THE STATE OF SOUTH CAROLINA
In the Supreme Court

APPEAL FROM SPARTANBURG COUNTY
Court of Common Pleas

Roger L. Couch, Circuit Court Judge

Case No. 2007-CP-42-1438

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

Respondent,

v.

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

Defendants,

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

Appellant.

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INTRODUCTION

The State argues for an unprecedented and unreasonably expansive view of liability under the South Carolina Unfair Trade Practices Act ("SCUTPA"). At the same time, the State advocates for an unduly restrictive interpretation of SCUTPA's exemption for "regulated activity" and an impermissibly narrow reading of the Due Process, Excessive Fines, and Free Speech Clauses of the United States and South Carolina Constitutions.

The State contends in its brief that it may recover on the theory that it was "unlawful" to distribute the FDA-approved package insert, or label, in South Carolina, even though the FDA required that Janssen use the approved label throughout the United States. In fact, the State takes the position that it may recover more than $150 million in label-related penalties on the strength of its litigation experts' opinions to the effect that the FDA should not have approved the label and authorized its use. And, the State argues that it may recover more than $170 million in letter-related penalties because an FDA reviewer concluded, in an informal and advisory "Warning Letter," that Janssen's November 10, 2003 letter to healthcare professionals did not comply with federal regulations and was therefore "false or misleading," even though the issues raised by the Warning Letter later were resolved informally and cooperatively. All of those claims are preempted or barred by federal law, and the label claim also is barred by the SCUTPA regulated activity exemption.

The State, like the trial court, maintains that it does not matter that there was no proof that any South Carolina physician was deceived or was likely to be deceived by the statements in the label or the letter. The State says that it does not matter that there was no evidence that any South Carolina physician ever wrote a prescription for Risperdal

that would not have been written but for the statements. According to the State, it does not matter that no South Carolina patient, or anyone else, was harmed in any way by anything Janssen did or said. Proof of harm or the likelihood of harm, however, is required by SCUTPA and by the United States and South Carolina Constitutions.

Indeed, the State, like the trial court, argues that it does not even matter whether the statements it now challenges as "deceptive" and "unfair" were true. The trial court rested its Penalty Order, in part, on the suggestion in an article it found online that "[l]ying has nothing to do with truth and falsity." Adopting that view, the State now says that it does not matter that the trial court excluded scientific and statistical evidence showing that the challenged statements were true, or that the FDA later reversed course and endorsed Janssen's position on the key issue in the "letter" case. Those facts, it argues, have nothing to do with "deception." But the State's positions are inconsistent with SCUTPA's requirements and with constitutional mandates.

As for penalties, the State defends the imposition of more than $327 million in monetary penalties in a case in which there was no proven harm or loss. The leading Supreme Court case on "excessive fines," however, holds that penalties must not be grossly disproportional to the harm caused. Finally, the State attempts to justify the assessment of penalties for "violations" that were not the violations that the jury found and for "violations" that were not proven. But the trial court did not, as the State contends, have "discretion" to impose penalties for such "violations."

DISTORTIONS OF THE RECORD

This reply brief will not revisit all of the grounds for reversal advanced in Janssen's Initial Brief.[1] Before turning to the arguments in the State's brief that do warrant a response, however, Janssen must address certain statements in the State's "summary of the facts" that create misimpressions about matters that were, in fact, undisputed.

The November 2003 Mailing. The State's "summary of the facts" leaves the impression that the November 2003 mailing did not disclose the newly required "diabetes" warning. The State, citing Exhibit P-1736, says that "the body of this Dear Doctor Letter did not include the text of the new Warning." (Resp't's Br. 12.)

But the letter's very first sentence gave notice of the new warning: "The Food and Drug Administration (FDA) has requested **all** manufacturers of atypical antipsychotics to include a warning regarding hyperglycemia and diabetes mellitus in their product labeling." (Ex. D-351, R. _.) And the letter actually enclosed the new package insert, or label, with the full diabetes warning: "In an effort to keep you updated with the most current product information available for the management of your patients, enclosed please find updated prescribing information for RISPERDAL® (risperidone)." (*Id.*) Plaintiff's Exhibit 1736, to which the State directs this Court, is incomplete. (*See*

[1] For example, Janssen anticipated in its Initial Brief, and therefore need not address here, the State's argument that it makes no difference, for purposes of the statute of limitations, that the State may have known of its claims more than three years before it filed suit because the only knowledge that matters is that of the State's Attorney General. Likewise, Janssen will not again address the obvious problems with the State's opening and closing statements – the suggestions that Janssen should be punished because it is a successful out-of-state business. And Janssen will not discuss again each of the issues surrounding the trial court's erroneous rulings excluding evidence relevant to Janssen's defenses.

Tr. 485:10-486:12, R. _.) A complete version of the letter, with its enclosure, was introduced by defendants as Exhibit D-351. (Tr. 1863:10-13, R. _.)

The State also "quotes" inaccurately from the letter. In the letter's third paragraph, Janssen stated: "Although confirmatory research is still needed, a body of evidence from published peer-reviewed epidemiology research[1-8] suggests that RISPERDAL is not associated with an increased risk of diabetes when compared to untreated patients or patients treated with conventional antipsychotics." (Ex. D-351, R. _.) Notes 1-8 appear on the second page of the letter and are references to every published peer-reviewed epidemiological study that examined the issue. (*See id.*) Janssen's statement was a statement about the peer-reviewed literature and the conclusions that Janssen believed might be drawn from it. When the State "quoted" from the letter in its "summary of the facts," however, it omitted the words "from published peer-reviewed epidemiology research"; it omitted the superscript notes "1-8"; and it made no reference to the listing, on the letter's next page, of the body of published epidemiological research to which Janssen's letter referred. (Resp't's Br. 12.)

"Warnings." The State says that "[a]t no time from 1994 until November 2003 did Janssen put a Warning for diabetes or hyperglycemia . . . on Risperdal's label." (Resp't's Br. 5.) It also asserts that "Risperdal's label did not carry a Warning for hyperprolactinemia until the FDA took action in 2007." (*Id.* at 14.) It thus suggests that Janssen made no disclosures about diabetes and hyperprolactinemia risks until forced to do so by the FDA.

The State's reference to "Warnings," with an upper-case "W," however, is misleading. All of the FDA-approved labels from 1993 on did, in fact, disclose that

significant weight gain had been observed during the clinical trials of Risperdal and that diabetes had been reported in patients taking Risperdal. (Exs. P-643, R. _; P-648, R. _; P-649, R. _; P-653, R. _; P-656-1, P-657, R. _.) And all of the FDA-approved labels did warn of the risks of hyperprolactinemia at some length. (*Id.*; *see also* P-661, R. _; P-662, R. _; P-665, R. _.) While those disclosures were not located in the "Warnings" section of the label, the undisputed fact is that the FDA had approved the placement of that risk information in other sections.

The statement that "Risperdal's label did not carry a Warning for hyperprolactinemia until the FDA took action in 2007" is doubly misleading. The FDA "action" that was taken in 2007 was the implementation of new labeling regulations, applicable to all pharmaceutical manufacturers and most prescription drugs, which did away with the distinction in labels between "Warnings" and "Precautions." When the new regulations were applied to the Risperdal label in 2007, the discussion of hyperprolactinemia that had been in the "Precautions" section of the Risperdal label appeared in the new "Warnings and Precautions" section. That formatting revision was not significant. The FDA revised its labeling requirements to eliminate the distinction between "Warnings" and "Precautions" because it had determined that "the distinction between warnings and precautions is not meaningful to practitioners who use labeling." Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3946 (Jan. 24, 2006).

