NO. _____

In the
Supreme Court of the United States

ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., F/K/A JANSSEN PHARMACEUTICAL, INC., AND/OR JANSSEN, L.P.,

Petitioner,

v.

SOUTH CAROLINA EX REL. ALAN WILSON, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE STATE OF SOUTH CAROLINA,

Respondent.

On Petition for Writ of Certiorari to the Supreme Court of South Carolina

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

In 2007, the South Carolina Attorney General sued Petitioner under the South Carolina Unfair Trade Practices Act (SCUTPA) seeking civil penalties for certain statements made in an FDA-approved prescription-drug label and a letter to physicians. Under SCUTPA, South Carolina can recover statutory penalties of up to $5,000 per violation for actions or statements that are "unfair" or have the "capacity" or "tendency" to deceive. South Carolina need not make any showing of knowing falsity, reliance, or actual injury to recover statutory penalties. In the proceedings below, the South Carolina courts imposed a staggering $124 million civil penalty against Petitioner even though there was no proof that anyone relied on, or was injured by, the purportedly "unfair" or "deceptive" statements.

The questions presented are:

(1) Whether a state violates the First Amendment by penalizing a defendant for the content of its speech without requiring proof that the speech contains a knowing or reckless falsehood;

(2) Whether the Federal Food, Drug, and Cosmetic Act preempts a state enforcement action that serves no compensatory purpose and instead simply seeks to *penalize* a pharmaceutical company for actions that are comprehensively regulated and overseen by the Food and Drug Administration; and

(3) Whether the imposition of a $124 million civil penalty, without any showing of actual deception, reliance, or injury, violates the Excessive Fines Clause.

PARTIES TO THE PROCEEDING

Petitioner Ortho-McNeil-Janssen Pharmaceuticals, Inc., was a defendant in the South Carolina trial court and appellant in the South Carolina Supreme Court. Respondent, the State of South Carolina, was the plaintiff in the state trial court and appellee in the South Carolina Supreme Court.

CORPORATE DISCLOSURE STATEMENT

Ortho-McNeil-Janssen Pharmaceuticals, Inc., is the former corporate name of Janssen Pharmaceuticals, Inc., which is a wholly owned subsidiary of Johnson & Johnson, a publicly held corporation. No other publicly traded corporation owns 10% or more of the stock of Johnson & Johnson.

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PETITION FOR WRIT OF CERTIORARI

In 2007, the South Carolina Attorney General brought an enforcement action against Petitioner Ortho-McNeil-Janssen Pharmaceuticals, Inc. (Janssen) under the South Carolina Unfair Trade Practices Act (SCUTPA). The attorney general alleged that Janssen sent a purportedly "unfair" or "deceptive" letter to healthcare providers about its antipsychotic medicine Risperdal, and that Risperdal's FDA-approved label did not include adequate warnings about certain potential side effects.

In the proceedings below, the South Carolina courts imposed a $124 million civil penalty against Janssen even though there was no finding of knowing or reckless falsehood and no showing that *anyone* relied on, or was injured by, the purportedly unfair or deceptive statements. Indeed, the South Carolina Supreme Court readily acknowledged that Janssen's conduct "likely had little impact on the community of prescribing physicians" because the risks associated with atypical antipsychotics were "well known." Pet.App.58.

Unsurprisingly, a case that culminated in a nine-figure civil penalty despite no showing of intentional deception, reliance, or actual harm was a product of grave legal errors. Those errors go to the heart of the critical lines separating protected speech from actionable fraud, state from federal authority, and appropriate from excessive fines. These issues individually and collectively warrant this Court's review. In direct contravention of this Court's precedents interpreting the First Amendment, the

lower courts punished Janssen for the content of its speech without requiring any showing that this speech contained a "knowing or reckless falsehood." *United States v. Alvarez*, 132 S. Ct. 2537, 2545 (2012) (plurality op.); *see also Illinois ex rel. Madigan v. Telemarketing Assocs.*, 538 U.S. 600, 620 (2003).

This enforcement action also impermissibly encroaches upon regulatory authority that belongs solely to the federal government under the Federal Food, Drug, and Cosmetic Act (FDCA). Unlike the situation in *Wyeth v. Levine*, 555 U.S. 555 (2009), this state-law enforcement action serves no compensatory purpose and simply seeks to *punish* Janssen for its FDA-regulated conduct, which is a role that belongs exclusively to the federal government.

Finally, the staggering $124 million civil penalty violates the Excessive Fines Clause, which prohibits the imposition of penalties that are grossly disproportionate to the gravity of the offense. A nine-figure penalty in a case with *zero* proof of injury, harm, or financial loss does not come close to passing constitutional muster under any conceivable standard of proportionality.

* * *

This case is unfortunately not an outlier. In recent years, state attorneys general have increasingly invoked expansive and amorphous unfair trade practices statutes to obtain huge penalties against companies in a number of different industries. When faced with the prospect of massive civil penalties based on poorly defined notions of "unfair" conduct, many companies are forced to settle even meritless claims rather than risk a catastrophic jury

verdict. This case starkly illustrates the flaws of expansive and uncabined "unfair trade practices" suits. It also offers this Court an opportunity to reaffirm and clarify several important doctrinal tools under the First Amendment, Supremacy Clause, and Excessive Fines Clause that would stem some of the worst abuses. The petition for certiorari should be granted.

OPINIONS BELOW

The South Carolina Supreme Court's substituted opinion on rehearing is not yet reported, but is reproduced at Pet.App.1-69. The trial court's penalty order is unreported and is reproduced at Pet.App.131-50.

JURISDICTION

The South Carolina Supreme Court issued its initial decision on February 25, 2015. *See* Pet.App.70-130. That court granted a timely petition for rehearing and issued a substituted opinion on July 8, 2015. *See* Pet.App.1-69. On September 17, 2015, the Chief Justice extended the deadline for filing a petition for writ of certiorari to November 5, 2015. *See* No. 15A303. This Court has jurisdiction under 28 U.S.C. §1257(a).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The First, Eighth, and Fourteenth Amendments to the U.S. Constitution are reproduced at Pet.App.151-54. The relevant provisions of SCUTPA, S.C. Code Ann. §§39-5-20 & 39-5-110, are reproduced at Pet.App.155-56.

STATEMENT OF THE CASE

A. SCUTPA's Broad Reach and Amorphous Standards

Like many other states, South Carolina has a statute aimed at preventing "unfair" or "deceptive" trade practices. SCUTPA declares unlawful "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." S.C. Code Ann. §39-5-20(a).

SCUTPA is a remarkably expansive statute in several key respects. First, the statute defines unfair and deceptive practices so broadly that it can encompass statements that are neither false nor actually deceptive. Liability under SCUTPA is not limited to statements that are untruthful or have a "capacity or tendency to deceive." *Wright v. Craft*, 640 S.E.2d 486, 500 (S.C. Ct. App. 2006). Instead, a statement can also be challenged as "unfair" if the State deems it to be "offensive to public policy or ... immoral, unethical, or oppressive." *Gentry v. Yonce*, 522 S.E.2d 137, 143 (S.C. 1999). The South Carolina courts have provided little, if any, guidance about what is "immoral," "unethical," or "oppressive."

Similarly, SCUTPA does not require proof of *intent* to deceive; rather, the statute merely requires a representation with "the capacity, effect, or tendency to deceive." *Young v. Century Lincoln-Mercury*, 396 S.E.2d 105, 108 (S.C. Ct. App. 1989). And, although SCUTPA authorizes penalties only for "willful" violations, the statute defines "willful" so broadly that it encompasses even negligent conduct. A "willful" violation occurs "when the party committing the violation knew *or should have known* that his conduct"

violated SCUTPA. S.C. Code Ann. §39-5-110(a), (c) (emphasis added). In short, the State need not prove that the defendant's actions were knowing or reckless to establish a violation. *See* R.7665 ("There is no need to show that a representation was intended to deceive....").[1]

Moreover, when the South Carolina Attorney General brings a SCUTPA action, the State can obtain civil penalties without showing that anyone relied on the purportedly unfair or deceptive statements or incurred actual injury or loss as a result of those statements. That is, the Attorney General can penalize a defendant under SCUTPA even when the challenged conduct did not result in "*actual* loss, injury, or damage." Pet.App.19.

SCUTPA authorizes civil penalties of up to $5,000 "per violation," S.C. Code Ann. §39-5-110(a), but the statute provides no guidance about what constitutes a "violation." For example, if a company sends an identical "unfair" letter to all 5 million residents of South Carolina, does that constitute one violation or 5 million violations? The statute does not address this critical issue, even though the definition of the "violation" in this situation could increase the maximum penalty from $5,000 to $25 billion. The size of a civil penalty under SCUTPA can quickly spiral out of control depending on how narrowly or broadly a court defines the relevant violation.

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[1] "R." refers to the Record on Appeal before the South Carolina Supreme Court.

B. Janssen's Introduction of Risperdal

Janssen is a pharmaceutical company that manufactures the antipsychotic medicine Risperdal, which is among a class of medications prescribed to treat schizophrenia, bipolar disorder, and other serious mental health conditions. It is an "atypical" antipsychotic medication, meaning that it affects a different part of the brain than older, "typical" antipsychotics. The State's medical expert described Risperdal and other atypical antipsychotics as a "godsend" and "miracle" for their remarkable potential to treat debilitating psychiatric illnesses. R.589-91.

In December 1993, the FDA approved Risperdal as safe and effective. R.3253. Risperdal continues to be prescribed by thousands of physicians to countless individuals suffering from schizophrenia and other serious mental health conditions. Like all prescription medicines, Risperdal has an FDA-approved package insert, or "label," that includes information for healthcare providers regarding safe use of the product and potential side effects. Since its initial approval of Risperdal's label in December 1993, the FDA has approved multiple revised versions of the label to address new indications and additional product information. *See* R.3283-3396, 3496-3500, 3777-87, 5837-40, 5851-98.

In 1994, Janssen introduced Risperdal in the United States. Following the product's introduction, Janssen continued to study and monitor Risperdal's efficacy and safety. Those studies examined the incidence of certain conditions or side effects that may be associated with Risperdal treatment, including weight gain, diabetes, and hyperglycemia. For years,

Janssen has also closely studied the potential risk of hyperprolactinemia, which is a type of hormonal imbalance that results in elevated levels of prolactin. As early as 1993, Janssen included in the "Precautions" section of its FDA-approved label a statement that "Risperdal elevates prolactin levels." R.979, 1038. Janssen communicated repeatedly with the FDA about this potential risk. In August 2007—pursuant to new FDA labeling regulations[2]—Janssen moved the discussion of hyperprolactinemia that had been in the "Precautions" section to a newly-combined "Warnings and Precautions" section. According to the State's experts, the Risperdal package insert was "inadequate" because the discussion of hyperprolactinemia was included in the "Precautions" section rather than the formerly standalone "Warnings" section between 1994 and 2007. R.675, 856.

Janssen also closely studied diabetes and hyperglycemia as potential side effects of Risperdal. In September 2003, the FDA required all medications in Risperdal's class to adopt a warning regarding those conditions. Janssen updated its label in October 2003 to reflect that warning.

After modifying its label, Janssen sent a letter in November 2003 to healthcare providers nationwide. This letter was intended to notify providers of the revision to Risperdal's label and provide additional context about the changes. Janssen's letter enclosed the new FDA-approved label and discussed the results

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[2] *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3946 (Jan. 24, 2006).

of several recent studies of the side effects of Risperdal and other antipsychotic medications. For example, the letter stated that "[a]lthough confirmatory research is still needed, a body of evidence from published peer-reviewed epidemiology research suggests that RISPERDAL is not associated with an increased risk of diabetes when compared to untreated patients or patients treated with conventional antipsychotics." R.5841. As support for that statement, the letter cited all eight published, peer-reviewed epidemiology studies addressing these comparative risks. R.5842.

In April 2004, the FDA's Division of Drug Marketing, Advertising, and Communications issued a "warning letter" to Janssen. The Division stated that it believed the November 2003 letter was "false or misleading" under the FDCA.[3] R.3107. Janssen responded with a summary of the extensive scientific support for the statements in its letter. R.3758-59. But the company also voluntarily agreed to send a "corrective" letter addressing the concerns raised by the FDA. The corrective letter (sent in July 2004) did not admit wrongdoing or disavow Janssen's earlier statements about the scientific evidence, but it did include a summary of the FDA's concerns with the original letter. R.3229-30. Satisfied with Janssen's resolution of this issue, the FDA notified Janssen in

[3] Under the FDCA, "false or misleading" is a term of art that can encompass any alleged noncompliance with federal labeling or promotional regulations. *See*, *e.g.*, 21 U.S.C. §§321(n), 352(a); 21 C.F.R. §§201.1-201.58, 202.1. That is, a statement can be "false or misleading" for purposes of the FDCA even if it is truthful and non-deceptive.

October 2004 that it "consider[ed] this matter closed." R.1467-69, 7315. Since then, the FDA has taken no further action regarding the November 2003 letter.

C. Proceedings Before the Trial Court

South Carolina, however, decided that the FDA's resolution of these complex scientific issues was insufficient. In April 2007, the South Carolina Attorney General (represented by private counsel working on contingency) brought an enforcement action against Janssen under SCUTPA, alleging that Risperdal's FDA-approved label did not include adequate warnings about certain potential side effects, and that Janssen's November 2003 letter was "unfair" or "deceptive."

The court held a two-week jury trial on liability in March 2011. The State did not identify a single healthcare provider in South Carolina who was actually deceived or misled by the Risperdal label or the November 2003 letter. Nor did the State attempt to show that the purportedly unfair or deceptive statements caused actual harm to any patient or monetary loss to the State.

At the close of evidence, the trial court, over Janssen's objection, instructed the jury in the most expansive manner possible. Even though the State unquestionably sought to penalize Janssen for the content of its speech, the court did not require a finding that Janssen's speech was actually false, much less that it contained a knowing or reckless falsehood. To the contrary, the court made clear that liability under SCUTPA could be predicated on any conduct deemed "immoral" or "unethical," or that "offends established public policy." R.7665. The court further

noted that "[t]here is no need to show that a representation was intended to deceive." *Id.* Even a merely negligent statement was sufficient to establish liability because a violation "occurs when [a] party ... knew or *should have known* that the conduct constituted an unfair or deceptive trade practice." R.7668 (emphasis added). The trial court also refused to require proof of injury or causation, instructing the jury that "the Plaintiff is not required to prove that anyone actually relied to their detriment or injury" on any of Janssen's statements. R.7667.

The jury returned a verdict finding Janssen liable for two violations of SCUTPA, concluding that Janssen had engaged in unfair or deceptive trade practices in the November 2003 letter and in its FDA-approved label, and that those violations were "willful." R.3030-31.

The trial court then proceeded to the penalty phase, where it imposed a staggering $327,073,700 civil penalty for what it deemed to be 553,055 SCUTPA violations. Pet.App.149. Those half-million purported violations fell into three buckets. First, the court counted as a *separate* violation each of the 7,184 mailings in South Carolina of the November 2003 letter. *Id.* Even though each healthcare provider received the same letter, the court imposed a penalty of $4,000 *per letter*. Second, the court imposed an additional $4,000 penalty for 36,372 sales calls with healthcare providers over the ensuing nine months, even though undisputed evidence showed that the November 2003 letter was not discussed during the vast majority of those calls. *Id.*; *see* R.1153, 2215-16, 2581. Third, the court imposed a penalty of $300 for

each of 509,499 sample boxes that contained the FDA-approved label that the jury found to be "unfair" or "deceptive." Pet.App.149.

In its post-trial briefing, Janssen argued, *inter alia*, that the jury instructions did not comply with the First Amendment, that the Attorney General's claims were preempted by federal law, and that the massive civil penalty was unconstitutionally excessive. The trial court rejected each of those arguments and entered judgment for the State.

D. The South Carolina Supreme Court's Decision

On February 25, 2015, the South Carolina Supreme Court affirmed the jury's finding of liability and imposed a remitted but still massive civil penalty. Pet.App.72. That court subsequently granted rehearing, withdrew its initial opinion, and issued a slightly modified opinion and judgment.

The South Carolina Supreme Court rejected each of Janssen's challenges to the jury's finding of liability. The court found that the State had met its burden of proving that Janssen's actions were "unfair" or had a "tendency to deceive." Pet.App.31. Even though the verdict was based on the content of Janssen's speech, the court concluded that "the First Amendment does not bar imposition of liability." Pet.App.33. Because "the jury found that Janssen's acts were unfair or deceptive," the court concluded that "Janssen may not avail itself of the protections of the First Amendment to shield itself from its deceptive conduct and false representations." Pet.App.34-35.

The court also rejected Janssen's argument that the State's SCUTPA claims were preempted by the

FDCA. Pet.App.50-55. The court concluded that *Wyeth v. Levine* foreclosed any preemption defense even though the claims at issue here (unlike *Wyeth*) served no compensatory purpose, required no proof of reliance, causation, or actual injury, and simply sought to *penalize* Janssen for its FDA-approved label and FDA-regulated conduct.

As for the civil penalty, the South Carolina Supreme Court remitted the per-violation penalty on the labeling claim from $300 per sample box to $100 per box, multiplied by 228,447 boxes, for a total of $22.8 million.[4] Pet.App.59. The court did not even attempt to explain why a $300-per-box penalty was "excessive" but a $100-per-box penalty was not. With respect to the November 2003 letter, the court affirmed a penalty of $4,000 for each of the 7,184 letters. Pet.App.60. And with respect to the sales calls, the court remitted the penalty from $4,000 per call to $2,000. *Id.* Once again, the court provided no explanation of why a $4,000-per-call penalty was excessive but a $2,000-per-call penalty was perfectly acceptable.

Finally, the court held that the total civil penalty of $124 million was not unconstitutionally excessive. The court readily acknowledged that Janssen's conduct "likely had little impact on the community of prescribing physicians" because the risks associated with atypical antipsychotics were "well known." Pet.App.58. Despite those findings, the court held in a single, conclusory sentence that the nine-figure civil

[4] The court reduced the number of boxes subject to a penalty on the ground that claims arising before January 24, 2004 were barred by the statute of limitations. Pet.App.59.

penalty "bears a rational relationship to the gravity of Janssen's conduct in perpetuating a marketing scheme in South Carolina designed to be unfair and deceptive." Pet.App.62. And the court further noted that "the penalty awards per violation are within the range set by the legislature in enacting SCUTPA." *Id.* The South Carolina Supreme Court thus remanded with instructions to enter judgment for the State in the amount of $124,324,700.

REASONS FOR GRANTING THE PETITION

The South Carolina state courts penalized Janssen $124 million for making statements that were not found to be knowingly false, were not shown to influence a single physician's prescribing decisions, and did not result in any actual harm or injury. That outcome "sounds absurd, because it is." *Sekhar v. United States*, 133 S. Ct. 2720, 2727 (2013). The judgment in this case was the product of multiple serious constitutional errors that individually and collectively warrant this Court's review.

I. The South Carolina courts' application of SCUTPA violates the First Amendment and conflicts with several of this Court's decisions. The State penalized Janssen $124 million for the content of its speech even though there was no finding that the statements in question involved a "knowing or reckless falsehood." *Alvarez*, 132 S. Ct. at 2545 (plurality op.); *see also id.* at 2552-53 (Breyer, J., concurring in judgment); *Telemarketing Associates*, 538 U.S. at 620. And SCUTPA includes none of the other safeguards—such as a "clear and convincing evidence" standard—that this Court has required in order to allow a state to punish a company for the

content of its speech. *See Telemarketing Associates*, 538 U.S. at 620. This Court's review is needed to ensure that vague and open-ended prohibitions on "unfair" or "deceptive" practices are not applied in a manner that will inevitably chill protected speech.

II. By penalizing Janssen without any compensatory purpose or proof of actual harm, South Carolina has also encroached upon core federal regulatory authority that Congress has given solely to the FDA. The State's SCUTPA claims are preempted by the FDCA because they serve no purpose other than to *punish* Janssen for the content of its FDA-approved label and for statements in a letter to healthcare providers that had already been addressed to the FDA's satisfaction. Those claims have no special nexus to South Carolina, as Janssen used the same label and letter throughout the nation. Yet South Carolina's massive overpunishment will directly undermine the FDA's efforts to enforce a complex federal regulatory scheme, without providing compensation to any individuals suffering actual injuries.

On the labeling claim, the South Carolina courts imposed a $23 million civil penalty based on nothing more than a disagreement with the content of Janssen's FDA-approved label. Although the FDA had already weighed the relevant scientific evidence and approved the Risperdal label several times over more than a decade, South Carolina now seeks to punish Janssen for the very same statements that passed muster with the FDA. South Carolina has effectively used SCUTPA to create a parallel state enforcement regime to oversee the contents of FDA-

approved labels and *punish* companies whose labels the State deems inadequate. And, unlike the FDA approval process, which relies on technical experts to regulate drug labels, South Carolina has turned these complex regulatory determinations over to lay juries applying amorphous standards of "unfair" or "deceptive" conduct. It is difficult to imagine a more straightforward example of a conflict between state and federal law.

Similar concerns infect South Carolina's application of SCUTPA to Janssen's November 2003 letter to healthcare providers. The FDA raised concerns about that letter in April 2004, and Janssen addressed those concerns through a corrective letter shortly thereafter. That was the end of the matter as far as the FDA was concerned, yet South Carolina has now penalized Janssen $101 million for the very same conduct that has already been addressed to the FDA's satisfaction.

III. The imposition of a massive $124 million civil penalty in the absence of *any* showing of injury, harm, or reliance violates the Eighth Amendment's Excessive Fines Clause. This case presents an ideal vehicle for this Court to clarify and reaffirm several important principles regarding the scope of the Excessive Fines Clause.

First, the Court should reaffirm that the Excessive Fines Clause prohibits a civil penalty that is grossly disproportionate to the amount of harm caused by the defendant's conduct. This Court has found unconstitutional a $357,000 penalty for a "reporting offense" that resulted in "minimal" or "minor" harm. *United States v. Bajakajian*, 524 U.S.

321, 337-40 (1998). It should follow *a fortiori* that a $124 million civil penalty in a case with *zero* showing of actual injury or harm is also unconstitutional. There will inevitably be some difficult cases at the margin when applying a proportionality standard, but this is not one of them. The Court should reaffirm that a massive civil penalty in the face of zero actual harm runs afoul of the Excessive Fines Clause.

Second, this Court should make clear that the Excessive Fines Clause requires close scrutiny of *both* the per-violation statutory penalty *and* the aggregate penalty once all the "violations" have been tallied up. The South Carolina Supreme Court rejected Janssen's Excessive Fines Clause arguments primarily because the per-violation penalty did not exceed the statutory limit of $5,000. But it defies reality to suggest that a nine-figure penalty can escape constitutional scrutiny merely because the legislature deemed a $5,000-per-violation fine appropriate. The legislature said nothing about what constitutes a "violation," and the conduct here involving the November 2003 letter and the Risperdal label could just as easily have yielded a $10,000 fine for two violations as a $124 million fine for nearly 300,000 "violations." The fact that each purported "violation" resulted in a relatively modest within-statutory-limit penalty does not immunize the *overall* award from a constitutional challenge under the Excessive Fines Clause.

Third, courts should be especially vigilant in their review under the Excessive Fines Clause when a massive penalty is based on poorly defined triggering conduct that provides the defendant with little notice of its total potential exposure. Here, Janssen was

fined $124 million under a statute that could extend even to non-deceptive statements; that required no showing of intent to deceive, reliance, or actual injury; and that provided zero guidance about how to count the "violations" that could increase the maximum penalty from $5,000 to more than $1 billion. When a defendant has little or no notice of both the conduct that gives rise to the violation and the potential magnitude of the penalty, any resulting penalty should be subject to especially exacting scrutiny under the Excessive Fines Clause.

IV. This case starkly illustrates the recent trend in which state attorneys general have used open-ended and expansive "unfair trade practices" statutes to seek recovery of massive sums from companies in a number of different industries. Faced with the risk of a catastrophic jury verdict, most defendants will choose to settle even dubious claims rather than take their chances in litigation. Because this is one of the rare cases to have been litigated through to final judgment, it presents an excellent vehicle for this Court to reaffirm and clarify several of the most important protections available to a defendant facing an open-ended enforcement action under an "unfair trade practices" statute. The Court should grant certiorari to restore some semblance of balance to a process that has tipped far too heavily in favor of uncabined enforcement authority.

I. The South Carolina Courts Violated The First Amendment By Penalizing Janssen For The Content Of Its Speech Without Any Finding That The Speech Was Knowingly Or Recklessly False.

The South Carolina Supreme Court affirmed the finding of liability and imposed a nine-figure civil penalty based on the content of Janssen's speech even though the jury had not found that this speech contained a knowing or reckless falsehood. *See* R.7665 ("There is no need to show that a representation was intended to deceive...."). The South Carolina Supreme Court nonetheless held that "Janssen may not avail itself of the protections of the First Amendment." Pet.App.35. That holding was demonstrably wrong, and certiorari on this issue is warranted to ensure that states do not apply their amorphous "unfair trade practices" statutes in a manner that chills protected speech.

A. In *Telemarketing Associates*, 538 U.S. 600, this Court addressed a First Amendment challenge to the Illinois Attorney General's fraud claim against a telemarketer that engaged in fundraising for charitable organizations. The Court held that the First Amendment did not bar the attorney general's claim, but only after ascertaining that the state statute at issue contained several important safeguards to protect the critical speech interests at stake.

The Court emphasized that it was "[o]f prime importance" that "in a properly tailored fraud action the State bears the full burden of proof." *Id.* at 620. Under the Illinois statute, a "[f]alse statement alone

does not subject a fundraiser to fraud liability." *Id.* Instead, the attorney general needed to prove that "the defendant made a false representation of a material fact *knowing that the representation was false*," and that the defendant "made the representation *with the intent to mislead the listener, and succeeded in doing so*." *Id.* (emphasis added). And the State's burden was further heightened by the fact that these showings of knowing or intentional falsity "must be made by clear and convincing evidence." *Id.* This Court concluded that the Illinois statute's "[e]xacting proof requirements" were consistent with the First Amendment because they "provide sufficient breathing room for protected speech." *Id.*

The Court recently reaffirmed those fundamental First Amendment principles in *Alvarez*, 132 S. Ct. 2537, which struck down the Stolen Valor Act as a content-based restriction on false speech about military service. The plurality opinion "reject[ed] the notion that false speech should be in a general category that is presumptively unprotected." *Id.* at 2546-47. Consistent with the Court's holding in *Telemarking Associates*, the plurality emphasized that even false speech is generally protected unless it contains "a knowing or reckless falsehood" or causes some other type of serious harm. *Id.* at 2545. The concurring opinion agreed that false speech is entitled to constitutional protection and indicated that knowing falsity is required in order to penalize a person for his speech. *See id.* at 2552-53 (Breyer, J., concurring in judgment). As Justice Breyer explained, the statute should be interpreted as "criminalizing only false factual statements made with knowledge of

their falsity and with the intent that they be taken as true." *Id.*

B. The South Carolina courts unquestionably punished Janssen for the content of its speech. The judgment below imposed a nine-figure civil penalty for statements Janssen made about complex scientific evidence in its November 2003 letter to healthcare providers, and for statements about potential side effects in Janssen's FDA-approved Risperdal label. There is no serious question that "[s]peech in aid of pharmaceutical marketing … is a form of expression protected by the Free Speech Clause of the First Amendment." *Sorrell v. IMS Health*, 131 S. Ct. 2653, 2659 (2011).

Yet SCUTPA lacks each and every one of the safeguards for protected speech that were necessary to this Court's holding in *Telemarketing Associates*. A violation of SCUTPA can be established even without "evidence that anyone was actually deceived." Pet.App.19. Indeed, SCUTPA's expansive liability standard extends to statements a jury deems "immoral," "unethical," "oppressive," or offensive to public policy, regardless of whether they are true or false. R.7665. And, contrary to both *Telemarketing Associates* and *Alvarez*, the State need not show that the defendant made a *knowing or intentional* false statement. *See* R.7665 ("There is no need to show that a representation was intended to deceive...."). Although SCUTPA requires proof of "willful" misconduct, that is a misnomer because "willful" is defined as encompassing merely negligent conduct. *See* R.7668 ("willful" means only that the defendant "knew or should have known that the conduct

constituted an unfair or deceptive trade practice"). And, unlike the Illinois statute at issue in *Telemarketing Associates*, SCUTPA does not require proof of falsity by clear and convincing evidence.

Needless to say, a regime in which a company can be assessed a nine-figure civil penalty for a statement that was not intentionally deceptive cannot be squared with the First Amendment. *Telemarketing Associates* and *Alvarez* make clear that a state seeking to penalize a defendant for the content of its speech must adopt adequate speech-protective safeguards, such as a requirement that liability be imposed only for knowingly or intentionally false statements. Consistent with those decisions, Janssen requested a jury instruction that would have required the State to prove "by clear and convincing evidence ... that the statement was false" and that the defendant "made the statement knowing it was false or with a high degree of awareness that it was probably false." R.2938. Yet the trial court refused to give this instruction, and the South Carolina Supreme Court rejected Janssen's First Amendment argument.

SCUTPA's muddled standards about the types of speech prohibited, along with weak requirements as to the defendant's mental state, flatly contradict this Court's carefully calibrated requirements for penalizing a defendant based on the content of its protected speech. Certiorari is warranted to correct this serious constitutional error and ensure that amorphous and expansive state-law prohibitions on

"unfair" or "deceptive" conduct are not applied in a manner that will inevitably chill protected speech.[5]

II. South Carolina's Claims Are Preempted By The FDCA Because They Seek To Penalize Janssen For FDA-Approved Conduct Without Serving Any Compensatory Purpose.

This state-law enforcement action serves no purpose other than to *punish* Janssen for the content of its FDA-approved label and for statements made in a letter to healthcare providers that had already been addressed to the FDA's satisfaction. Those claims involve statements with no special nexus to South Carolina—the letter and label were uniform across the nation. Yet South Carolina's action will directly undermine the FDA's efforts to enforce a uniform federal regulatory scheme, and these claims far exceed the limited class of tort claims on behalf of *actually injured individuals* that this Court allowed to proceed in *Wyeth v. Levine*. The claims here are plainly preempted.

A. The South Carolina Supreme Court drastically expanded the scope of this Court's *Wyeth* decision by

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[5] In a transparent attempt to shield its holding from this Court's review, the South Carolina Supreme Court concluded, as it did with respect to at least nine other issues, that Janssen failed to preserve its First Amendment arguments. That does not withstand scrutiny. In its written submission requesting its preferred jury charge and at the charging conference, Janssen requested jury instructions on these First Amendment issues. *See* R.2376, 2938-39. And Janssen again raised these issues in its motion for judgment notwithstanding the verdict or for a new trial. *See* R.9457, 9489-91.

allowing South Carolina to punish Janssen for the content of its FDA-approved label. *Wyeth* involved a state-law failure-to-warn claim seeking money damages for injuries suffered by the user of a nausea medication. 555 U.S. at 559-60. This Court concluded that when an individual seeks compensation for actual injuries through a state-law tort action, those "common-law claims do not stand as an obstacle to the accomplishment of Congress' purposes in the FDCA." *Id.* at 581. In so holding, this Court emphasized the "*distinct compensatory function*" that state-law tort suits can serve, noting that the prospect of compensation may "motivate injured persons to come forward with information." *Id.* at 579 (emphasis added).

At the same time, however, the Court expressed hesitation about extending its holding to other types of state-law claims, "recogniz[ing] that some state-law claims might well frustrate the achievement of congressional objectives." *Id.* at 581. That concern was echoed in Justice Breyer's concurrence, which observed that some state-law actions could pose risks to the federal regulatory scheme by, for example, "rais[ing] prices to the point where those who are sick are unable to obtain the drugs they need." *Id.* at 582 (Breyer, J., concurring).

