), 321(n). Here, not only was the jury uninformed of this important difference in applicable standards, but

[7] The Court's emphasis on the 2004 DDMAC letter overlooks the trial court's erroneous rejection of Janssen's objection to it as inadmissible hearsay, which the Court declined to consider on the ground that Janssen only objected to its use in opening statement and failed to state the specific grounds for its objection. Op. No. 27502 at 45 n.12. But again, this misapprehends what occurred at trial. Janssen filed a pretrial motion to exclude the 2004 DDMAC letter arguing specifically that the letter was inadmissible hearsay and unfairly prejudicial. R. 7747. When the State offered the letter into evidence, Janssen reasserted its "earlier objections," R. 531, which the trial court overruled. There can be no question on this record that the trial court was advised of Janssen's hearsay objection to the 2004 DDMAC letter and that the trial court overruled it at the time of admission. The issue is therefore properly preserved for appeal. *See State v. Mueller*, 460 S.E.2d 409, 410 (S.C. Ct. App. 1995) (party making pre-trial motion *in limine* to exclude evidence preserves objection for appellate review by "renew[ing] his objection at trial when the evidence is presented in order to preserve the issue for appeal"). On the merits of the objection, the 2004 DDMAC letter should have been excluded as inadmissible hearsay. *See Ortho-McNeil-Janssen Pharmaceuticals, Inc. v. Arkansas*, 432 S.W.3d 563 (Ark. 2014) (reversing Arkansas Deceptive Trade Practices Act claim on ground that 2004 DDMAC letter should have been excluded as inadmissible and prejudicial hearsay).

the jury was also improperly prevented from learning that the FDA in fact now agrees with Janssen's underlying scientific position that Zyprexa carries greater diabetes risk.[8]

Finally, in defense of the improper liability standard it would now apply under SCUTPA and the extraordinary penalties it would assess against Janssen, the Court states that "the deceptive marketing that gave rise to this action also formed the basis of federal civil and criminal claims ... [that have] thus far resulted in agreed upon penalties in excess of $2 billion." Op. No. 27502 at 70. This is not an accurate characterization of the federal settlement and the Court's reliance on it is inappropriate. The federal settlement is not part of the record here and there was no testimony about it below. It encompassed claims relating not only to Risperdal but to other drugs and other companies. With regard to Risperdal, except for a limited admission concerning conduct underlying the company's strict liability misdemeanor plea, the settlement included no admission or finding of liability for any of the charged conduct.

The misdemeanor plea admitted only that between March 2002 and December 2003—a period entirely predating the statute of limitations bar here—Janssen marketed Risperdal for "off-label" uses not then approved by the FDA, in violation of the FDCA's

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[8] The Court's opinion also overlooks or misapprehends other important details about the November 2003 DDL. The opinion implies that the letter did not include the new class labeling, but it is undisputed that the letter both referenced and enclosed the new labeling. (R. 5837-42.) In addition, the opinion overlooks that the letter's statement that "[h]yperglycemia-related adverse events have infrequently been reported in patients receiving RISPERDAL" is a verbatim quotation from the revised FDA-mandated labeling. (R. 5841.) Finally, the opinion incorrectly implies that Janssen's corrective letter admitted the validity of the DDMAC's allegations in the Warning Letter. But in fact, by agreement with DDMAC resolving the matter, the corrective letter merely reported that DDMAC had made those allegations, not that Janssen agreed with them. (R. 5843-44.)

misbranding provisions.[9] The settled civil claims, asserted under the False Claims Act, also focused predominantly on alleged off-label marketing, alleging that it had caused physicians to submit ineligible reimbursement claims to government payors.[10] Notably, neither the criminal nor the civil charges alleged that Risperdal's approved labeling was inadequate or misleading. And while the civil complaint mentioned the November 2003 DDL letter, it did not allege that the letter contained false statements or mischaracterized the cited studies. Instead, it merely noted that the FDA had issued a warning letter identifying concerns with the way the DDL had characterized the diabetes risk of Risperdal, and that Janssen sent a second DDL letter reporting those concerns.[11]