Risperdal v. Zyprexa. The State says in its brief that Janssen was trying to differentiate Risperdal from Zyprexa by claiming that Risperdal causes less weight gain and therefore has less diabetes risk. Implying that there really was no difference between

the two medicines, it reports that a study comparing the weight gain liabilities of Risperdal and Zyprexa, RIS-USA-113, "did not show Risperdal's superiority to Zyprexa on weight gain." (Resp't's Br. 7.) And it asserts that an "epidemiological study," ERI, "showed that Risperdal patients had a higher incidence rate of diabetes than did Zyprexa patients." (*Id.* at 8.)

The record, however, reveals that Risperdal and Zyprexa are very different with respect to weight gain and diabetes risk. The parties' experts agreed that Zyprexa causes much more weight gain than Risperdal. (Tr. 617:1-8 (Wirshing: Zyprexa causes twice as much weight gain as Risperdal), R. _; *id.* at 987:11-988:6 (Plunkett: "Zyprexa has a greater risk of producing weight gain"), R. _; *id.* at 2349:8-20 (Newcomer: Zyprexa causes five times as much weight gain as Risperdal), R. _.) As the experts acknowledged, Zyprexa therefore has more diabetes risk than Risperdal. (Tr. 489:10-12 (Wirshing: "[I]f you cause an increase in weight gain, you will cause an increase in diabetic risk . . . ."), R. _; *id.* at 987:11-988:6 (Plunkett: "Zyprexa has a greater risk of producing . . . diabetes . . . ."), R. _.)

To be sure, the differences do not show up in RIS-USA-113 and ERI. But the State's own experts acknowledged the differences as a matter of scientific fact, notwithstanding the failure of RIS-USA-113 and ERI to demonstrate them.[2] Had the trial

[2] There was extensive discussion at trial about why the topline results of RIS-USA-113 and the data from ERI were not consistent with the weight of the evidence about the respective weight gain and diabetes risks of Risperdal and Zyprexa. After months of review of the topline results of RIS-USA-113, Janssen had concluded that it could not draw scientifically reliable conclusions from the study. The State's experts did not testify that the data were reliable or that Janssen's view of the study was incorrect. As for ERI, which the State characterizes as an "epidemiological study," the undisputed evidence is

(continued...)

court admitted the 2007 Zyprexa label, (Penalty Hr'g Ex. D-2, R. _), it would have been clear that the FDA also has concluded that Zyprexa has more weight gain and diabetes risk than other antipsychotics. The State's "summary of the facts," however, relying on the aberrant data from RIS-USA-113 and ERI, wrongly suggests that any effort to differentiate Risperdal from Zyprexa was improper.

ARGUMENT

I. THE STATE DID NOT PROVE A VIOLATION OF SCUTPA.

A. The State Did Not Prove the Requisite "Impact on the Marketplace."

The State argues that it may recover for "deceptive" statements even if it cannot show that they were likely to deceive anyone, and that it may recover for "unfair" statements even if it cannot show that the statements were likely to have any impact on the persons to whom the statements were addressed. "Whether an act or practice is unfair or deceptive within the meaning of the UTPA," however, "depends upon the surrounding facts and the impact of the transaction on the marketplace." *deBondt v. Carlton Motorcars, Inc.*, 342 S.C. 254, 269, 536 S.E.2d 399, 407 (Ct. App. 2000). The State has not shown, or even attempted to show, any "impact . . . on the marketplace," and thus has not established that the statements in the label or in the letter were "unfair or deceptive."

An act or practice is not "deceptive" unless it has a "tendency to deceive" or is "likely to deceive" the persons in the "marketplace" at whom the act or practice is directed – in this case, the physicians for whom the label was written and to whom the letter was sent. The "tendency to deceive" standard is set forth in *deBondt*. *Id.*, 536

(. . . continued)

that it was nothing more than a preliminary report of crude data. (Tr. 888:2-18, R. _; 1322:24-1323:3, R. _; 1462:2-10, R. _.)

S.E.2d at 407. "Likely to deceive" is the formulation of the standard used by the Federal Trade Commission and federal courts when interpreting Section 5(a)(1) of the Federal Trade Commission Act. FTC Policy Statement on Deception, 2 Fed. Trade Comm'n App. D-2 (Oct. 14, 1983); *FTC v. Tashman*, 318 F.3d 1273, 1277 (11th Cir. 2003). The FTC standard is important because the South Carolina General Assembly has instructed courts construing SCUTPA's "unfair or deceptive acts or practices" language to look to "the interpretations given by the Federal Trade Commission and the Federal Courts to § 5(a)(1) of the Federal Trade Commission Act . . . as from time to time amended." S.C. Code § 39-5-20(b).

Whether an act or practice is "unfair" likewise turns on "the impact of the transaction on the marketplace." *deBondt*, 342 S.C. at 269, 536 S.E.2d at 407. South Carolina cases have not clearly delineated the nature of the required impact in an unfairness case. For more than thirty years, however, the FTC, interpreting the Federal Trade Commission Act, has required proof that the act or practice is likely to cause substantial injury. FTC Policy Statement on Unfairness, 2 Fed. Trade Comm'n App. D-1 (Dec. 17, 1980) (identifying substantial injury as an essential element of an "unfairness" action).

Relying on *Spiegel, Inc. v. FTC*, 540 F.2d 287, 293 (7th Cir. 1976), the State argues that "substantial injury" is not really the FTC standard. (Resp't's Br. 53.) *Spiegel*, however, predates the FTC's Policy Statement on Unfairness, which established the requirement of proof of substantial injury because "not every consumer injury is legally 'unfair.'" FTC Policy Statement on Unfairness. The Commission explained, "We recognize that the concept of consumer unfairness is one whose precise meaning is

not immediately obvious, and also recognize that this uncertainty has been honestly troublesome for some businesses and some members of the legal profession." *Id.* In 1994, Congress codified the Policy Statement's "substantial injury" requirement by adding a new subsection to Section 5 of the Federal Trade Commission Act. *See* 15 U.S.C. § 45(n). There can be no dispute now that likelihood of substantial injury is a required element of an "unfairness" claim.

The State failed to prove "impact" under any of these standards. At trial, the State did not even attempt to prove that the statements in the Risperdal label or the November 10, 2003 letter had any impact on the physicians for whom the label was written or to whom the letter was sent.[3] The State called no South Carolina physicians as witnesses. It presented no evidence that the statements had a "tendency to deceive" or were "likely to deceive" any South Carolina physicians or to cause any injury, much less "substantial" injury. It offered no proof that the statements caused any South Carolina physicians to prescribe Risperdal when they would not otherwise have prescribed it, and no proof that the statements were likely to impact prescribing decisions.