B. SCUTPA gives South Carolina sweeping power to regulate and punish conduct that is already subject to the FDA's comprehensive and exclusive federal regulatory scheme. *See* 21 U.S.C. §337(a) (exclusive federal enforcement authority over FDA labeling requirements). Not only can South Carolina impose massive civil penalties, but it can do so solely

as a punitive measure without any compensatory purpose or any showing of reliance or actual injury.

On the labeling claim, the South Carolina courts imposed a $23 million civil penalty based on nothing more than a disagreement with the content of Janssen's FDA-approved label. *See* Pet.App.17 n.11 (concluding that Janssen's label "underrepresented and minimized the frequency and severity of the risks associated with Risperdal"). It is difficult to imagine a more clear-cut example of a conflict with the comprehensive scheme of federal regulation. The very same label that was reviewed and approved multiple times by the expert federal regulator that oversees the pharmaceutical industry subsequently became the basis for a massive civil penalty simply because the State disagreed with Janssen's FDA-approved wording. Through SCUTPA, South Carolina has effectively created a parallel state enforcement regime to determine for itself whether FDA-approved labels are sufficient. And, unlike the FDA, which relies on technical experts to regulate, South Carolina has empowered lay juries to determine whether a challenged label is actionably unfair or deceptive. Moreover, allowing 50 different states to regulate FDA-approved labels through *ad hoc* civil enforcement actions would be especially intolerable given that federal law requires Janssen and other pharmaceutical companies to use the same label throughout the nation.

The labeling claim here is categorically different from the tort suit that was allowed to proceed in *Wyeth*. As noted above, common-law tort suits are compensatory in nature, which means that the

defendant must pay damages or change its behavior only when its actions have actual consequences. If a pharmaceutical company adopts a new warning in response to a tort suit by an injured individual, it would be responding to a tangible and concrete harm that a court found to have been *caused* by the defendant's actions or omissions.

No similar incentives exist in state enforcement actions where the state does not need to demonstrate actual injury or reliance. Such lawsuits do not "uncover unknown drug *hazards*" or encourage "*injured* persons to come forward with information." *Wyeth*, 555 U.S. at 579 (emphasis added). To the contrary, under expansive unfair trade practices statutes such as SCUTPA, any purportedly "deceptive" or "unfair" label, regardless of its real-world consequences, can be subject to draconian civil penalties. Here, the State imposed a massive civil penalty against a company that had done nothing more than use the label that was expressly authorized by the FDA for nationwide use.

Opening the door to state regulation of FDA-approved labels through enforcement actions that require no proof of reliance or harm would upset the carefully crafted federal regulatory scheme and create real dangers to public safety. If states were allowed to pursue enforcement actions untethered to any actual injury or compensatory purpose, then pharmaceutical companies' FDA-approved labels could become micro-managed by 50 different jurisdictions. Labeling would inevitably become over-regulated and subject to conflicting mandates, and companies would be forced to apply warnings that even the FDA did not believe

were needed to protect the public.[6] It would thus be deeply problematic to allow states to regulate FDA-approved labels through enforcement actions even if the sole objective were to force changes to wording the states deemed unfair or deceptive. But it is utterly intolerable to *also* allow all 50 states to impose severe monetary penalties for any purported "unfair" statement in a label, even when it has harmed no one.

In sum, the FDA's regulatory scheme seeks to balance the well-recognized benefits of accurate labeling with the significant costs associated with over-labeling. South Carolina's SCUTPA action, in contrast, makes no pretense of any such nuanced analysis and disrupts the careful balance struck by the FDA. By penalizing purportedly "unfair" or "deceptive" statements in an FDA-approved label without any consideration for those statements' real-world effects, this enforcement action intrudes upon the FDA's exclusive authority over pharmaceutical labeling and bears no resemblance to the compensatory personal-injury lawsuits that this Court allowed in *Wyeth*.

C. Similar problems infect South Carolina's application of SCUTPA to impose a $101 million civil penalty for statements Janssen made in its November 2003 letter (and for subsequent sales calls to healthcare providers). Once again, the State's SCUTPA claim had a punitive rather than

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[6] As the FDA has recognized, "[o]verwarning, just like underwarning, can similarly have a negative effect on patient safety and public health." 71 Fed. Reg. at 3935; *see also* Labeling and Prescription Drug Advertising, 44 Fed. Reg. 37,434, 37,447 (June 26, 1979).

compensatory purpose because there was no showing that the purported misstatements affected a single doctor's prescribing decisions or caused actual injury to any patient. Once again, the November 2003 letter deemed actionable in South Carolina was the same letter sent to providers throughout the nation.

Moreover, Janssen had already fully addressed the purported misstatements in the letter *to the FDA's satisfaction*. The FDA has a well-established system in place to identify problematic content, provide notice, and have the regulated entity take corrective action. *See* Food & Drug Admin., Regulatory Procedures Manual §4-1, at 4-2 to -33 (2012), *available at* http://perma.cc/vqm9-blqw; R.7080-7102 (2004 Manual). After Janssen sent its letter to healthcare providers in November 2003, the FDA sent a "warning letter" in April 2004 taking issue with certain statements. Janssen quickly responded to the FDA's warning by explaining the scientific basis for its statements and sending a corrective letter in July 2004 that addressed the issues raised by the FDA. As far as the FDA was concerned, that was the end of the matter. R.1467-69, 7315

The expert federal regulator that oversees the pharmaceutical industry thus determined that the November 2003 letter warranted, at most, a correction. Yet the State of South Carolina believes that the very same letter warrants a $101 million civil penalty. That same letter was sent to healthcare providers in every state. If every state took the same approach as South Carolina and viewed each purported foot-fault in a letter or label as an opportunity to add hundreds of millions of dollars to

the public fisc, then the inevitable result would be companies "rais[ing] prices to the point where those who are sick are unable to obtain the drugs they need." *Wyeth*, 555 U.S. at 582 (Breyer, J., concurring). Allowing South Carolina to penalize Janssen for the exact same conduct that the FDA has already addressed to its satisfaction undercuts the FDA's considered regulatory judgment and is squarely preempted by federal law.[7]

III. A $124 Million Civil Penalty For Conduct That Harmed No One Violates The Excessive Fines Clause.

The Eighth Amendment provides that "[e]xcessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." The Excessive Fines Clause is "intended to prevent the government from abusing its power to punish." *Austin v. United States*, 509 U.S. 602, 607 (1993). In particular, this provision prohibits the imposition of penalties that are "grossly disproportional to the gravity of a defendant's offense." *Bajakajian*, 524 U.S. at 334. The Clause "limits the government's power to extract payments, whether in cash or in kind, 'as punishment for some offense,'" and it applies to civil penalties imposed even "in part" for punitive purposes. *Austin*, 509 U.S. at 609-10 (quoting

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[7] The South Carolina Supreme Court again attempted to insulate its questionable decision by asserting that Janssen had failed to preserve its preemption arguments. That is incorrect, as Janssen's preemption arguments were repeatedly raised throughout this litigation, including in motions for directed verdict and judgment notwithstanding the verdict. *See, e.g.*, R.8871, 8880-81, 9031-32, 9047-49.

Browning-Ferris Indus. v. Kelco Disposal, 492 U.S. 257, 265 (1989)).

There may be borderline cases in which it is difficult to determine whether a civil penalty is unconstitutionally excessive. This is not one of them. The $124 million civil penalty in this case is so unmoored from any conceivable notion of harm or culpability that it provides this Court with an ideal opportunity to clarify and reaffirm several important principles regarding the scope of the Excessive Fines Clause.

A. First, this Court should reaffirm the basic principle that a penalty cannot dwarf the amount of harm or loss that the penalized conduct caused. The "touchstone of the constitutional inquiry under the Excessive Fines Clause is the principle of proportionality: The amount of the forfeiture must bear some relationship to the gravity of the offense that it is designed to punish." *Bajakajian*, 524 U.S. at 334. This Court has refused to apply a "strict" test of proportionality, but has made clear that a penalty is unconstitutionally excessive if it is "grossly disproportional to the gravity of the defendant's offense." *Id.* at 336-37.

In *Bajakajian*, the Court found unconstitutional a $357,144 forfeiture for a mere "reporting offense." *Id.* at 337. In its proportionality analysis, the Court noted that "[t]he harm that respondent caused was … minimal," and that "[f]ailure to report his currency affected only one party, the Government, and in a relatively minor way." *Id.* at 339. The Court thus concluded that the penalty "bears no articulable

correlation to any injury suffered by the Government." *Id.* at 339-40.

The holding in *Bajakajian* is consistent with the standards governing review of punitive-damage awards under the Due Process Clause. One of the "guideposts" that this Court has established in that context is the ratio of the punitive-damage award to "the actual harm inflicted on the plaintiff." *BMW of N. Am. v. Gore*, 517 U.S. 559, 580 (1996); *see also State Farm Mut. Auto. Ins. v. Campbell*, 538 U.S. 408, 418 (2003). Indeed, this Court has recognized that the proportionality factor is "perhaps [the] most commonly cited indicium of an unreasonable or excessive punitive damages award." *BMW*, 517 U.S. at 580. The Court noted that "few awards exceeding a single-digit ratio between punitive and compensatory damages … will satisfy due process." *State Farm*, 538 U.S. at 425.

The judgment below does not come close to satisfying any plausible standard of proportionality. The defendant's actions in *Bajakajian* resulted in "minor" or "minimal" harm to the government, but that was insufficient to justify a $357,000 penalty. This should be an even easier case because the penalty is orders of magnitude larger than the one in *Bajakajian* even though there was *zero* proof that Janssen's conduct harmed the State or anyone else. As the South Carolina Supreme Court acknowledged, Janssen's conduct "likely had little impact on the community of prescribing physicians" because the risks associated with atypical antipsychotics were "well known." Pet.App.58; *see also* Pet.App.145 (trial court conceding that its goal was "to penalize the

actions of the Defendants and ... not ... to award damages based upon any measure of damages or ill-gotten gain").

It is an understatement to say a $124 million penalty is "grossly disproportionate" to $0 of proven harm. That award would not come close to passing muster under the Due Process Clause if it had been an award of punitive damages. This Court should reaffirm that proportionality review of a civil penalty under the Excessive Fines Clause is at least as robust as the substantive review of a punitive-damage award under the Due Process Clause.

B. This Court should also grant certiorari to make clear that courts cannot shield a massive civil penalty from meaningful review under the Excessive Fines Clause merely by multiplying a comparatively small per-violation penalty over an arbitrarily large number of purported "violations," and then emphasizing that the legislature authorized the punishment. The Excessive Fines Clause requires close scrutiny of *both* the per-violation statutory penalty *and* the aggregate penalty once all the "violations" have been added up. And there is no room for deference to legislative judgments when the legislature has not meaningfully defined what constitutes a "violation."

SCUTPA authorizes a civil penalty of up to $5,000 "per violation." S.C. Code Ann. §39-5-110(a). Yet the South Carolina courts turned that seemingly modest figure into a massive, nine-figure penalty by treating two allegedly "unfair" or "deceptive" acts as thousands of separate violations. Even though each healthcare provider received an *identical* copy of the November

2003 letter, the court imposed a penalty of $4,000 for each of the 7,184 mailings, resulting in a fine of $28 million. Pet.App.60. Even more egregiously, Janssen was then penalized another $72 million for each of 36,372 subsequent sales calls to healthcare providers, even though undisputed evidence showed that the November 2003 letter was not discussed during the vast majority of those calls. *Id.*; *see* R.1153, 2215-16, 2581. And, as to the labeling claim, Janssen was assessed a $100 penalty for each of the 228,447 sample boxes it had distributed during the relevant period even though, again, each box had an identical label (as federal law required) and multiple boxes may have been delivered to a provider at the same time. After adding all of this up, the South Carolina courts found 272,000 violations and imposed a $124 million penalty for what were, in reality, a grand total of *two* purported misstatements, one in the letter and one in the label.

The South Carolina Supreme Court held that this penalty was not unconstitutionally excessive because "the penalty awards per violation are within the range set by the legislature in enacting SCUTPA." Pet.App.62. Several other courts have similarly suggested that the government can insulate its penalties from meaningful excessive-fines review by selecting a statutorily prescribed per-violation penalty and then multiplying that penalty by some arbitrarily excessive number of "violations." *See, e.g.*, *Pharaon v. Bd. of Governors of Fed. Reserve Sys.*, 135 F.3d 148, 157 (D.C. Cir. 1998); *United States v. Emerson*, 107 F.3d 77, 80 (1st Cir. 1997).

This Court should make clear both (1) that deference to the legislature is a non sequitur when the legislature has not meaningfully clarified what constitutes a violation, and (2) that judicial review of a civil penalty under the Excessive Fines Clause must consider *both* the per-violation penalty *and* the aggregate penalty. Indeed, in *Bajakajian* itself, the Court found a penalty to be unconstitutionally excessive even though it was unquestionably authorized by statute. *See* 524 U.S. at 337. The Excessive Fines Clause would be rendered a dead letter in many of the most egregious cases if a penalty could escape meaningful constitutional scrutiny merely because it involved an aggregation of thousands of violations, especially where the legislation is silent as to how that conduct translates into "violations."

Here, for example, the South Carolina courts concluded that the labeling claim resulted in 228,447 separate violations, equating each sample box to a separate violation. The subdivision of the label violation into 228,447 separate violations was essentially random. There was no suggestion that physicians scrutinized the label on each and every sample box. And doctors used the same label in deciding whether to write non-sample prescriptions for Risperdal.

But while the selection of the number of violations was essentially arbitrary, it drove the South Carolina Supreme Court's Excessive Fines analysis and rendered it meaningless. Based on the 228,447 separate violations, Janssen could have been subject to up to *$1.1 billion* in civil penalties if the courts had

imposed the $5,000 maximum per-violation penalty. The actual penalty of $100 per sample box (arbitrarily reduced from $300 per sample box) seems relatively modest compared to the $1.1 billion authorized by the legislature. But, of course, the legislature authorized no such thing, because it never focused on what constitutes a separate violation meriting a $5,000 fine. This Court should clarify that the Excessive Fines analysis must focus on the overall penalty and cannot be short-circuited by deference to legislative judgments the legislature never made.

C. At a minimum, this Court should hold that the Excessive Fines Clause requires especially close constitutional scrutiny of a civil penalty when a poorly defined statute provides little notice to the defendant as to the types of triggering events that might lead to a massive penalty. A penalty should be found unconstitutionally excessive if the defendant has no way to predict both the full magnitude of potential liability and the specific conduct that gives rise to a violation. Here, Janssen was fined $124 million under a statute that could extend even to truthful, non-deceptive statements; that required no showing of intent to deceive, reliance, or actual damages; and that provided zero guidance about how to count the "violations" that could increase the maximum penalty from $5,000 to more than $1 billion.

Indeed, the South Carolina Supreme Court's attempt to reduce the penalty to what it deemed to be an appropriate amount only underscores the utter lack of notice as to the potential size of the penalty. With respect to the 36,372 sales calls to healthcare providers, the court reduced the per-violation penalty

from $4,000 to $2,000 (thereby reducing the overall penalty from $145 million to $73 million). Pet.App.60. And, with respect to the 228,447 sample boxes, the court reduced the per-violation penalty from $300 per box to $100 per box (and the overall penalty from $68 million to $23 million). But the court provided literally no explanation about why the remitted figures were not still excessive in their own right. The arbitrary reduction of an astronomical penalty to a lower, but still astronomical, figure cannot insulate the penalty from constitutional scrutiny, especially when the defendant remains in the dark about how the court arrived at the figures in question.

This Court's decisions in the punitive-damages context are again instructive. At the heart of the Court's concern about runaway punitive-damage awards is the need for defendants to have adequate notice of the scope of liability they might face. "Elementary notions of fairness enshrined in our constitutional jurisprudence dictate that a person receive fair notice not only of the conduct that will subject him to punishment, but also of the severity of the penalty that a State may impose." *BMW*, 517 U.S. at 574. The same concerns animating this Court's punitive-damages jurisprudence should apply with equal or greater force in the Excessive Fines Clause context given that the Clause is expressly designed to "prevent the government from abusing its power to punish." *Austin*, 509 U.S. at 607. When a defendant has little or no notice of both the conduct that gives rise to the violation and the potential magnitude of the penalty, any resulting penalty should be subject to particularly exacting scrutiny under the Excessive Fines Clause.

IV. Certiorari Is Warranted Because The Issues Presented Are Critical, Recurring, And Likely To Evade This Court's Review.

This case is not an outlier. In recent years, state attorneys general have increasingly used vague prohibitions on "unfair" trade practices, such as those in SCUTPA, to seek massive penalties against companies in a number of different industries. Some portion of the recovery is often kept by the office that brings the suit, which means that "[a]gencies and their attorneys have reasons, unrelated to deterrence, to attempt to maximize the dollars collected through enforcement." Margaret H. Lemos & Max Minzner, *For-Profit Public Enforcement*, 127 Harv. L. Rev. 853, 912 (2014); *see also id.* at 857 (noting that "[f]inancially motivated agencies are apt to initiate more enforcement actions [and] reduce their focus on nonmonetary remedies").

The potential penalties in such cases can quickly spiral out of control. If, somewhere in the thousands of pages of material that a company publishes about one of its products, a state can find a single statement that is purportedly "unfair" or has a "tendency to deceive," it can seek cascading civil penalties even if that statement caused no injury whatsoever. And many enforcement actions—like this case—may not even be based on conduct that was uniquely directed at the state in question. A company that makes one purported misstatement in one document that nobody actually read could find itself subject to civil enforcement actions in 50 different jurisdictions. And the most important safeguards for defendants in private civil litigation or criminal prosecutions—such

as heightened mens rea standards or required proof of reliance, causation, materiality, and actual injury—are typically absent in unfair trade practices actions brought by state attorneys general. The inevitable result will be that defendants are forced to settle even dubious claims for large sums to avoid the risk of a catastrophic jury verdict.

Although the SCUTPA statutory scheme is by no means unique, this case is unique in that it is one of the rare unfair trade practices cases that has actually been litigated through final judgment. This case thus starkly illustrates the flaws of a regime in which a single, relatively small state can impose a nine-figure penalty for conduct that resulted in no actual harm or loss. This case also offers the Court an important opportunity to clarify several common-sense doctrinal tools under the First Amendment, Supremacy Clause, and Excessive Fines Clause that will help rein in some of the worst abuses of open-ended "unfair trade practices" enforcement actions.

CONCLUSION

For the foregoing reasons, this Court should grant the petition for certiorari.

Respectfully submitted,

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November 5, 2015

APPENDIX

TABLE OF APPENDICES

Appendix A

SUPREME COURT OF SOUTH CAROLINA

No. 12-206987

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 PHARMACEUTICAL, INC., AND/OR JANSSEN, L.P., AND JOHNSON & JOHNSON, INC.,

Defendants,

OF WHOM ORTHO–MCNEIL–JANSSEN PHARMACEUTICALS, INC. IS THE APPELLANT.

Filed: July 8, 2015

ORDER

This matter comes before the Court on the petition of Appellant Ortho–McNeil–Janssen Pharmaceuticals, Inc., for rehearing of this Court's opinion in *State ex rel. Wilson v. Ortho–McNeil–Janssen Pharmaceuticals, Inc.,* Op. No. 27502 (S.C.Sup.Ct. filed Feb. 25, 2015). We grant the petition, dispense with further briefing, and file a

substituted opinion, which is attached to this order.[1] While Appellant persists in pursuing issues not preserved for appellate review, we find it necessary to issue a substitute opinion to correct a mathematical calculation and to clarify that the unfair trade practices judgment against Appellant is supported by federal law, including the federal "tendency to deceive" standard, and thus, complies with S.C.Code Ann. § 39–5–20(b) (1985).

IT IS SO ORDERED.

s/ Jean H. Toal, C.J.

s/ Costa M. Pleicones, J.

s/ Donald W. Beatty, J.

s/ John W. Kittredge, J.

s/ Kaye G. Hearn, J.

KITTREDGE, J:

Appellant Ortho–McNeil–Janssen Pharmaceuticals (Janssen) is a pharmaceutical company that manufactures the antipsychotic drug Risperdal. Risperdal is among a class of drugs prescribed primarily for the treatment of schizophrenia. The Attorney General of South Carolina believed that Janssen had violated the South Carolina Unfair Trade Practices Act (SCUTPA)[2] by engaging in unfair methods of competition by willfully failing to disclose known risks and side effects associated with Risperdal.

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[1] The separate opinion of Justice Pleicones, which has not been amended, is also attached.

[2] S.C.Code Ann. §§ 39–5–10 to –180 (1985 & Supp.2013).

On January 24, 2007, the State and Janssen entered into a tolling agreement concerning the statute of limitations. SCUTPA has a three-year statute of limitations, as section 39–5–150 of the South Carolina Code provides that "[n]o action may be brought under this article more than three years after discovery of the unlawful conduct which is the subject of the suit." The State filed its Complaint on April 23, 2007, seeking statutory civil penalties against Janssen on two claims. The first claim arose from the content of the written material furnished by Janssen since 1994 with each Risperdal prescription, the so-called labeling claim. The second claim centered on alleged false information contained in a November 2003 Janssen-generated letter sent to the South Carolina community of prescribing physicians, the so-called Dear Doctor Letter. Because both claims arose more than three years prior to January 24, 2007, Janssen pled the statute of limitations as a bar to the Complaint.

The matter proceeded to trial. A jury rendered a liability verdict against Janssen on both claims. The trial court rejected Janssen's defenses, including the statute of limitations, finding that both claims were timely. The trial court imposed civil penalties against Janssen for both claims totaling $327,073,700 based on 553,055 separate violations of SCUTPA in connection with its deceptive conduct in the sales and marketing of Risperdal.

Janssen appeals. Because this is an action at law, our review of factual challenges is limited to determining whether there is any evidence to support the verdict. As for properly preserved questions of law,

our review is plenary. We affirm the liability judgment on the labeling claim but modify the judgment to limit the imposition of civil penalties to a period of three years from the date of the tolling agreement, which is essentially coextensive with the three-year statute of limitations, subject to an additional three months by virtue of the time period between the January 24, 2007, tolling agreement and the filing of the Complaint on April 23, 2007. We further remit the civil penalties on the labeling claim to $22,844,700. We affirm the liability judgment on the DDL claim, but remit those civil penalties to $101,480,000. Accordingly, we affirm in part, reverse in part, and remand for entry of judgment against Janssen in the amount of $124,324,700.

I.

A. FDA Regulatory Process and Background

A brief summary of the Food and Drug Administration's (FDA) regulatory authority over the pharmaceutical industry and the evolution of antipsychotic drugs provides a helpful backdrop to the facts of this case. "In the 1930's, Congress became increasingly concerned about unsafe drugs and fraudulent marketing, and it enacted the Federal Food, Drug, and Cosmetic Act (FDCA)."[3] *Wyeth v. Levine,* 555 U.S. 555, 566, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009) (citation omitted). The FDCA's "most substantial innovation was its provision for premarket approval of new drugs." *Id.* Following implementation

[3] The FDCA is codified at 21 U.S.C. §§ 301–399f (2006 & Supp. V 2011).

of the FDCA, the FDA "required every manufacturer to submit a new drug application, including reports of investigations and specimens of proposed labeling" for regulatory review and approval.[4] *Id.* "Until its application became effective, a manufacturer was prohibited from distributing a drug." *Id.* FDA regulations require a new drug application to "include all clinical studies, as well as preclinical studies related to a drug's efficacy, toxicity, and pharmacological properties." *Merck KGaA v. Integra Lifesciences I, Ltd.,* 545 U.S. 193, 196, 125 S.Ct. 2372, 162 L.Ed.2d 160 (2005) (citing 21 C.F.R. § 314.50(d)(2), (5) (2005)).

The FDA new drug approval process includes specific procedures through which warning labels are drafted, approved, and required to be included in the packaging of manufactured drugs. A drug label "must contain a summary of the essential scientific information needed for the safe and effective use of the drug," and the label "must be informative and accurate and neither promotional in tone nor false or misleading in any particular." 21 C.F.R. § 201.56(a)(1)-(2) (2014). Indeed, federal regulations set forth detailed requirements as to the content, the formatting, and the order of required information about potential risks and the safe and effective use of a drug. *Id.* § 201.57(c) (2014). Specifically, FDA

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[4] Prior to submitting a new drug application to the FDA for approval, the developer of the drug must first "gain authorization to conduct clinical trials (tests on humans) by submitting an investigational new drug application (IND)." *Merck KGaA v. Integra Lifesciences I, Ltd.,* 545 U.S. 193, 196, 125 S.Ct. 2372, 162 L.Ed.2d 160 (2005) (citations omitted).

regulations require drug labels to include, *inter alia:* (1) "black box" warnings about serious risks that may lead to death or serious injury; (2) contraindications describing any situations in which the drug should not be used because the risk of use outweighs any possible therapeutic benefit; (3) warnings and precautions about significant adverse reactions and other potential safety hazards; and (4) any adverse reactions for which there is a basis to believe a causal relationship exists between the drug and the occurrence of the adverse event. *Id.* As these FDA regulations make clear, the category in which a particular risk appears on a drug label is a critical indicator of both the degree of the risk and also the likelihood and severity of the adverse consequences the drug may cause.

After a new drug application has been approved, the drug's sponsor has continuing duties to the FDA to ensure the long term efficacy and safety of the approved drug. For example, once drugs are approved by the FDA, the drug's sponsor is required to review, and report to the FDA, all "adverse drug experience"[5] information it receives from any source, including

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[5] FDA regulations define an "adverse drug experience" as:

> Any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: An adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action.

21 C.F.R. § 314.80(a) (2014).

adverse experiences reported during the process of post-marketing clinical trials. 21 C.F.R. § 314.80(b), (c) (2014). As new risks and side effects are discovered, a manufacturer must revise a drug's label "to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established." 21 C.F.R. § 201.57(c)(6)(i). As the FDA does not conduct independent scientific testing, it is incumbent upon sponsors to disclose all clinical data to ensure the safe and effective use of drugs.

Some have expressed a growing concern regarding the pharmaceutical industry's reticence to disclose negative clinical data, and the impact this has on the public health and welfare. Indeed, it has been stated that:

> [T]he failure to disclose study results not only impacts clinical trial participants, but the health of the general public may be put in jeopardy as well. For drugs that have received FDA approval, post-market clinical trials investigating new uses of the medication often reveal important information concerning side effects and related adverse complications with the treatment. To the extent that prescribing physicians do not have this essential data, they could inadvertently be putting their patients at serious risk by continuing to recommend the medication.
>
> Over the past few years, numerous scandals in the drug industry illustrate that concealing

> unfavorable research results is far from an isolated practice..... In a quest to boost sales and increase corporate profits, the temptation to hide or selectively disclose clinical trial data has proven to be too much.

Christine D. Galbraith, *Dying to Know: A Demand for Genuine Public Access to Clinical Trial Results Data,* 78 Miss. L.J. 705, 710 (2009).

"The FDA's premarket approval of a new drug application includes the approval of the exact text in the proposed label." *Wyeth,* 555 U.S. at 568, 129 S.Ct. 1187 (citing 21 U.S.C. § 355 (2006); 21 C.F.R. § 314.105(b) (2008)). Subsequent to approval of the new drug application, a drug manufacturer must submit a supplemental application to the FDA in order to effect any changes in the drug label. *Id.* (citing 21 U.S.C. § 355 (2006); 21 C.F.R. § 314.105(b) (2008))."There is, however, an FDA regulation that permits a manufacturer to make certain changes to its label *before* receiving the agency's approval." *Id.* (emphasis added).

> Among other things, this "changes being effected" (CBE) regulation provides that if a manufacturer is changing a label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval.

Id. (quoting 21 C.F.R. §§ 314.70(c)(6)(iii)(A), (C)).

Following FDA approval of a new drug (or a new indication for an existing drug), pharmaceutical companies may begin to market the drug, subject to federal regulations. See, e.g., 21 C.F.R. § 203.2 (2014) ("The purpose of this part is ... to protect the public health...."). Typical pharmaceutical marketing strategies include both direct sales calls (i.e., visits to prescribing doctors to distribute literature and samples) and academic writings and speaking events led by healthcare professionals.

B. Risperdal

Risperdal (risperidone) is an antipsychotic drug primarily used to treat schizophrenia. Schizophrenia is a chronic, debilitating mental illness that affects approximately 1% of the population. Following onset, schizophrenia is a lifelong, incurable disease, and treatment almost always involves the use of an antipsychotic drug. Between the 1950s and 1990s, medical practitioners prescribed typical antipsychotics such as Thorazine (chlorpromazine), Prolixin (fluphenazine), Haldol (haloperidol), Loxitane (loxapine), and Mellaril (thioridazine) to treat schizophrenia. Although effective, these typical antipsychotics posed a number of negative side effects, including involuntary muscle movements and tardive dyskinesia, a long-lasting movement disorder.

By the 1980s, clozapine was being investigated for the treatment of schizophrenia on the theory that it might be more effective and cause fewer movement disorders than typical antipsychotics. Clozapine was termed an "atypical antipsychotic" because it affected a different part of the brain than the older, typical antipsychotics. The medical community soon

discovered that clozapine, too, had negative side effects, including agranulocytosis—a dramatic and sometimes deadly decrease in white blood cell count. Thus, in spite of its efficacy in treating the symptoms of schizophrenia, clozapine was usually used only as a "last resort" drug, prescribed for only about 10% of the schizophrenic population.

In 1994, Janssen introduced Risperdal in the United States as the second atypical antipsychotic drug on the market. In the first several years Risperdal was on the market, it steadily captured market share from typical antipsychotics, despite costing ten times as much. From 1994 to 1996, Risperdal held a unique place in the market—it was promoted as being more effective than the older, typical antipsychotics, without the dangerous side effects associated with clozapine. In 1996, Eli Lilly (Lilly) introduced a third atypical antipsychotic drug to the market: Zyprexa. Zyprexa was dramatically successful when it hit the market, and Lilly and Janssen competed to capture the antipsychotic market.

Spurred by this fierce competition, Janssen developed a marketing strategy to distinguish Risperdal and protect its market share. By 1998, Janssen was promoting Risperdal as having a lower risk of weight gain and a lower metabolic risk profile than Zyprexa.[6] Despite the claims made by Janssen,

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[6] In turn, Lilly differentiated Zyprexa as posing a lower risk for movement disorders and hyperprolactinemia, a hormonal imbalance causing serious and lasting reproductive side effects, when compared to Risperdal. This type of relative comparison sales technique is not new. *See P. Lorillard Co. v. Fed. Trade*

post-marketing studies, some as early as 1994, revealed Risperdal posed a serious risk of substantial weight gain, increased prolactin levels,[7] and

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Comm'n, 186 F.2d 52, 56 (4th Cir. 1950) (involving advertisements claiming Old Gold cigarettes and the smoke therefrom contained lower amounts of harmful nicotine, tars, and resins and were "less irritating to the throat" than any of the six other leading cigarette brands).

[7] Prolactin is a hormone that causes breasts to grow and produce milk and regulates reproductive functions such as menstruation in females and sperm production in males. Hyperprolactinemia is a condition involving increased prolactin levels in women who are not pregnant and in men. Hyperprolactinemia can impair adolescent growth and cause enlarged breasts and the production of breast milk *in both males and females.* Additionally, elevated prolactin levels cause menstrual cycle disruptions in females and disturb testosterone and semen production in males.