The size of the federal settlement reflects not only the differences in the alleged claims but also the settlement's nationwide scope. The size of the agreed payment therefore has no bearing on what might constitute permissible punishment for the claims alleged here. *See BMW of N. Am., Inc. v. Gore*, 517 U.S. 559 (1996) (state cannot constitutionally punish for conduct occurring outside its borders). The same is true of Janssen's nationwide net revenues from Risperdal, also referenced in the Court's opinion. Op. No. 27502 at 66 n.27; *cf. Sulton v. HealthSouth Corp.*, 400 S.C. 412, 421-22, 734 S.E.2d 641,

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[9] U.S. Dep't of Justice, Janssen Pharmaceuticals, Inc. Guilty Plea Agreement (Nov. 4, 2013), *available at* http://www.justice.gov/sites/default/files/opa/legacy/2013/11/04/janssen-plea-agreement.pdf. *See United States v. Watkins*, 278 F.3d 961, 964 (9th Cir. 2002) ("An article may be misbranded pursuant to the misdemeanor provision 'without any conscious fraud at all,' thus creating a form of strict criminal liability." (citation omitted)).

[10] U.S. Dep't of Justice, Janssen Pharmaceuticals, Inc. Settlement Agreement (Nov. 4, 2013), *available at* http://www.justice.gov/sites/default/files/opa/legacy/2013/11/04/civ-settlement-agreement-pa.pdf.

[11] U.S. Dep't of Justice, Janssen Pharmaceuticals, Inc. Civil Complaint (Nov. 4, 2013), *available at* http://www.justice.gov/sites/default/files/opa/legacy/2013/11/04/us-complaint-pa.pdf.

645-66 (2012) (corporation's net operating revenues were not a proper consideration in assessing punitive damages).

In sum, the record in this case does not support the jury's verdict under the FTC deceptive and unfair practice standards applicable to the claims here. For this reason, the petition for rehearing should be granted and the judgment should be reversed. At a minimum, the trial court's failure to instruct the jury on the correct liability standards for deceptive and unfair practices requires a new trial. *See S.C. Dep't of Transp. v. First Carolina Corp. of S.C.*, 372 S.C. 295, 303, 641 S.E.2d 903, 907-08 (S.C. 2007) (defective verdict question with prejudicial effect constitutes reversible error); *see also Sulton v. HealthSouth Corp.*, 400 S.C. 412, 419, 734 S.E.2d 641, 645 (S.C. 2012) (finding verdict form's "overall structure both confusing and prejudicial").

B. Under the Court's Reasoning, SCUTPA's Regulated Activity Exemption Bars the State's Labeling Claim During the Limitations Period

The Court held that SCUTPA's three-year statute of limitations barred imposition of penalties on the State's labeling claim for conduct occurring before January 24, 2004. But the Court overlooked the impact of its statute of limitations holding on the State's ability to maintain its labeling claim.[12] Because it is undisputed that Risperdal's labeling was revised to include both diabetes and CVAE warnings *before* the limitations period began, the State's *only* viable remaining liability theory on the labeling claim concerns placement of hyperprolactinemia risk information. But the record does not show that

[12] SCUTPA is a penal statute and, therefore, the Court was required to strictly construe it against the State. *See Dykeman v. Wells Fargo Home Mortg., Inc.*, 381 S.C. 333, 337, 673 S.E.2d 804, 806 (S.C. 2009) ("Penal statutes must be strictly construed."); *see also State v. Elwell*, 403 S.C. 606, 612, 743 S.E.2d 802, 806 (S.C. 2013) ("[P]enal statutes will be strictly construed against the State.").

Janssen could have changed the hyperprolactinemia Precaution using the CBE process—in fact it shows the opposite. The State's labeling claim is therefore barred by the regulated activity exemption.

As an initial matter, the Court mistakenly held that Janssen failed to preserve for appellate review the question of whether SCUTPA's regulated activity exemption barred the State's labeling claim. The Court's opinion states that "Janssen fails to identify any specific trial court rulings claimed to constitute error." Op. No. 27502 at 54. But Janssen specifically raised this issue in its Motion for Judgment Notwithstanding the Verdict and its two antecedent directed verdict motions, *see* R. 9031, 8601, 8870-71, and Janssen's Initial Brief on Appeal specifically argued that the trial court erred "in denying Janssen's Motion for Judgment Notwithstanding the Verdict, or in the Alternative, for a New Trial" when it held that the labeling claim was not barred by the regulated activity exemption. *See* Final Br. of Appellant at 1; *see also id.* at 4 (citing Dec. 20, 2011 Order denying JNOV motion). Janssen thus expressly and adequately preserved the issue. *See* Rule 208(b)(4), SCACR.