In its brief, the State contends that "impact" required nothing more than proof that the challenged conduct has the "potential for repetition," and therefore could implicate the "public interest." (Resp't's Br. 36, 39-42.) But the State is confusing two distinct

[3] The State argues that Dr. Wirshing "explained in great detail the bases for each of his opinions that the Dear Doctor Letter and the label were deceptive and untrue." (Resp't's Br. 38.) While Dr. Wirshing did testify that certain statements or implications that might be drawn from those statements were "untrue," he did not testify that any statements had any impact on the "marketplace" – South Carolina physicians – so as to make the statements "deceptive" for purposes of SCUTPA as explained in *deBondt*. The State also relies on testimony by Dr. Plunkett. (Resp't's Br. 39.) But Dr. Plunkett, like Dr. Wirshing, knew nothing about the impact of the statements on South Carolina physicians. (Tr. 953:22-954:20, R. _.)

elements of an "unfair or deceptive practices" claim. As *deBondt* explains, to recover on such a claim, a plaintiff must *first* prove that the challenged acts or practices were "unfair or deceptive" by showing, among other things, that the acts or practices had an impact on the marketplace to which they were directed – i.e., that they were likely to deceive or likely to cause substantial injury. Once the plaintiff has established that the acts or practices were unfair or deceptive, it must *then* show that its claim is something more than an effort to recover for a private wrong – i.e., that the unfair or deceptive acts or practices had "an impact upon the public interest."[4] It can satisfy the second, but not the first, element by proving "potential for repetition." *deBondt*, 342 S.C. at 270, 536 S.E.2d at 407.

This wholesale failure of proof defeats the State's claim that the challenged statements in the label or the letter were "deceptive" or "unfair" under SCUTPA.

B. The Label Claim Is Barred by SCUTPA's Regulated Activity Exemption.

The SCUTPA regulated activity exemption is intended to prevent Monday morning quarterbacking of decisions made by expert regulators. The Risperdal label was repeatedly reviewed and approved by the FDA. The State's label claim is an undisguised attack on those approvals, and the exemption thus bars the claim.

At trial, the State's experts testified that the FDA should never have approved the Risperdal label because it did not contain the "Warnings" that the State believes federal law required. The State's medical expert, for example, testified that the FDA should not

[4] The State makes the same mistake in its penalty arguments. One of the factors to be considered in assessing penalties is "the injury to the public." *United States v. Reader's Digest Ass'n*, 662 F.2d 955, 967 (3d Cir. 1981). The State confuses that requirement with the liability proof requirement of "impact on the public interest."

have approved the placement of disclosures about weight gain and related diabetes risk in the Adverse Reactions section of the label rather than in the Warnings section: "It's my testimony that, that, weight gain should have been in the, the warning section from the very beginning." (Tr. 564:16-18, R. _; *see also id.* at 402:3-403:25, R. _; 504:22-505:12, R. _.) When asked, "Now, the FDA did not agree with you, did they," he responded, "Apparently not." (Tr. 564:19-20, R. _.)

Similarly, the State's regulatory expert testified that the FDA-approved label, from its first approval in 1993, inadequately warned of the risk of hyperprolactinemia because the discussion of that risk appeared in the Precautions section of the label rather than in the Warnings section, where, she opined, federal law required it to be. (Tr. 672:22-680:16, R. _; 824:9-21, R. _.) According to that expert, the approved label was "inadequate" until 2007 when the Precautions and Warnings sections were combined in accordance with new FDA labeling regulations.

Because, in its view, the approved Risperdal label did not comply with federal law and should never have been approved, the State now takes the position that the FDA should never have allowed or authorized the distribution of the approved label. But there is no exception to the SCUTPA regulated activity exemption for acts or practices that "should not have been permitted." "Approval" triggers the exemption, even if the approval was, in the State's opinion, unwise or improper. *Ward v. Dick Dyer & Assocs., Inc.*, 304 S.C. 152, 155, 403 S.E.2d 310, 312 (1991) (exemption applies when allegedly

deceptive act or practice was allowed, authorized, or required by law or regulation).[5] And there is no dispute that the FDA repeatedly approved the Risperdal label.

Notwithstanding the exemption's plain language, the State argues that the exemption is "inapplicable" because "Janssen's conduct that violated SCUTPA also violated federal laws and regulations." (Resp't's Br. 27.) It thus proposes a construction of SCUTPA that would require a determination that there was a violation of federal law before liability could be imposed. Such a construction would turn the exemption on its head, authorizing the very regulatory second-guessing that the South Carolina legislature expressly forbade. It would impermissibly require, for this and other SCUTPA claims challenging an approved prescription drug label, a determination that the FDA had failed to apply correctly its own regulatory standards.[6]

The State may not condition liability on a determination that Janssen violated federal law or that the FDA misapplied its regulations. State-law claims conditioned on proof of violations of federal drug labeling law are expressly prohibited by the federal Food, Drug, and Cosmetics Act ("FDCA"), which bars states from bringing actions "for the enforcement, or to restrain violations of" the federal statute. 21 U.S.C. § 337(a). In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 n.4 (2001), the United

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[5] In its brief, the State suggests that Janssen is advocating for a "general activity" test – i.e., an exemption for all acts and practices related to prescription drugs because prescription drugs are "regulated." Janssen, however, argues only that the plain language of the regulated activity exemption should be applied to bar claims for acts and practices that were, in fact, approved and authorized by its federal regulator.

[6] The trial court did not instruct the jury that it could not find a violation of SCUTPA unless it found that the conduct that violated SCUTPA also violated federal law. To the contrary, the court's instructions allowed the jury to find a label-related violation of SCUTPA if the label was "unfair" or Janssen's conduct was "unethical." Thus, there is no basis for the State's "no exemption" argument.

States Supreme Court noted that Section 337(a) "leaves no doubt that" the federal government has the exclusive authority to "file suit for noncompliance" with the FDCA. Federal courts consistently have held that state-law claims are barred if they exist solely by reason of the FDCA or regulations implementing the FDCA. *See, e.g., Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 379 (5th Cir. 2012). Federal courts also have precluded state-law claims when they "would not exist if the FDCA did not exist." *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009).

A state statute that conditions recovery on a violation of federal law also is invalid under *Buckman's* "obstacle preemption" holding. On that basis, the *Lofton* court held that a safe harbor provision that applies only when there is proof of fraud on the FDA "intrudes on the competency of the FDA and its relationship with regulated entities" and is, therefore, preempted. 672 F.3d at 380-81. Similarly, a regulated activity exemption, or safe harbor provision, that applies only when there is proof of a violation of federal prescription drug labeling law would be preempted, for a state-court determination of noncompliance with federal labeling law would be no less intrusive. That determination, like the determination that there was fraud on the FDA, would involve second-guessing by the state of the FDA's "delicate balance of statutory objectives." *Buckman*, 531 U.S. at 348. Resolution of that claim, like resolution of a fraud on the FDA claim, would require litigants to "re-tread[] the FDA's administrative ground." *Lofton*, 672 F.3d at 380.

Because the label was approved by the FDA, and because the use of the approved label in South Carolina, as in the rest of the United States, was authorized and required by federal law, the regulated activity exemption bars the State's label claim. The trial court

should have directed a verdict for Janssen on the label claim, and should have granted Janssen's motion for judgment notwithstanding the verdict.