At trial, the State presented testimony of Dr. Magali Haas, a Janssen medical research doctor, who admitted that Risperdal is associated with elevated prolactin levels, which are more of a concern for developing adolescents than for fully formed adults, and that scientists do not know if the reproductive dysfunction linked with Risperdal is reversible. During the relevant time period, Risperdal was not approved by the FDA for use in patients under the age of eighteen; however, Dr. Haas testified that "much of Risperdal's market in the U.S." was attributable to prescription sales for patients under the age of eighteen and that Janssen spent millions of dollars for medical marketing activities involving the unapproved use of Risperdal in children and adolescents. Moreover, Dr. Haas acknowledged that despite Janssen's awareness of the heightened reproductive risks Risperdal posed to children and adolescents, no warnings or information about those concerns appeared on the Risperdal label because the FDA had not approved Risperdal for use in patients under the age of eighteen.

hyperprolactinemia in patients taking atypical antipsychotics.

This increased the long-term risk of developing various kinds of cancer, osteoarthritis, cardiovascular disease, and stroke. Additionally, atypical antipsychotics greatly increased the risk of diabetes mellitus, which can have very serious, even life-threatening consequences. By 1997, Janssen also had information that Risperdal posed a serious risk of stroke, cardiac arrest, and sudden death in the elderly. Despite this clinical information, it was several years before Janssen updated the Risperdal label to accurately reflect the frequency and severity of the risk of hyperprolactinemia, weight gain and diabetes, or stroke, cardiac arrest, and sudden death in the elderly.

In 1997, Janssen commissioned a clinical trial (Trial 113) designed to establish Risperdal's superiority over Zyprexa as to metabolic side effects, including weight gain and diabetes. In 1999, the results of Trial 113 were not what Janssen desired, as the study concluded that there was no difference between Risperdal and Zyprexa in terms of long-term weight gain or the onset of diabetes mellitus.[8] Janssen did not disclose or publish the results of Trial 113 and continued to claim that Risperdal was superior to Zyprexa in terms of these negative metabolic side effects.

By August 2000, Janssen also received results from two epidemiological studies. One study was

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[8] Trial 113 showed Risperdal was significantly more likely than Zyprexa to result in increased prolactin levels.

based on a review of the records of patients treated with atypical antipsychotics in a New England insurance database (ERI study). The ERI study showed that Risperdal patients developed diabetes mellitus at a significantly higher incident rate than patients taking Zyprexa. The second study was commissioned by Janssen (HECON study), and it concluded that Risperdal was not associated with an increased risk of diabetes mellitus. By this time, and notwithstanding Janssen's furtive efforts, the risks and adverse side effects associated with atypical antipsychotic drugs were fairly well known.

In May 2000, the FDA asked sponsors of atypical antipsychotic drugs to submit a comprehensive review of all clinical data pertaining to metabolic side effects. In response, Janssen did not disclose the results of the Trial 113 study but disclosed *only* the favorable results from its own HECON study, affirmatively indicating to the FDA that no long-term trials pertaining to metabolic side effects had taken place. The FDA's review was not thwarted by Janssen's efforts, as the FDA's investigation prompted it to request that product labeling for all atypical antipsychotic medications, including Risperdal, include a warning about hyperglycemia and diabetes.

Janssen was concerned that the FDA-mandated label warning would result in a substantial loss of Risperdal market share. Notwithstanding the Trial 113 and ERI study results suggesting an association between Risperdal and diabetes, in October 2000, Janssen's Associate Director of Central Nervous System Medical Affairs wrote an email to her colleagues urging that Janssen must avoid Risperdal

being "lumped in to [sic] the atypical class for diabetes.... [W]e need to work hard on a strategy to avoid risperdal being thought of as a diabetes-inducing medication. Instead, when worried about diabetes, we want doctors to prescribe Risperdal."

Janssen then determined it would take control of how the message surrounding the new diabetes warning would be communicated. Janssen officials' strategy was to "soften the blow" through what is known in the industry as a Dear Doctor Letter (DDL). The inspiration came from a DDL that Lilly sent to prescribers, informing them that the entire class of atypical antipsychotics was now subject to a new "class label" for diabetes and hyperglycemia. A senior vice president for Janssen's parent company wrote in an internal email that "Lilly's DDL is pretty clever. How much commercial liability would we incur if we sent a similar letter about Risperdal, assuming the FDA is unwilling to communicate the issue?"

On November 10, 2003, Janssen disseminated a DDL, which did not include the text of the new diabetes/hyperglycemia warning, but stated:

> Hyperglycemia-related adverse events have infrequently been reported in patients receiving RISPERDAL. Although confirmatory research is still needed, a body of evidence from published peer-reviewed epidemiology research suggests that RISPERDAL is not associated with an increased risk of diabetes when compared to untreated patients or patients treated with conventional antipsychotics. Evidence also suggests that RISPERDAL is associated with

> a lower risk of diabetes than some other studied atypical antipsychotics.

To put it mildly, the November 2003 DDL contained false information.

Additionally, in training its employees on the labeling update, Janssen communicated to its field sales team that Risperdal had a "0%" increased diabetes risk compared to placebo. This was part of the message communicated to physicians in DDL follow-up visits with physicians.

Meanwhile, by January 2004, Janssen had updated the Risperdal label to include the new diabetes/hyperglycemia warning. Janssen determined that the negative sales impact had been minimal because of its deceptive efforts in the November 2003 DDL. In other words, the November 2003 DDL worked, as far as Janssen was concerned, in protecting its market share.

Thereafter, in April 2004, the FDA's Division of Drug Marketing Advertising and Communications (DDMAC)[9] issued a "Warning Letter" to Janssen, characterizing the November 2003 DDL as "false or misleading" in violation of the FDCA. Specifically, the letter provided:

> DDMAC has concluded that the DHCP[10] letter is false or misleading in violation of Sections 502(a) and 201(n) of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C.

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[9] This agency is now known as the Office of Prescription Drug Promotion (OPDP).

[10] Dear Health Care Provider, which is another term for a Dear Doctor Letter.

> 352(a) and 321(n)) because it fails to disclose the addition of information relating to hyperglycemia and diabetes mellitus to the approved product labeling, minimizes the risk of hyperglycemia-related adverse events, which in extreme cases is associated with serious adverse events including ketoacidosis, hyperosmolar coma, and death, fails to recommend regular glucose control monitoring to identify diabetes mellitus as soon as possible, and misleadingly claims that Risperdal is safer than other atypical antipsychotics. The healthcare community relies on DHCP letters for accurate and timely information regarding serious risks and associated changes in labeling and the dissemination of this letter at a time critical to educating healthcare providers is a serious public health issue.

The FDA also determined that the scientific studies referenced in the DDL "do not represent the weight of the pertinent scientific evidence" nor did the DDL accurately describe the results of the cited studies. As a result of the FDA's warning, Janssen issued a corrective letter in July 2004, acknowledging that the November 2003 DDL "omitted material information about Risperdal, minimized potentially fatal risks, and made misleading claims suggesting superior safety to other atypical antipsychotics without adequate substantiation, in violation of the [FDCA]."

As to Risperdal's label, Janssen did not update the label to include a boxed warning regarding the risk of stroke, cardiac arrest, and sudden death in the

elderly until February 2005, and no warning about hyperprolactinemia appeared in the label until August 2008.[11]

C. The State's Unfair Trade Practice Claim

In April of 2007, the Attorney General of South Carolina filed a state law claim against Janssen, seeking civil penalties under SCUTPA. The State pursued two claims against Janssen, one in connection with the Risperdal label (the labeling claim) and the second concerning the November 2003 DDL (the DDL claim). Following a twelve-day trial, the jury returned a verdict on liability in favor of the State, finding that Janssen's actions with respect to both the labeling and DDL claims were willful violations of SCUTPA.

After dismissing the jury, the trial court separately considered evidence and arguments during a two-day hearing to determine the appropriate penalty for Janssen's SCUTPA violations. The trial court issued an order assessing penalties against Janssen of $152,849,700 for the labeling claim and

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[11] To be sure, prior versions of the Risperdal label mentioned the risk of "cerebrovascular adverse events" in elderly patients, increased prolactin levels, and hyperprolactinemia; however, Janssen's categorization of those risks on the label underrepresented and minimized the frequency and severity of the risks associated with Risperdal. As noted, the category in which a particular risk appears on a drug label is a critical indicator of both the degree of the risk and also the likelihood and severity of the adverse consequences the drug may cause. *See* 21 C.F.R. §§ 201.56, 201.57 (setting forth detailed requirements on the content and format of information on drug labels to ensure labels are not inaccurate, false, or misleading and convey all pertinent information regarding the safe and effective use of drugs).

$174,224,000 for the DDL claim, for a total penalty of $327,073,700. This appeal followed. This case was transferred from the court of appeals to this Court pursuant to Rule 204(b), SCACR.

II. Analysis Concerning Liability

The SCUTPA was modeled after the Federal Trade Commission Act, which provides "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful." 15 U.S.C. § 45(a)(1). SCUTPA "declares unfair or deceptive acts or practices in trade or commerce unlawful." *Singleton v. Stokes Motors, Inc.,* 358 S.C. 369, 379, 595 S.E.2d 461, 466 (2004) (citing S.C.Code Ann. § 39–5–20(a) (2002)). "An unfair trade practice has been defined as a practice which is offensive to public policy or which is immoral, unethical, or oppressive." *deBondt v. Carlton Motorcars, Inc.,* 342 S.C. 254, 269, 536 S.E.2d 399, 407 (Ct.App.2000) (citing *Young v. Century Lincoln–Mercury, Inc.,* 302 S.C. 320, 326, 396 S.E.2d 105, 108 (Ct.App.1989), *aff'd in part, rev'd in part on other grounds,* 309 S.C. 263, 422 S.E.2d 103 (1992)). "A deceptive practice is one which has a tendency to deceive." *Id.* "Whether an act or practice is unfair or deceptive within the meaning of the [SC]UTPA depends upon the surrounding facts and the impact of the transaction on the marketplace." *Id.* (citing *Young,* 302 S.C. at 326, 396 S.E.2d at 108).

The terms "unfair" and "deceptive" are not defined in SCUTPA; rather, in section 39–5–20(b) of the Act, the legislature directs that in construing those terms, the courts of our state "will be guided by" decisions from the federal courts, the Federal Trade

Commission Act (FTCA), and interpretations given by the Federal Trade Commission (FTC). Thus, South Carolina has been guided by federal law, which recognizes the public interest involved and requires a showing of a "tendency to deceive." *See State ex rel. McLeod v. Brown,* 278 S.C. 281, 285, 294 S.E.2d 781, 783 (1982) (quoting *U.S. Retail Credit Assoc., Inc. v. FTC,* 300 F.2d 212, 221 (4th Cir.1962)) (" 'It is in the public interest generally to prevent the use of false and misleading statements in the conduct of business ... [and] actual deception need not be shown; a finding of a tendency to deceive and mislead will suffice.'") (ellipsis in original). In *State ex rel. McLeod,* we followed the "Fourth Circuit Court of Appeals ['] [holding] that the requisite capacity to deceive could be found without evidence that anyone was actually deceived." *Id.* at 285, 294 S.E.2d at 783 (citing *Royal Oil Corp. v. FTC,* 262 F.2d 741 (4th Cir.1959)).

SCUTPA provides for both civil actions brought by private citizens and enforcement actions brought by the Attorney General on behalf of the State. S.C.Code Ann. §§ 39–5–50(a), –110(a), –140(a) (1985). While the only section of SCUTPA at issue in this case is an enforcement action brought by the Attorney General, we note the distinction between the two types of actions. In an action brought by a citizen under section 39–5–140(a) of the South Carolina Code, there is a requirement beyond the tendency to deceive element that the person suffer an "ascertainable loss of money or property, real or personal, as a result of the use or employment by another person of an unfair or deceptive method, act or practice." Thus, SCUTPA requires that a private claimant suffer an *actual* loss, injury, or damage, and requires a causal connection

between the injury-in-fact and the complained of unfair or deceptive acts or practices. S.C.Code Ann. § 39–5–140(a).[12]

Conversely, in an enforcement action brought by the Attorney General, there is no actual impact requirement. *See* S.C.Code Ann. § 39–5–50(a). The Attorney General "may recover on behalf of the State a civil penalty of not exceeding five thousand dollars per violation." S.C.Code Ann. § 39–5–110(a). "The legislature intended ... [SCUTPA] to control and eliminate the large scale use of unfair and deceptive trade practices within the state of South Carolina."*Noack Enters. v. Country Corner Interiors of Hilton Head Island, Inc.,* 290 S.C. 475, 477, 351 S.E.2d 347, 349 (Ct.App.1986) (quotations and citations omitted).

We note at the outset of our analysis that the State did not file this case because of concern with Risperdal's efficacy as an atypical antipsychotic.[13]

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[12] "Under section 39–5–140, a plaintiff can recover treble damages where 'the use or employment of the unfair or deceptive ... act or practice was a willful or knowing violation of § 39–5–20.'" *Wright v. Craft,* 372 S.C. 1, 23–24, 640 S.E.2d 486, 498 (Ct.App.2006) (quoting *Noack Enters., Inc. v. Country Corner Interiors of Hilton Head Island, Inc.,* 290 S.C. 475, 477, 351 S.E.2d 347, 348–49 (Ct.App.1986)).

[13] Similar Risperdal litigation against Janssen and its parent company, Johnson & Johnson, has been ongoing throughout the United States. In November 2013, Johnson & Johnson agreed to pay more than $2.2 billion in civil and criminal settlements with the United States Department of Justice to resolve claims that it improperly marketed Risperdal.

Following oral argument, we received supplemental citations filed by Janssen regarding similar litigation in Louisiana and

Risperdal, like virtually all pharmaceutical drugs, has risks and side effects. The State filed this case because of its belief that Janssen engaged in unfair and deceptive conduct in South Carolina by failing to properly disclose Risperdal's risks and side effects in an attempt to mislead prescribing physicians and the public. The jury verdict, which is supported by evidence, bears out the State's allegations that Janssen engaged in a systematic pattern of deceptive conduct.

Janssen raises a number of issues in their appeal. Many assignments of error are an attempt to relitigate factual disputes, which we are not permitted to do. Moreover, while we reach the merits of a number of issues, many are not preserved for this Court's review, and we address them only briefly.

A. Opening and Closing Arguments

Janssen claims that various portions of the State's opening and closing arguments were inflammatory and unduly prejudicial and thus warrant a new trial. Specifically, Janssen claims that the State invited the jury to impose liability on the basis of Janssen's size and commercial success by repeatedly referring to Janssen's profits from selling Risperdal and claiming that Janssen put "profits over safety."

We find that Janssen's arguments on appeal are procedurally barred. Although Janssen noted a generalized "continuing objection" at the outset of trial, apparently believing it could make a more

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Arkansas. After closely examining the reported decisions in those states, we have determined that the cases involve statutory claims which do not mirror the SCUTPA.

specific after-the-fact objection to any alleged improper argument or evidence, such an approach is wholly inconsistent with our law requiring a contemporaneous objection. *See Young v. Warr,* 252 S.C. 179, 200, 165 S.E.2d 797, 807 (1969) ("[T]he proper course to be pursued when counsel makes an improper argument is for opposing counsel to immediately object and to have a record made of the statements or language complained of and to ask the court for a distinct ruling thereon." (citing *Crocker v. Weathers,* 240 S.C. 412, 424, 126 S.E.2d 335, 340 (1962))). This rule is designed to enable the trial court to timely address and remedy a founded objection. *See Herron v. Century BMW,* 395 S.C. 461, 465, 719 S.E.2d 640, 642 (2011) ("'Issue preservation rules are designed to give the trial court a fair opportunity to rule on the issues, and thus provide us with a platform for meaningful appellate review.'" (quoting *Queen's Grant II Horizontal Prop. Regime v. Greenwood Dev. Corp.,* 368 S.C. 342, 373, 628 S.E.2d 902, 919 (Ct.App.2006))). Here, absent a contemporaneous objection identifying the particular comments complained of and the basis for the objection, Janssen has waived its right to complain about this issue on appeal. *Webb v. CSX Transp., Inc.,* 364 S.C. 639, 655, 615 S.E.2d 440, 449 (2005) (holding that the failure to contemporaneously object precluded the defendant from raising an issue on appeal (citing *Taylor v. Medenica,* 324 S.C. 200, 212, 479 S.E.2d 35, 41 (1996))).[14]

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[14] We acknowledge the rule in South Carolina that counsel is not required to harass the trial judge by making continued objections after an issue has been ruled upon. *See Dunn v.*

Moreover, Janssen's "continuing objection" at trial concerning the propriety of counsel's statements to the jury was limited to relevance, which is an entirely different basis than the inflammatory/unduly prejudicial argument that Janssen now advances on appeal. Thus, even generously construing Janssen's pre-trial objection as sufficient to preserve the objection, Janssen's claim is nonetheless procedurally barred from appellate review because Janssen argues a different basis on appeal than was argued at trial. *State v. Dunbar,* 356 S.C. 138, 142, 587 S.E.2d 691, 694 (2003) ("A party may not argue one ground at trial and an alternate ground on appeal."(citing *State v. Prioleau,* 345 S.C. 404, 411, 548 S.E.2d 213, 216 (2001); *State v. Benton,* 338 S.C. 151, 157, 526 S.E.2d 228, 231 (2000))).

Janssen's claims of error are without merit in any event. Janssen relies on our holding in *Branham v. Ford Motor Co.,* 390 S.C. 203, 701 S.E.2d 5 (2010), in urging this Court to order a new trial. In *Branham,* the plaintiff's attorney strayed beyond the parameters of permissible jury argument and sought

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Charleston Coca–Cola Bottling Co., 311 S.C. 43, 45–46, 426 S.E.2d 756, 758 (1993) (noting that where a trial judge has fair opportunity to consider and rule upon an issue, it is not incumbent upon counsel "to harass the judge by parading the issue before [the trial judge] again"). However, that is not the situation before us, for Janssen failed to bring to the trial court's attention any of the comments of which it now complains or specify the basis for its objection, much less obtain a ruling from the trial court. Thus, because the trial court did not have a fair opportunity to consider and rule upon Janssen's specific objections, it was incumbent upon Janssen's counsel to object contemporaneously.

punitive damages for the damage caused to non-parties. *Id.* at 235, 701 S.E.2d at 22. We ordered a new trial, holding that "[t]he closing argument invited the jury to base its verdict on passion rather than reason.... [and] denied [defendant] a fair trial." *Id.* We find that *Branham* is readily distinguishable from this case. Here, counsel for the State directly linked the elements of SCUTPA to Janssen's misleading and deceptive practices and its motivations to retain (and increase) Risperdal market share. Such arguments were within proper bounds as the State sought to establish that Janssen acted willfully and contrary to the public interest. In addition, the nature of counsel's comments is more closely associated with what Janssen believes was a grossly excessive award of civil penalties, and the jury's role was limited to determining liability. The jury had no role in determining the amount of the civil penalties.

B. Admission of 1994, 1999, and 2004 DDMAC Letters

Janssen argues that the admission of several DDMAC letters was reversible error because the letters constitute inadmissible hearsay and should also have been excluded under Rule 403, SCRE. Once again, we find that Janssen has not preserved these assignments of error for appellate review.[15] Even if we

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[15] Janssen's contemporaneous objection at trial to admission of the 1994 DDMAC letter was on the basis of relevance, not on the basis of hearsay or Rule 403, SCRE. *See Talley v. S.C. Higher Educ. Tuition Grants Comm.,* 289 S.C. 483, 487, 347 S.E.2d 99, 101 (1986) ("It is an axiomatic rule of law that issues may not be raised for the first time on appeal." (citing *Am. Hardware Supply Co. v. Whitmire,* 278 S.C. 607, 609, 300 S.E.2d 289, 290 (1983))). While it appears that Janssen was more specific in objecting to

were to reach the merits of these claims, however, we would affirm the admission of these letters pursuant to Rule 220(b)(1), SCACR. This evidence was relevant to the issue of liability and concomitantly the statute of limitations concerning the labeling claim, which, as discussed below, inures to Janssen's benefit.

C. Adverse Impact

Janssen argues that the State's SCUTPA claims fail as a matter of law because the State failed to show that Janssen's unfair and deceptive conduct had an adverse impact within South Carolina. We disagree, for the conflicting evidence presented a jury question as to whether Janssen had violated SCUTPA. Concerning the "adverse impact" legal argument, we reject Janssen's attempt to ascribe an injury-in-fact element in an individual claim to an Attorney General

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the admission of the 1999 DDMAC letter—objecting on relevancy, hearsay, and Rule 403, SCRE grounds—the trial judge did not specifically rule on the hearsay or Rule 403, SCRE, issues. Thus, Janssen's assignment of error is not preserved for appellate review. *Kleckley v. Nw. Nat. Cas. Co.,* 338 S.C. 131, 138, 526 S.E.2d 218, 221 (2000) (citing *Anonymous (M–156–90) v. State Bd. of Med. Exam'rs,* 329 S.C. 371, 375, 496 S.E.2d 17, 18–19 (1998); *Camp v. Springs Mortg. Corp.,* 310 S.C. 514, 516, 426 S.E.2d 304, 305 (1993)) ("An issue not raised to or addressed by the trial court or the Court of Appeals is not properly preserved for review by the Supreme Court...."). Regarding the 2004 DDMAC letter, no challenge is preserved for our review. Janssen's pre-trial objection to admission of the letter was only with regard to use or mention of the letter during opening statements, and Janssen's counsel did not state the specific grounds for the objection. *Wilder Corp. v. Wilke,* 330 S.C. 71, 76, 497 S.E.2d 731, 733 (1998) ("[A]n objection must be sufficiently specific to inform the trial court of the point being urged by the objector.") (citation omitted).

directed claim.[16] Janssen's attempt to judicially impose an injury-in-fact element to an Attorney General initiated SCUTPA claim is nothing more than an "if we lied, nobody fell for it" defense, which we reject.

The provisions of SCUTPA allow three types of enforcement actions: (1) lawsuits initiated by the Attorney General seeking injunctive relief; (2) lawsuits by the Attorney General seeking civil penalties; or (3) lawsuits by private parties who have suffered ascertainable losses. S.C.Code Ann. §§ 39–5–50, –110, –140; *see also* Michael R. Smith, Note, *Recent Developments Under the South Carolina Unfair Trade Practices Act,* 44 S.C. L. Rev. 543, 543–44 (1993) (discussing generally various provisions of SCUTPA). Although this case is an appeal from a lawsuit by the Attorney General seeking civil penalties, we note some important distinctions between actions brought by the Attorney General and those brought by private parties.

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[16] After this Court issued its initial opinion, Janssen filed a petition for rehearing. This substituted opinion is in response to Janssen's rehearing petition, primarily to correct the calculation of the penalty associated with the labeling claim. In the rehearing petition, however, Janssen candidly acknowledges that federal standards "do not require enforcement authorities to prove actual injury or actual deception." Petition for Rehearing, p. 10 ("[FTC] 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.").

To recover actual damages under SCUTPA, a private claimant must suffer an actual loss, injury, or damages, and the claimant must demonstrate a causal connection between the injury-in-fact and the complained of unfair or deceptive acts or practices. S.C.Code Ann. § 39–5–140(a). Additionally, a private party may recover treble damages if the unlawful acts at issue are determined to be willful or knowing. *Id.* On the other hand, where the Attorney General files suit on behalf of the State, he is not required to show any injury-in-fact to recover a civil penalty.[17] *See* S.C.Code Ann. §§ 39–5–110, –140. Rather, SCUTPA allows the Attorney General to recover statutory

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[17] Other states have similar provisions. *See, e.g., Mulligan v. QVC, Inc.,* 382 Ill.App.3d 620, 321 Ill.Dec. 257, 888 N.E.2d 1190, 1196 (2008) ("Although the Attorney General may prosecute a violation of the [Consumer Fraud and Deceptive Business Practices] Act without showing that any person has in fact been damaged, it is well settled that in order to maintain a private cause of action under the Consumer Fraud Act, a plaintiff must prove that she suffered actual damage as a result of a violation of the Act." (citation omitted)); *Edmonds v. Hough,* 344 S.W.3d 219, 223 (Mo.Ct.App.2011) ("The [Merchandising Practices] Act eliminates the need for the Attorney General to prove intent to defraud or reliance in order for the court to find that a defendant has engaged in unlawful practices. Intent and reliance are not necessary elements of the cause of action." (quotations and citations omitted)). We recognize, however, there are jurisdictions that require the state to show an injury-in-fact as an element of unfair trade practice type claim. Following oral argument in this case, Janssen has submitted supplemental authority consisting of court decisions from other states reversing trial court verdicts against Janssen. We have carefully reviewed those decisions and conclude they are not persuasive, for the cases submitted by Janssen involve different claims with elements that do not mirror the South Carolina UTPA.

damages of up to $5,000 per violation upon a showing that the unlawful acts at issue are willful.[18] S.C.Code Ann. § 39–5–110(a). If the Attorney General determines that an enforcement action "would be in the public interest," he is statutorily authorized to proceed without making any such showing of injury-in-fact or reliance. S.C.Code Ann. § 39–5–50(a). As noted above, the Attorney General must establish that a defendant's conduct has a tendency to deceive.

Indeed, the "in the public interest" aspect of an Attorney General SCUTPA claim mirrors one of the underlying purposes of the FTCA—namely, "to make clear that the protection of the consumer from unfair trade practices, equally with the protection of competitors and the competitive process, is a concern of public policy." Statement of Basis and Purpose, Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of

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[18] "[A] willful violation occurs when the party committing the violation knew or should have known that his conduct" was unlawful. S.C.Code Ann. § 39–5–110(c). In addition to the civil penalty, the Attorney General is authorized to seek injunctive relief when he "has reasonable cause to believe that any person is using, has used or is about to use any method, act or practice declared by § 39–5–20 to be unlawful." S.C.Code Ann. § 39–5–50(a). To be sure, the legislature has granted the Attorney General broad investigative powers. *See* S.C.Code Ann. § 39–5–70(a) ("When it appears to the Attorney General that a person has engaged in, is engaging in, or is about to engage in any act or practice declared to be unlawful by this article[,] ... [he may serve] an investigative demand...."). While an individual statutory claim necessarily includes an injury-in-fact element, an Attorney General initiated claim does not. It is the protection of the people of South Carolina that lies at the center of an Attorney General directed claim.

Smoking, 29 Fed. Reg. 8324, 8349 (1964). As the Federal Trade Commission has stated, most enforcement actions are brought "not to second-guess the wisdom of particular consumer decisions, but rather to halt some form of seller behavior that unreasonably creates or takes advantage of an obstacle to the free exercise of consumer decisionmaking." Federal Trade Commission, Policy Statement on Unfairness (Dec. 17, 1980) [hereinafter Unfairness Policy Statement], *available at* https://www.ftc.gov/public-statements/1980/12/ftc-policy-statement-unfairness.

Thus, Janssen misconstrues the legislature's manifest purpose in providing for an Attorney General directed claim, for a SCUTPA action brought by the State is to protect the citizens of South Carolina from unfair or deceptive acts in the conduct of any trade or commerce.[19] Janssen's contention to the contrary is not only fundamentally at odds with unambiguous legislative intent in authorizing an Attorney General SCUTPA claim, but is also inconsistent with well-established law.

On the issue of liability, our case law interpreting and applying SCUTPA is clear—while a private party SCUTPA action requires the traditional showing of an injury, an action brought by the Attorney General on behalf of the State contains no actual injury element. For the foregoing reasons, we hold that, although the State had the burden of proving Janssen's

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[19] In terms of public policy, the South Carolina Constitution provides that "[t]he health, welfare, and safety of the lives and property of the people of this State ... are matters of public concern." S.C. Const. art. XII, § 1.

representations had a *tendency to deceive,* the State was not required to show actual deception or that those representations caused any appreciable injury-in-fact or adversely impacted the marketplace. The tendency to deceive standard is derived from federal law and is therefore in compliance with section 39–5–20(b). *See Kraft, Inc. v. FTC,* 970 F.2d 311, 314 (7th Cir.1992) (finding "an advertisement is deceptive under the [FTCA] if it is *likely to mislead* consumers") (emphasis added); *Trans World Accounts, Inc. v. FTC,* 594 F.2d 212, 214 (9th Cir.1979) ("Proof of actual deception is unnecessary to establish a violation of Section 5 [of the FTCA]. Misrepresentations are condemned if they possess a *tendency to deceive*.") (emphasis added); *Beneficial Corp. v. FTC,* 542 F.2d 611, 617 (3d Cir.1976) ("[T]he *tendency of the advertising to deceive* must be judged by viewing it as a whole, without emphasizing isolated words or phrases apart from their context. An intent to deceive is not an element of a deceptive advertising charge under [the FTCA]. Moreover, the FTC has been sustained in finding that advertising is misleading even absent evidence of that actual effect on customers; *the likelihood or propensity of deception is the criterion by which advertising is measured*.") (emphasis added); *Goodman v. FTC,* 244 F.2d 584, 602 (9th Cir.1957) ("One of the objects of the Federal Trade Commission Act is to eradicate business methods having a *capacity to deceive*.") (emphasis added); Federal Trade Commission, Policy Statement on Deception (Oct. 14, 1983) [hereinafter Policy Statement on Deception], *available at* https://www.ftc.gov/public-statements/1983/10/ftc-policy-statement-deception (noting that in evaluating

conduct, "[t]he issue is whether the act or practice is *likely to mislead,* rather than whether it causes actual deceptions") (emphasis added).

We find ample support in the record that the State presented sufficient evidence for the SCUTPA claim to go to the jury. Although we reject Janssen's effort to impose an injury-in-fact element in an Attorney General initiated claim, we believe the argument carries persuasive weight in the assessment of an appropriate penalty, which we address in the penalty section.

D. Exclusion of Dr. Wecker's Expert Testimony

Janssen claims that the trial court erred in excluding the testimony of Dr. William Wecker, an expert statistician whose testimony, according to Janssen, would have shown that Janssen's representations in the Risperdal label and the November 2003 DDL had no impact on any prescribing physicians. The import of Dr. Wecker's testimony would have been that, notwithstanding Janssen's false representations, the community of prescribing physicians was well aware of the risks and side effects of Risperdal.

We are again presented with an issue that was not properly preserved for appellate review. When the trial court filed its order on February 25, 2011, excluding the testimony of Dr. Wecker on relevancy grounds, Janssen waited until March 21, 2011, to make an offer of proof of his testimony. The offer of proof came too late. *TNS Mills, Inc. v. S.C. Dep't of Rev.,* 331 S.C. 611, 628, 503 S.E.2d 471, 480 (1998) (noting that a failure to make a proffer of what

an excluded witness's testimony would have been precludes appellate review); *see also Greenville Mem'l Auditorium v. Martin,* 301 S.C. 242, 244, 391 S.E.2d 546, 547 (1990) ("An alleged erroneous exclusion of evidence is not a basis for establishing prejudice on appeal in absence of an adequate proffer of evidence in the court below." (citations omitted)).[20]

On the merits, for the reasons discussed in the previous section, we would not find reversible error in any event. We do acknowledge there was evidence presented, which otherwise 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. Excluding Dr. Wecker's testimony, therefore, resulted in no prejudice to Janssen. Yet, as discussed above, Janssen's relevancy argument is based on the false premise that actual harm resulting from the deceptive conduct is a necessary element of an Attorney General directed claim.

E. First Amendment

Janssen argues that the liability verdict and the penalty award impermissibly restrict its right to free speech. We disagree.

Again, Janssen has not preserved this issue for review. Although Janssen requested a First Amendment jury instruction and raised the issue in

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[20] It is for the same reason we reject Janssen's claim that the trial court erred by excluding the testimony of the twenty surveyed physicians and evidence of the 2007 Zyprexa product insert and 2010 Latuda product insert.

its motion for JNOV, Janssen failed to raise any First Amendment issues in its motion for a directed verdict. Janssen's failure to raise this issue in its motion for a directed verdict precludes any appellate review. *In re McCracken,* 346 S.C. 87, 93, 551 S.E.2d 235, 238 (2001) ("[S]ince only grounds raised in the directed verdict motion may properly be reasserted in the jnov motion, and since no grounds were raised in the directed verdict motion, no jnov claim is preserved for our review." (citing *Duncan v. Hampton Cnty. Sch. Dist. # 2*, 335 S.C. 535, 545, 517 S.E.2d 449, 454 (Ct.App.1999))).