The Court did go on to address Janssen's merits argument that the regulated activity exemption bars SCUTPA liability for the content of the FDA-approved Risperdal label, holding that Janssen was "not entitled to avail itself of" the exemption because FDA regulations authorized and required Janssen to strengthen the warnings in the label through the FDA's CBE process. Op. No. 27502 at 54. The Court noted that FDA regulations require a manufacturer to revise a drug's label "[a]s new risks and side effects are discovered." Op. No. 27502 at 35 (citing 21 C.F.R. § 201.57(c)(6)(i)). Because "the State sought civil penalties based on Janssen's actions in failing to discharge its ongoing af-

firmative duty to keep its label updated and ensure 'that its warnings remain adequate as long as the drug is on the market,' *Wyeth*, 555 U.S. at 571 (citing 21 C.F.R. § 201.80(e); 21 C.F.R. 314.80(b); 73 Fed. Reg. 49605)," Op. No. 27502 at 55, the Court held that the regulated activity exemption did not bar the State's claim. *Id.* at 54.[13]

But the Court did not evaluate whether any "new risks and side effects" were discovered that required the use of a revised label *during the applicable limitations period.* In order to do so, the Court would have had to first identify whether and how the State alleged Risperdal's label to be deficient on January 24, 2004, the beginning of the limitations period. By that time, Janssen had already updated Risperdal's label to move information about the risk of diabetes and cerebrovascular adverse events (CVAE) in the el-

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[13] Janssen disagrees with the Court's conclusion that the State has the authority to seek civil penalties based on its contention that a prescription drug manufacturer failed to update Warning information in an FDA-approved label as early as required by applicable FDA regulations. Likewise, Janssen disagrees with the Court's statement that Janssen did not adequately preserve its argument that the FDCA preempts this claim. The case cited in the Court's opinion, *Freeman v. A. & M. Mobile Home Sales, Inc.*, 359 S.E.2d 532, 535 (S.C. Ct. App. 1987), holds only that "before a motion [JNOV] can properly be made, . . . a party must move for a directed verdict at the close of all the evidence." Janssen is unaware of any South Carolina authority holding that to preserve an issue for appellate review, a party must first assert it in an initial motion for directed verdict made at the close of the plaintiff's case. On the contrary, the cases if anything imply otherwise. *See Evans v. Wabash Life Ins. Co.*, 247 S.C. 464, 466, 148 S.E.2d 153 (1966) (presentation of evidence after close of plaintiffs' case waives any right to sufficiency of evidence review in light of plaintiff's evidence alone, even if nonsuit motion was made; to preserve right to review, defendant must make an appropriate motion to trial court "after all of the evidence is in"). Nor is it correct that Janssen did not make the same preemption argument in the trial court that it advances on appeal. In its initial directed verdict motion at the close of the State's case, Janssen argued that the FDA's approval of Risperdal's labeling barred the State's claim under SCUTPA's regulated activity exemption. R. 8601, 8609. In its directed verdict motion at the close of all evidence, Janssen renewed that argument and, as Janssen believes South Carolina law permits, added the further argument that the FDA labeling approval preempted the State's claim and *Wyeth* did not save it. R. 8871, 8880. After renewing the argument in its JNOV motion, Janssen advanced the same labeling preemption argument on appeal. *See* Final Br. of Appellant at 12-17.

derly to the Warnings section, satisfying the State's contention that 21 C.F.R. § 201.57(e) required the information to appear there. The "new" information the State relied on at trial to support its contention that Janssen had a duty to update the Risperdal label before the FDA requested it—Trial 113 and the ERI insurance claims data—related to the potential risk of diabetes, which was moved to the Warnings section in October 2003. CVAE risk had been moved to the Warnings section even before then, in April 2003. Although the Court's opinion observes that Janssen did not "include a boxed warning regarding the risk of stroke, cardiac arrest, and sudden death in the elderly until February 2005," Op. No. 27502 at 41, the State did not allege that Janssen should have done so at an earlier date,[14] and FDA regulations in any event make clear that Janssen could not have done so. Manufacturers are not permitted to unilaterally add boxed warnings to prescription drug labels—for boxed warnings, the CBE process does not apply. *See* 21 C.F.R. § 314.70(b)(2)(v)(C); 21 C.F.R. § 257(a).