II. THE STATE'S CLAIMS ARE PRECLUDED BY FEDERAL LAW.

The State argues that federal prescription drug labeling law and SCUTPA have the same consumer-protection "goal" and that they both proscribe false and misleading statements. It therefore characterizes federal and state law as "parallel" and argues that the State's claims are not preempted. (Resp't's Br. 17-18, 29-30.) The United States Supreme Court, however, recently rejected just such a "parallel goals" argument, holding that a state law with the "same aim as federal law" was nevertheless preempted because differences between state and federal enforcement could interfere with the federal regulatory scheme. *See Arizona v. United States*, __ U.S. __, 132 S. Ct. 2492, 2502-07 (2012). The State's label and letter claims, and the enormous monetary penalties imposed by the State, similarly interfere with federal regulation of prescription drug labeling and federal enforcement of federal labeling law.[7] Both claims are preempted or precluded by federal law.

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[7] The State cites to recent trial court judgments in Louisiana and Arkansas for the proposition that other courts have imposed state-law penalties in state-plaintiff Risperdal cases. (Resp't's Br. 69.) Those cases, now on appeal, were brought by the same Texas lawyers representing the State here and rest on equally infirm efforts to second-guess the FDA or to capitalize on FDA regulatory action. No appellate court has endorsed the theories used by the State's counsel in those cases. Indeed, the appellate courts that have decided state-plaintiff Risperdal cases have ruled in Janssen's favor. *See Commonwealth v. Ortho-McNeil-Janssen Pharm., Inc.*, No. 802 CD 2011, 2012 WL 3030512 (Pa. Commw. Ct. July 26, 2012) (affirming compulsory nonsuits, at the close of the Commonwealth's case, on fraud and unjust enrichment claims); *State ex rel. McGraw v. Johnson & Johnson*, 704 S.E. 2d 677, 689-90 (W. Va. 2010) (holding that the 2004 Warning Letter was "informal and advisory").

A. The State's Label Claim Is Preempted Because It Interferes with Federal Regulation of Prescription Drug Labeling.

Federal prescription drug labeling law dictates both the content and the form of the label; it specifies what must be included in the label and where in the label it must be placed. *See* 21 U.S.C. § 352; 21 C.F.R. §§ 201.1-.59. The FDA approves the label if it determines that the label complies with the federal requirements and contains nothing that is false or misleading. *See* 21 U.S.C. § 355(d).[8] Under federal law, the approved label must be used in all fifty states. *See* 21 C.F.R. § 201.100(c). Only the FDA and the U.S. Department of Justice may enforce federal prescription drug labeling law and the comprehensive federal labeling regulations. *See* 21 U.S.C. § 337(a).

The FDA first approved the Risperdal label in December 1993. (Tr. 2021:24-2022:1, R. _.) In the years that followed, it repeatedly approved revised versions of the label. (Tr. 911:3-6, R. _; 2021:24-2023:12, R. _; 2033:6-14, R. _; Ex. D-3180, R. _.) Each time, it determined that the label was not false or misleading; each time, it required that the approved label language be used verbatim. (*See, e.g.*, Exs. P-571, R. _; D-841, R. _; D-3180, R. _; D-843, R. _.) Now, a state court jury has decided that the distribution of that FDA-approved label in South Carolina was "unlawful" because the label, at some point in time, contained a statement that was false or misleading or because the distribution of the label was "unfair." And a state trial court has assessed a monetary penalty for each time the label was shown to have been distributed in South Carolina. Yet the State contends that there is no conflict between federal law and South Carolina

[8] The FDA must approve any revisions to the label, although some changes may be made without *prior* approval. *See, e.g.*, 21 C.F.R. § 314.70(c)(6)(iii), (c)(7).

law and that its penalty action does not present an obstacle to the exclusively federal regulation of prescription drug labeling. (Resp't's Br. 16-22.)

The State stresses that it "did not seek or obtain an injunction." (*Id.* at 22.) Thus, "Janssen may pay the State's penalties award without changing Risperdal's labeling." (*Id.*) Janssen, it says, may comply with both federal and state law by distributing the FDA-approved label as required by federal law and paying the state-imposed penalty for doing so. (*Id.* at 22-23.) But a state law declaring the federally mandated distribution of the FDA-approved label "unlawful" obviously conflicts with federal law. And a state law that provides for a penalty of as much as $5,000 each time a pharmaceutical manufacturer distributes an FDA-approved label in the state surely stands as an obstacle to the congressionally mandated nationwide uniformity of prescription drug labeling and interferes with the FDA's regulation of prescription drugs and prescription drug marketing. It does not matter that the State, in a particular case, may not have sought an injunction because the challenged label was no longer in use. *See Arizona*, 132 S. Ct. at 2502-07 (finding preemption based on differences between state and federal enforcement). State laws that interfere with federal regulation – that present an obstacle to the achievement of the objectives of federal law – are preempted. *See State v. 192 Coin-Operated Video Game Machs.*, 338 S.C. 176, 186, 525 S.E.2d 872, 877 (2000) (citing *Michigan Canners & Freezers Ass'n v. Agric. Mktg. & Bargaining Bd.*, 467 U.S. 461, 469 (1984)). States may not outlaw the federally approved label or penalize its use.

The State's response to Janssen's obstacle preemption argument is "*Wyeth v. Levine*." *Wyeth*, the State says, "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.'" (Resp't's Br. 18.) After *Wyeth*, the State argues, there can be no "obstacle" preemption of a state's challenge to a federal labeling decision. The State, however, is misreading *Wyeth*.

Wyeth held only that federal prescription drug labeling law does not preempt individual state-law tort claims seeking compensation for injuries caused by the breach of a state-law duty to warn about a product's risks. 555 U.S. 555, 581 (2009). The *Wyeth* court's "no preemption" holding rested on the observation that the personal injury products liability suit before it fell within "'a field which the States have traditionally occupied,'" *id.* at 565 (internal citation omitted), and the conclusion that the United States Congress "did not regard state tort litigation as an obstacle to achieving its purposes," *id.* at 575. "Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs," the Court said, because "[e]vidently, it determined that widely available state rights of action provided appropriate relief for injured consumers." *Id.* at 574. The Court referred repeatedly to "state tort suits" and specifically to common law personal injury actions. *Id.* at 574 n.7, 579, 579 n.12, 580, 581.

The trial court in *Wyeth* had "noted that state law serves a compensatory function distinct from federal regulation," *id.* at 563, and the *Wyeth* majority likewise observed that state-law personal injury actions "serve a distinct compensatory function," *id.* at 579. Given that distinction between compensation and regulation and the abundant evidence that Congress did not mean to interfere with the "widely available state rights of action" with which it was familiar, the Court held that "Wyeth has not persuaded us that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling." *Id.* at 574, 581.

But this is not a "failure-to-warn claim[] like Levine's." This action serves no "compensatory function." In fact, the State has not alleged, much less proved, that anyone was harmed, or that the State lost any money. Rather, this case is a direct attack on "the federal regulation of drug labeling." Indeed, in its brief, the State unabashedly characterizes its claim as a "state law challenge[] against FDA-approved labels." (Resp't's Br. 29.) The State has premised its action on the notion that the decisions entrusted by Congress to the federal regulator were wrong, and the State is seeking to punish Janssen for its compliance with the federal mandate that it use the FDA-approved label.