There is no error in any event, for the First Amendment does not bar imposition of liability on Janssen for violating SCUTPA. Janssen relies on the false premise that its conduct was not unfair and deceptive. While commercial speech is entitled to First Amendment protections, the Constitution does not erect a blanket shield insulating commercial speech from liability in all circumstances. In this regard, we find Janssen's reliance on ——U.S.——, 131 S.Ct. 2653, 180 L.Ed.2d 544 (2011), is misplaced. The Supreme Court of the United States held in *Sorrell* that "[s]peech in aid of pharmaceutical marketing ... is a form of expression protected by the Free Speech Clause of the First Amendment." *Id.* at 2659. *Sorrell*, however, does not deal with deceptive commercial speech. Instead, the *Sorrell* Court invalidated a Vermont law that regulated the type of pharmacy records that a drug manufacturer could obtain and use in marketing prescription drugs. *Id.* at 2659. The State of Vermont never argued "that the provision challenged ... will prevent false or misleading speech," nor did it argue that the

detailing[21] at issue was "false or misleading within the meaning of [the Supreme] Court's First Amendment precedents." *Id.* at 2672. We do not construe *Sorrell* as foreclosing a state from prohibiting unfair and deceptive prescription drug marketing.

Indeed, it is a well-settled proposition that "[t]he government may ban forms of communication more likely to deceive the public than to inform it, or commercial speech related to illegal activity." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.,* 447 U.S. 557, 563–64, 100 S.Ct. 2343, 65 L.Ed.2d 341 (1980) (internal citations omitted). The State correctly notes that commercial speech is not protected by the First Amendment unless it concerns lawful activity and is not misleading. *Johnson v. Collins Entm't Co.,* 349 S.C. 613, 624, 564 S.E.2d 653, 659 (2002).

Here, the jury found that Janssen's acts were unfair or deceptive, and thus unlawful under SCUTPA. In an action at law tried to a jury, the jury's factual findings will not be disturbed unless a review of the record discloses that there is no evidence that reasonably supports the jury's findings. *City of North Myrtle Beach v. E. Cherry Grove Realty Co.,* 397 S.C. 497, 502, 725 S.E.2d 676, 678 (2012). The record is replete with evidence that reasonably supports a

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[21] Pharmaceutical companies such as Janssen "promote their drugs to doctors through a process called 'detailing.' This often involves a scheduled visit to a doctor's office to persuade the doctor to prescribe a particular pharmaceutical. Detailers bring drug samples as well as medical studies that explain the 'details' and potential advantages of various prescription drugs." *Sorrell,* 131 S.Ct. at 2659.

finding that Janssen's conduct was unfair and deceptive. Thus, we conclude Janssen may not avail itself of the protections of the First Amendment to shield itself from its deceptive conduct and false representations.

F. Jury Instructions

Janssen argues that the trial court erred by failing to charge the jury on federal law regarding "unfairness" and instead looking to South Carolina law to define the term. We disagree and reject the premise that the jury charges on unfairness and the tendency to deceive standard are creations of state law; they are rooted in federal law.

Modeled after the language of the Federal Trade Commission Act (FTCA),[22] SCUTPA declares unlawful any unfair or deceptive acts or practices in trade or commerce. *Compare* 15 U.S.C. § 45(a)(1) (2012) ("Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful."), *with* S.C.Code Ann. § 39–5–20(a) ("Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."). SCUTPA does not define the terms "unfair" and "deceptive"; rather, the legislature intended the courts to be guided by federal interpretations of those terms. S.C.Code Ann. § 39–5–20(b) (1985) (instructing South Carolina courts to take guidance from "the interpretations given by the Federal Trade Commission and the Federal Courts to § 5(a)(1)" of the FTCA).

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[22] 15 U.S.C. §§ 41–77 (2012).

The trial court charged the jury:

> I'm gonna [sic] go back and read 39–5–20 to you one more time because this Code Section refers back to violations of that. [Section] 39–5–20, again, says unfair or deceptive acts or practices, in the conduct of any trade or commerce, are hereby declared unlawful.
>
> Now, for an act to be a violation of the South Carolina Unfair Trade Practices Act, the act or practice complained of must be unfair or deceptive. Now, whether an act or practice is unfair or deceptive, within the meaning of the act, depends upon the facts and circumstances surrounding what someone's done and the impact of that act or transaction on the market place.
>
> Now, the plaintiff claims that the defendant has committed, committed unfair trade practices. A trade, practice, or act is an unfair trade, practice, or act if it offends established public policy or is immoral, unethical, or oppressive. This does not include act[s] or practices or representations that are nothing more than dealer talk, trade talk, or what is called puffing.
>
> Even a truthful statement may be deceptive, under the Unfair Trade Practices Act, if it has a capacity or tendency to deceive when taken in the context of the circumstances surrounding the making of the statement or the doing of the act.
>
> Further, a false or misleading act or practice is one which has the capacity or the tendency

> to deceive. There is no need to show that a representation was intended to deceive, but it must be shown that the act, the statement had the capacity or effect or the tendency to deceive.

We find no reversible error in the trial court's failure to charge the precise verbiage of section 45(n) of the FTCA. We do not discern the wide chasm between the federal and state definitions of "unfair" that Janssen urges. The FTC has issued "Policy Statements" that provide guidance on the statutory terms. For example, in the Policy Statement on Deception, the FTC reviewed case law and Commission decisions and noted that "deception cases" may include representations or omissions in connection with the sale of a product "without adequate disclosures." Policy Statement on Deception, *supra.* FTC guidance further instructs that "there must be a representation, omission, or practice that is likely to mislead the consumer" and that "the act or practice must be considered from the perspective of the reasonable consumer." *Id.* The FTC has additionally issued a Policy Statement on Unfairness, which acknowledged that the concept of "unfairness is one whose precise meaning is not immediately obvious." Policy Statement on Unfairness, *supra.* FTC guidance provides the following general characteristics of an unfair practice claim: "(1) whether the practice injures consumers;[23] (2) whether it violates established public policy; (3) whether it is unethical or unscrupulous." *Id.*

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[23] As previously discussed, an Attorney General enforcement action does not require a showing of injury in fact. This is in accord with federal guidance. *See* Policy Statement on

The jury instruction was in substantial accord with the FTC guidance. Janssen makes the argument that there was no tendency to deceive (or likelihood of causing consumer injury) because the intended audience of its representations was the medical community, and further because the medical community knew or should have known the truth, Janssen must be absolved of any liability. Janssen's argument is not without merit, for the context surrounding a practice or representation is a weighty consideration. *See* Policy Statement on Deception, *supra* ("[A] practice or representation directed to a well-educated group, such as prescription drug advertisement to doctors, would be judged in light of the knowledge and sophistication of that group.") Janssen essentially seeks a categorical rule that insulates a pharmaceutical company from SCUTPA liability for misrepresentations made to prescribing physicians, a sophisticated group. We decline to recognize such a rule.

This "sophisticated audience" argument was vetted by the parties and charged to the jury in that the jury was required to assess the alleged unfair and deceptive practice in light of the "facts and circumstances surrounding what someone's done" and "in the context of the circumstances surrounding the making of the statement or the doing of the act."[24]

Unfairness, *supra* (stating that practices that undermine free and informed consumer decisions undermine a well-functioning market and are properly banned as unfair practices under the FTCA).

[24] The charge is in accord with the law that "[w]hether an act or practice is unfair or deceptive within the meaning of the [SC]UTPA depends on the surrounding facts and the impact of

Whether Janssen's actions and representations to the medical community constituted a violation of SCUTPA was a jury question. The jury has spoken, and we are not permitted to weigh the evidence and invade the province of the jury.

In construing the charge as a whole, as we must, we conclude it properly defined an unfair trade practice in accordance with section 39–5–20(a) and (b). *See Proctor v. Dep't of Health & Envtl. Control,* 368 S.C. 279, 310, 628 S.E.2d 496, 513 (Ct.App.2006) (quoting *Burroughs v. Worsham,* 352 S.C. 382, 391, 574 S.E.2d 215, 220 (Ct.App.2002)) (" 'The substance of the law is what must be instructed to the jury, not any particular verbiage.... A jury charge which is substantially correct and covers the law does not require reversal.'") (ellipsis in original); *id.* at 310, 628 S.E.2d at 513 (citing *Daves v. Cleary,* 355 S.C. 216, 224, 584 S.E.2d 423, 427 (Ct.App.2003)) ("When reviewing a jury charge for alleged error, the appellate court must consider the charge as a whole in light of the evidence and issues presented at trial.").

G. Regulated Activity Exception to SCUTPA

Janssen claims that the State's labeling claim was barred by SCUTPA's regulated activity exemption. We hold that Janssen has failed to preserve this issue for appellate review. However, even if we were to reach

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the transaction on the marketplace."(*Wright v. Craft,* 372 S.C. 1, 26, 640 S.E.2d 486, 500 (Ct.App.2006) (citing *deBondt,* 342 S.C. at 269, 536 S.E.2d at 407)); *see also* Policy Statement on Unfairness, *supra* (noting that unwarranted or undisclosed health and safety risks may support a finding of unfairness).

the merits, we would find that Janssen is not entitled to avail itself of the regulated activity exemption.

SCUTPA expressly provides that it is inapplicable to "[a]ctions or transactions permitted under laws administered by any regulatory body or officer acting under statutory authority of this State or the United States." S.C.Code § 39–5–40(a) (1985). "This exception exempts an entity from liability where its actions are lawful or where it does something required by law, or does something that would otherwise be a violation of the Act, but which is allowed under other statutes or regulations." *Dema v. Tenet Physician Servs.–Hilton Head, Inc.,* 383 S.C. 115, 123, 678 S.E.2d 430, 434 (2009) (quotations omitted). Janssen argues that, after approval of a proposed label, the FDA both authorized and required the use of that approved label. Thus, Janssen argues that FDA approval of the label triggers SCUTPA's regulated activity exemption and prohibits any claim in connection with the sufficiency of the label.

Initially, Janssen fails to identify any specific trial court rulings claimed to constitute error. Because of this, Janssen's argument does not sufficiently identify with particularity the alleged error, and Janssen has abandoned its claim on appeal. *See* Rule 208(b)(4), SCACR ("The brief shall contain references to the transcript, pleadings, orders, exhibits, or other materials which may be properly included in the Record on Appeal ... to support the salient facts alleged. References shall also be made to where relevant objections and rulings occurred in the transcript."); *see also First Sav. Bank v. McLean,* 314 S.C. 361, 363, 444 S.E.2d 513, 514 (1994) ("Mere

allegations of error are not sufficient to demonstrate an abuse of discretion. On appeal, the burden of showing abuse of discretion is on the party challenging the trial court's ruling."(citation omitted)).

However, even if Janssen had properly preserved this issue, we note that Janssen was not entitled to avail itself of this SCUTPA provision. *Wyeth* makes clear that "a central premise of federal drug regulation [is] that the manufacturer bears responsibility for the content of its label at all times."555 U.S. at 570–71, 129 S.Ct. 1187. "[The manufacturer] is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Id.* at 571, 129 S.Ct. 1187 (citing 21 C.F.R. § 201.80(e); 21 C.F.R. § 314.80(b); 73 Fed. Reg. 49605). *Wyeth* clearly rejects the notion that a manufacturer's decision not to include a stronger warning is authorized by the FDA—absent evidence that the FDA affirmatively considered and rejected the stronger warning after being supplied with an evaluation or analysis of the specific dangers presented. *Id.* at 572–73, 129 S.Ct. 1187. The very purpose of the "changes being effected" corollary to the FDCA authorizes manufacturers to strengthen the warnings on a label without FDA approval, as long as the manufacturer files a supplemental new drug application. *Id.* at 568, 129 S.Ct. 1187; 21 C.F.R. § 314.70(c)(6)(iii)(A), (C) (2013). Indeed, the United States Supreme Court in *Wyeth* noted that "Congress enacted the FDCA to bolster consumer protection against harmful products. Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs in the [FDCA]. Evidently, it determined that widely available state rights of action

provided appropriate relief for injured consumers." *Id.* at 574, 129 S.Ct. 1187. Accordingly, Janssen cannot shield itself from liability by claiming that the FDA's approval of its label constituted an express authorization of its labeling decisions. *See id.* at 583, 129 S.Ct. 1187 (Thomas, J., concurring in the judgment) ("[F]ederal law does not give drug manufacturers an unconditional right to market their federally approved drug at all times with the precise label initially approved by the FDA.").

H. Statute of Limitations

Janssen claims that the trial court erred by granting the State's motion for a directed verdict on the statute of limitations on the labeling claim and the DDL claim. We disagree concerning the DDL claim and affirm, but agree in part with Janssen regarding the labeling claim. The statute of limitations bars the labeling claim insofar as the trial court imposed civil penalties for violations that occurred more than three years prior to the parties' tolling agreement. Because of the ongoing nature of Janssen's deceptive conduct, we affirm the judgment on the labeling claim but limit the imposition of civil penalties to a three-year period, coextensive with the statute of limitations, subject only to the additional period of time between the tolling agreement and the filing of the Complaint.

At the close of all of the evidence, the State moved for a directed verdict as to Janssen's statute of limitations defense, arguing that Janssen failed to present any evidence that the Attorney General's office had actual or constructive notice of Janssen's unlawful conduct prior to the commencement of the

three year statute of limitations.[25] Specifically, the State argued there was no evidence that the Attorney General, more than three years prior to the commencement of the statute of limitations on January 24, 2004, knew or should have known about the deceptiveness of the DDL and the Risperdal label, the concealed studies, or the unlawful promotion of Risperdal in South Carolina.

The trial court granted the State's motion for a directed verdict, finding that neither the DDL claim nor the labeling claim was barred by the three-year statute of limitations. Specifically, the trial court noted that although the medical community was generally aware of the risks associated with Risperdal, some even as early as the mid–1990s, the point in time at which the side-effects of Risperdal became known was not the gravamen of the State's claims. Rather, the specific conduct at issue was Janssen's false and misleading statements in the DDL and Janssen's failure to update its label to reflect the known degree of risks associated with Risperdal. Accordingly, the relevant inquiry was the point at which the State should have known that Janssen's *conduct* as to the DDL and the Risperdal label was unfair or deceptive and, thus, gave rise to a SCUTPA claim.

As to the DDL claim, the trial court found that claim was not barred by the statute of limitations because there was no evidence that the false or misleading nature of the DDL could have been discovered before the DDMAC issued its warning

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[25] The Complaint was filed on April 23, 2007, but, as noted, the State and Janssen entered into a tolling agreement concerning the statute of limitations on January 24, 2007.

letter to Janssen in April 2004, which was within the timeframe of the tolling agreement. As to the labeling claim, the trial court found that because Janssen took affirmative steps to prevent disclosure of unfavorable clinical trial results that revealed the serious degree of risks associated with Risperdal, the statute of limitations was equitably tolled during the period of time in which Janssen knew, but failed to disclose and shielded from public knowledge, the true degree of risks associated with Risperdal. The trial court found the labeling claim likewise was not barred by the statute of limitations, and awarded a civil penalty for each of the of 509,499 Risperdal "sample boxes" distributed in South Carolina from 1998 through the date of the Complaint, April 23, 2007, each of which included the drug label in the sample packaging.

Janssen argues this was error and that both claims are barred by the statute of limitations because the State had actual or constructive knowledge of the claims before January 24, 2004. Specifically, as to the DDL claim, Janssen contends that the claim was discoverable from the face of the DDL itself, and therefore, the statute of limitations began to run at the time the DDL was mailed in November 2003. As to the labeling claim, Janssen contends that claim is barred because the risks associated with Risperdal were widely known by the mid–1990s and that the alleged inadequacies in the labeling were apparent from the face of the label itself; therefore, Janssen posits that the labels themselves put the State on notice of its labeling claim as early as 1994, and that the three-year statute of limitations thus ran long before the State's Complaint was filed in 2007. Janssen further argues the doctrine of equitable tolling should be

sparingly applied and that there is no basis for applying it here.

We first address the DDL claim. SCUTPA provides for a three-year statute of limitations. S.C.Code Ann. § 39–5–150 (1985). Under the discovery rule, the three-year clock starts ticking on the date the injured party either knows or should have known by the exercise of reasonable diligence that a cause of action arises from wrongful conduct. *Dean v. Ruscon Corp.,* 321 S.C. 360, 363, 468 S.E.2d 645, 647 (1996) (citation omitted). We have carefully reviewed the record in light of the appropriate standard of review, and we agree with the trial court. As a matter of law, the only reasonable conclusion supported by the evidence at trial was that the existence of a claim, i.e. the deceptive and unfair nature of Janssen's conduct in disseminating the DDL, could not have reasonably been discovered prior to April 2004 when the FDA issued the Warning Letter to Janssen.[26] *See id.* at 366, 468 S.E.2d at 648 (finding that where the only reasonable conclusion supported by the evidence was that the lawsuit accrued on a particular date, there was no issue for the jury to decide and a directed verdict was proper). We affirm the trial court's finding that the DDL claim was timely.

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[26] Considerable argument is presented over whether the discovery rule should be analyzed through the person of the Attorney General or the typical approach of the reasonably prudent person. We need not decide the "relevant plaintiff" question and purported distinction between the two, for the result would be the same here.

We turn to the labeling claim. The procedural dilemma we confront is that the statute of limitations issue concerning the labeling claim was resolved at trial through principles of equitable tolling. A determination in equity is not proper for a directed verdict motion insofar as determining what matters should be submitted to the jury. It was therefore legal error to resolve the issue of equitable tolling pursuant to a directed verdict motion. Under our *de novo* review of this equitable issue, we agree with Janssen that there is an insufficient basis for application of that doctrine to preserve the timeliness of all labeling violations, reaching back to the time Risperdal was first introduced in 1994. *See Hooper v. Ebenezer Sr. Servs. & Rehab. Ctr.,* 386 S.C. 108, 117, 687 S.E.2d 29, 33 (2009) (noting the doctrine of equitable tolling should be used sparingly and only when the interests of justice demand its use). However, we do not view the error as one mandating reversal and a new trial, given the continuing nature of the accrual of labeling violations.

Clearly, much of the labeling claim accrued more than three years prior to the January 24, 2007 tolling agreement. The risks associated with atypical antipsychotics, like Risperdal, were becoming well known by the late 1990s. The State's experts testified that the Risperdal label was inadequate as early as 1994 when Janssen began marketing the drug. By all accounts, in the early 2000s, evidence of the risks was pervasive.[27] We find that the only reasonable

[27] This underscores Janssen's point that the community of prescribing physicians should have known of the risks associated with Risperdal, and Janssen's resulting contention that the

conclusion supported by the evidence is that the Attorney General knew, or most assuredly should have known, of potential SCUTPA violations regarding the Risperdal label prior to January 24, 2004. Thus, the labeling violations occurring prior to January 24, 2004, were therefore barred by the statute of limitations.

Nevertheless, the labeling claim presents ongoing violations of SCUTPA that continued *after* January 24, 2004 and during the three-year-period prior to the tolling agreement. In requesting that the entire labeling claim be dismissed as time barred, Janssen assumes, wrongly so, that its ability to successfully invoke the statute of limitations to bar the labeling claim prior to January 24, 2004, ends the labeling claim altogether. We reject Janssen's position, for Janssen misapprehends the statute of limitations and the concept of continuous accrual of this SCUTPA cause of action. The labeling claim presents a series of discrete, independently actionable wrongs that are at the core of the typical unfair trade practice action. The principles of this type of continuous accrual respond to

> the inequities that would arise if the expiration of the statute of limitations period following a first breach of duty or instance of misconduct were treated as sufficient to bar suit for any subsequent breach or misconduct; parties engaged in long-standing malfeasance would thereby obtain immunity in perpetuity from suit even for recent and

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allegedly deceptive practices had little or no effect on the practice and frequency of prescribing Risperdal.

> ongoing malfeasance. In addition, where misfeasance is ongoing, a defendant's claim to repose, the principal justification underlying the limitations defense, is vitiated.... [Accordingly,] separate, recurring invasions of the same right can each trigger their own statute of limitations.... Generally speaking, continuous accrual applies whenever there is a continuing or recurring obligation: [w]hen an obligation or liability arises on a recurring basis, a cause of action accrues each time a wrongful act occurs, triggering a new limitations period.

Aryeh v. Canon Bus. Solutions, Inc., 55 Cal.4th 1185, 151 Cal.Rptr.3d 827, 292 P.3d 871, 880 (2013) (quotations and citations omitted) (distinguishing the continuous accrual doctrine from the continuing violation doctrine, which involves a single injury that is the product of a series of small harms, any one of which is not actionable on its own). *See Estate of Livingston v. Livingston,* 404 S.C. 137, 147–48, 744 S.E.2d 203, 209 (Ct.App.2013) (finding a new statute of limitations begins to run after each separate injury, and therefore statute of limitations barred only claims falling outside the three-year time period and did not bar claims occurring within that time), *cert. granted,* No. 2013–001505 (S.C.Sup.Ct. filed Oct. 24, 2014); *see also Hogar Dulce Hogar v. Cmty. Dev. Comm'n of Escondido,* 110 Cal.App.4th 1288, 2 Cal.Rptr.3d 497, 502 (2003) ("When an obligation or liability arises on a recurring basis, a cause of action accrues each time a wrongful act occurs, triggering a new limitations period." (citation omitted)); *cf. Anonymous Taxpayer v. S.C. Dep't of Rev.,* 377 S.C. 425, 440–41, 661 S.E.2d 73,

81 (2008) (finding that, under the facts presented, the particular claim alleged by plaintiff constituted only one cause of action, and therefore, there was no continuing injury that would trigger a new limitations period).

Indeed, the language of SCUTPA itself contemplates that an unlawful method, act, or practice may result in multiple statutory violations, and it is the violations themselves that cause the statute of limitations to begin to run. S.C.Code Ann. § 39–5–110(a) ("If a court finds that any person is willfully using or has willfully used a method, act or practice declared unlawful by § 39–5–20, the Attorney General ... may recover on behalf of the State a civil penalty of not exceeding five thousand dollars *per violation*." (emphasis added)). We adopt the view that aligns with legislative intent as reflected in section 39–5–110, a common sense approach recognizing that the SCUTPA statute of limitations begins to run anew with each violation. Thus, where a claim involves a series of ongoing violations, recovery is limited to a period coextensive with the applicable statute of limitations.

In sum, we agree with the State regarding the DDL claim, for we find that claim, in the exercise of reasonable diligence, could have been discovered no earlier than April 2004 when the FDA issued its warning letter to Janssen. However, we agree with Janssen concerning the labeling claim insofar as civil penalties were awarded for violations occurring from 1998 until January 24, 2004 (three years prior to the tolling agreement). Under these facts, it was error to award the State civil penalties for violations in

connection with the labeling claim outside the statute of limitations. An award for civil penalties within the statute of limitations was proper.

I. Preemption

Janssen argues that both the labeling claim and the DDL claim are preempted by federal law. Specifically, Janssen argues the labeling claim is barred by implied conflict preemption and that the DDL claim is barred by the express preemption provision of the FDCA, 21 U.S.C. § 337(a) (2006). We disagree.

When "Congress has 'legislated ... in a field which the States have traditionally occupied,' we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (quotations and citations omitted) (ellipses in original).

"In 1962, Congress amended the FDCA and shifted the burden of proof from the FDA to the manufacturer." *Wyeth,* 555 U.S. at 567, 129 S.Ct. 1187. "Before 1962, the [FDA] had to prove harm to keep a drug out of the market, but the amendments required the manufacturer to demonstrate that its drug was safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling before it could distribute the drug." *Id.* (quotations and citations omitted). "In addition, the amendments required the manufacturer to prove the drug's effectiveness by introducing substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use

prescribed, recommended, or suggested in the proposed labeling." *Id.* (quotations and citations omitted). "As [Congress] enlarged the FDA's powers to protect the public health and assure the safety, effectiveness, and reliability of drugs, Congress took care to preserve state law." *Id.* (quotations and citations omitted). "The 1962 amendments [to the FDCA] added a saving clause, indicating that a provision of state law would only be invalidated upon a direct and positive conflict with the FDCA." *Id.* (quotations and citations omitted). "Consistent with that provision, state common-law suits 'continued unabated despite ... FDA regulation.'" *Id.* (quoting *Riegel v. Medtronic, Inc.,* 552 U.S. 312, 340, 128 S.Ct. 999, 169 L.Ed.2d 892 (2008) (Ginsburg, J., dissenting)).[28]

Based upon *Wyeth,* we find that the State's DDL claim is not expressly preempted by federal law. Additionally, we find that Janssen has not preserved their implied conflict preemption claim for appellate review. Even assuming Janssen's argument regarding implied preemption is not procedurally barred, however, we find it to be without merit.

1. Express Preemption of the DDL Claim

Janssen argues that the State's claim regarding the DDL relies on a single piece of evidence—the April 2004 DDMAC warning letter characterizing Janssen's DDL as "false and misleading." As such, Janssen

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[28] The FDA did not have the authority to mandate a manufacturer change its label until amendments to the FDCA in 2007. 21 U.S.C. § 355(o)(4) (Supp. V 2011).

asserts the DDL claim is based solely on a violation of the FDCA, which provides no private right of action. Janssen thus concludes that this "federal claim" is preempted and may not be maintained. Because Janssen's argument is based on a false premise, we disagree.

It is true that the State pursued a SCUTPA claim based on the November 2003 DDL. It is also true that the State introduced the April 2004 DDMAC warning letter as evidence in support of its DDL claim. It is not true that the sole evidence establishing the false and misleading nature of the DDL comes from the subsequent April 2004 DDMAC warning letter. Janssen not only views the DDL claim myopically, but conflates the concepts of evidence and claims. There was substantial additional evidence relating to the deception surrounding the November 2003 DDL, much of which is noted above. For example, the State presented evidence that, scientific proof to the contrary, Janssen's Risperdal sales strategy specifically sought to differentiate Risperdal from competing drugs by emphasizing that Risperdal caused less weight gain relative to other atypical antipsychotics such as Zyprexa.

Moreover, the State presented internal emails between Janssen executives, one of which included discussion of Janssen's desire to gain market share over competitors by avoiding being subjected to a class labeling requirement as to diabetes/hyperglycemia. Yet another email indicated that at least one Janssen scientist supported glucose screening and monitoring for Risperdal patients, but that such a position was "not the company line." Janssen's broad, aggressive,

and deceptive marketing strategy resulted in the discrete DDL claim. In short, the record is replete with evidence beyond the 2004 DDMAC warning letter to support the State's DDL claim. Further, at the end of trial, the jury was charged with determining several factual issues, each of which was based solely on the provisions of SCUTPA, and the trial judge assessed penalties under SCUTPA framework. Accordingly, we find that the State's SCUTPA claim concerning the DDL is not preempted by the FDCA.

2. Implied Conflict Preemption of the Labeling Claim

Janssen argues that the State's labeling claim is barred by implied conflict preemption. Janssen failed to raise the doctrine of implied conflict preemption in its motion for summary judgment or its initial directed verdict motion at the close of the State's case-in-chief. Accordingly, this argument was waived because it was not asserted in Janssen's initial motion for directed verdict.[29] *See Freeman v. A. & M. Mobile Home Sales, Inc.,* 293 S.C. 255, 258–59, 359 S.E.2d 532, 535 (Ct.App.1987).

Additionally, Janssen's argument on appeal is substantively different than the argument below.

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[29] Notably, Janssen did raise express preemption as to the DDL in its initial directed verdict motion. However, counsel for Janssen candidly acknowledged in its renewed directed verdict motion at the close of the evidence, "[W]e have an argument that hasn't been made by us before, and that is that the package insert claim, the claim dealing with the label, is preempted by federal law." Further, counsel for Janssen stated, "We're arguing something quite different that we haven't argued before. We haven't [previously] argued about Wyeth against Levine."

Before the trial court, Janssen moved for a directed verdict, arguing that the *Wyeth* "exception to preemption" did not apply since the State failed to establish that Janssen could have, and should have, updated the Risperdal label without prior FDA approval. Given this purported failure of proof, Janssen argued that the State's labeling claim was preempted. The trial court rejected Janssen's argument and found that *Wyeth* was controlling. In contrast, Janssen now argues that the State's SCUTPA claims sought to impose labeling requirements different from those required by the FDA, and thus, according to Janssen, the doctrine of implied conflict preemption bars the State's claims. This argument, however, is not preserved for appellate review. *See Dunbar,* 356 S.C. at 142, 587 S.E.2d at 694 ("A party may not argue one ground at trial and an alternate ground on appeal." (citing *Prioleau,* 345 S.C. at 411, 548 S.E.2d at 216; *Benton,* 338 S.C. at 157, 526 S.E.2d at 231)).

Nonetheless, even were we to find Janssen's argument not to be procedurally barred, we would find it is without merit. Janssen suggests that the State sought to impose labeling requirements different than those imposed by the FDA. The State's claim, however, did not seek to penalize Janssen for distributing its FDA-approved label. Rather, the State sought civil penalties based on Janssen's actions in failing to discharge its ongoing, affirmative 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, 129 S.Ct. 1187 (citing 21 C.F.R. § 201.80(e); 21 C.F.R. § 314.80(b); 73 Fed. Reg. 49605).

Further, we reject Janssen's argument that *Wyeth* is inapposite because this case involves an enforcement action by the Attorney General on behalf of the State. Regardless of whether a state-law enforcement action is brought by a private individual or an attorney general on behalf of a state, *Wyeth* makes clear that federal labeling standards are "a floor upon which States could build" and noted the FDA's agency position that, "in establishing minimal standards for drug labels, it did not intend to preclude the states from imposing additional labeling requirements." *Id.* at 577–78, 129 S.Ct. 1187 (quotations omitted). Rather, "[f]ailure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times." *Id.* at 579, 129 S.Ct. 1187. Indeed, "federal law does not give drug manufacturers an unconditional right to market their federally approved drug at all times with the precise label initially approved by the FDA." *Id.* at 583, 129 S.Ct. 1187 (Thomas, J. concurring in the judgment). Janssen's claim is without merit.