As of the beginning of the applicable limitations period, the State alleged the label to be deficient *only* because information about risk of hyperprolactinemia appeared in the Precautions section rather than the Warnings section. But the State did not contend that

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[14] On appeal, the State argued that the label was inadequate only with regard its warning about the potential risks of diabetes and hyperprolactinemia. *See* Resp't Final Br. at 4 (noting that claim at trial involved only "Warnings on Risperdal's label as to diabetes/hyperglycemia and hyperprolactinemia safety risks"). The State argued that Janssen engaged in "unfair or deceptive" conduct by not adding the class diabetes warning to the label before the FDA requested it and by distributing a label that "did not carry a Warning for hyperprolactinemia," *id.* at 4, prior to the FDA's 2006 regulatory action that combined the Warnings and Precautions sections into a single section captioned "Warnings and Precautions." *See* FDA, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3946 (Jan. 24, 2006) (finding that "the distinction between warnings and precautions is not meaningful to practitioners who use labeling").

any new information about the risk of hyperprolactinemia in Risperdal patients emerged after the FDA first approved Risperdal's label in December 1993. Its theory was that the hyperprolactinemia risk information was misplaced based on information "known from the day the drug was developed." R. 857 (testimony of State's expert Dr. Laura Plunkett).

SCUTPA's regulated activity exemption bars this labeling claim because no "new risks and side effects" triggered an obligation to update the label through the CBE process after the FDA's initial approval. *See* Op. No. 27502 at 35. In the absence of data or studies showing new or greater risks or side effects, the CBE process does not apply. *See In re Celexa & Lexapro Mktg. Sales Practices Litig.*, --- F.3d ---, 2015 WL 727970, at *6-9 (1st Cir. Feb. 20, 2015). In contrast to the claim asserted in *Wyeth* that data received after FDA approval warranted a label change, the State's allegation that Risperdal's label inadequately warned of hyperprolactinemia risk amounted to an assertion that FDA erred when it approved "the exact text in the proposed label," *see Wyeth*, 555 U.S. at 568, based on "all clinical studies, as well as preclinical studies related to a drug's efficacy, toxicity, and pharmacological properties." Op. No. 27502 at 34 (quoting *Merck KGaA v. Integra Lifesciences, Ltd.*, 545 U.S. 193, 196 (2005)); *see also* 21 C.F.R. § 314.50(d)(2), (5) (2005). SCUTPA's regulated activity exemption bars such a claim, because the conduct targeted by the State was "permitted under laws administered by [a] regulatory body or officer acting under statutory authority of ... the United States." S.C. Code § 39-5-40(a). The Court should vacate its Opinion on this point and hold that the regulated activity exemption bars what remains of the State's labeling claim after application of the Court's statute of limitations ruling.

C. At a Minimum, the Court's Statute of Limitations Holding Requires That the Verdict on the State's Labeling Claim Be Vacated and the Case Remanded for a New Trial

Even if SCUTPA's regulated activity exemption did not bar the State's labeling claim, the Court's statute of limitations holding requires at least that the judgment on the labeling claim be reversed and remanded for a new trial because the verdict form does not allow the Court to discern whether the jury based its verdict on conduct during the limitations period. Although the Court held that the statute of limitations barred liability on the labeling claim for conduct that occurred before January 24, 2004, the jury was asked only whether Janssen "engaged in unfair or deceptive acts or practices in the conduct of any trade or commerce" in the Risperdal package insert, *see* R. 3031, without regard to the limitations period or the different alleged labeling deficiencies.