Moreover, there is no basis for an argument that Congress "did not regard" this sort of litigation "as an obstacle to achieving its purposes." *Wyeth*, 555 U.S. at 575. Here, Congress has provided explicitly for comprehensive federal regulation of the form and content of the label and for federal enforcement of labeling law. And there is no indication whatsoever that Congress anticipated, and intended to allow, a lawsuit like this one – an action seeking to substitute the views of a state attorney general and a state jury for the considered decisions of the FDA. As the Supreme Court recognized, "some state-law claims might well frustrate the achievement of congressional objectives" by interfering with federal drug regulation. *Wyeth*, 555 U.S. at 581. The State's label claim is such a claim.

The difference between "compensation" claims and claims that interfere in an impermissible way with the relationship between the federal regulator and the entities it regulates was "the dispositive factor for federal preemption in *Buckman*." *Lofton*, 672 F.3d at 377. *Buckman* was not, as the State contends, a "case limited to state law claims

for fraud *committed on the FDA*." (Resp't's Br. 23.) Its holding turned not on the happenstance that the claims at issue were "fraud on the FDA claims" but on the fact that such claims disrupted the regulator-regulated entity relationship. For the same reason the *Buckman* state-law fraud claim was preempted, any other state-law claim that would "exert an extraneous pull on the [regulatory] scheme established by Congress" also would be preempted. *Buckman*, 531 U.S. at 353. Federal labeling decisions, like the enforcement of the federal disclosure rules involved in *Buckman*, require the interpretation and application of complex regulations and the balancing of competing interests and objectives by the regulator. Back-door attacks on those decisions, via state consumer protection law, inevitably will "exert an extraneous pull" on the federal regulatory scheme.[9]

Federal prescription drug labeling law thus preempts the State's labeling claim. Claims like the State's present a formidable obstacle to the accomplishment of key objectives of federal labeling law: federal regulation of prescription drug labeling and the use of a label approved by the FDA, without variation, throughout the United States. And they interfere with the relationship between the FDA and the pharmaceutical companies it regulates.

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[9] Even if *Buckman* were, as the State would have it, "limited to state law claims for fraud committed on the FDA," the State's label claim still would be preempted. In its brief, the State points to Janssen's decision "to keep those results [of RIS-USA-113 and ERI] from public and regulatory view." (Resp't's Br. 39.) "Hiding those results that showed reasonable association with the serious hazards of diabetes/hyperglycemia and weight gain," the State argues, "allowed Janssen to steer clear of adding to or strengthening Risperdal's Warnings." (*Id.*) The State made the same assertions at trial, and the trial court relied on them in its Penalty Order. (Penalty Order at 9-10 (Janssen "submitted voluminous responses to that request [from the FDA], but did not disclose the top line results of study 113 or ERI . . ."), R. _.)

B. The State's Letter Claim Is Barred Because It Is an Impermissible Attempt to Enforce Federal Law and Interferes with Federal Enforcement of Prescription Drug Labeling Law.

As explained in Janssen's Initial Brief, the State offered little or no evidence that the November 10, 2003 letter was deceptive or unfair other than the April 2004 DDMAC Warning Letter, which said that the November letter was "false or misleading" in violation of federal law. The State's letter claim therefore is barred, for states may not enforce that federal law. *See* 21 U.S.C. § 337(a).

The State responds that its medical expert, Dr. Wirshing, and its regulatory expert, Dr. Plunkett, did not rely "only" on the April 2004 Warning Letter, with its assertion that Janssen violated regulatory standards, as support for their conclusion that the November 10, 2003 letter contained false statements. (Resp't's Br. 31.) Most, if not all, of Dr. Wirshing's and Dr. Plunkett's opinions, however, were tied to the Warning Letter. Repeatedly, they were asked whether they agreed with the FDA, and repeatedly they said that they did. Then, in closing arguments, the State's counsel invited the jury to find that the November 10, 2003 letter was unfair and deceptive and violative of SCUTPA because "the FDA thought so." (Tr. 2542:6, R. _.)

On the central issue, the supposedly "deceptive" attempt to differentiate Risperdal from Zyprexa with respect to weight gain and the diabetes risk associated with weight gain, Dr. Wirshing's and Dr. Plunkett's "falsity" opinions were based entirely on the federal regulatory standards about which the Warning Letter spoke. Dr. Wirshing testified that he "agree[d] with the FDA's assessment that Janssen's November 10th, 2003, letter was false and misleading" because "it was designed to distinguish themselves from, from the class label, which is an absolute distinction to what the FDA wanted."

(Tr. 497:23-498:3, R. _.) Dr. Plunkett explicitly tied her opinion as to the "falsity" of the letter's statement about differential risks of diabetes to "the FDA standard":

> Q. And the third statement is evidence also suggests that Risperdal is associated with a lower risk of diabetes than some other studied atypical antipsychotics. Do you believe that's false also?
>
> A. Based upon the FDA standard, absolutely.
>
> Q. Okay. And, so, your belief as to whether that was false or true is predicated upon the FDA's standard, is that correct?
>
> A. Which is the standard that applies to a Dear Doctor Letter. Absolutely.

(Tr. 1007:6-15, R. _.)

The State's evidence, then, was primarily evidence of "regulatory violations," not falsity. Indeed, Dr. Wirshing and Dr. Plunkett conceded on cross-examination that the statement in the November letter that "[e]vidence also suggests that Risperdal is associated with a lower risk of diabetes than some other antipsychotics" was true. As Dr. Wirshing explained, diabetes risk is tied to weight gain; the more weight gained, the greater the diabetes risk. (Tr. 489:10-13, R. _.) Zyprexa, the two experts agreed, causes substantially more weight gain than Risperdal. (Tr. 616:19-617:23 (Wirshing: Zyprexa causes "on average about twice" as much weight gain as Risperdal), R. _; Tr. 987:16-988:6 (Plunkett: "Zyprexa has a greater risk of producing weight gain and diabetes in individuals."), R. _.)

The trial court's instruction that the State's claim was "not an effort to enforce any federal law or regulations" could not have dispelled the confusion inevitably caused by the expert testimony about violations of federal regulations and counsel's arguments about the significance of those violations. (*See* Tr. 2665:3-4, R. _.) And even if the State had offered evidence other than the evidence of regulatory violations – evidence that was

sufficient to support the verdict – there would remain a substantial risk that the jury's verdict was, at least in part, based on the Warning Letter and FDA regulatory standards, and a new trial would be in order. All that the trial court said in its charge was that a finding of a violation of federal law "in and of itself" would not suffice. (Tr. 2665:8-9, R. _.)

Not only is the State's "parallel enforcement" claim as to the letter barred by the "exclusively federal enforcement" provision of the FDCA, but it also is barred by obstacle preemption. As discussed in *Buckman*, the FDCA arms the FDA with a variety of enforcement tools that the agency employs, in its discretion, to achieve its regulatory objectives. 531 U.S. at 348-49. Warning Letters are used to notify regulated entities about potential regulatory violations and to solicit voluntary corrective measures, obviating the need for formal enforcement proceedings. (Ex. D-4337, R. _, Ch. 4, FDA Regulatory Procedures Manual: Advisory Actions at 4-2 (2004).) As the record shows, the July 21, 2004 corrective letter was the result of a cooperative effort by Janssen and the FDA to ensure that the FDA's concerns about the November 10, 2003 letter, set forth in the Warning Letter, were made known to prescribers. The State, however, urged the jury to find liability on the letter claim because Janssen "caved in immediately" when it received the Warning Letter: "[A]fter they received that warning letter, these Defendants folded like a cheap suit." (Tr. 2544:7, R. _ .)