Having affirmed the trial court concerning Janssen's liability in connection with both the labeling claim and the DDL claim, we turn now to the penalty award.[30]

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[30] Janssen raises a number of other issues, each of which we have carefully reviewed and find to be without merit or unpreserved. We affirm based upon Rule 220(b)(1), SCACR, and the following authorities: *Fields v. J. Haynes Waters Builders, Inc.,* 376 S.C. 545, 557, 658 S.E.2d 80, 86 (2008) (holding that in order to warrant reversal, the appealing party must show both the error of the ruling and resulting prejudice) (citing *Fields v.*

III. Penalty Award

SCUTPA allows the Attorney General to recover on behalf of the State a civil penalty of up to $5,000 per violation. S.C.Code Ann. § 39–5–110(a). Undoubtedly, Janssen's deceptive conduct relating to Risperdal warrants a civil penalty, and because the civil penalty award under section 39–5–110(a) is within the discretion of the trial court, we review the trial court's penalty award under an abuse of discretion standard. *State ex rel. McLeod v. C & L Corp., Inc.,* 280 S.C. 519, 528, 313 S.E.2d 334, 340 (Ct.App.1984) ("The party challenging a discretionary

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Reg. Med. Ctr. Orangeburg, 363 S.C. 19, 26, 609 S.E.2d 506, 509 (2005)); *Webb v. CSX Transp., Inc.,* 364 S.C. 639, 655, 615 S.E.2d 440, 449 (2005) (finding the failure to raise a contemporaneous objection at trial waives the right to complain about an issue on appeal) (citing *Taylor v. Medenica,* 324 S.C. 200, 214 n. 9, 479 S.E.2d 35, 42 n. 9 (1996)); *Futch v. McAllister Towing of Georgetown, Inc.,* 335 S.C. 598, 613, 518 S.E.2d 591, 598 (1999) (noting that an appellate court need not address remaining issues when disposition of prior issues is dispositive) (citing *Whiteside v. Cherokee Cnty. Sch. Dist. No. One,* 311 S.C. 335, 340, 428 S.E.2d 886, 889 (1993)); *Wilder Corp. v. Wilke,* 330 S.C. 71, 76, 497 S.E.2d 731, 733 (1998) ("[A]n objection must be sufficiently specific to inform the trial court of the point being urged by the objector." (citation omitted)); *Talley v. South Carolina Higher Educ. Tuition Grants Comm.,* 289 S.C. 483, 487, 347 S.E.2d 99, 101 (1986) ("It is an axiomatic rule of law that issues may not be raised for the first time on appeal." (citing *Am. Hardware Supply Co. v. Whitmire,* 278 S.C. 607, 609, 300 S.E.2d 289, 290 (1983))); *Eaddy v. Smurfit–Stone Container Corp.,* 355 S.C. 154, 164, 584 S.E.2d 390, 396 (Ct.App.2003) ("[S]hort, conclusory statements made without supporting authority are deemed abandoned on appeal and therefore not preserved for our review." (citing *Glasscock, Inc. v. U.S. Fid. & Guar. Co.,* 348 S.C. 76, 81, 557 S.E.2d 689, 691 (Ct.App.2001))).

ruling of the trial court has the burden of showing a clear abuse of discretion."); *accord Vanderbilt Mortg. & Fin., Inc. v. Cole,* 230 W.Va. 505, 740 S.E.2d 562, 566 (2013) (holding a trial court's award of civil penalties pursuant to state statute will not be disturbed on appeal unless it clearly appears the trial court abused its discretion).

The State argued, and the trial court agreed, that the distribution of each sample box containing the deceptive labeling, each DDL, and each follow-up sales call to the DDL by a Janssen representative constituted a separate SCUTPA violation. The trial court adopted a multi-factor test used by the United States Court of Appeals for the Third Circuit in determining an appropriate civil penalty: "(1) the good or bad faith of the defendants; (2) the injury to the public; (3) the defendant's ability to pay; (4) the desire to eliminate the benefits derived by a violation; and (5) the necessity of vindicating the authority of [the regulatory agency]." *United States v. Reader's Digest Ass'n, Inc.,* 662 F.2d 955, 967 (3d Cir.1981).[31]

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[31] Application of the *Reader's Digest* factors was proper here. Given that this is our first opportunity to address the appropriate factors for assessing a civil penalty in an Attorney General directed claim under SCUTPA, we direct that, prospectively, the following list of non-exclusive factors be used in assessing civil penalties under SCUTPA: (1) the degree of culpability and good or bad faith of the defendant; (2) the duration of the defendant's unlawful conduct; (3) active concealment of information by the defendant; (4) defendant's awareness of the unfair or deceptive nature of their conduct; (5) prior similar conduct by the defendant; (6) the defendant's ability to pay; (7) the deterrence value of the assessed penalties; and (8) the actual impact or injury to the public resulting from defendant's unlawful conduct. We further authorize our able trial judges to consider any other

Janssen challenges the penalty award on numerous grounds, including the argument that the total penalty, in excess of $327,000,000, is excessive. We agree with Janssen in part. There are certain factors common to the labeling and DDL claims. First, Janssen's deceit was substantial. In order to maintain its market share, Janssen's furtive efforts to mislead prescribing physicians about the risks and side effects associated with Risperdal were reprehensible and in callous disregard for the health and welfare of the public. Janssen's desire for market share and increased sales[32] knew no bounds, leading to its egregious violation of South Carolina law, particularly in connection with the DDL. Janssen's conduct is irrefutably linked to its longstanding efforts to conceal the truth regarding Risperdal. This corrupt corporate culture through the years was a factor, and understandably so, in the trial court's imposition of such a substantial penalty.

We agree in part with Janssen that its conduct likely had little impact on the community of prescribing physicians. The truth about the risks associated with atypical antipsychotics was well known, particularly in the pharmaceutical industry. This begs the question of why Janssen would go to such lengths to perpetuate and defend a lie. Whatever the answer, the point remains that Janssen did go to such lengths. Yet, the absence of significant actual harm resulting from Janssen's deceptive conduct

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factors they deem appropriate under the circumstances. In issuing a ruling, the trial court should make sufficient findings of fact concerning all relevant factors to enable appellate review.

[32] Since 1994, Risperdal sales approximated $30 billion.

leads us to conclude the trial court erred in part in its penalty assessment.

A. Violations and Reduced Civil Penalty

1. Labeling Claim

The trial court assessed a $300 civil penalty against Janssen for each Risperdal "sample box" distributed to South Carolina prescribers from 1998 through the date of the Complaint, April 23, 2007, for a total of 509,499 violations. As discussed, we reverse the civil penalties awarded for conduct that occurred prior to January 24, 2004, for that part of the State's labeling claim is barred by the statute of limitations. Based on the record, during the period of time from February 2004 until the filing of the Complaint in April 2007, Janssen made 20,575 visits to prescribing physicians in South Carolina and distributed 228,447 sample boxes containing deceptive labeling.

Janssen challenges the penalty award of $300 per sample box on numerous grounds, including the argument that the penalty is excessive. We agree and find the $300 penalty per sample box excessive. Based on the totality of the circumstances and consideration of the Reader's Digest factors, we remit the penalty to $100 per sample box, for a civil penalty of $22,844,700.

2. DDL Claim

Janssen mailed 7,184 DDLs to South Carolina physicians in November 2003. The trial court considered each letter a separate violation and imposed a penalty of $4,000 per letter, for a penalty of $28,736,000. In addition, the trial court counted each follow-up sales call to the DDL by a Janssen representative as a separate violation. There were

36,372 follow-up sales calls. The trial court again assessed a penalty of $4,000 for each sales call, for a penalty of $145,488,000.

Janssen challenges the penalty award on numerous grounds, including excessiveness. While the question presented is close, we cannot say that the trial court abused its discretion in assessing the $28,736,000 penalty associated with the 7,184 DDLs. A $4,000 penalty per each DDL is indeed substantial. But Janssen's deceit, as described above, was also substantial. The DDL was especially egregious, for it represented not mere nondisclosure but a corporately sanctioned decision to affirmatively lie and an attempt to mislead the medical community. We affirm the civil penalty of $28,736,000 penalty associated with the 7,184 DDLs.

Janssen's misconduct in the more than 36,000 follow-up visits may be similarly viewed, for the follow-up visits were designed to continue the false DDL narrative. Nevertheless, a penalty of $4,000 per follow-up visit is excessive as a matter of law under the circumstances. We find in most instances, these were follow-up calls to the same prescribing physicians who received the DDL in the mail. In fact, in many instances there were multiple calls to the *same* physicians. We remit the penalty to $2,000 per follow-up sales call, for a penalty of $72,744,000. When combined with the penalty for the DDL mailing, the total penalty assessed against Janssen for the DDL claim is $101,480,000.

The combined civil penalty for the labeling and DDL claims is $124,324,700.

B. Constitutionality of the Penalty Award

Janssen also raises a number of constitutional challenges to the trial court's penalty order. First, Janssen claims that the $327 million penalty violates the Excessive Fines Clause of the Eighth Amendment to the U.S. Constitution and Article 1, Section 15 of the South Carolina Constitution. Second, Janssen claims that the penalty award violates due process because it is grossly excessive. We analyze this argument on the basis of the remitted penalty of approximately $124 million. We find no constitutional violation.

"The touchstone of the constitutional inquiry under the Excessive Fines Clause [of the U.S. Constitution] is the principle of proportionality: The amount of the forfeiture must bear some relationship to the gravity of the offense that it is designed to punish." *United States v. Bajakajian,* 524 U.S. 321, 334, 118 S.Ct. 2028, 141 L.Ed.2d 314 (1998); *see also Medlock v. One 1985 Jeep Cherokee VIN 1JCWB7828FT129001,* 322 S.C. 127, 132, 470 S.E.2d 373, 377 (1996) (adopting the federal "instrumentality" standard in the context of civil forfeitures for purposes of South Carolina's "excessive fines" analysis). The Court will only find a violation of the Excessive Fines Clause if the penalty is "*grossly* disproportional to the gravity of a defendant's offense." *Bajakajian,* 524 U.S. at 334, 118 S.Ct. 2028 (emphasis added). "The Ninth Circuit and other federal courts have consistently found that civil penalty awards in which the amount of the award is less than the statutory maximum do not run afoul of the Excessive Fines Clause." *United States v. Mackby,*

221 F.Supp.2d 1106, 1110 (N.D.Cal.2002) (citing cases from the First Circuit, Ninth Circuit, and D.C. Circuit). This is so because legislative pronouncements regarding the proper range of fines "represent the collective opinion of the American people as to what is and is not excessive. Given that excessiveness is a highly subjective judgment, the courts should be hesitant to substitute their opinion for that of the people." *United States v. 817 N.E. 29th Drive, Wilton Manors, Fla.,* 175 F.3d 1304, 1309 (11th Cir.1999) (citing *Bajakajian,* 524 U.S. at 336, 118 S.Ct. 2028).

We find that the penalty in this case, now substantially reduced, bears a rational relationship to the gravity of Janssen's conduct in perpetuating a marketing scheme in South Carolina designed to be unfair and deceptive under our law. Furthermore, the penalty awards per violation are within the range set by the legislature in enacting SCUTPA. Accordingly, the penalty award is not grossly disproportionate to Janssen's pattern of unfair and deceptive behavior, and, thus, we hold that the award does not violate the Excessive Fines Clause of the South Carolina or the United States Constitution. We turn now to Janssen's due process argument.

The Due Process Clause of the U.S. Constitution "places a limitation upon the power of the states to prescribe penalties for violations of their laws." *St. Louis, Iron Mt. & S. Ry. Co. v. Williams,* 251 U.S. 63, 66, 40 S.Ct. 71, 64 L.Ed. 139 (1919). States, however, "still possess a wide latitude of discretion in the matter, and ... their enactments transcend the limitation only where the penalty prescribed is so

severe and oppressive as to be wholly disproportioned to the offense and obviously unreasonable." *Id.* at 66–67, 40 S.Ct. 71 (citations omitted); *see also Shipman v. Du Pre,* 222 S.C. 475, 480, 73 S.E.2d 716, 718 (1952) (embracing the *Williams* standard).

Given the evidence that demonstrates Janssen's pattern of unfair and deceptive behavior, we find that the penalties in this case are not violative of the Due Process Clause. We decline to set forth a bright-line rule or ratio to delineate what level of penalties are appropriate, instead undertaking a case-by-case determination based on the severity of the underlying conduct. While the penalty award against Janssen is quite large, the penalty must be analyzed in context in view of the clear legislative intent of SCUTPA to deter unfair and deceptive behavior in the conduct of trade and commerce in South Carolina. When all factors are considered, we find that the penalty award does not violate the Due Process Clause.[33]

And finally, we comment on the amicus curiae brief filed by the South Carolina Chamber of Commerce. The Chamber seeks clarity from this Court

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[33] While Janssen's parent company has paid more than $2 billion to settle Risperdal related federal litigation, there have been a number of state court actions. In submitting supplemental authority to the Court concerning the amount of the penalty, Janssen notes that the "Arkansas matter" was settled "for $7.75 million" and "an average of $4.89 million settlement per state [was] reached in the multi-state settlement announced by the Texas Attorney General." We have considered Janssen's understandable settlement of many state court claims, but we decline to rely on average settlements as dispositive, especially when we are constrained by an abuse of discretion standard of review.

to provide a predictable and favorable business climate in this state. The Chamber is especially distressed by the $327 million penalty, which it views as excessive and as "overt hostility toward business." While we agree the penalty awarded by the trial court was excessive, the Chamber's additional concerns are based on a series of false premises. The Chamber posits that Janssen's conduct is being "judged according to subjective, intangible standards." More to the point, the implication is that South Carolina stands alone in arbitrarily singling-out Janssen for what amounts to nothing more than an aggressive marketing strategy. That is simply not the case. Because of its deceptive conduct in the marketing of Risperdal, Janssen has been the subject of litigation throughout the country. Indeed, the deceptive marketing that gave rise to this action also formed the basis of federal civil and criminal claims against Janssen and its parent company for, among other things, making "false statements about the safety and efficacy of Risperdal." The federal litigation has thus far resulted in agreed upon penalties in excess of $2 billion. When viewed objectively based on the jury verdict, Janssen over the course of many years consciously engaged in lies and deception in the marketing of Risperdal. Thus, the suggestion that the Attorney General of South Carolina stands alone in pursuing amorphous and subjective claims against Janssen is without merit. Moreover, the argument that today's decision will impermissibly chill business in South Carolina must likewise be rejected. *See FTC v. IFC Credit Corp.,* 543 F.Supp.2d 925, 940 (N.D.Ill.2008) (quoting *Kewanee Oil Co. v. Bicron Corp.,* 416 U.S. 470, 481–482, 94 S.Ct. 1879, 40

L.Ed.2d 315 (1974)) ("If the FTC were to prevail at trial, all that would be 'chilled' would be unfair and deceptive practices—a result consistent with the principle that '[t]he necessity of good faith and honest, fair dealing, is the very life and spirit of the commercial world.'"); *id.* (citing *FTC v. Algoma Lumber Co.,* 291 U.S. 67, 54 S.Ct. 315, 78 L.Ed. 655 (1934)) ("Fair competition is not attained by balancing a gain in money against a misrepresentation of the thing supplied. The courts must set their faces against a conception of business standards so corrupting in its tendency."); *FTC v. Standard Educ. Soc'y,* 86 F.2d 692, 696 (2d Cir.1936) ("[The FTC's] duty ... is to discover and make explicit those unexpressed standards of fair dealing which the conscience of the community may progressively develop."), *rev'd on other grounds,* 302 U.S. 112, 58 S.Ct. 113, 82 L.Ed. 141 (1937) (reversing that part of the Second Circuit's holding which modified and weakened the FTC's cease and desist order). Surely the Chamber desires a legal system that honors the rule of law and one which does not insulate businesses from liability for unfair and deceptive practices.

Our decision today is faithful to objective legal principles, legislative intent in SCUTPA and the rule of law. Moreover, we have set forth clear guidance for the business community, the Bench and the Bar for determining what conduct is actionable under SCUTPA and what factors bear on the determination of an appropriate penalty—precisely the type of clarity the Chamber seeks.

IV. Conclusion

Based on the statute of limitations, we reverse the judgment on labeling claim to the extent the trial court awarded civil penalties for conduct prior to January 24, 2004. We otherwise affirm as modified the judgment on the labeling claim and remit the civil penalty to $22,844,700. We affirm the liability judgment on the DDL claim, but remit those civil penalties to $101,480,000. We remand to the trial court for entry of judgment in the amount of $124,324,700.

AFFIRMED IN PART, REVERSED IN PART AND REMANDED.

TOAL, C.J., BEATTY and HEARN, JJ., concur.

PLEICONES, J., dissenting in a separate opinion.

PLEICONES, J:

With great respect for the majority's thorough treatment of these complex issues, I dissent from those portions of its opinion addressing: (1) the timeliness of the labeling claim; and (2) the reduction of the DDL penalty award.

I. Statute of Limitations

I agree the Attorney General knew or should have known prior to January 24, 2004 that he may have had a SCUTPA claim against Janssen based, in part, on research indicating Janssen's Risperdal label misled consumers insofar as it failed to disclose the drug's side effects. *See Kreutner v. David,* 320 S.C. 283, 285–86, 465 S.E.2d 88, 90 (1995) (discussing the discovery rule for purposes of triggering the limitations period and finding that where the evidence is overwhelming a reasonable person should have known she might

have a claim at a time beyond the statute of limitations, then such claim is time-barred). I therefore agree with the majority's conclusion that the Attorney General's SCUTPA claim for labeling violations occurring before January 24, 2004 was time-barred, and that the trial judge erred in holding equitable tolling removed the bar.

My disagreement is with the majority's application of the continuous accrual doctrine. I would not apply the doctrine in this appeal because doing so does not affirm the statute of limitations ruling to the extent the trial judge found the pre-January 24, 2004 labeling claim timely and permitted that claim to go to the jury. In my opinion, we may invoke our authority to affirm on any ground appearing in the record only when the result is to affirm the trial judge's ruling in toto. *See* Rule 220(c), SCACR. Here, the effect of applying the continuous accrual doctrine is only a partial affirmance. Further, we 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. I do not agree that reducing the amount of the penalty for the labeling claim cures the prejudice to Janssen given the unreliability of the jury's liability determination. Thus, I respectfully submit we should not apply the continuous accrual doctrine[34] in this appeal as doing so prejudices Janssen.

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[34] I leave for another day whether we should adopt this doctrine in the context of SCUTPA or other statutory claims.

Accordingly, I would reverse the jury's finding of liability because the labeling claim is barred by the statute of limitations. I would also reverse the trial judge's labeling claim penalty because the claim is untimely.

DDL PENALTY AWARD

As for the reduction of the DDL penalty award, I would find the trial judge did not abuse his discretion in awarding $174,224,000 based on Janssen mailing 7,184 deceptive DDLs and following up with 36,372 sales calls to sanction the deception already perpetrated. *See State ex rel. McLeod v. C & L Corp.,* 280 S.C. 519, 528, 313 S.E.2d 334, 340 (Ct.App.1984) (reviewing the award of civil penalties under an abuse of discretion standard). As for Janssen's contention that the follow-up sales calls were made to the same prescribing physicians who had already received the DDL, I would find the trial judge properly considered this argument and exercised his discretion in finding Janssen's culpability (*Reader's Digest*[35] Factor 2*)* outweighed the actual impact or injury resulting from Janssen's unlawful conduct (*Reader's Digest* Factor 8).

Ultimately, the trial judge was in the best position to evaluate Janssen's conduct, the degree of culpability, the duration of Janssen's conduct, Janssen's active concealment of Risperdal's side effects to South Carolina health care providers,

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[35] *United States v. Reader's Digest Ass'n,* 662 F.2d 955, 967 (3d Cir.1981) (outlining the multi-factor analysis to determine the propriety of a statutory penalty, which the trial judge applied, the majority has adopted, and with which I concur).

Janssen's awareness of its deceptive conduct, Janssen's ability to pay, and the actual impact, if any, resulting from Janssen's deceptive conduct. *See Reader's Digest Ass'n,* 662 F.2d at 967. Based on the trial judge's articulation of the *Reader's Digest* factors and his proper consideration of those factors, I would find Janssen has not shown the court abused its discretion in awarding a $174,224,000 civil penalty for the DDL claim, an amount within the limits set forth in SCUTPA. *See Wallace v. Timmons,* 237 S.C. 411, 421, 117 S.E.2d 567, 572 (1960) (stating that in reviewing a trial judge's decision under an abuse of discretion standard, this Court may not substitute its judgment simply because it might have reached a different conclusion had it been in the trial judge's place). Therefore, I would affirm the trial judge's penalty award of $174,224,000 as to the DDL claim.

Appendix B

THE SUPREME COURT
OF SOUTH CAROLINA

No. 12-206987

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 PHARMACEUTICAL, INC., AND/OR JANSSEN, L.P., AND JOHNSON & JOHNSON, INC.,

Defendants,

OF WHOM ORTHO–MCNEIL–JANSSEN PHARMACEUTICALS, INC. IS THE APPELLANT.

Filed: February 25, 2015

OPINION

KITTREDGE, J.:

Appellant Ortho-McNeil-Janssen Pharmaceuticals (Janssen) is a pharmaceutical company that manufactures the antipsychotic drug Risperdal. Risperdal is among a class of drugs prescribed primarily for the treatment of

schizophrenia. The Attorney General of South Carolina believed that Janssen had violated the South Carolina Unfair Trade Practices Act (SCUTPA)[1] by engaging in unfair methods of competition by willfully failing to disclose known risks and side effects associated with Risperdal.

On January 24, 2007, the State and Janssen entered into a tolling agreement concerning the statute of limitations. SCUTPA has a three-year statute of limitations, as section 39-5-150 of the South Carolina Code provides that "[n]o action may be brought under this article more than three years after discovery of the unlawful conduct which is the subject of the suit." The State filed its Complaint on April 23, 2007, seeking statutory civil penalties against Janssen on two claims. The first claim arose from the content of the written material furnished by Janssen since 1994 with each Risperdal prescription, the so-called labeling claim. The second claim centered on alleged false information contained in a November 2003 Janssen-generated letter sent to the South Carolina community of prescribing physicians, the so-called Dear Doctor Letter. Because both claims arose more than three years prior to January 24, 2007, Janssen pled the statute of limitations as a bar to the Complaint.

The matter proceeded to trial. A jury rendered a liability verdict against Janssen on both claims. The trial court rejected Janssen's defenses, including the statute of limitations, finding that both claims were timely. The trial court imposed civil penalties against

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[1] S.C. Code Ann. §§ 39-5-10 to -180 (1985 & Supp. 2013).

Janssen for both claims totaling $327,073,700 based on 553,055 separate violations of SCUTPA in connection with its deceptive conduct in the sales and marketing of Risperdal. Janssen appeals. We affirm the liability judgment on the labeling claim but modify the judgment to limit the imposition of civil penalties to a period of three years from the date of the tolling agreement, which is essentially coextensive with the three-year statute of limitations, subject to an additional three months by virtue of the time period between the January 24, 2007, tolling agreement and the filing of the Complaint on April 23, 2007. We further remit the civil penalties on the labeling claim to $34,545,400. We affirm the liability judgment on the DDL claim, but remit those civil penalties to $101,480,000. Accordingly, we affirm in part, reverse in part, and remand for entry of judgment against Janssen in the amount of $136,025,400.

I. FDA Regulatory Process and Background

A brief summary of the Food and Drug Administration's (FDA) regulatory authority over the pharmaceutical industry and the evolution of antipsychotic drugs provides a helpful backdrop to the facts of this case. "In the 1930's, Congress became increasingly concerned about unsafe drugs and fraudulent marketing, and it enacted the Federal Food, Drug, and Cosmetic Act (FDCA)."[2] *Wyeth v. Levine*, 555 U.S. 555, 566 (2009) (citation omitted). The FDCA's "most substantial innovation was its provision for premarket approval of new drugs." *Id.*

[2] The FDCA is codified at 21 U.S.C. §§ 301–399f (2006 & Supp. V 2011).

Following implementation of the FDCA, the FDA "required every manufacturer to submit a new drug application, including reports of investigations and specimens of proposed labeling" for regulatory review and approval.[3] *Id.* "Until its application became effective, a manufacturer was prohibited from distributing a drug." *Id.* FDA regulations require a new drug application to "include all clinical studies, as well as preclinical studies related to a drug's efficacy, toxicity, and pharmacological properties." *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 196 (2005) (citing 21 C.F.R. § 314.50(d)(2), (5) (2005)).

The FDA new drug approval process includes specific procedures through which warning labels are drafted, approved, and required to be included in the packaging of manufactured drugs. A drug label "must contain a summary of the essential scientific information needed for the safe and effective use of the drug," and the label "must be informative and accurate and neither promotional in tone nor false or misleading in any particular." 21 C.F.R. § 201.56(a)(1)–(2) (2014). Indeed, federal regulations set forth detailed requirements as to the content, the formatting, and the order of required information about potential risks and the safe and effective use of a drug. *Id.* § 201.57(c) (2014). Specifically, FDA regulations require drug labels to include, *inter alia*:

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[3] Prior to submitting a new drug application to the FDA for approval, the developer of the drug must first "gain authorization to conduct clinical trials (tests on humans) by submitting an investigational new drug application (IND)." *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 196 (2005) (citations omitted).

(1) "black box" warnings about serious risks that may lead to death or serious injury; (2) contraindications describing any situations in which the drug should not be used because the risk of use outweighs any possible therapeutic benefit; (3) warnings and precautions about significant adverse reactions and other potential safety hazards; and (4) any adverse reactions for which there is a basis to believe a causal relationship exists between the drug and the occurrence of the adverse event. *Id*. As these FDA regulations make clear, the category in which a particular risk appears on a drug label is a critical indicator of both the degree of the risk and also the likelihood and severity of the adverse consequences the drug may cause.

After a new drug application has been approved, the drug's sponsor has continuing duties to the FDA to ensure the long term efficacy and safety of the approved drug. For example, once drugs are approved by the FDA, the drug's sponsor is required to review, and report to the FDA, all "adverse drug experience"[4] information it receives from any source, including adverse experiences reported during the process of

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[4] FDA regulations define an "adverse drug experience" as:

> Any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: An adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action.

21 C.F.R. § 314.80(a) (2014).

post-marketing clinical trials. 21 C.F.R. § 314.80(b), (c) (2014). As new risks and side effects are discovered, a manufacturer must revise a drug's label "to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established." 21 C.F.R. § 201.57(c)(6)(i). As the FDA does not conduct independent scientific testing, it is incumbent upon sponsors to disclose all clinical data to ensure the safe and effective use of drugs.

Some have expressed a growing concern regarding the pharmaceutical industry's reticence to disclose negative clinical data, and the impact this has on the public health and welfare. Indeed, it has been stated that:

> [T]he failure to disclose study results not only impacts clinical trial participants, but the health of the general public may be put in jeopardy as well. For drugs that have received FDA approval, post-market clinical trials investigating new uses of the medication often reveal important information concerning side effects and related adverse complications with the treatment. To the extent that prescribing physicians do not have this essential data, they could inadvertently be putting their patients at serious risk by continuing to recommend the medication.
>
> Over the past few years, numerous scandals in the drug industry illustrate that concealing unfavorable research results is far from an

> isolated practice. . . . . In a quest to boost sales and increase corporate profits, the temptation to hide or selectively disclose clinical trial data has proven to be too much.

Christine D. Galbraith, *Dying to Know: A Demand for Genuine Public Access to Clinical Trial Results Data*, 78 Miss. L.J. 705, 710 (2009).

"The FDA's premarket approval of a new drug application includes the approval of the exact text in the proposed label." *Wyeth*, 555 U.S. at 568 (citing 21 U.S.C. § 355 (2006); 21 C.F.R. § 314.105(b) (2008)). Subsequent to approval of the new drug application, a drug manufacturer must submit a supplemental application to the FDA in order to effect any changes in the drug label. *Id.* (citing 21 U.S.C. § 355 (2006); 21 C.F.R. § 314.105(b) (2008)). "There is, however, an FDA regulation that permits a manufacturer to make certain changes to its label *before* receiving the agency's approval." *Id.* (emphasis added).

> Among other things, this "changes being effected" (CBE) regulation provides that if a manufacturer is changing a label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval.

Id. (quoting 21 C.F.R. §§ 314.70(c)(6)(iii)(A), (C)).

Following FDA approval of a new drug (or a new indication for an existing drug), pharmaceutical

companies may begin to market the drug, subject to federal regulations. *See, e.g.,* 21 C.F.R. § 203.2 (2014) ("The purpose of this part is . . . to protect the public health . . . ."). Typical pharmaceutical marketing strategies include both direct sales calls (i.e., visits to prescribing doctors to distribute literature and samples) and academic writings and speaking events led by healthcare professionals.

Risperdal (risperidone) is an antipsychotic drug primarily used to treat schizophrenia. Schizophrenia is a chronic, debilitating mental illness that affects approximately 1% of the population. Following onset, schizophrenia is a lifelong, incurable disease, and treatment almost always involves the use of an antipsychotic drug. Between the 1950s and 1990s, medical practitioners prescribed typical antipsychotics such as Thorazine (chlorpromazine), Prolixin (fluphenazine), Haldol (haloperidol), Loxitane (loxapine), and Mellaril (thioridazine) to treat schizophrenia. Although effective, these typical antipsychotics posed a number of negative side effects, including involuntary muscle movements and tardive dyskinesia, a long-lasting movement disorder.

By the 1980s, clozapine was being investigated for the treatment of schizophrenia on the theory that it might be more effective and cause fewer movement disorders than typical antipsychotics. Clozapine was termed an "atypical antipsychotic" because it affected a different part of the brain than the older, typical antipsychotics. The medical community soon discovered that clozapine, too, had negative side effects, including agranulocytosis—a dramatic and sometimes deadly decrease in white blood cell count.

Thus, in spite of its efficacy in treating the symptoms of schizophrenia, clozapine was usually used only as a "last resort" drug, prescribed for only about 10% of the schizophrenic population.

In 1994, Janssen introduced Risperdal in the United States as the second atypical antipsychotic drug on the market. From 1994 to 1996, Risperdal held a unique place in the market—it was promoted as being more effective than the older, typical antipsychotics, without the dangerous side effects associated with clozapine. In 1996, Eli Lilly (Lilly) introduced a third atypical antipsychotic drug to the market: Zyprexa. Zyprexa was dramatically successful when it hit the market, and Lilly and Janssen competed to capture the antipsychotic market.

Spurred by this fierce competition, Janssen developed a marketing strategy to distinguish Risperdal and protect its market share. By 1998, Janssen was promoting Risperdal as having a lower risk of weight gain and a lower metabolic risk profile than Zyprexa.[5] Despite the claims made by Janssen, post-marketing studies, some as early as 1994, revealed Risperdal posed a serious risk of substantial weight gain, increased prolactin levels, and hyperprolactinemia in patients taking atypical antipsychotics. This increased the long-term risk of developing various kinds of cancer, osteoarthritis, cardiovascular disease, and stroke. Additionally, atypical antipsychotics greatly increased the risk of

[5] In turn, Lilly differentiated Zyprexa as posing a lower risk for movement disorders and hyperprolactinemia, a hormonal imbalance causing serious and lasting reproductive side effects, when compared to Risperdal.

diabetes mellitus, which can have very serious, even life-threatening consequences. By 1997, Janssen also had information that Risperdal posed a serious risk of stroke, cardiac arrest, and sudden death in the elderly. Despite this clinical information, it was several years before Janssen updated the Risperdal label to accurately reflect the frequency and severity of the risk of hyperprolactinemia, weight gain and diabetes, or stroke, cardiac arrest, and sudden death in the elderly.

In 1997, Janssen commissioned a clinical trial (Trial 113) designed to establish Risperdal's superiority over Zyprexa as to metabolic side effects, including weight gain and diabetes. In 1999, the results of Trial 113 were not what Janssen desired, as the study concluded that there was no difference between Risperdal and Zyprexa in terms of long-term weight gain or the onset of diabetes mellitus. Janssen did not disclose or publish the results of Trial 113 and continued to claim that Risperdal was superior to Zyprexa in terms of these negative metabolic side effects.

By August 2000, Janssen also received results from two epidemiological studies. One study was based on a review of the records of patients treated with atypical antipsychotics in a New England insurance database (ERI study). The ERI study showed that Risperdal patients developed diabetes mellitus at a significantly higher incident rate than patients taking Zyprexa. The second study was commissioned by Janssen (HECON study), and it concluded that Risperdal was not associated with an increased risk of diabetes mellitus. By this time, and

notwithstanding Janssen's furtive efforts, the risks and adverse side effects associated with atypical antipsychotic drugs were fairly well known.

In May 2000, the FDA asked sponsors of atypical antipsychotic drugs to submit a comprehensive review of all clinical data pertaining to metabolic side effects. In response, Janssen did not disclose the results of the Trial 113 study but disclosed *only* the favorable results from its own HECON study, affirmatively indicating to the FDA that no long-term trials pertaining to metabolic side effects had taken place. The FDA's review was not thwarted by Janssen's efforts, as the FDA's investigation prompted it to request that product labeling for all atypical antipsychotic medications, including Risperdal, include a warning about hyperglycemia and diabetes.