The jury was thus permitted to base its verdict on conduct occurring at any point in time between Risperdal's 1994 launch and the State's April 2007 Complaint date. As the Court's review of the trial proceedings illustrates, the State's labeling claim focused predominantly on conduct that predated the limitations period, most notably Janssen's failure to add a diabetes Warning to the Risperdal label after receiving the results from Trial 113 in 1999 and the ERI data in 2000. But that alleged labeling deficiency was rectified in October 2003 by the addition of the FDA-mandated class warning, *before* the commencement of the limitations period. As the record currently stands, the Court has authorized a penalty of more than $36 million for a Risperdal label deemed inadequate by the jury as to an unspecified risk at some unspecified date between 1994 and the State's filing of its Complaint. If the jury deemed the hyperprolactinemia precaution to be adequate, but based its verdict on the time-barred failure to implement an earlier diabetes warning, the verdict would be improper. *See* Op. No. 27502 at 72 (Pleicones, J., dissent-

ing) ("[W]e have no way of knowing whether the jury's liability determination was based on conduct outside the limitations period since we cannot know whether this jury would have found a SCUTPA violation had it considered only Janssen's labeling conduct after January 24, 2004."). Because it is impossible to tell whether the jury returned a permissible verdict in light of the Court's statute of limitations ruling, the judgment on the labeling claim should at least be reversed and the claim remanded for a new trial. *See First Carolina Corp. of S.C.*, 372 S.C. at 303, 641 S.E.2d at 907-08 ("special verdict question may be so defective in its formulation that its submission results in a prejudicial effect which constitutes reversible error") (citation omitted).

D. The Court Miscalculated the Penalty Imposed on the Labeling Claim Because It Overlooked Evidence of the Exact Number of Risperdal Sample Boxes Distributed During the Limitations Period.

After the jury found that Risperdal's labeling violated SCUTPA, the trial court held all 509,499 sample boxes distributed from 1998 through April 2007 to be separate SCUTPA violations. Although the Court affirmed the jury's liability finding, it ruled that the statute of limitations barred any penalties for violations accruing more than three years prior to the date of the tolling agreement, *i.e.*, before January 24, 2004. The Court then undertook to estimate the number of sample boxes distributed during the limitations period (roughly February 2004 to April 2007) from information submitted at the penalty hearing. Dividing the 509,499 sample boxes distributed from 1998 through April 2007 by the 30,333 sales visits during that time span where samples were distributed, the Court calculated that on average, Janssen's sales representatives left "16.79 sample boxes per

visit." Op. No. 27502 at 67 n.28.[15] Then, multiplying this per-visit average by the "20,575 visits to prescribing physicians in South Carolina" made from February 2004 through April 2007, the Court estimated that Janssen "distributed 345,454 sample boxes containing deceptive labeling" during the limitations period.

But the Court overlooked other record evidence showing that its use of the average number of sample boxes distributed per-visit since 1998 to estimate the number of sample boxes distributed during the 3-year limitations period beginning in 2004 yields a result that is not only incorrect but 50% too high. In particular, Exhibit P-2720, which the State also introduced at the penalty hearing, shows the *exact* number of sample boxes distributed each month before and after the limitations bar. R. 5835. It shows that only 228,447 sample boxes were distributed from February 2004 through April 2007, 117,007 less than the Court estimated using the 1998-2007 per-visit average. *Id.* Based on the actual number of boxes distributed during the limitations period, the Court should have remitted the penalty on the State's labeling claim to $22,844,700, not $34,545,400. *Cf. Gauld v. O'Shaughnessy Realty Co.*, 380 S.C. 548, 559, 671 S.E.2d 79, 85-86 (S.C. Ct. App. 2009) ("[E]vidence should be such as to enable the court or jury to determine the amount [of damages] with reasonable certainty or accuracy. Neither the existence, causation nor amount of damages can be left to conjecture, guess, or speculation.").

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[15] *See* R. 5436, Letter from Steven J. Pugh, Esquire, to Donald C. Coggins, Esquire, April 13, 2011 ("Janssen has concluded that between 1998 and 2007, 509,499 multi-dose Risperdal sample boxes were distributed to South Carolina healthcare professionals. Further, the number of unique sampling events during this period total 30,333."); R. 2556 ("Janssen says that they have concluded that between 1998 and 2007, 509,499 multi-dose Risperdal sample boxes were distributed to South Carolina healthcare professionals, and then, further, the number of unique sampling events during this time period totaled 30,333.").