Allowing states to base penalty actions, even in part, on cooperative efforts to ensure compliance with FDA regulations will inevitably diminish the utility of Warning Letters and other informal regulatory compliance techniques. Regulated entities will have incentives to dispute, rather than resolve, issues raised by Warning Letters and other

notices of possible regulatory infractions, and the FDA might be deterred from using them. Under *Buckman*, 531 U.S. at 350, and *Arizona*, 132 S. Ct. at 2502-07, state-law claims that diminish the effectiveness of the FDA's enforcement mechanisms and interfere with the FDA's enforcement prerogatives are impliedly preempted.

III. THE TRIAL COURT COMMITTED PREJUDICIAL ERROR WHEN IT ADMITTED THE DDMAC LETTERS.

The State defends the admission of the 1994, 1999, and 2004 DDMAC letters on two grounds. First, the State contends that the DDMAC letters were not admitted for the truth of the matters asserted and, therefore, were not hearsay. Second, the State argues that even if they were hearsay, they fell within the "public records and reports" exception to the hearsay rule. The State is incorrect on both scores.

As shown by the quotations from the trial record in Janssen's Initial Brief, the State offered the April 2004 DDMAC Warning Letter for the "truth" of its statement that the November 10, 2003 letter was "false or misleading." (*See* Janssen's Br. 22-25.) Similarly, the State offered the 1994 and 1999 DDMAC letters for the "truth" of their characterizations of other Janssen statements as "false or misleading." (*See, e.g.*, Tr. 700:21-701:11, R. _; 1041:14-1049:4, R. _; 2528:4-6, R. _; 2546:11-25, R. _.)

If there were any doubt about this, the State's brief would dispel it. For example, the State goes so far as to assert that the 2004 Warning Letter constituted proof of deception because the jury "rightly considered evidence . . . that the FDA found the Dear Doctor Letter . . . misleadingly claim[ed] that Risperdal is safer than other atypical antipsychotics." (Resp't's Br. 38-39.) In seeking to justify the more than $170 million in civil penalties related to the November 2003 mailing, the State cites as "evidence" the regulatory allegations contained in the informal and advisory Warning Letter. (*See*

Resp't's Br. 47 ("[T]he 2004 Warning Letter was offered . . . to show . . . the official conclusions that the FDA reached . . . .").) And the State contends that all three of "[t]he letters were probative" of "whether Janssen's conduct adversely affected the public interest" and were "evidence indicating that Janssen had not . . . complied" with FDA rules and regulations. (Resp't's Br. 51.)

The State's public records exception argument fares no better than its "not offered for the truth" argument. Rule 803(8) of the South Carolina Rules of Evidence provides an exception to the hearsay rule for certain "matters observed." That limited exception for "matters observed" does not extend to "opinions formed" or "conclusions reached." It refers only to information that is concrete and factual. *See, e.g.*, *State v. Pearson*, 223 S.C. 377, 383, 76 S.E. 151, 153-54 (1953) ("[A] record of a primary fact made by a public officer in the performance of official duty" is admissible, whereas "records of investigations and inquiries conducted . . . involving the exercise of judgment and discretion, expressions of opinion, and making conclusions" are not. (quotation marks and citations omitted)). The State concedes that the letters contained "conclusions." (Resp't's Br. 52.) Those conclusions should not have been admitted into evidence.

That the conclusions were not contained in "investigative notes" makes no difference. The Rule provides that no part of "investigative notes involving opinions, judgments, and conclusions" will ever be admissible. It does not provide for the admission into evidence of conclusions contained in documents other than investigative notes, even though they were not and could not have been "matters observed."[10]

[10] There likewise is no merit to the State's contention that Warning Letters are not beyond the scope of the public records exception because the FDA has a duty to issue

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The DDMAC letters were hearsay and they were not admissible pursuant to the public records exception to the hearsay rule. The trial court's admission of the letters into evidence, and the State's reliance upon them for proof that the statements in the November 10, 2003 letter were "deceptive" or "unfair" or as evidence that Janssen violated the FDA rules, were improper and severely prejudicial. The trial court compounded the prejudice by excluding evidence that the statements in the November letter were true and that the November letter had no impact on the South Carolina marketplace. That left the focus on the violation of regulatory standards alleged in the Warning Letter and not where it should have been – on the likelihood that the November 2003 mailing would deceive physicians.

IV. THE JURY'S VERDICT AND RESULTING PENALTY AWARD VIOLATED CONSTITUTIONAL FREE SPEECH PROTECTIONS.

Because the trial court concluded that the Risperdal label and the November 10, 2003 letter were not entitled to First Amendment protection, it did not require the jury to find that Janssen made false statements, as opposed to "unfair" statements,[11] that the statements caused harm, or that Janssen knew that its statements

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them akin to the duty of a public servant to keep records of transactions or occurrences, such as a record of visitors to a government office. The FDA has the *authority* to issue Untitled Letters and Warning Letters, but has no *duty* to issue them. (Ex. D-4337, R. _, Ch. 4, FDA Regulatory Procedures Manual: Advisory Actions at 4-2 (2004) ("FDA is under no legal obligation to warn individuals or firms that they or their products are in violation of the law before taking enforcement action.").)

[11] The State's insistence that *Sorrell v. IMS Health, Inc.*, __ U.S. __, 131 S. Ct. 2653 (2011) has "no bearing on the deceptiveness or unfairness of drug manufacturers' 'commercial speech,'" (Resp't's Br. 73), is incorrect. In *Sorrell*, the Supreme Court rejected a Vermont statute targeting "unfair" pharmaceutical marketing practices because

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were false or made them with reckless disregard of their truth or falsity. The trial court also imposed more than $327 million in penalties without any showing that the penalties were no more restrictive of speech than reasonably necessary. The State defends those decisions, arguing that speech that is false or misleading does not "come within the First Amendment." (Resp't's Br. 70-71.)

As a threshold matter, there was no jury finding that the statements in the label and the letter were "false or misleading," as the State effectively concedes when it says, in its brief, that it was required to prove only that the label and letter were "unfair." (*Id.* at 37-38.) Even if there had been such a finding, Janssen still would be entitled to First Amendment protections. Only a few weeks after the State filed its brief, the United States Supreme Court struck down the Stolen Valor Act of 2005, which made it a crime to claim falsely to have received the Congressional Medal of Honor. *United States v. Alvarez*, __ U.S. __, 132 S. Ct. 2537 (2012). Ruling that the Act could not withstand the "exacting scrutiny" given all content-based restrictions of speech, the Court flatly rejected the argument that speech is not protected by the First Amendment simply because it is false or misleading. *Id.* at 2545 (plurality). It held, instead, that the First Amendment protects even an "intended, undoubted lie." *Id.* at 2542-43. The plurality explained that "the Constitution 'demands that content-based restrictions on speech be presumed invalid . . . and that the Government bear the burden of showing their constitutionality.'" *Id.* at 2544 (citation omitted).

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there was no showing that the marketing was "false or misleading within the meaning of [the] Court's First Amendment precedents." 131 S. Ct. at 2672.