Janssen was concerned that the FDA-mandated label warning would result in a substantial loss of Risperdal market share. Notwithstanding the Trial 113 and ERI study results suggesting an association between Risperdal and diabetes, in October 2000, Janssen's Associate Director of Central Nervous System Medical Affairs wrote an email to her colleagues urging that Janssen must avoid Risperdal being "lumped in to [sic] the atypical class for diabetes. . . . [W]e need to work hard on a strategy to avoid Risperdal being thought of as a diabetes-inducing medication. Instead, when worried about diabetes, we want doctors to prescribe Risperdal."

Janssen then determined it would take control of how the message surrounding the new diabetes warning would be communicated. Janssen officials' strategy was to "soften the blow" through what is

known in the industry as a Dear Doctor Letter (DDL). The inspiration came from a DDL that Lilly sent to prescribers, informing them that the entire class of atypical antipsychotics was now subject to a new "class label" for diabetes and hyperglycemia. A senior vice president for Janssen's parent company wrote in an internal email that "Lilly's DDL is pretty clever. How much commercial liability would we incur if we sent a similar letter about Risperdal, assuming the FDA is unwilling to communicate the issue?"

On November 10, 2003, Janssen disseminated a DDL, which did not include the text of the new diabetes/hyperglycemia warning, but stated:

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

To put it mildly, the November 2003 DDL contained false information.

Additionally, in training its employees on the labeling update, Janssen communicated to its field sales team that Risperdal had a "0%" increased diabetes risk compared to placebo. This was part of the

message communicated to physicians in DDL follow-up visits with physicians.

Meanwhile, by January 2004, Janssen had updated the Risperdal label to include the new diabetes/hyperglycemia warning. Janssen determined that the negative sales impact had been minimal because of its deceptive efforts in the November 2003 DDL. In other words, the November 2003 DDL worked, as far as Janssen was concerned, in protecting its market share.

Thereafter, in April 2004, the FDA's Division of Drug Marketing Advertising and Communications (DDMAC)[6] issued a "Warning Letter" to Janssen, characterizing the November 2003 DDL as "false or misleading" in violation of the FDCA. Specifically, the letter provided:

> DDMAC has concluded that the DHCP[7] letter is false or misleading in violation of Sections 502(a) and 201(n) of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. 325(a) and 321(n)) because it fails to disclose the addition of information relating to hyperglycemia and diabetes mellitus to the approved product labeling, minimizes the risk of hyperglycemia-related adverse events, which in extreme cases is associated with serious adverse events including ketoacidosis, hyperosmolar coma, and death, fails to

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[6] This agency is now known as the Office of Prescription Drug Promotion (OPDP).

[7] Dear Health Care Provider, which is another term for a Dear Doctor Letter.

> recommend regular glucose control monitoring to identify diabetes mellitus as soon as possible, and misleadingly claims that Risperdal is safer than other atypical antipsychotics. The healthcare community relies on DHCP letters for accurate and timely information regarding serious risks and associated changes in labeling and the dissemination of this letter at a time critical to educating healthcare providers is a serious public health issue.

The FDA also determined that the scientific studies referenced in the DDL "do not represent the weight of the pertinent scientific evidence" nor did the DDL accurately describe the results of the cited studies. As a result of the FDA's warning, Janssen issued a corrective letter in July 2004, acknowledging that the November 2003 DDL "omitted material information about Risperdal, minimized potentially fatal risks, and made misleading claims suggesting superior safety to other atypical antipsychotics without adequate substantiation, in violation of the [FDCA]."

As to Risperdal's label, Janssen did not update the label to include a boxed warning regarding the risk of stroke, cardiac arrest, and sudden death in the elderly until February 2005, and no warning about hyperprolactinemia appeared in the label until August 2008.[8]

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[8] To be sure, prior versions of the Risperdal label mentioned the risk of "cerebrovascular adverse events" in elderly patients, increased prolactin levels, and hyperprolactinemia; however, Janssen's categorization of those risks on the label underrepresented and minimized the frequency and severity of

In April of 2007, the Attorney General of South Carolina filed a state law claim against Janssen, seeking civil penalties under SCUTPA. The State pursued two claims against Janssen, one in connection with the Risperdal label (the labeling claim) and the second concerning the November 2003 DDL (the DDL claim). Following a twelve-day trial, the jury returned a verdict on liability in favor of the State, finding that Janssen's actions with respect to both the labeling and DDL claims were willful violations of SCUTPA.

After dismissing the jury, the trial court separately considered evidence and arguments during a two-day hearing to determine the appropriate penalty for Janssen's SCUTPA violations. The trial court issued an order assessing penalties against Janssen of $152,849,700 for the labeling claim and $174,224,000 for the DDL claim, for a total penalty of $327,073,700. This appeal followed. This case was transferred from the court of appeals to this Court pursuant to Rule 204(b), SCACR.

II. Analysis Concerning Liability

SCUTPA "declares unfair or deceptive acts or practices in trade or commerce unlawful." *Singleton v. Stokes Motors, Inc.*, 358 S.C. 369, 379, 595 S.E.2d 461,

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the risks associated with Risperdal. As noted, the category in which a particular risk appears on a drug label is a critical indicator of both the degree of the risk and also the likelihood and severity of the adverse consequences the drug may cause. *See* 21 C.F.R. §§ 201.56, 201.57 (setting forth detailed requirements on the content and format of information on drug labels to ensure labels are not inaccurate, false, or misleading and convey all pertinent information regarding the safe and effective use of drugs).

466 (2004) (citing S.C. Code Ann. § 39-5-20(a) (2002)). "An unfair trade practice has been defined as a practice which is offensive to public policy or which is immoral, unethical, or oppressive." *deBondt v. Carlton Motorcars, Inc.*, 342 S.C. 254, 269, 536 S.E.2d 399, 407 (Ct. App. 2000) (citing *Young v. Century Lincoln-Mercury, Inc.*, 302 S.C. 320, 326, 396 S.E.2d 105, 108 (Ct. App. 1989), *aff'd in part, rev'd in part on other grounds*, 309 S.C. 263, 422 S.E.2d 103 (1992)).

SCUTPA provides for both civil actions brought by private citizens and enforcement actions brought by the Attorney General on behalf of the State. S.C. Code Ann. §§ 39-5-50(a), -110(a), -140(a) (1985). While the only section of SCUTPA at issue in this case is an enforcement action brought by the Attorney General, we note the distinction between the two types of actions. In an action brought by a citizen under section 39-5-140(a) of the South Carolina Code, there is a requirement that the person suffer an "ascertainable loss of money or property, real or personal, as a result of the use or employment by another person of an unfair or deceptive method, act or practice . . . ." Thus, SCUTPA requires that a private claimant suffer an *actual* loss, injury, or damage, and requires a causal connection between the injury-in-fact and the complained of unfair or deceptive acts or practices. S.C. Code Ann. § 39-5-140(a).[9]

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[9] "Under section 39-5-140, a plaintiff can recover treble damages where 'the use or employment of the unfair or deceptive . . . act or practice was a willful or knowing violation of § 39-5-20.'" *Wright v. Craft*, 372 S.C. 1, 23–24, 640 S.E.2d 486, 498 (Ct. App. 2006) (quoting *Noack Enters., Inc. v. Country Corner*

Conversely, an enforcement action brought by the Attorney General has no such actual impact requirement. *See* S.C. Code Ann. § 39-5-50(a). The Attorney General "may recover on behalf of the State a civil penalty of not exceeding five thousand dollars per violation." S.C. Code Ann. § 39-5-110(a). "The legislature intended . . . [SCUTPA] to control and eliminate the large scale use of unfair and deceptive trade practices within the state of South Carolina." *Noack Enters. v. Country Corner Interiors of Hilton Head Island, Inc.*, 290 S.C. 475, 477, 351 S.E.2d 347, 349 (Ct. App. 1986) (quotations and citations omitted).

At the outset of our analysis, our review of the extensive record compels us to acknowledge that Risperdal has been an effective drug. The State did not file this case because of concern with Risperdal's efficacy as an atypical antipsychotic.[10] Risperdal, like virtually all pharmaceutical drugs, has risks and side effects. The State filed this case because of its belief that Janssen engaged in unfair and deceptive conduct in South Carolina by failing to properly disclose

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Interiors of Hilton Head Island, Inc., 290 S.C. 475, 477, 351 S.E.2d 347, 348–49 (Ct. App. 1986)).

[10] Similar Risperdal litigation against Janssen and its parent company, Johnson & Johnson, has been ongoing throughout the United States. In November 2013, Johnson & Johnson agreed to pay more than $2.2 billion in civil and criminal settlements with the United States Department of Justice to resolve claims that it improperly marketed Risperdal.

Following oral argument, we received supplemental citations filed by Janssen regarding similar litigation in Louisiana and Arkansas. After closely examining the reported decisions in those states, we have determined that the cases involve statutory claims which do not mirror the SCUTPA.

Risperdal's risks and side effects in an attempt to mislead prescribing physicians and the public. An objective review of the evidence and law bears out the State's allegations that Janssen engaged in a systematic pattern of deceptive conduct.

Janssen raises a number of issues in their appeal. While we reach the merits of a number of these issues, many of the issues are not preserved for this Court's review, and we address them only briefly.

A. Opening and Closing Arguments

Janssen claims that various portions of the State's opening and closing arguments were inflammatory and unduly prejudicial and thus warrant a new trial. Specifically, Janssen claims that the State invited the jury to impose liability on the basis of Janssen's size and commercial success by repeatedly referring to Janssen's profits from selling Risperdal and claiming that Janssen put "profits over safety."

We find that Janssen's arguments on appeal are procedurally barred. Although Janssen noted a generalized "continuing objection" at the outset of trial, apparently believing it could make a more specific after-the-fact objection to any alleged improper argument or evidence, such an approach is wholly inconsistent with our law requiring a contemporaneous objection. *See Young v. Warr*, 252 S.C. 179, 200, 165 S.E.2d 797, 807 (1969) ("[T]he proper course to be pursued when counsel makes an improper argument is for opposing counsel to immediately object and to have a record made of the statements or language complained of and to ask the court for a distinct ruling thereon." (citing *Crocker v. Weathers*, 240 S.C. 412, 424, 126 S.E.2d 335, 340

(1962))). This rule is designed to enable the trial court to timely address and remedy a founded objection. *See Herron v. Century BMW*, 395 S.C. 461, 465, 719 S.E.2d 640, 642 (2011) ("'Issue preservation rules are designed to give the trial court a fair opportunity to rule on the issues, and thus provide us with a platform for meaningful appellate review.'" (quoting *Queen's Grant II Horizontal Prop. Regime v. Greenwood Dev. Corp.*, 368 S.C. 342, 373, 628 S.E.2d 902, 919 (Ct. App. 2006))). Here, absent a contemporaneous objection identifying the particular comments complained of and the basis for the objection, Janssen has waived its right to complain about this issue on appeal. *Webb v. CSX Transp., Inc.*, 364 S.C. 639, 655, 615 S.E.2d 440, 449 (2005) (holding that the failure to contemporaneously object precluded the defendant from raising an issue on appeal (citing *Taylor v. Medenica*, 324 S.C. 200, 212, 479 S.E.2d 35, 41 (1996))).[11]

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[11] We acknowledge the rule in South Carolina that counsel is not required to harass the trial judge by making continued objections after an issue has been ruled upon. *See Dunn v. Charleston Coca-Cola Bottling Co.*, 311 S.C. 43, 45–46, 426 S.E.2d 756, 758 (1993) (noting that where a trial judge has fair opportunity to consider and rule upon an issue, it is not incumbent upon counsel "to harass the judge by parading the issue before [the trial judge] again"). However, that is not the situation before us, for Janssen failed to bring to the trial court's attention any of the comments of which it now complains or specify the basis for its objection, much less obtain a ruling from the trial court. Thus, because the trial court did not have a fair opportunity to consider and rule upon Janssen's specific objections, it was incumbent upon Janssen's counsel to object contemporaneously.

Moreover, Janssen's "continuing objection" at trial concerning the propriety of counsel's statements to the jury was limited to relevance, which is an entirely different basis than the inflammatory/unduly prejudicial argument that Janssen now advances on appeal. Thus, even generously construing Janssen's pre-trial objection as sufficient to preserve the objection, Janssen's claim is nonetheless procedurally barred from appellate review because Janssen argues a different basis on appeal than was argued at trial. *State v. Dunbar*, 356 S.C. 138, 142, 587 S.E.2d 691, 694 (2003) ("A party may not argue one ground at trial and an alternate ground on appeal." (citing *State v. Prioleau*, 345 S.C. 404, 411, 548 S.E.2d 213, 216 (2001); *State v. Benton*, 338 S.C. 151, 157, 526 S.E.2d 228, 231 (2000))).

Janssen's claims of error are without merit in any event. Janssen relies on our holding in *Branham v. Ford Motor Co.*, 390 S.C. 203, 701 S.E.2d 5 (2010), in urging this Court to order a new trial. In *Branham*, the plaintiff's attorney strayed beyond the parameters of permissible jury argument and sought punitive damages for the damage caused to non-parties. *Id.* at 235, 701 S.E.2d at 22. We ordered a new trial, holding that "[t]he closing argument invited the jury to base its verdict on passion rather than reason. . . . [and] denied [defendant] a fair trial." *Id.* We find that *Branham* is readily distinguishable from this case. Here, counsel for the State directly linked the elements of SCUTPA to Janssen's misleading and deceptive practices and its motivations to retain (and increase) Risperdal market share. Such arguments were within proper bounds as the State sought to establish that Janssen acted willfully and contrary to

the public interest. In addition, the nature of counsel's comments is more closely associated with what Janssen believes was a grossly excessive award of civil penalties, and the jury's role was limited to determining liability. The jury had no role in determining the amount of the civil penalties.

B. Admission of 1994, 1999, and 2004 DDMAC Letters

Janssen argues that the admission of several DDMAC letters was reversible error because the letters constitute inadmissible hearsay and should also have been excluded under Rule 403, SCRE. Once again, we find that Janssen has not preserved these assignments of error for appellate review.[12] Even if we

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[12] Janssen's contemporaneous objection at trial to admission of the 1994 DDMAC letter was on the basis of relevance, not on the basis of hearsay or Rule 403, SCRE. *See Talley v. S.C. Higher Educ. Tuition Grants Comm.*, 289 S.C. 483, 487, 347 S.E.2d 99, 101 (1986) ("It is an axiomatic rule of law that issues may not be raised for the first time on appeal." (citing *Am. Hardware Supply Co. v. Whitmire*, 278 S.C. 607, 609, 300 S.E.2d 289, 290 (1983))). While it appears that Janssen was more specific in objecting to the admission of the 1999 DDMAC letter—objecting on relevancy, hearsay, and Rule 403, SCRE grounds—the trial judge did not specifically rule on the hearsay or Rule 403, SCRE, issues. Thus, Janssen's assignment of error is not preserved for appellate review. *Kleckley v. Nw. Nat. Cas. Co.*, 338 S.C. 131, 138, 526 S.E.2d 218, 221 (2000) ("An issue not raised to or addressed by the trial court or the Court of Appeals is not properly preserved for review by the Supreme Court . . . ." (citing *Anonymous (M-156-90) v. State Bd. of Med. Exam'rs*, 329 S.C. 371, 375, 496 S.E.2d 17, 18–19 (1998); *Camp v. Springs Mortg. Corp.*, 310 S.C. 514, 516, 426 S.E.2d 304, 305 (1993))). Regarding the 2004 DDMAC letter, no challenge is preserved for our review. Janssen's pre-trial objection to admission of the letter was only with regard to use or mention of the letter during opening

were to reach the merits of these claims, however, we would affirm the admission of these letters pursuant to Rule 220(b)(1), SCACR. This evidence was relevant to the issue of liability and concomitantly the statute of limitations concerning the labeling claim, which, as discussed below, inures to Janssen's benefit.

C. Adverse Impact

Janssen argues that the State's SCUTPA claims fail as a matter of law because the State failed to show that Janssen's unfair and deceptive conduct had an adverse impact within South Carolina. We disagree. We reject Janssen's attempt to ascribe an injury-in-fact element in an individual claim to an Attorney General directed claim, for to do so would be judicial engrafting of an element beyond that imposed by the legislature. In the context of this case, Janssen's attempt to judicially impose an injury-in-fact element to an Attorney General initiated SCUTPA claim is nothing more than an "if we lied, nobody fell for it" defense. In this regard, we observe that Janssen seeks to impose an absurd adverse impact element in a claim concerning alleged unfair and deceptive marketing of prescription medicines. In many instances, as here, the manifestations of adverse consequences from prescription medicines are not immediate, but occur over time. Such is generally the case with Risperdal. In any event, Janssen's deceptive conduct had an adverse impact on the citizens of South Carolina, for

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statements, and Janssen's counsel did not state the specific grounds for the objection. *Wilder Corp. v. Wilke*, 330 S.C. 71, 76, 497 S.E.2d 731, 733 (1998) ("[A]n objection must be sufficiently specific to inform the trial court of the point being urged by the objector." (citation omitted)).

Janssen maintained its superior market share, which, after all, was what Janssen sought to achieve by its dishonesty.

The provisions of SCUTPA allow three types of enforcement actions: (1) lawsuits initiated by the Attorney General seeking injunctive relief; (2) lawsuits by the Attorney General seeking civil penalties; or (3) lawsuits by private parties who have suffered ascertainable losses. S.C. Code Ann. §§ 39-5-50, -110, -140; *see also* Michael R. Smith, Note, *Recent Developments Under the South Carolina Unfair Trade Practices Act*, 44 S.C. L. Rev. 543, 543–44 (1993) (discussing generally various provisions of SCUTPA). Although this case is an appeal from a lawsuit by the Attorney General seeking civil penalties, we note some important distinctions between actions brought by the Attorney General and those brought by private parties.

To recover actual damages under SCUTPA, a private claimant must suffer an actual loss, injury, or damages, and the claimant must demonstrate a causal connection between the injury-in-fact and the complained of unfair or deceptive acts or practices. S.C. Code Ann. § 39-5-140(a). Additionally, a private party may recover treble damages if the unlawful acts at issue are determined to be willful or knowing. *Id*. On the other hand, where the Attorney General files suit on behalf of the State, he is not required to show any injury-in-fact to recover a civil penalty.[13] *See* S.C.

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[13] Other states have similar provisions. *See*, *e.g.*, *Mulligan v. QVC, Inc.,* 888 N.E.2d 1190, 1196 (Ill. App. Ct. 2008) ("Although the Attorney General may prosecute a violation of the [Consumer Fraud and Deceptive Business Practices] Act without showing

Code Ann. §§ 39-5-110, -140. Rather, SCUTPA allows the Attorney General to recover statutory damages of up to $5,000 per violation upon a showing that the unlawful acts at issue are willful.[14] S.C. Code Ann.

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that any person has in fact been damaged, it is well settled that in order to maintain a private cause of action under the Consumer Fraud Act, a plaintiff must prove that she suffered actual damage as a result of a violation of the Act." (citation omitted)); *Edmonds v. Hough*, 344 S.W.3d 219, 223 (Mo. Ct. App. 2011) ("The [Merchandising Practices] Act eliminates the need for the Attorney General to prove intent to defraud or reliance in order for the court to find that a defendant has engaged in unlawful practices. Intent and reliance are not necessary elements of the cause of action." (quotations and citations omitted)). We recognize, however, there are jurisdictions that require the state to show an injury in-fact as an element of unfair trade practice type claim. Following oral argument in this case, Janssen has submitted supplemental authority consisting of court decisions from other states reversing trial court verdicts against Janssen. We have carefully reviewed those decisions and conclude they are not persuasive, for the cases submitted by Janssen involve different claims with elements that do not mirror the South Carolina UFTPA.

[14] "[A] willful violation occurs when the party committing the violation knew or should have known that his conduct" was unlawful. S.C. Code Ann. § 39-5110(c). In addition to the civil penalty, the Attorney General is authorized to seek injunctive relief when he "has reasonable cause to believe that any person is using, has used or is about to use any method, act or practice declared by § 39-5-20 to be unlawful . . . ." S.C. Code Ann. § 39-5-50(a). To be sure, the legislature has granted the Attorney General broad investigative powers. *See* S.C. Code Ann. § 39-5-70(a) ("When it appears to the Attorney General that a person has engaged in, is engaging in, or is about to engage in any act or practice declared to be unlawful by this article[,] . . . [he may serve] an investigative demand . . . ."). While an individual statutory claim necessarily includes an injury-in-fact element, an Attorney General initiated claim does not. It is the protection of

§ 39-5-110(a). If the Attorney General determines that an enforcement action "would be in the public interest," he is statutorily authorized to proceed without making any such showing of injury-in-fact or reliance.[15] S.C. Code Ann. § 39-5-50(a). Thus, Janssen misconstrues the legislature's manifest purpose in providing for an Attorney General directed claim, for a SCUTPA action brought by the State is to protect the citizens of South Carolina from unfair or deceptive acts in the conduct of any trade or commerce. Janssen's contention to the contrary is not only fundamentally at odds with unambiguous legislative intent in authorizing an Attorney General SCUTPA claim, but is also inconsistent with well-established South Carolina law.

On the issue of liability, our case law interpreting and applying SCUTPA is clear—while a private party SCUTPA action requires the traditional showing of an injury, an action brought by the Attorney General on behalf of the State contains no actual injury element. For the foregoing reasons, we hold that, although the State had the burden of proving Janssen's

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the people of South Carolina that lies at the center of an Attorney General directed claim.

[15] "'It is in the public interest generally to prevent the use of false and misleading statements in the conduct of business . . . [and] actual deception need not be shown; a finding of a tendency [and capacity] to deceive and mislead will suffice.'" *State ex rel. McLeod v. Brown*, 278 S.C. 281, 285, 294 S.E.2d 781, 783 (1982) (quoting *U.S. Retail Credit Assoc., Inc. v. F.T.C.*, 300 F.2d 212, 221 (4th Cir. 1962)) (ellipsis in original). Additionally, "[t]he health, welfare, and safety of the lives and property of the people of this State . . . are matters of public concern." S.C. Const. art. XII, § 1.

representations had a *tendency to deceive*, the State was not required to show actual deception or that those representations caused any appreciable injury-in-fact or adversely impacted the marketplace. We find ample support in the record that the State met its burden of proving that Janssen's actions had the tendency to deceive. Janssen's unfettered desire for sales and market share led it to engage in a systematic pattern of intentional nondisclosure, false representations, and deceptive conduct in violation of SCUTPA. Most assuredly, Janssen intended to deceive the public and the medical community. Although we reject Janssen's effort to impose an injury-in-fact element in an Attorney General initiated claim, we believe the argument carries persuasive weight in the assessment of an appropriate penalty, which we address in the penalty section.

D. Exclusion of Dr. Wecker's Expert Testimony

Janssen claims that the trial court erred in excluding the testimony of Dr. William Wecker, an expert statistician whose testimony, according to Janssen, would have shown that Janssen's representations in the Risperdal label and the November 2003 DDL had no impact on any prescribing physicians. The import of Dr. Wecker's testimony would have been that, notwithstanding Janssen's false representations, the community of prescribing physicians was well aware of the risks and side effects of Risperdal.

We are again presented with an issue that was not properly preserved for appellate review. When the trial court filed its order on February 25, 2011,

excluding the testimony of Dr. Wecker on relevancy grounds, Janssen waited until March 21, 2011, to make an offer of proof of his testimony. The offer of proof came too late. *TNS Mills, Inc. v. S.C. Dep't of Rev.*, 331 S.C. 611, 628, 503 S.E.2d 471, 480 (1998) (noting that a failure to make a proffer of what an excluded witness's testimony would have been precludes appellate review); *see also Greenville Mem'l Auditorium v. Martin*, 301 S.C. 242, 244, 391 S.E.2d 546, 547 (1990) ("An alleged erroneous exclusion of evidence is not a basis for establishing prejudice on appeal in absence of an adequate proffer of evidence in the court below." (citations omitted)).[16]

On the merits, for the reasons discussed in the previous section, we would not find reversible error in any event. We do acknowledge there was evidence presented, which otherwise 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. Excluding Dr. Wecker's testimony, therefore, resulted in no prejudice to Janssen. Yet, as discussed above, Janssen's relevancy argument is based on the false premise that actual harm resulting from the deceptive conduct is a necessary element of an Attorney General directed claim.

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[16] It is for the same reason we reject Janssen's claim that the trial court erred by excluding the testimony of the twenty surveyed physicians and evidence of the 2007 Zyprexa product insert and 2010 Latuda product insert.

E. First Amendment

Janssen argues that the liability verdict and the penalty award impermissibly restrict its right to free speech. We disagree.

Again, Janssen has not preserved this issue for review. Although Janssen requested a First Amendment jury instruction and raised the issue in its motion for JNOV, Janssen failed to raise any First Amendment issues in its motion for a directed verdict. Janssen's failure to raise this issue in its motion for a directed verdict precludes any appellate review. *In re McCracken*, 346 S.C. 87, 93, 551 S.E.2d 235, 238 (2001) ("[S]ince only grounds raised in the directed verdict motion may properly be reasserted in the jnov motion, and since no grounds were raised in the directed verdict motion, no jnov claim is preserved for our review." (citing *Duncan v. Hampton Cnty. Sch. Dist. #2*, 335 S.C. 535, 545, 517 S.E.2d 449, 454 (Ct. App. 1999))).

There is no error in any event, for the First Amendment does not bar imposition of liability on Janssen for violating SCUTPA. Janssen relies on the false premise that its conduct was not unfair and deceptive. While commercial speech is entitled to First Amendment protections, the Constitution does not erect a blanket shield insulating commercial speech from liability in all circumstances. In this regard, we find Janssen's reliance on *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011), is misplaced. The Supreme Court of the United States held in *Sorrell* that "[s]peech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment." *Id.* at 2659. *Sorrell*,

however, does not deal with deceptive commercial speech. Instead, the *Sorrell* Court invalidated a Vermont law that regulated the type of pharmacy records that a drug manufacturer could obtain and use in marketing prescription drugs. *Id.* at 2659. The State of Vermont never argued "that the provision challenged . . . will prevent false or misleading speech," nor did it argue that the detailing[17] at issue was "false or misleading within the meaning of [the Supreme] Court's First Amendment precedents." *Id.* at 2672. We do not construe *Sorrell* as foreclosing a state from prohibiting unfair and deceptive prescription drug marketing.

Indeed, it is a well-settled proposition that "[t]he government may ban forms of communication more likely to deceive the public than to inform it, or commercial speech related to illegal activity." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 563–64 (1980) (internal citations omitted). The State correctly notes that commercial speech is not protected by the First Amendment unless it concerns lawful activity and is not misleading. *Johnson v. Collins Entm't Co.*, 349 S.C. 613, 624, 564 S.E.2d 653, 659 (2002).

Here, the jury found that Janssen's acts were unfair or deceptive, and thus unlawful under

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[17] Pharmaceutical companies such as Janssen "promote their drugs to doctors through a process called 'detailing.' This often involves a scheduled visit to a doctor's office to persuade the doctor to prescribe a particular pharmaceutical. Detailers bring drug samples as well as medical studies that explain the 'details' and potential advantages of various prescription drugs." *Sorrell*, 131 S. Ct. at 2659.

SCUTPA. In an action at law tried to a jury, the jury's factual findings will not be disturbed unless a review of the record discloses that there is no evidence that reasonably supports the jury's findings. *City of North Myrtle Beach v. E. Cherry Grove Realty Co.*, 397 S.C. 497, 502, 725 S.E.2d 676, 678 (2012). The record is replete with evidence that reasonably supports a finding that Janssen's conduct was unfair and deceptive. Thus, we conclude Janssen may not avail itself of the protections of the First Amendment to shield itself from its deceptive conduct and false representations.

F. Jury Instructions

Janssen argues that the trial court erred by failing to charge the jury on federal law regarding "unfairness" and instead looking to South Carolina law to define the term. We disagree.

Modeled after the language of the Federal Trade Commission Act (FTCA),[18] SCUTPA declares unlawful any unfair or deceptive acts or practices in trade or commerce. *Compare* 15 U.S.C. § 45(a)(1) (2012) ("Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful."), *with* S.C. Code Ann. § 39-5-20(a) ("Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."). SCUTPA does not define the terms "unfair" and "deceptive"; rather, the legislature intended the courts to be guided by federal interpretations of those terms. S.C. Code Ann. § 395-

[18] 15 U.S.C. §§ 41–77 (2012).

20(b) (1985) (instructing South Carolina courts to take guidance from "the interpretations given by the Federal Trade Commission and the Federal Courts to § 5(a)(1)" of the FTCA); *see also Wright v. Craft*, 372 S.C. 1, 26, 640 S.E.2d 486, 500 (Ct. App. 2006) ("Whether an act or practice is unfair or deceptive within the meaning of the [SC]UTPA depends on the surrounding facts and the impact of the transaction on the marketplace." (citing *deBondt*, 342 S.C. at 269, 536 S.E.2d at 407)).

To this end, our courts have interpreted those terms consistent with legislative intent. "'An act is "unfair" when it is offensive to public policy or when it is immoral, unethical, or oppressive.'" *Health Promotion Specialists, LLC v. South Carolina Bd. of Dentistry*, 403 S.C. 623, 638, 743 S.E.2d 808, 816 (2013) (quoting *Gentry v. Yonce,* 337 S.C. 1, 12, 522 S.E.2d 137, 143 (1999)). "'An act is "deceptive" when it has a tendency to deceive.'" *Id.* (quoting *Gentry*, 337 S.C. at 12, 522 S.E.2d at 143).

At trial, Janssen requested a jury instruction based on section 45(n) of the FTCA as it relates to determining whether an act or practice is "unfair."[19]

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[19] Section 45(n) of the FTCA prohibits the Federal Trade Commission (FTC) from declaring an act or practice to be "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." 15 U.S.C. § 45(n) (2012). Further, in determining whether an act or practice is unfair, section 45(n) provides that the FTC may consider established public policy along with all other evidence, but such public policy considerations may not serve as the primary basis for a finding of unfairness. *Id.*

Specifically, Janssen asked the trial court to instruct the jury that in order to find dissemination of the November 2003 DDL to be an "unfair" trade practice, the jury must find "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." 15 U.S.C. § 45(n) (2012). We find no error, and we view this assignment of error as closely aligned with Janssen's view that an Attorney General directed action will not lie in the absence of an actual loss or damage, a view which we reject. Nevertheless, while there is little evidence of actual harm, there is overwhelming evidence of Janssen's longstanding pattern of deception in pursuit of its goal to deceive prescribing physicians and the public, as well as maintain and increase market share as a result of its deceptive practices.

Janssen also requested that the jury be instructed that a violation of public policy is not, in and of itself, a basis for finding Janssen's conduct to be an unfair trade practice and that a violation of public policy may not even be the primary basis upon which the jury based a finding of liability. According to Janssen, its requested jury instructions reflect the definition of "unfair" set forth in the FTCA, by which South Carolina courts are to be guided. We find no reversible error.

Although SCUTPA refers to the FTCA for guidance, we find that the language of section 39-5-20(b) of the South Carolina Code reveals that federal interpretations are persuasive but not binding authority. Our appellate courts have amassed a strong

and consistent body of case law defining "unfair" under SCUTPA. In the absence of a legislative response, it would be inappropriate for this Court to depart from settled South Carolina precedent. Moreover, we do not discern the wide chasm between the federal and state definitions of "unfair" that Janssen urges. We find that the jury instructions as given correctly stated South Carolina law and afforded the proper test for determining whether Janssen's conduct was "unfair" under SCUTPA. Thus, we hold that the trial court did not abuse its discretion by declining to adopt Janssen's proposed jury instructions. *See Pittman v. Stevens*, 364 S.C. 337, 340, 613 S.E.2d 378, 379 (2005) ("The trial judge is required to charge only the current and correct law of South Carolina." (citing *McCourt v. Abernathy*, 318 S.C. 301, 305, 457 S.E.2d 603, 606 (1995))).