E. The Record Does Not Support the Imposition of a SCUTPA Penalty for Every Janssen Presentation Sales Call Between November 10, 2003 and July 21, 2004

The Court also overlooked or misapprehended facts and law governing the State's DDL claim, beginning with its decision to uphold the imposition of civil penalties for 36,372 sales representative visits to South Carolina healthcare providers between November 10, 2003—the date Janssen sent the DDL to doctors—and July 21, 2004—the date Janssen resolved its regulatory disagreement over the content of the DDL by sending a corrective letter negotiated with FDA. Op. No. 27502 at 67-68. The plain text of SCUTPA is clear—civil penalties may be imposed only for "violations." *See* S.C. Code Ann. § 39-5-110(a). The trial record contains no evidence of what occurred during any of those sales calls, and therefore no basis to conclude any of them constituted a violation.

The record does not show what sales representatives communicated to doctors about Risperdal on these sales calls. Indeed, the State's expert admitted there was no such evidence in the sales call data he reviewed. R. 2581. Sales representatives could have talked to doctors about Risperdal's newly approved indication for bipolar mania (obtained in December 2003), or about the doctor's practice and experience with the medication. Without evidence of what actually occurred on any of these individual calls, the record cannot conceivably support the conclusion that sales representatives made unfair or deceptive statements in violation of SCUTPA on *all* 36,372 of them. Consistent with this record, the jury found only that Janssen made unfair or deceptive statements "in" the November 2003 letter. R. 3030-31. The jury was not asked to and did not find that Janssen violated SCUTPA during sales calls "designed to continue the false DDL narrative." Op. No. 27502 at 68. Nor did the trial judge so find. The trial judge purported to assess a penalty for every "sales call[] where the letter [was] published" in South Carolina between

November 10, 2003 and July 21, 2004, as if Janssen sales representatives handed the letter out to the same doctors over and over again, every time they visited for almost ten months. R. 43. The record flatly contradicted this idea. R. 1153 ("We showed it one time" and "that was it"); R. 2196 ("for one rotation"). At best, the record supports a conclusion that sales representatives handed out 3,149 copies of the DDL, because the company made Risperdal-related sales calls on 3,149 South Carolina doctors during the November 10, 2003 to July 21, 2004 time period. R. 7672.

Yet even if the record supported the proposition that the DDL was "presented" on some sales calls, the award impermissibly penalizes the same misconduct numerous times. Imposing duplicative penalties for distribution "to the same prescribing physicians who received the DDL in the mail," Op. No. 27502 at 68, contradicts the reasoning of multiple courts that have found it inappropriate to penalize multiple statements to the same person as separate violations. *See, e.g.*, *Walnut Creek Manor v. Fair Emp't & Hous. Comm'n*, 814 P.2d 704, 721 (Cal. 1991) ("number of violations is to be determined by the number of persons to whom the misrepresentations were made" (citation omitted), *superseded by statute on other grounds*, *Larson v. City & Cnty. of San Francisco*, 123 Cal. Rptr. 3d 40, 53 (Cal. Ct. App. 2011)); *State* ex rel. *Corbin v. United Energy Corp.*, 725 P.2d 752, 759 (Ariz. Ct. App. 1986) (affirming determination that "there could be only one violation of the consumer fraud act for each consumer").

But the even greater problem with the Court's decision to affirm the imposition of penalties for 36,372 sales calls as separate SCUTPA violations is the absence of evidence of what was communicated at any of them. At $2,000 per violation, the result is an unprecedented $72.7 million in penalties based on nothing more than "conjecture, guess, or

speculation," *Gauld*, 380 S.C. at 559, 671 S.E.2d at 85-86, about what might have happened when sales representatives visited doctors. The Court should grant rehearing to correct this result.

V.
CONCLUSION

For the foregoing reasons, Janssen submits that this Court misapprehended or overlooked matters of both fact and law that compel a different outcome in this case. Accordingly, rehearing is warranted and the Court should withdraw its current opinion and issue a new opinion consistent with the relief requested by Janssen in its appellate briefing and in this Petition for Rehearing.

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Columbia, South Carolina
March 27, 2015

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
Appellate Case No. 2012-206987

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

v.

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

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

Proof of Service

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

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