To meet that burden, the State must show that its interest is sufficiently compelling, by proving that the challenged speech was likely to cause "real harm." *Id.* at 2544-47. To ensure that the pursuit of the State's interest does not chill protected speech, the State also must prove that the speech consisted of a "knowing or reckless falsehood." *Id.* at 2545. *Alvarez* explains that the requirement of proof that the statement was made "with knowledge that it was false or in reckless disregard of whether it was false or not," is not, as the State contends in its brief, applicable only to "media-related defamation cases." (Resp't's Br. 74.) To the contrary, "even when the utterance is false, the great principles of the Constitution which secure freedom of expression . . . preclude attaching adverse consequences to any except the knowing or reckless falsehood." *Alvarez*, 132 S. Ct. at 2545 (plurality) (citing *Ill. ex rel. Madigan v. Telemarketing Assocs., Inc.*, 538 U.S. 600, 620 (2003), a consumer fraud case); *see also id.* at 2553 (concurrence) (noting that the requirement of proof that a false factual statement was "made with knowledge of [its] falsity and with the intent that [it] be taken as true" is necessary to provide "'breathing room'" for more valuable speech). *Alvarez* makes clear that the requirement of proof that a falsehood was "knowing or reckless" applies when the speech, like the speech here, relates to conclusions and opinions about the meaning and significance of scientific evidence,[12] when all the evidence is not yet in and the conclusions and the opinions are not "easily verifiable facts." *Id.* at 2552 (concurrence).

[12]At pages 71-72 of its brief, the State argues that the statements in the letter and label were not statements about matters of public concern. But that contention in the "First Amendment" section of the State's brief contrasts markedly with its arguments elsewhere about the "impact on the public interest" of the label- and letter-related "violations."

Moreover, although the government may, in very limited circumstances, impose content-based restrictions on "knowing or reckless falsehood[s]" that cause legally cognizable harm, the First Amendment requires a "clear showing" that "the Government's chosen restriction on the speech at issue be 'actually necessary' to achieve its interest." *Id.* at 2545, 2549-50 (plurality). The government thus must show that the restriction it seeks to impose is the "least restrictive means among available, effective alternatives." *Id.* at 2551 (quotation marks and citation omitted). In particular, the State must show "why counterspeech would not suffice to advance its interest." *Id.* at 2549. As Justice Kennedy wrote, "The remedy for speech that is false is speech that is true." *Id.* at 2550.

Here, the trial court did not instruct the jury about the requirements of the First Amendment and there was no jury finding of a "knowing or reckless falsehood" or a "likelihood" of harm. At trial, Janssen proposed jury instructions that set forth the requirements of proof for imposing liability for constitutionally protected speech, (Defs.' Requested Jury Instructions Nos. 13, 16, 17, 18, 19, R. _), and a verdict form that reflected these requirements, (Defs.' Requested Verdict Sheet, R. _). But when the State objected, the trial court adopted a charge and submitted to the jury a verdict form that incorporated none of those essential limitations and protections.[13]

Then, at the penalty stage, the trial court, believing that the First Amendment was inapplicable, did not address whether a monetary penalty was "actually necessary"

[13] Because there was no proof of a likelihood of harm and no clear evidence of a knowing or reckless falsehood, the trial court should have entered a judgment in favor of Janssen. At the very least, the faulty jury instructions and verdict form entitle Janssen to a new trial.

or whether "counterspeech" would sufficiently serve the State's interests. By contrast, the FDA, with primary regulatory authority over the label and the letter, never required anything more than prospective changes to the label – it asked all manufacturers of atypical antipsychotics to add a "diabetes" warning – and concluded that any problem with the November 10, 2003 letter was cured by the distribution of a "corrective" letter that simply reported that the FDA had reached different conclusions about the pertinent scientific evidence. In other words, the agency with scientific and regulatory expertise concluded that counterspeech would suffice. The trial court should have deferred to, or at least considered, that conclusion. At the very least, the trial court should have considered whether the imposition of the extraordinary $327 million in penalties was "necessary" and was the least restrictive means to accomplish the State's objectives, or whether some lesser punishment would have been enough.

V. THE PENALTY IS NOT TIED TO THE JURY'S VERDICT AND NOT CONSISTENT WITH THE RECORD EVIDENCE AND VIOLATES THE EXCESSIVE FINES AND DUE PROCESS CLAUSES.

The trial court imposed more than $327 million in penalties although there was no evidence of deception, impact, or harm. The court took the position that it was irrelevant, even at the penalty stage, whether the statements the State challenged were true, whether they had any impact on prescribers, and whether there was any harm or loss. It based its label-related penalties, tied to the distribution of samples, on a mischaracterization of the jury's findings. And it based its letter-related penalties, in substantial part, on a misstatement of the facts of record as to "presentation sales calls." The penalty award thus was both arbitrary and unauthorized – because it was

not tied to the record and because the trial court misapplied the governing law – and unconstitutionally excessive.

Samples

A fundamental flaw in the trial court's penalty analysis, as it related to the label claim, was the assessment of penalties based on the number of boxes of Risperdal samples. Between 1998 and 2007, 509,499 multi-dose Risperdal sample boxes were distributed to South Carolina healthcare professionals. (Penalty Hr'g Ex. P-1, R _.)[14] The trial court imposed a $300 penalty for each of the 509,499 sample boxes, for a total label-related penalty of $152,849,700. (Penalty Order at 16-17, R. _.) The trial court said, in its Penalty Order, that it "consider[ed] each publication of the Risperdal label" with a sample box "to be a separate violation." (*Id.* at 16, R. _.)

In its "summary of the facts," the State says that "the jury unanimously found that Risperdal's product label," or package insert, "violated SCUTPA from 1994 to 2007." (Resp't's Br. 4.) Later in the brief, when discussing penalties, the State says that the "label" distributed with each of the sample boxes from 1994 to 2007 was "unanimously found by the jury to be unfair and deceptive." (*Id.* at 56.) The jury, however, was not asked to find, and did not find, that all of the labels in use from 1994 to 2007 were unfair and deceptive. Over Janssen's objection, the trial court asked the jury only whether Janssen "engaged in unfair or deceptive acts or practices in the conduct of any trade or commerce in its label." (Verdict Form, R. _.) All that the jury found, then, was that at least one of the labels in use between 1994 and 2007 was violative of SCUTPA. The trial court erred when it imposed penalties for every label accompanying a sample box for the

[14] There was no evidence of the number of sample boxes distributed before 1998.

entire period. The penalties were not, as the statute requires, tied to the "violations" found by the jury. *See* S.C. Code Ann. § 39-5-110(a).

Tacitly acknowledging the trial court's error, the State now argues that it introduced evidence "that the label was deceptive or unfair throughout the time period from 1994 to 2007." (Resp't's Br. 58-59.) But the question is "what violations the jury found," not "what evidence was introduced" or "what violations might the jury have found, if it had accepted all of the State's arguments." The trial court did not have "discretion," as the State now suggests, to substitute its view for that of the jury as to what was a violation of the statute. The $152,849,700 in label-related penalties is not authorized by the statute, and must be set aside. Because there is no record evidence upon which any other label-based penalty could be imposed, no penalty should have been assessed on the label claim.

Sales Calls

The trial court made a similar error when it based the bulk of the letter-related penalties on "presentation sales calls," for the record did not support the imposition of those penalties. The trial court assessed a penalty of $4,000 for each "sales call[] where letter published" in South Carolina between November 10, 2003 and July 21, 2004. (Penalty Order at 17, R. _.) According to the trial court, there were 36,372 such sales calls. (*Id.*, R. _.)