G. Regulated Activity Exception to SCUTPA

Janssen claims that the State's labeling claim was barred by SCUTPA's regulated activity exemption. We hold that Janssen has failed to preserve this issue for appellate review. However, even if we were to reach the merits, we would find that Janssen is not entitled to avail itself of the regulated activity exemption.

SCUTPA expressly provides that it is inapplicable to "[a]ctions or transactions permitted under laws administered by any regulatory body or officer acting under statutory authority of this State or the United States." S.C. Code § 39-5-40(a) (1985). "This exception exempts an entity from liability where its actions are lawful or where it does something required by law, or does something that would otherwise be a violation of

the Act, but which is allowed under other statutes or regulations." *Dema v. Tenet Physician Servs. Hilton Head, Inc.*, 383 S.C. 115, 123, 678 S.E.2d 430, 434 (2009) (quotations omitted). Janssen argues that, after approval of a proposed label, the FDA both authorized and required the use of that approved label. Thus, Janssen argues that FDA approval of the label triggers SCUTPA's regulated activity exemption and prohibits any claim in connection with the sufficiency of the label.

Initially, Janssen fails to identify any specific trial court rulings claimed to constitute error. Because of this, Janssen's argument does not sufficiently identify with particularity the alleged error, and Janssen has abandoned its claim on appeal. *See* Rule 208(b)(4), SCACR ("The brief shall contain references to the transcript, pleadings, orders, exhibits, or other materials which may be properly included in the Record on Appeal . . . to support the salient facts alleged. References shall also be made to where relevant objections and rulings occurred in the transcript."); *see also First Sav. Bank v. McLean*, 314 S.C. 361, 363, 444 S.E.2d 513, 514 (1994) ("Mere allegations of error are not sufficient to demonstrate an abuse of discretion. On appeal, the burden of showing abuse of discretion is on the party challenging the trial court's ruling." (citation omitted)).

However, even if Janssen had properly preserved this issue, we note that Janssen was not entitled to avail itself of this SCUTPA provision. *Wyeth* makes clear that "a central premise of federal drug regulation [is] that the manufacturer bears responsibility for the content of its label at all times." 555 U.S. at 570–71.

"[The manufacturer] is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Id*. at 571 (citing 21 C.F.R. § 201.80(e); 21 C.F.R. § 314.80(b); 73 Fed. Reg. 49605). *Wyeth* clearly rejects the notion that a manufacturer's decision not to include a stronger warning is authorized by the FDA—absent evidence that the FDA affirmatively considered and rejected the stronger warning after being supplied with an evaluation or analysis of the specific dangers presented. *Id*. at 572–73. The very purpose of the "changes being effected" corollary to the FDCA authorizes manufacturers to strengthen the warnings on a label without FDA approval, as long as the manufacturer files a supplemental new drug application. *Id*. at 568; 21 C.F.R. § 314.70(c)(6)(iii)(A), (C) (2013). Indeed, the United States Supreme Court in *Wyeth* noted that "Congress enacted the FDCA to bolster consumer protection against harmful products. Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs in the [FDCA]. Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers." *Id*. at 574. Accordingly, Janssen cannot shield itself from liability by claiming that the FDA's approval of its label constituted an express authorization of its labeling decisions. *See id*. at 583 (Thomas, J., concurring in the judgment) ("[F]ederal law does not give drug manufacturers an unconditional right to market their federally approved drug at all times with the precise label initially approved by the FDA.").

H. Statute of Limitations

Janssen claims that the trial court erred by granting the State's motion for a directed verdict on the statute of limitations on the labeling claim and the DDL claim. We disagree concerning the DDL claim and affirm, but agree in part with Janssen regarding the labeling claim. The statute of limitations bars the labeling claim insofar as the trial court imposed civil penalties for violations that occurred more than three years prior to the parties' tolling agreement. Because of the ongoing nature of Janssen's deceptive conduct, we affirm the judgment on the labeling claim but limit the imposition of civil penalties to a three-year period, coextensive with the statute of limitations, subject only to the additional period of time between the tolling agreement and the filing of the Complaint.

At the close of all of the evidence, the State moved for a directed verdict as to Janssen's statute of limitations defense, arguing that Janssen failed to present any evidence that the Attorney General's office had actual or constructive notice of Janssen's unlawful conduct prior to the commencement of the three year statute of limitations.[20] Specifically, the State argued there was no evidence that the Attorney General, more than three years prior to the commencement of the statute of limitations on January 24, 2004, knew or should have known about the deceptiveness of the DDL and the Risperdal label,

[20] The Complaint was filed on April 23, 2007, but, as noted, the State and Janssen entered into a tolling agreement concerning the statute of limitations on January 24, 2007.

the concealed studies, or the unlawful promotion of Risperdal in South Carolina.

The trial court granted the State's motion for a directed verdict, finding that neither the DDL claim nor the labeling claim was barred by the three-year statute of limitations. Specifically, the trial court noted that although the medical community at large was aware of the risks associated with Risperdal, some even as early as the mid-1990s, the point in time at which the side-effects of Risperdal became known was not the gravamen of the State's claims. Rather, the specific conduct at issue was Janssen's false and misleading statements in the DDL and Janssen's failure to update its label to reflect the known degree of risks associated with Risperdal. Accordingly, the relevant inquiry was the point at which the State should have known that Janssen's *conduct* as to the DDL and the Risperdal label was unfair or deceptive and, thus, gave rise to a SCUTPA claim.

As to the DDL claim, the trial court found that claim was not barred by the statute of limitations because there was no evidence that the false or misleading nature of the DDL could have been discovered before the DDMAC issued its warning letter to Janssen in April 2004, which was within the timeframe of the tolling agreement. As to the labeling claim, the trial court found that because Janssen took affirmative steps to prevent disclosure of unfavorable clinical trial results that revealed the serious degree of risks associated with Risperdal, the statute of limitations was equitably tolled during the period of time in which Janssen knew, but failed to disclose and shielded from public knowledge, the true degree of

risks associated with Risperdal. The trial court found the labeling claim likewise was not barred by the statute of limitations, and awarded a civil penalty for each of the of 509,499 Risperdal "sample boxes" distributed in South Carolina from 1998 through the date of the Complaint, April 23, 2007, each of which included the drug label in the sample packaging.

Janssen argues this was error and that both claims are barred by the statute of limitations because the State had actual or constructive knowledge of the claims before January 24, 2004. Specifically, as to the DDL claim, Janssen contends that the claim was discoverable from the face of the DDL itself, and therefore, the statute of limitations began to run at the time the DDL was mailed in November 2003. As to the labeling claim, Janssen contends that claim is barred because the risks associated with Risperdal were widely known by the mid-1990s and that the alleged inadequacies in the labeling were apparent from the face of the label itself; therefore, Janssen posits that the labels themselves put the State on notice of its labeling claim as early as 1994, and that the three-year statute of limitations thus ran long before the State's Complaint was filed in 2007. Janssen further argues the doctrine of equitable tolling should be sparingly applied and that there is no basis for applying it here.

We first address the DDL claim. SCUTPA provides for a three-year statute of limitations. S.C. Code Ann. § 39-5-150 (1985). Under the discovery rule, the three-year clock starts ticking on the date the injured party either knows or should have known by the exercise of reasonable diligence that a cause of

action arises from wrongful conduct. *Dean v. Ruscon Corp.*, 321 S.C. 360, 363, 468 S.E.2d 645, 647 (1996) (citation omitted). We have carefully reviewed the record in light of the appropriate standard of review, and we agree with the trial court. As a matter of law, the only reasonable conclusion supported by the evidence at trial was that the existence of a claim, i.e. the deceptive and unfair nature of Janssen's conduct in disseminating the DDL, could not have reasonably been discovered prior to April 2004 when the FDA issued the Warning Letter to Janssen.[21] *See id.* at 366, 468 S.E.2d at 648 (finding that where the only reasonable conclusion supported by the evidence was that the lawsuit accrued on a particular date, there was no issue for the jury to decide and a directed verdict was proper). We affirm the trial court's finding that the DDL claim was timely.

We turn to the labeling claim. The procedural dilemma we confront is that the statute of limitations issue concerning the labeling claim was resolved at trial through principles of equitable tolling. A determination in equity is not proper for a directed verdict motion insofar as determining what matters should be submitted to the jury. It was therefore legal error to resolve the issue of equitable tolling pursuant to a directed verdict motion. Under our *de novo* review of this equitable issue, we agree with Janssen that

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[21] Considerable argument is presented over whether the discovery rule should be analyzed through the person of the Attorney General or the typical approach of the reasonably prudent person. We need not decide the "relevant plaintiff" question and purported distinction between the two, for the result would be the same here.

there is an insufficient basis for application of that doctrine to preserve the timeliness of all labeling violations, reaching back to the time Risperdal was first introduced in 1994. *See Hooper v. Ebenezer Sr. Servs. & Rehab. Ctr.*, 386 S.C. 108, 117, 687 S.E.2d 29, 33 (2009) (noting the doctrine of equitable tolling should be used sparingly and only when the interests of justice demand its use). However, we do not view the error as one mandating reversal and a new trial, given the continuing nature of the accrual of labeling violations.

Clearly, much of the labeling claim accrued more than three years prior to the January 24, 2007 tolling agreement. The risks associated with atypical antipsychotics, like Risperdal, were becoming well known by the late 1990s. The State's experts testified that the Risperdal label was inadequate as early as 1994 when Janssen began marketing the drug. By all accounts, in the early 2000s, evidence of the risks was pervasive.[22] We find that the only reasonable conclusion supported by the evidence is that the Attorney General knew, or most assuredly should have known, of potential SCUTPA violations regarding the Risperdal label prior to January 24, 2004. Thus, the labeling violations occurring prior to January 24, 2004, were therefore barred by the statute of limitations.

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[22] This 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.

Nevertheless, the labeling claim presents ongoing violations of SCUTPA that continued *after* January 24, 2004 and during the three-year-period prior to the tolling agreement. In requesting that the entire labeling claim be dismissed as time barred, Janssen assumes, wrongly so, that its ability to successfully invoke the statute of limitations to bar the labeling claim prior to January 24, 2004, ends the labeling claim altogether. We reject Janssen's position, for Janssen misapprehends the statute of limitations and the concept of continuous accrual of this SCUTPA cause of action. The labeling claim presents a series of discrete, independently actionable wrongs that are at the core of the typical unfair trade practice action. The principles of this type of continuous accrual respond to

> the inequities that would arise if the expiration of the statute of limitations period following a first breach of duty or instance of misconduct were treated as sufficient to bar suit for any subsequent breach or misconduct; parties engaged in long-standing malfeasance would thereby obtain immunity in perpetuity from suit even for recent and ongoing malfeasance. In addition, where misfeasance is ongoing, a defendant's claim to repose, the principal justification underlying the limitations defense, is vitiated. . . . [Accordingly,] separate, recurring invasions of the same right can each trigger their own statute of limitations. . . . Generally speaking, continuous accrual applies whenever there is a continuing or recurring obligation: [w]hen an obligation or liability arises on a recurring basis, a cause of action accrues each time a

> wrongful act occurs, triggering a new limitations period.

Aryeh v. Canon Bus. Solutions, Inc., 292 P.3d 871, 880 (Cal. 2013) (quotations and citations omitted) (distinguishing the continuous accrual doctrine from the continuing violation doctrine, which involves a single injury that is the product of a series of small harms, any one of which is not actionable on its own). *See Estate of Livingston v. Livingston*, 404 S.C. 137, 147–48, 744 S.E.2d 203, 209 (Ct. App. 2013) (finding a new statute of limitations begins to run after each separate injury, and therefore statute of limitations barred only claims falling outside the three-year time period and did not bar claims occurring within that time), *cert. granted*, No. 2013-001505 (S.C. Sup. Ct. filed Oct. 24, 2014); *see also Hogar Dulce Hogar v. Cmty. Dev. Comm'n of Escondido*, 2 Cal. Rptr. 3d 497, 502 (Ct. App. 2003) ("When an obligation or liability arises on a recurring basis, a cause of action accrues each time a wrongful act occurs, triggering a new limitations period." (citation omitted)); *cf. Anonymous Taxpayer v. S.C. Dep't of Rev.*, 377 S.C. 425, 440–41, 661 S.E.2d 73, 81 (2008) (finding that, under the facts presented, the particular claim alleged by plaintiff constituted only one cause of action, and therefore, there was no continuing injury that would trigger a new limitations period).

Indeed, the language of SCUTPA itself contemplates that an unlawful method, act, or practice may result in multiple statutory violations, and it is the violations themselves that cause the statute of limitations to begin to run. S.C. Code Ann. § 39-5-110(a) ("If a court finds that any person is

willfully using or has willfully used a method, act or practice declared unlawful by § 39-5-20, the Attorney General . . . may recover on behalf of the State a civil penalty of not exceeding five thousand dollars *per violation*." (emphasis added)). We adopt the view that aligns with legislative intent as reflected in section 39-5-110, a common sense approach recognizing that the SCUTPA statute of limitations begins to run anew with each violation. Thus, where a claim involves a series of ongoing violations, recovery is limited to a period coextensive with the applicable statute of limitations.

In sum, we agree with the State regarding the DDL claim, for we find that claim, in the exercise of reasonable diligence, could have been discovered no earlier than April 2004 when the FDA issued its warning letter to Janssen. However, we agree with Janssen concerning the labeling claim insofar as civil penalties were awarded for violations occurring from 1998 until January 24, 2004 (three years prior to the tolling agreement). Under these facts, it was error to award the State civil penalties for violations in connection with the labeling claim outside the statute of limitations. An award for civil penalties within the statute of limitations was proper.

I. Preemption

Janssen argues that both the labeling claim and the DDL claim are preempted by federal law. Specifically, Janssen argues the labeling claim is barred by implied conflict preemption and that the DDL claim is barred by the express preemption provision of the FDCA, 21 U.S.C. § 337(a) (2006). We disagree.

When "Congress has 'legislated . . . in a field which the States have traditionally occupied,' we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quotations and citations omitted) (ellipses in original).

"In 1962, Congress amended the FDCA and shifted the burden of proof from the FDA to the manufacturer." *Wyeth*, 555 U.S. at 567. "Before 1962, the [FDA] had to prove harm to keep a drug out of the market, but the amendments required the manufacturer to demonstrate that its drug was safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling before it could distribute the drug." *Id.* (quotations and citations omitted). "In addition, the amendments required the manufacturer to prove the drug's effectiveness by introducing substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling." *Id.* (quotations and citations omitted). "As [Congress] enlarged the FDA's powers to protect the public health and assure the safety, effectiveness, and reliability of drugs, Congress took care to preserve state law." *Id.* (quotations and citations omitted). "The 1962 amendments [to the FDCA] added a saving clause, indicating that a provision of state law would only be invalidated upon a direct and positive conflict with the FDCA." *Id.* (quotations and citations omitted). "Consistent with that provision, state common-law suits 'continued

unabated despite . . . FDA regulation.'" *Id.* (quoting *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 340 (2008) (Ginsburg, J., dissenting)).[23]

Based upon *Wyeth*, we find that the State's DDL claim is not expressly preempted by federal law. Additionally, we find that Janssen has not preserved their implied conflict preemption claim for appellate review. Even assuming Janssen's argument regarding implied preemption is not procedurally barred, however, we find it to be without merit.

1. Express Preemption of the DDL Claim

Janssen argues that the State's claim regarding the DDL relies on a single piece of evidence—the April 2004 DDMAC warning letter characterizing Janssen's DDL as "false and misleading." As such, Janssen asserts the DDL claim is based solely on a violation of the FDCA, which provides no private right of action. Janssen thus concludes that this "federal claim" is preempted and may not be maintained. Because Janssen's argument is based on a false premise, we disagree.

It is true that the State pursued a SCUTPA claim based on the November 2003 DDL. It is also true that the State introduced the April 2004 DDMAC warning letter as evidence in support of its DDL claim. It is not true that the sole evidence establishing the false and misleading nature of the DDL comes from the subsequent April 2004 DDMAC warning letter.

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[23] The FDA did not have the authority to mandate a manufacturer change its label until amendments to the FDCA in 2007. 21 U.S.C. § 355(o)(4) (Supp. V 2011).

Janssen not only views the DDL claim myopically, but conflates the concepts of evidence and claims. There was substantial additional evidence relating to the deception surrounding the November 2003 DDL, much of which is noted above. For example, the State presented evidence that, scientific proof to the contrary, Janssen's Risperdal sales strategy specifically sought to differentiate Risperdal from competing drugs by emphasizing that Risperdal caused less weight gain relative to other atypical antipsychotics such as Zyprexa.

Moreover, the State presented internal emails between Janssen executives, one of which included discussion of Janssen's desire to gain market share over competitors by avoiding being subjected to a class labeling requirement as to diabetes/hyperglycemia. Yet another email indicated that at least one Janssen scientist supported glucose screening and monitoring for Risperdal patients, but that such a position was "not the company line." Janssen's broad, aggressive, and deceptive marketing strategy resulted in the discrete DDL claim. In short, the record is replete with evidence beyond the 2004 DDMAC warning letter to support the State's DDL claim. Further, at the end of trial, the jury was charged with determining several factual issues, each of which was based solely on the provisions of SCUTPA, and the trial judge assessed penalties under SCUTPA framework. Accordingly, we find that the State's SCUTPA claim concerning the DDL is not preempted by the FDCA.

2. Implied Conflict Preemption of the Labeling Claim

Janssen argues that the State's labeling claim is barred by implied conflict preemption. Janssen failed to raise the doctrine of implied conflict preemption in its motion for summary judgment or its initial directed verdict motion at the close of the State's case-in-chief. Accordingly, this argument was waived because it was not asserted in Janssen's initial motion for directed verdict.[24] *See Freeman v. A. & M. Mobile Home Sales, Inc.*, 293 S.C. 255, 258–59, 359 S.E.2d 532, 535 (Ct. App. 1987).

Additionally, Janssen's argument on appeal is substantively different than the argument below. Before the trial court, Janssen moved for a directed verdict, arguing that the *Wyeth* "exception to preemption" did not apply since the State failed to establish that Janssen could have, and should have, updated the Risperdal label without prior FDA approval. Given this purported failure of proof, Janssen argued that the State's labeling claim was preempted. The trial court rejected Janssen's argument and found that *Wyeth* was controlling. In contrast, Janssen now argues that the State's SCUTPA claims sought to impose labeling

[24] Notably, Janssen did raise express preemption as to the DDL in its initial directed verdict motion. However, counsel for Janssen candidly acknowledged in its renewed directed verdict motion at the close of the evidence, "[W]e have an argument that hasn't been made by us before, and that is that the package insert claim, the claim dealing with the label, is preempted by federal law." Further, counsel for Janssen stated, "We're arguing something quite different that we haven't argued before. We haven't [previously] argued about Wyeth against Levine."

requirements different from those required by the FDA, and thus, according to Janssen, the doctrine of implied conflict preemption bars the State's claims. This argument, however, is not preserved for appellate review. *See Dunbar*, 356 S.C. at 142, 587 S.E.2d at 694 ("A party may not argue one ground at trial and an alternate ground on appeal." (citing *Prioleau*, 345 S.C. at 411, 548 S.E.2d at 216; *Benton*, 338 S.C. at 157, 526 S.E.2d at 231)).

Nonetheless, even were we to find Janssen's argument not to be procedurally barred, we would find it is without merit. Janssen suggests that the State sought to impose labeling requirements different than those imposed by the FDA. The State's claim, however, did not seek to penalize Janssen for distributing its FDA-approved label. Rather, the State sought civil penalties based on Janssen's actions in failing to discharge its ongoing, affirmative 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).

Further, we reject Janssen's argument that *Wyeth* is inapposite because this case involves an enforcement action by the Attorney General on behalf of the State. Regardless of whether a state-law enforcement action is brought by a private individual or an attorney general on behalf of a state, *Wyeth* makes clear that federal labeling standards are "a floor upon which States could build" and noted the FDA's agency position that, "in establishing minimal standards for drug labels, it did not intend to preclude the states from imposing additional labeling

requirements." *Id.* at 577–78 (quotations omitted). Rather, "[f]ailure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times." *Id.* at 579. Indeed, "federal law does not give drug manufacturers an unconditional right to market their federally approved drug at all times with the precise label initially approved by the FDA." *Id.* at 583 (Thomas, J. concurring in the judgment). Janssen's claim is without merit.

Having affirmed the trial court concerning Janssen's liability in connection with both the labeling claim and the DDL claim, we turn now to the penalty award.[25]

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[25] Janssen raises a number of other issues, each of which we have carefully reviewed and find to be without merit or unpreserved. We affirm based upon Rule 220(b)(1), SCACR, and the following authorities**:** *Fields v. J. Haynes Waters Builders, Inc.*, 376 S.C. 545, 557, 658 S.E.2d 80, 86 (2008) (holding that in order to warrant reversal, the appealing party must show both the error of the ruling and resulting prejudice) (citing *Fields v. Reg. Med. Ctr. Orangeburg,* 363 S.C. 19, 26, 609 S.E.2d 506, 509 (2005)); *Webb v. CSX Transp., Inc.*, 364 S.C. 639, 655, 615 S.E.2d 440, 449 (2005) (finding the failure to raise a contemporaneous objection at trial waives the right to complain about an issue on appeal) (citing *Taylor v. Medenica,* 324 S.C. 200, 214 n.9, 479 S.E.2d 35, 42 n.9 (1996)); *Futch v. McAllister Towing of Georgetown, Inc.*, 335 S.C. 598, 613, 518 S.E.2d 591, 598 (1999) (noting that an appellate court need not address remaining issues when disposition of prior issues is dispositive) (citing *Whiteside v. Cherokee Cnty. Sch. Dist. No. One,* 311 S.C. 335, 340, 428 S.E.2d 886, 889 (1993)); *Wilder Corp. v. Wilke*, 330 S.C. 71, 76, 497 S.E.2d 731, 733 (1998) ("[A]n objection must be sufficiently specific to inform the trial court of the point being urged by the objector." (citation omitted)); *Talley v. South Carolina Higher Educ. Tuition Grants Comm.*, 289 S.C. 483, 487, 347 S.E.2d 99,

III. Penalty Award

SCUTPA allows the Attorney General to recover on behalf of the State a civil penalty of up to $5,000 per violation. S.C. Code Ann. § 39-5-110(a). Undoubtedly, Janssen's deceptive conduct relating to Risperdal warrants a civil penalty, and because the civil penalty award under section 39-5-110(a) is within the discretion of the trial court, we review the trial court's penalty award under an abuse of discretion standard. *State ex rel. McLeod v. C & L Corp., Inc.*, 280 S.C. 519, 528, 313 S.E.2d 334, 340 (Ct. App. 1984) ("The party challenging a discretionary ruling of the trial court has the burden of showing a clear abuse of discretion."); *accord Vanderbilt Mortg. & Fin., Inc. v. Cole*, 740 S.E.2d 562, 566 (W.Va. 2013) (holding a trial court's award of civil penalties pursuant to state statute will not be disturbed on appeal unless it clearly appears the trial court abused its discretion).

The State argued, and the trial court agreed, that the distribution of each sample box containing the deceptive labeling, each DDL, and each follow-up sales call to the DDL by a Janssen representative constituted a separate SCUTPA violation. The trial court adopted a multi-factor test used by the United States Court of Appeals for the Third Circuit in

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101 (1986) ("It is an axiomatic rule of law that issues may not be raised for the first time on appeal." (citing *Am. Hardware Supply Co. v. Whitmire*, 278 S.C. 607, 609, 300 S.E.2d 289, 290 (1983))); *Eaddy v. Smurfit-Stone Container Corp.*, 355 S.C. 154, 164, 584 S.E.2d 390, 396 (Ct. App. 2003) ("[S]hort, conclusory statements made without supporting authority are deemed abandoned on appeal and therefore not preserved for our review." (citing *Glasscock, Inc. v. U.S. Fid. & Guar. Co.*, 348 S.C. 76, 81, 557 S.E.2d 689, 691 (Ct. App. 2001))).

determining an appropriate civil penalty: "(1) the good or bad faith of the defendants; (2) the injury to the public; (3) the defendant's ability to pay; (4) the desire to eliminate the benefits derived by a violation; and (5) the necessity of vindicating the authority of [the regulatory agency]." *United States v. Reader's Digest Ass'n, Inc.*, 662 F.2d 955, 967 (3d Cir. 1981).[26]

Janssen challenges the penalty award on numerous grounds, including the argument that the total penalty, in excess of $327,000,000, is excessive. We agree with Janssen in part. There are certain factors common to the labeling and DDL claims. First, Janssen's deceit was substantial. In order to maintain its market share, Janssen's furtive efforts to mislead prescribing physicians about the risks and side effects associated with Risperdal were reprehensible and in callous disregard for the health and welfare of the public. Janssen's desire for market share and

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[26] Application of the *Reader's Digest* factors was proper here. Given that this is our first opportunity to address the appropriate factors for assessing a civil penalty in an Attorney General directed claim under SCUTPA, we direct that, prospectively, the following list of non-exclusive factors be used in assessing civil penalties under SCUTPA: (1) the degree of culpability and good or bad faith of the defendant; (2) the duration of the defendant's unlawful conduct; (3) active concealment of information by the defendant; (4) defendant's awareness of the unfair or deceptive nature of their conduct; (5) prior similar conduct by the defendant; (6) the defendant's ability to pay; (7) the deterrence value of the assessed penalties; and (8) the actual impact or injury to the public resulting from defendant's unlawful conduct. We further authorize our able trial judges to consider any other factors they deem appropriate under the circumstances. In issuing a ruling, the trial court should make sufficient findings of fact concerning all relevant factors to enable appellate review.

increased sales[27] knew no bounds, leading to its egregious violation of South Carolina law, particularly in connection with the DDL. Janssen's conduct is irrefutably linked to its longstanding efforts to conceal the truth regarding Risperdal. This corrupt corporate culture through the years was a factor, and understandably so, in the trial court's imposition of such a substantial penalty.

We agree in part with Janssen that its conduct had little impact on the community of prescribing physicians. The truth about the risks associated with atypical antipsychotics was well known, particularly in the pharmaceutical and medical professions. This begs the question of why Janssen would go to such lengths to perpetuate and defend a lie. Whatever the answer, the point remains that Janssen did go to such lengths. Yet, the absence of significant actual harm resulting from Janssen's deceptive conduct leads us to conclude the trial court erred in part in its penalty assessment.

A. Violations and Reduced Civil Penalty

1. Labeling Claim

The trial court assessed a $300 civil penalty against Janssen for each Risperdal "sample box" distributed to South Carolina prescribers from 1998 through the date of the Complaint, April 23, 2007, for a total of 509,499 violations. As discussed, we reverse the civil penalties awarded for conduct that occurred prior to January 24, 2004, for that part of the State's labeling claim is barred by the statute of limitations. Based on the record, during the period of time from

[27] Since 1994, Risperdal sales approximated $30 billion.

February 2004 until the filing of the Complaint in April of 2007, Janssen made 20,575 visits to prescribing physicians in South Carolina and distributed 345,454 sample boxes containing deceptive labeling.[28]

Janssen challenges the penalty award of $300 per sample box on numerous grounds, including the argument that the penalty is excessive. We agree and find the $300 penalty per sample box excessive. Based on the totality of the circumstances and consideration of the *Reader's Digest* factors, we remit the penalty to $100 per sample box, for a civil penalty of $34,545,400.

2. DDL Claim

Janssen mailed 7,184 DDLs to South Carolina physicians in November 2003. The trial court considered each letter a separate violation and imposed a penalty of $4,000 per letter, for a penalty of $28,736,000. In addition, the trial court counted each follow-up sales call to the DDL by a Janssen representative as a separate violation. There were 36,372 follow-up sales calls. The trial court again assessed a penalty of $4,000 for each sales call, for a penalty of $145,488,000.

Janssen challenges the penalty award on numerous grounds, including excessiveness. While the question presented is close, we cannot say that the trial court abused its discretion in assessing the

[28] We arrive at this number based on documents submitted by Janssen showing the total samples distributed and the total number of visits to prescribing physicians. (20,575 visits times 16.79 sample boxes per visit equals a total of 345,454.25 sample boxes, rounded to 345,454).

$28,736,000 penalty associated with the 7,184 DDLs. A $4,000 penalty per each DDL is indeed substantial. But Janssen's deceit, as described above, was also substantial. The DDL was especially egregious, for it represented not mere nondisclosure but a corporately sanctioned decision to affirmatively lie and an attempt to mislead the medical community. We affirm the civil penalty of $28,736,000 penalty associated with the 7,184 DDLs.

Janssen's misconduct in the more than 36,000 follow-up visits may be similarly viewed, for the follow-up visits were designed to continue the false DDL narrative. Nevertheless, a penalty of $4,000 per follow-up visit is excessive as a matter of law under the circumstances. We find in most instances, these were follow-up calls to the same prescribing physicians who received the DDL in the mail. In fact, in many instances there were multiple calls to the *same* physicians. We remit the penalty to $2,000 per follow-up sales call, for a penalty of $72,744,000. When combined with the penalty for the DDL mailing, the total penalty assessed against Janssen for the DDL claim is $101,480,000.

The combined civil penalty for the labeling and DDL claims is $136,025,400.

B. Constitutionality of the Penalty Award

Janssen also raises a number of constitutional challenges to the trial court's penalty order. First, Janssen claims that the $327 million penalty violates the Excessive Fines Clause of the Eighth Amendment to the U.S. Constitution and Article 1, Section 15 of the South Carolina Constitution. Second, Janssen claims that the penalty award violates due process

because it is grossly excessive. We analyze this argument on the basis of the remitted penalty of approximately $136 million. We find no constitutional violation.

"The touchstone of the constitutional inquiry under the Excessive Fines Clause [of the U.S. Constitution] is the principle of proportionality: The amount of the forfeiture must bear some relationship to the gravity of the offense that it is designed to punish." *United States v. Bajakajian*, 524 U.S. 321, 334 (1998); *see also Medlock v. One 1985 Jeep Cherokee VIN 1JCWB7828FT129001*, 322 S.C. 127, 132, 470 S.E.2d 373, 377 (1996) (adopting the federal "instrumentality" standard in the context of civil forfeitures for purposes of South Carolina's "excessive fines" analysis). The Court will only find a violation of the Excessive Fines Clause if the penalty is "*grossly* disproportional to the gravity of a defendant's offense." *Bajakajian*, 524 U.S. at 334 (emphasis added). "The Ninth Circuit and other federal courts have consistently found that civil penalty awards in which the amount of the award is less than the statutory maximum do not run afoul of the Excessive Fines Clause." *United States v. Mackby*, 221 F. Supp. 2d 1106, 1110 (N.D. Cal. 2002) (citing cases from the First Circuit, Ninth Circuit, and D.C. Circuit). This is so because legislative pronouncements regarding the proper range of fines "represent the collective opinion of the American people as to what is and is not excessive. Given that excessiveness is a highly subjective judgment, the courts should be hesitant to substitute their opinion for that of the people." *United States v. 817 N.E. 29th Drive, Wilton Manors, Fla.*, 175

F.3d 1304, 1309 (11th Cir. 1999) (citing *Bajakajian*, 524 U.S. at 336).

We find that the penalty in this case, now reduced, bears a rational relationship to the gravity of Janssen's conduct in perpetuating a marketing scheme in South Carolina designed to be unfair and deceptive under our law. Furthermore, the penalty awards per violation are within the range set by the legislature in enacting SCUTPA. Accordingly, the penalty award is not grossly disproportionate to Janssen's pattern of unfair and deceptive behavior, and, thus, we hold that the award does not violate the Excessive Fines Clause of the South Carolina or the United States Constitution. We turn now to Janssen's due process argument.

The Due Process Clause of the U.S. Constitution "places a limitation upon the power of the states to prescribe penalties for violations of their laws . . . ." *St. Louis, Iron Mt. & S. Ry. Co. v. Williams*, 251 U.S. 63, 66 (1919). States, however, "still possess a wide latitude of discretion in the matter, and . . . their enactments transcend the limitation only where the penalty prescribed is so severe and oppressive as to be wholly disproportioned to the offense and obviously unreasonable." *Id.* at 66–67 (citations omitted); *see also Shipman v. Du Pre*, 222 S.C. 475, 480, 73 S.E.2d 716, 718 (1952) (embracing the *Williams* standard).

Given the evidence that demonstrates Janssen's pattern of unfair and deceptive behavior, we find that the penalties in this case are not violative of the Due Process Clause. We decline to set forth a bright-line rule or ratio to delineate what level of penalties are appropriate, instead undertaking a case-by-case

determination based on the severity of the underlying conduct. While the penalty award against Janssen is quite large, the penalty must be analyzed in context in view of the clear legislative intent of SCUTPA to deter unfair and deceptive behavior in the conduct of trade and commerce in South Carolina. When all factors are considered, we find that the penalty award does not violate the Due Process Clause.

And finally, we comment on the amicus curiae brief filed by the South Carolina Chamber of Commerce. The Chamber seeks clarity from this Court to provide a predictable and favorable business climate in this state. The Chamber is especially distressed by the $327 million penalty, which it views as excessive and as "overt hostility toward business." While we agree the penalty awarded by the trial court was excessive, the Chamber's additional concerns are based on a series of false premises. The Chamber posits that Janssen's conduct is being "judged according to subjective, intangible standards." More to the point, the implication is that South Carolina stands alone in arbitrarily singling-out Janssen for what amounts to nothing more than an aggressive marketing strategy. That is simply not the case. Because of its deceptive conduct in the marketing of Risperdal, Janssen has been the subject of litigation throughout the country. Indeed, the deceptive marketing that gave rise to this action also formed the basis of federal civil and criminal claims against Janssen and its parent company; the federal litigation has thus far resulted in agreed upon penalties in excess of $2 billion. When viewed objectively, Janssen over the course of many years consciously engaged in lies and deception in the marketing of Risperdal.

Thus, the suggestion that the Attorney General of South Carolina stands alone in pursuing amorphous and subjective claims against Janssen is without merit. Surely the Chamber desires a legal system that honors the rule of law and one which does not insulate businesses from liability for unfair and deceptive practices. Our decision today is faithful to objective legal principles, legislative intent in SCUTPA and the rule of law. Moreover, we have set forth clear guidance for the business community, the Bench and the Bar for determining what conduct is actionable under SCUTPA and what factors bear on the determination of an appropriate penalty—precisely the type of clarity the Chamber seeks.

IV. Conclusion

Based on the statute of limitations, we reverse the judgment on labeling claim to the extent the trial court awarded civil penalties for conduct prior to January 24, 2004. We otherwise affirm as modified the judgment on the labeling claim and remit the civil penalty to $34,545,400. We affirm the liability judgment on the DDL claim, but remit those civil penalties to $101,480,000. We remand to the trial court for entry of judgment in the amount of $136,025,400.

AFFIRMED IN PART, REVERSED IN PART AND REMANDED.

TOAL, C.J., BEATTY, and HEARN, JJ., concur.

PLEICONES, J., dissenting in a separate opinion.

PLEICONES, J.: With great respect for the majority's thorough treatment of these complex issues, I dissent from those portions of its opinion

addressing: (1) the timeliness of the labeling claim; and (2) the reduction of the DDL penalty award.

I. Statute of Limitations

I agree the Attorney General knew or should have known prior to January 24, 2004 that he may have had a SCUTPA claim against Janssen based, in part, on research indicating Janssen's Risperdal label misled consumers insofar as it failed to disclose the drug's side effects. *See Kreutner v. David*, 320 S.C. 283, 285–86, 465 S.E.2d 88, 90 (1995) (discussing the discovery rule for purposes of triggering the limitations period and finding that where the evidence is overwhelming a reasonable person should have known she might have a claim at a time beyond the statute of limitations, then such claim is time-barred). I therefore agree with the majority's conclusion that the Attorney General's SCUTPA claim for labeling violations occurring before January 24, 2004 was time-barred, and that the trial judge erred in holding equitable tolling removed the bar.

My disagreement is with the majority's application of the continuous accrual doctrine. I would not apply the doctrine in this appeal because doing so does not affirm the statute of limitations ruling to the extent the trial judge found the pre-January 24, 2004 labeling claim timely and permitted that claim to go to the jury. In my opinion, we may invoke our authority to affirm on any ground appearing in the record only when the result is to affirm the trial judge's ruling in toto. *See* Rule 220(c), SCACR. Here, the effect of applying the continuous accrual doctrine is only a partial affirmance. Further, we 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. I do not agree that reducing the amount of the penalty for the labeling claim cures the prejudice to Janssen given the unreliability of the jury's liability determination. Thus, I respectfully submit we should not apply the continuous accrual doctrine[29] in this appeal as doing so prejudices Janssen.

Accordingly, I would reverse the jury's finding of liability because the labeling claim is barred by the statute of limitations. I would also reverse the trial judge's labeling claim penalty because the claim is untimely.

DDL PENALTY AWARD

As for the reduction of the DDL penalty award, I would find the trial judge did not abuse his discretion in awarding $174,224,000 based on Janssen mailing 7,184 deceptive DDLs and following up with 36,372 sales calls to sanction the deception already perpetrated. *See State ex rel. McLeod v. C & L Corp.*, 280 S.C. 519, 528, 313 S.E.2d 334, 340 (Ct. App. 1984) (reviewing the award of civil penalties under an abuse of discretion standard). As for Janssen's contention that the follow-up sales calls were made to the same prescribing physicians who had already received the DDL, I would find the trial judge properly considered this argument and exercised his discretion in finding

[29] I leave for another day whether we should adopt this doctrine in the context of SCUTPA or other statutory claims.

Janssen's culpability (*Reader's Digest*[30] Factor 2) outweighed the actual impact or injury resulting from Janssen's unlawful conduct (*Reader's Digest* Factor 8).

Ultimately, the trial judge was in the best position to evaluate Janssen's conduct, the degree of culpability, the duration of Janssen's conduct, Janssen's active concealment of Risperdal's side effects to South Carolina health care providers, Janssen's awareness of its deceptive conduct, Janssen's ability to pay, and the actual impact, if any, resulting from Janssen's deceptive conduct. *See Reader's Digest Ass'n*, 662 F.2d at 967. Based on the trial judge's articulation of the *Reader's Digest* factors and his proper consideration of those factors, I would find Janssen has not shown the court abused its discretion in awarding a $174,224,000 civil penalty for the DDL claim, an amount within the limits set forth in SCUTPA. *See Wallace v. Timmons*, 237 S.C. 411, 421, 117 S.E.2d 567, 572 (1960) (stating that in reviewing a trial judge's decision under an abuse of discretion standard, this Court may not substitute its judgment simply because it might have reached a different conclusion had it been in the trial judge's place). Therefore, I would affirm the trial judge's penalty award of $174,224,000 as to the DDL claim.

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[30] *United States v. Reader's Digest Ass'n*, 662 F.2d 955, 967 (3d Cir. 1981) (outlining the multi-factor analysis to determine the propriety of a statutory penalty, which the trial judge applied, the majority has adopted, and with which I concur).

Appendix C

THE COURT OF COMMON PLEAS
OF SOUTH CAROLINA
SPARTANBURG COUNTY

No. 07-CP-42-1438

EX. REL. ALAN WILSON, IN HIS CAPACITY AS ATTORNEY GENERAL OF THE STATE OF SOUTH CAROLINA,

Plaintiff,

v.

ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., F/K/A JANSSEN PHARMACEUTICAL, INC., AND/OR JANSSEN, L.P., AND JOHNSON & JOHNSON, INC.,

Defendants.

Filed: June 3, 2011

PENALTY ORDER

COUCH, J.:

The Jury has determined that Ortho-McNeil-Janssen Pharmaceutica, Inc., f/k/a Janssen Pharmaceutica, Inc., and/or Janssen L.P. (hereinafter referred to as simply Janssen) have violated the South Carolina Unfair Trade Practices Act (SCUTPA) by willfully engaging in unfair or deceptive practices in the manner in which they conducted their trade or commerce and in the marketing and labeling of Risperdal in the State of South Carolina. The question now before this Court is: What are the appropriate

penalties to be levied against those companies for their actions?

The statutes involved in this action are:

> South Carolina Code Section 39-5-20: Unfair methods of competition and unfair or deceptive acts or practices unlawful; application of interpretations of Federal act.
>
> (a) Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful.
>
> South Carolina Code Section 39-5-110: Civil penalties for willful violation or violations of injunction.
>
> (a) If a court finds that any person is willfully using or has willfully used a method, act or practice declared unlawful by Section 39-5-20, the Attorney General, upon petition to the court, may recover on behalf of the State a civil penalty of not exceeding five thousand dollars per violation.
>
> (c) For the purposes of this section, a willful violation occurs when the party committing the violation knew or should have known that his conduct was a violation of Section 39-5-20.

The South Carolina Unfair Trade Practices Act provides that when it has been determined that willful violations of the Act have occurred, the State may recover a civil penalty not to exceed five thousand dollars per violation. *Id.* It is within the judge's discretion to determine the total amount of the penalty, so long as it does not exceed the statutory

limitation. There can be no error of law in imposing a fine within the limits authorized by the Act. Within those limits, the amount of the fine is a matter within the judge's discretion. *State ex rel. McLeod v. C & L Corp., Inc.,* 280 S.C. 519, 313 S.E.2d 334, (S.C. App. 1984).

During the trial of this matter, certain information and testimony presented to this Court was placed on a list of contested evidence. I have reviewed the proffer of this evidence and make the following rulings:

- Evidence of the Louisiana legal action was excluded and not considered by this Court.
- Evidence concerning the Topomax criminal settlement was excluded and not considered by this Court
- Testimony of Dr. William Wecker, I find, did not meet the tests of reliability for expert witnesses established by our courts, and therefore, the testimony should not be entered into the record. Further, I find some of the conclusions reached by him are not supportable. This conclusion is based on other scientifically reliable evidence already entered into the record of this case. Therefore, even if his testimony had been admissible, I would have found his testimony to be totally unreliable, and it would have been given no weight by this Court.

Both the Plaintiff and the Defendants agree that the Court, when exercising its discretion in determining the measure of penalties to be assessed, should consider factors similar to these articulated in

United States v. Reader's Digest Ass'n, 662 F.2d 955, 967 (3rd Cir. 1981)

- The good faith or bad faith of the Defendant;
- The injury to the public;
- The desire to eliminate the benefits derived by a violation;
- The necessity of vindicating the authority of the agency involved; and;
- The Defendant's ability to pay.

I will begin my discussion of these factors by pointing out the Credo of the Defendants' parent company which expresses the standard of conduct to which the Defendants purport to hold themselves.

The Credo of Johnson & Johnson, as published on its website and referred to in its annual reports begins, "We believe our first responsibility is to the doctor, nurses and patients, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality."

This Court is aware that the Defendants are for-profit corporations which are in the business of developing new and better medicines for a whole host of human ailments. In many ways, the competitive environment in which they operate is the engine that drives the research and development of new and evermore effective medicines from which all of mankind benefits. In this case in particular, it is acknowledged by all concerned that Risperdal is an excellent drug for the treatment of mental illnesses. It has been a quality of life saver for millions of patients. It allows those who are treated with it to escape many

of the effects of their mental illnesses and live a more open and productive life.

Also, this Court is not so naive so as to not understand that these companies are in this business to generate a profit for their shareholders and investors. Pharmaceutical companies, such as the Defendants, must generate returns on their investments in order to assure their survival and continued vitality. However, as Janssen's parent company points out in its own credo, the first obligation which it owes is to the persons who prescribe, use and consume their products. It is the collision of these competing interests that has created the issues that we consider here. Additionally, it is the loss of the Company's focus, upon the primary objective of its credo, which brings us to this discussion.

A. The good faith or bad faith of the Defendant:

In discussing this factor, I am mindful of the position taken by the Defendants throughout this trial. That position is that what Defendants said about Risperdal was true or was later proven to be true. Therefore, they could not have been unfair or deceptive in their actions.

The statutes provide for punishment for "unfair" or "deceptive" methods, acts or practices in the conduct of trade or commerce. S.C. Code Ann. § 39-5-20 & 39-5-110. This Court has consistently ruled that those issues concerning fairness or deceptiveness must be weighed using the information that was available and existed when the statements were made. The actions must be weighed in light of the

intentions that existed when they were made. In considering the issues presented by this defense, I came upon an article by Joel Marks, in a magazine entitled *Philosophy Now,* issue 27; (*http://philosophynow.org/issue27/The_Truth_About_Lying*) in which he discussed the nuances of deception, lies and the truth. I found the following excerpts from that article to be very helpful in my analysis of this case.

"Lying has nothing to do with truth and falsity. It is simply not true that the definition of lying is stating a falsehood. Lying seems instead to be a relation between a belief and an intention. If you utter what you believe to be false (regardless of whether it is false) for the purpose of inducing another to believe that it is true, you have lied." *Id.*

"But deceiving is a broader category than lying." Mark goes on to explain, "This is important to recognize because it implies that any comparable act of deception, lie or not, is just as wrong." *Id.* It has become clear to me that the act of deception involves engaging in disingenuous actions by which one attempts to manipulate the intended audience into acting upon the deception in a certain desired fashion. Deceiving statements may involve issuing statements which are true but which are issued for the purpose of manipulation. In this Case, the manipulation was to get prescribers and patients to make treatment decisions based upon misleading or incomplete data or concealing data which would have impacted those decisions. Cases in our State have indicated that even true statements may serve as the basis for an action under the SCUTPA if they have the capacity or

tendency to deceive. *Wright v. Craft,* 372 S.C. 1, 372 S.E. 2d 486 (2006 S.C. App.).

Here, in this case, the Jury has found the methods, actions and practices of the Defendants to be unfair and deceptive.

i. Label

I will begin this discussion of the good or bad faith of the Defendant as it relates to the labeling of the drug Risperdal. The drug was approved by the FDA in 1994. The FDA approved the initial label for the drug and all subsequent labels. The law allowed the Defendant to unilaterally strengthen Risperdal's warning section of the label as soon as there was reasonable evidence of an association of a serious hazard with the drug. There was no requirement that this should be delayed until a causal relationship was proved. 21 C.F.R. §201.57(e) (2006).

Both Dr. Plunkett and Wirshing testified that the early evidence concerning the adverse events involving this drug, as well as its chemical makeup, should have given Janssen reason to strengthen the warnings in its label concerning diabetes, hyperglycemia and weight gain. During the early years (1994-1998) of marketing, evidence of adverse events began to appear indicating that there may be an increased risk of hyperprolactinemia, diabetes, hyperglycemia and weight gain. Also, during this time there was growing evidence of cardio vascular problems associated with the use of the drug in the elderly. The Defendants conducted and participated in studies specifically designed to shed light on the possible side effects of the drug. Specifically, these studies included RIS USA-113 & 275 and ERI. In the

case of ERI and Study 113, the results indicated a substantial relationship between the use of this drug and weight gain and diabetes. Rather than making the information gathered in these studies available to the medical, regulatory and scientific communities, the Defendants chose to use pretenses to keep them hidden. It is apparent to this Court that this information was not disclosed because it did not fit the marketing department's vision for the promotion and marketing of the drug, and ultimately the content of the label. The top line results of Study 113 became available to the Defendants in September of 1999. It is clear to this Court, particularly after the top line results of study 113 became available, that the Company systematically set about in a concerted effort to conceal that information and to manipulate the information available to the public for the purpose of protecting or improving its market share. They characterized the results of the study as "flawed" and hid the results until 2009. When the results were released, they were not termed as a "flawed study," but were characterized as one that had some problems with its methodology, which problems did not affect the overall results. These reports were only released after the patent on Risperdal had expired.

From 1999 to 2003, the Defendants continued to take actions to avoid the disclosure of information which was in its possession and failed to take action to strengthen the warnings in its label. In 2003, the FDA required a class change in the label, which resulted in the issuance of the Dear Doctor Letter discussed below. Throughout this period of time, the Plaintiffs showed during the trial that up through 2007 there was never a warning for weight gain or

hyperprolactinmia. The Plaintiffs showed by ample evidence that labeling issues followed the distribution of this drug throughout the period of its distribution. This Court is keenly aware that the issues involving the label vary throughout the period of time from the drug's launch in 1994 through 2007. I have made a conscious effort to average the penalty awarded for the labeling issue and have not awarded a penalty that is close to the maximum penalty available for those violations.

I do note that courts in this State have consistently upheld that medical patients have the right to make informed decisions concerning their treatment. It is elementary that the right to make informed treatment decisions would extend to, and include, the right of a patient to have made available to them, full and complete disclosures of the critical information in the package insert, in the label published on the Physician's Desk Reference or on the company's website. This need for full and complete disclosure of all available information is especially critical when the majority of the patients treated with this drug suffer from conditions which diminish their ability to make such critical decisions to the point that they may rely more heavily on the advice of their physicians or guardians. Because of the diminished mental capacity of the patients being treated, this Court finds the actions of the Defendants, upon this audience, to be detestable.

Based on the reasons stated above, and the considerable volume of evidence presented during the trial, this Court finds that the Defendants exhibited a callous disregard to a patient's right to have all

possible information available, and in the hands of their physician, before deciding to use or continue to use the drug. Further, I find that the Defendants allowed the "profit at all costs" mentality to cloud the vision of their own responsibilities as acknowledged in their credo.

Therefore, I find the bad faith of the Defendant to be considerable during the period of September 1999 until 2007 as it relates to labeling questions. There is absolutely no doubt in my mind that the desire to protect market share overshadowed the good judgment of those in control at Janssen.

I note that the evidence supplied to this Court concerning the number of Risperdal prescriptions filled in South Carolina, during the applicable time periods, involved those which were filled under State sponsored programs, and it did not contain reliable information as to the total number of prescriptions filled in the State from all sources. Therefore, it would require too much speculation on the part of the Court to attempt to tie the penalties to the total number of prescriptions filled in the State.

ii. Dear Doctor Letter

The Dear Doctor Letter, issued in November of 2003, was clearly an effort by the Company to manipulate the message about Risperdal. Specifically, the letter was sent during the same time period that the FDA was requiring a class label change, which required that all atypical anti-psychotics include in their labels a warning concerning the dangers of these drugs and their increased risk of diabetes. A careful review of the e-mail threads, both before and after the publication of that letter (which are replete in the

record), indicate a conscious effort by the company to "spin" the message, driven by marketing considerations, about Risperdal.

The manner in which the letter was written indicates to this Court evidence of a clever effort to deliver a deceptive message to prescribing physicians. Specifically, I am referring to the use of eight studies listed, by themselves, on the final page of the letter, some of which did not support the premise of the letter itself. Examples of the clever deception included in this letter include the effort to contrast itself with Zyprexa. This was done after the FDA had directed the Defendants not to do so, and there was no mention of ERI or Study 113. This is true particularly in light of the information which the Defendants were concealing from public disclosure or consideration. The continued reference by the Defendants to Study 113 as a "failed study" during the ten years that it was concealed; then, after the patent for Risperdal was lost in 2009, to release this as a properly conducted study, illustrated the level of deception to which the Defendants stooped. I note no mention, to the public or the FDA, of the Study 113 during the years that it was concealed. The effort to hide these studies (113,275 & ERI) even continued despite a request from the FDA, in May 2000, for the Defendants to make available all information that they had in possession concerning hyperglycemia and diabetes risks to Risperdal users. The Defendants submitted voluminous responses to that request, but did not disclose the top line results of study 113 or ERI; apparently, because those results were unfavorable to their marketing message. While this is not a "fraud on the FDA" case, this concealment shows that the

Company employed procedures and methods which almost guarantee repetition and further endangerment of the public.

I could not agree more with the Janssen executive, Scott Reines, who characterized the Dear Doctor Letter in an unfavorable light and railed against those in the Company who wrote, approved and distributed the Letter. He said in his e-mail of April 28, 2004, referring to the Dear Doctor Letter, "But no competent person would have let it go out." He then went on to say, "It's really a black mark for J&J."

This Court finds that the actions of the Company in regards to this Letter exhibited extreme bad faith. It was a conscious effort to deceive and was unfair in the manner in which it was composed and delivered. Additionally, it was done in such a fashion so as to directly influence the prescribing decisions of doctors. Who knows how many of those mothers, fathers and patients referenced in their Credo, to be owed their best, were influenced into making incorrect decisions concerning their drug therapy?

An example of the subtle manner in which the Letter was used to deliver only a "certain" message to physicians is evident in the fact that the November Letter was placed in the folios of the detail persons who visited the doctors, so that it could be shown and emphasized to each doctor on every visit. However, later, when the FDA required that a corrective letter be mailed, the corrective letter was not placed in the detail person's folios to be shown to the doctors on every visit.

B. Injury to the public

It is noted that the issues involved in this Case do not require direct proof of any specific injury to the public. Rather, the SCUTPA requires a showing that the unfair or deceptive act is capable of repetition, which shows that the violation would have an effect on the public's interest. I quote from my charge on the subject:

> "In addition, the plaintiff must prove that the unfair trade practice or act affected persons other than the parties to the transaction in which the act complained of occurred. Expressed differently, the plaintiff must prove that the unfair trade practice or act has an impact on the public's interest. The plaintiff must prove the adverse effect or impact on the public interest by specific facts.
>
> An action has an impact on the public interest if it is shown by the preponderance of the evidence that the unfair trade practice or act is capable of repetition.[1]
>
> Showing that an act is capable of repetition can be shown in several ways, but it can be shown in two specific ways:
>
> > (1) By showing the same kind of action has occurred in the past, thus making it likely they will continue to occur absent deterrence; or

[1] *Burbach v. Investors Mgmt. Corp.,* 326 S.C. 492, 484 S.E.2d 119 (Ct. App. 1997).

> (2) The company's procedures create a potential for repetition.
>
> These are ways to show the potential for repetition, but not the only ways, that the potential for repetition may be shown. It may be shown by other means."

My charge went on to say, "Since these two ways are not the only means for showing the potential for repetition or public impact, each case must be evaluated on its own merits to determine what a plaintiff must show to satisfy the potential for the repetition/public impact prong of the SCUTPA. *Daisy Outdoor Advertising, Inc. v. Abbott,* 322 S.C. 489, 497, 473 S.E.2d 47, 51 (1996). Nevertheless, a plaintiff has proven an adverse effect on public interests if he proves, by the preponderance of the evidence, and by specific facts, the potential for repetition exists". *Id*. at 493, 473 S.E.2d at 49.

In this Case, the Jury found that the actions of the Defendants did affect the public interest and were capable of repetition. Such a finding was necessary in order for the July to reach the verdict that they did. In considering the principles that are at issue in this Case, this Court finds that these issues involved are of critical importance to the public, which use and consume prescription drugs in general. Additionally, it is the belief of this Court that this group constitutes a large percentage of the total population. The public's interest in requiring that drug manufacturers fully disclose all information available to them concerning the effects of their drugs in a fair and non-deceptive manner is of paramount importance to the health and safety of those using the drugs. Only when full honest

and fair disclosure is done, can doctors and patients make fully informed decisions concerning possible side effects that may be suffered as a result of the drug therapy to be used by the patient. Therefore, the public interest affected by the actions of these Defendants is enormous.

C. Desire to eliminate the benefits derived from a violation

Quite frankly, in this Case, it would be virtually impossible to accurately determine the degree to which the Defendants benefitted from their actions. It is clear to this Court, that if the aim of these actions by the Defendants was to protect the market share of Risperdal; then it succeeded, in that the share did not suffer as a result of the ever expanding warnings. The purpose of this Court is to penalize the actions of the Defendants and is not intended to award damages based upon any measure of damages or ill-gotten gain. It is clear from the information stated below that the profits from this drug, to the Defendants, were enormous, and the penalties set by this Court represent a relatively small percentage of the overall profits generated by the companies. In determining this percentage, I note the relatively small percentage of the Defendant's business conducted in South Carolina in comparison to the overall worldwide scope of that business.

D. The necessity of vindicating the authority of the agency involved

The SCUTPA was enacted by the legislature as a consumer protection measure. The Attorney General has been granted broad powers to enforce that Act, particularly when a willful violation of the Act has

occurred. Here, the Jury determined that a willful violation of the Act occurred. In doing so, the Jury has determined that the public interest was affected by those wrongful actions and that those actions by the Defendants were willful and intentional.

It is clear, that when a company comes into this State and conducts its business in such an unfair manner, so as to deceive the public in the conduct of its trade or commerce, that there is a need for a central authority to challenge those actions and protect the public's interest. This protection of the public's interest should be done in such a manner so as to deter future violations of the Act, and to protect the public's interest to the extent necessary. The Legislature has clearly placed this burden and duty upon the Attorney General and it is the responsibility of that office to vindicate the public's interest in this Case.

E. The Defendant's ability to pay

In setting a penalty, it is necessary to consider what level of penalty is necessary to make the wrongdoer take notice of the problem and correct its future actions. Obviously, the level of the penalty will vary depending upon the financial ability of the wrongdoer to pay. This Court is aware that this is not a case involving the award of punitive damages, where the amount of punitive damages must bear some relationship to the amount of actual damages suffered. In those cases, the financial ability of the defendant alone will not support an award that far exceeds the actual damages suffered.

In this Case, however, the issue is the level of penalties that is appropriate to punish the wrong. I am limited by the statute as to the amount of penalties

that can be assessed per occurrence. Where the number of wrongs is extremely large and the profits derived enormous, the penalties must have a direct relationship to those numbers. Where deterrence and punishment is the aim, the financial ability of the wrongdoer is clearly a factor to be considered.

The Defendants, which were found to have been responsible for the unfair or deceptive acts or practices in the conduct of the defendant's trade or business, are wholly owned subsidiaries of the Johnson & Johnson Corporation. Janssen, itself, reports no separate financial information of which this Court was made aware. Therefore, the publically disclosed financial information, which was made available to this Court, is in the form of the annual report to shareholders of the parent corporation. It does not contain any separate financial information for the Defendants. It does contain information that was specific to Risperdal and some information specific to pharmaceutical operations. Profits for the Corporation and net cash and cash equivalents are reported for Johnson & Johnson and not its individual subsidiaries. The information considered by this Court in making a determination of the ability of the Defendants to pay includes:

Annual Sales of Risperdal worldwide per annual reports of Johnson & Johnson, Inc.:

1994	0.172 Billion
1995	0.343 Billion
1996	0.502 Billion
1998	0.588 Billion
1999	0.892 Billion

2000	1.083 Billion
2001	1.845 Billion
2002	2.146 Billion
2003	2.512 Billion
2004	3.05 Billion
2005	3.552 Billion
2006	4.180 Billion
2007*	4.697 Billion
2008	1.309 Billion
2009	1.425 Billion
2010	1.50 Billion
Total for the period…	29.796 Billion

*Patent for Risperdal expired in 2007.

Testimony at trial indicated that the profit margin for sales of Risperdal was 97% or $28.90 Billion for the period of 1994-2010.

Earnings: The 2010 Annual report for Johnson & Johnson, the parent corporation, indicates worldwide sales of $61.6 billion which generated a free cash flow of $14 billion. Johnson and Johnson, Inc. Annual Report 2010, p. 1.

The Pharmaceutical Division reported sales and operating profits of $7,086 billion for the year 2010. Form 10-K for 2010, Filed with the Securities and Exchange Commission

Number of Violations:

A. Label

It is clear that the label was published with each sample distributed to the public. Clearly, there were

other occasions when the label would have been published, such as through the Physician's Desk Reference or on the Defendants website; however, to find violations from those sources would require this Court to speculate as to the number of violations. Each distributed sample clearly contains a copy of the label and would be the most likely source of information for patients who are considering entering into an ongoing therapy with the drug. For purposes of this discussion, the Court considers each publication of the Risperdal label (package insert), by way of sample, to prescribers in the State of South Carolina until April 23, 2007, to be a separate violation.

Sample Boxes Distributed	509,499

This court finds the appropriate average penalty to be $300.00 per violation:

$152,849,700.00.

B. Dear Doctor Letter

Letters mailed	7,184
Sales calls where letter published	36,372
Total publications of letter	43,556

The Court finds the appropriate penalty to be $4,000.00 per violation: $174,224,000.00.

Based on the record of the Case, and the above, it is hereby, ORDERED, that the Defendants shall pay, to the State of South Carolina, through its Attorney General, Alan Wilson, penalties in the sum of Three hundred twenty-seven million, seventy-three thousand, seven hundred and 00/100 dollars. ($327,073,700.00)

IT IS SO ORDERED.

s/Roger L. Couch
Roger L. Couch,
Circuit Court Judge

Spartanburg, S.C.
June 3, 2011

Appendix D

U.S. CONST. AMEND. I

Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.

Appendix E

U.S. CONST. AMEND. VIII

Excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted.

Appendix F

U.S. CONST. AMEND. XIV

Section 1.

All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

Section 2.

Representatives shall be apportioned among the several States according to their respective numbers, counting the whole number of persons in each State, excluding Indians not taxed. But when the right to vote at any election for the choice of electors for President and Vice-President of the United States, Representatives in Congress, the Executive and Judicial officers of a State, or the members of the Legislature thereof, is denied to any of the male inhabitants of such State, being twenty-one years of age, and citizens of the United States, or in any way abridged, except for participation in rebellion, or other crime, the basis of representation therein shall be reduced in the proportion which the number of such male citizens shall bear to the whole number of male citizens twenty-one years of age in such State.

Section 3.

No person shall be a Senator or Representative in Congress, or elector of President and Vice-President,

or hold any office, civil or military, under the United States, or under any State, who, having previously taken an oath, as a member of Congress, or as an officer of the United States, or as a member of any State legislature, or as an executive or judicial officer of any State, to support the Constitution of the United States, shall have engaged in insurrection or rebellion against the same, or given aid or comfort to the enemies thereof. But Congress may by a vote of two-thirds of each House, remove such disability.

Section 4.

The validity of the public debt of the United States, authorized by law, including debts incurred for payment of pensions and bounties for services in suppressing insurrection or rebellion, shall not be questioned. But neither the United States nor any State shall assume or pay any debt or obligation incurred in aid of insurrection or rebellion against the United States, or any claim for the loss or emancipation of any slave; but all such debts, obligations and claims shall be held illegal and void.

Section 5.

The Congress shall have the power to enforce, by appropriate legislation, the provisions of this article.

Appendix G

S.C. CODE ANN. § 39-5-20

(a) Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful.

(b) It is the intent of the legislature that in construing paragraph (a) of this section 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.

Appendix H

S.C. CODE ANN. § 39-5-110

(a) If a court finds that any person is willfully using or has willfully used a method, act or practice declared unlawful by § 39-5-20, the Attorney General, upon petition to the court, may recover on behalf of the State a civil penalty of not exceeding five thousand dollars per violation.

(b) Any person who violates the terms of an injunction issued under § 39-5-50 shall forfeit and pay to the State a civil penalty of not more than fifteen thousand dollars per violation. For the purposes of this section, the court of common pleas issuing an injunction shall retain jurisdiction, and the cause shall be continued and in such cases the Attorney General acting in the name of the State may petition for recovery of civil penalties. Whenever the court determines that an injunction issued pursuant to § 39-5-50 has been violated, the court shall award reasonable costs to the State.

(c) For the purposes of this section, a willful violation occurs when the party committing the violation knew or should have known that his conduct was a violation of § 39-5-20.