There was no factual or record basis, however, for the conclusion that the November 10, 2003 letter was "published" on every sales call between November 10, 2003 and July 21, 2004. To the contrary, the undisputed testimony at trial was that the distribution of the November 10, 2003 letter by sales representatives was a

"one and done" event; the letter was not distributed on repeat visits to a physician. (*See, e.g.*, Tr. 1143:16-20, R. _.) The State does not address this testimony in its brief, and does not even attempt to defend the trial court's conclusion that the letter was "published" 36,372 times. Instead, the State argues that the trial court could have imposed a penalty for Janssen's "failure to *disclose the truth*" about the November 10, 2003 letter until July 21, 2004 and that a per-visit penalty is therefore appropriate. (Resp't's Br. 59-60.) The only letter-related violation found by the jury, however, was that Janssen made unfair or deceptive statements "in" the November 10, 2003 letter; the jury did not find that Janssen violated the statute by its "failure to disclose the truth" on sales calls. (Verdict Form, R. _.) Moreover, the trial court did not penalize Janssen for anything other than "publications of [the] letter." (Penalty Order at 17, R. _.) Because the State offered no proof of the number of sales calls on which the letter was actually "published," the "sales calls" penalty of $145,488,000 must be set aside.

Excessive Fines/Due Process

The State's effort to defend the $327 million penalty under the Excessive Fines and Due Process Clauses rests on the mistaken contention that a penalty that is less than the maximum penalty allowed by statute cannot be unconstitutional. The cases on which the State relies, however, say nothing of the sort. Indeed, the State's position is directly contrary to United States Supreme Court precedent.

United States v. Mackby, 221 F. Supp. 2d 1106 (N.D. Cal. 2002), *aff'd*, 339 F.3d 1013 (9th Cir. 2003), does not stand for the proposition that "'[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.'" *Compare Mackby*, 221 F. Supp. 2d at 1110, *with* Resp't's Br. 67. To the contrary, *Mackby* was decided by the district court on remand from the Ninth Circuit, which had concluded that the statutory minimum penalties *could* be "so grossly disproportionate to the gravity of Mackby's violation as to violate the Eighth Amendment." *United States v. Mackby*, 261 F.3d 821, 830 (9th Cir. 2001); *see also United States v. Bajakajian*, 524 U.S. 321, 337 (1998) (holding penalty requiring forfeiture of $334,144 violated Excessive Fines Clause where no harm to public fisc).[15]

Similarly, *St. Louis, Iron Mountain & Southern Railway Co. v. Williams*, 251 U.S. 63 (1919), did not hold that the minimum penalty prescribed by a statute cannot be excessive and unreasonable and therefore violate the Due Process Clause. *Compare Williams*, 251 U.S. at 66-67, *with* Resp't's Br. 67-68. Rather, *Williams* made clear that even the minimum penalty *would* violate the Due Process Clause if "the penalty prescribed is so severe and oppressive as to be wholly disproportioned to the offense and obviously unreasonable." 251 U.S. at 66-67. The "quotation" from *Williams* in the State's brief at 67 leaves a different impression, but only because the State has misleadingly substituted the words "a statute" for the reference in the opinion to the penalty that had been assessed.[16]

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[15] The State cites *Bajakajian*, 524 U.S. at 336, for the proposition that "judgments about the appropriate punishment for an offense belong in the first place to the legislature." The *Bajakajian* court went on to hold that the standard for an excessive fine is "gross disproportionality" and that the fine there, which was within the statutory range, nevertheless violated the Excessive Fines Clause. *Id.* at 336-37.

[16] The State also relies on *Williams* for the contention that because a "public wrong" or "public impact" was involved, there need not be *any* proportionality analysis. (Resp't's

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The State's argument that the Due Process Clause does not apply to "statutory damages" misses the mark in much the same way. All three cases the State cites acknowledge, expressly or tacitly, that statutory damages grossly disproportional to the offense *would* violate the Due Process Clause. *Verizon Cal., Inc. v. OnlineNIC, Inc.*, No. C08-2832, 2009 U.S. Dist. LEXIS 84235, at *20, *26-27 (N.D. Cal. 2009); *Zomba Ents., Inc. v. Panorama Records, Inc.*, 491 F.3d 574, 587-88 (6th Cir. 2007); *Lowry's Reports, Inc. v. Legg Mason, Inc.*, 302 F. Supp. 2d 455, 459-60 (D. Md. 2004). While some courts have questioned whether the "ratios" discussed in *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996), and *State Farm Mutual Auto Insurance Co. v. Campbell*, 538 U.S. 408 (2003), should be applied in a statutory penalties case, they have recognized that due process limitations on excessive punishment still apply. *See Parker v. Time Warner Entm't Co.*, 331 F.3d 13, 26 (2d Cir. 2003) (citing *Gore* and *Campbell* and noting that statutory penalties "might well encounter due process objections, somewhat analogous to those that the Supreme Court recently identified in setting constitutional limits on punitive damages"); *Verizon Cal., Inc.*, 2009 U.S. Dist. LEXIS 84235, at *26-27 (acknowledging that while there is an "imperfect fit" between statutory damages awards and the *Gore/Campbell* framework, that framework might apply in some instances because statutory penalties frequently serve a punitive purpose).

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Br. 67.) But *Williams* and the cases following it hold only that when a statute addresses public wrongs, the penalty need not be based on the extent of private injury. 251 U.S. at 66. Here, there was neither public nor private injury.

Thus, the fact that the penalty award is within the statutory range is not dispositive of the constitutionality of the award under the Excessive Fines and Due Process Clauses. Although there was no evidence of any harm, and although Janssen's federal regulator had concluded that there was no need for any enforcement action at all, the trial court assessed more than $327 million of penalties. The penalties awarded by the trial court were unconstitutionally excessive and cannot stand.

CONCLUSION

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

Respectfully submitted,

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Columbia, South Carolina
August 2, 2012.

THE STATE OF SOUTH CAROLINA
In The Supreme Court

APPEAL FROM SPARTANBURG COUNTY
Court of Common Pleas

Roger L. Couch, Circuit Court Judge

Case No. 2007-CP-42-1438

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

v.

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

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

PROOF OF SERVICE

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

Pleadings: **Initial Reply Brief of Appellant**

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August 2, 2012

The Honorable Daniel E. Shearouse
Clerk of Court
South Carolina Supreme Court
Post Office Box 11330
Columbia, SC 29211

RE: 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., and Johnson & Johnson, Inc.
Civil Action No. 2007-CP-42-1438
Our File No. 03501/01534

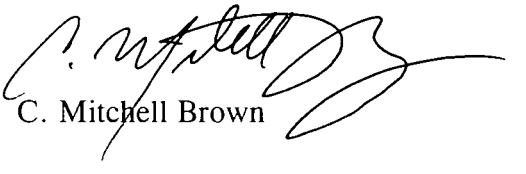
Dear Mr. Shearouse:

Enclosed please find the original and one copy of the Initial Reply Brief of Appellant and Appellant's Designation of Matter for the Record on Appeal in the above-referenced matter. We would ask that you file the originals and return clocked-in copies via our courier.

By copy of this letter to counsel of record, we are serving them with copies.

With kind regards, I remain

Sincerely yours,



C. Mitchell Brown

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Enclosures
cc: Alan Wilson, Attorney General
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