The Supreme Court of South Carolina

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.

Appellate Case No. 2012-206987

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,

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

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.

Columbia, South Carolina

July 8, 2015

THE STATE OF SOUTH CAROLINA
In The Supreme Court

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Appellate Case No. 2012-206987

Appeal from Spartanburg County
Roger L. Couch, Circuit Court Judge

Opinion No. 27502
Heard March 21, 2013 – Filed February 25, 2015
Withdrawn, Substituted and Refiled July 8, 2015

AFFIRMED IN PART, REVERSED IN PART AND REMANDED

Steven W. Hamm and Steven J. Pugh, both of Richardson, Plowden & Robinson, PA, of Columbia, C. Mitchell Brown, William C. Wood, Jr., A. Mattison Bogan and Miles E. Coleman, all of Nelson Mullins

Riley & Scarborough, LLP, of Columbia, Edward M. Posner and Chanda A. Miller, both of Drinker Biddle & Reath, of Philadelphia, Pennsylvania, for Appellant.

John B. White, Jr., and Donald C. Coggins, Jr., both of Harrison, White, Smith & Coggins, PC, of Spartanburg, John S. Simmons, of Simmons Law Firm, LLC, of Columbia, Attorney General Alan M. Wilson, Deputy Attorney General Robert D. Cook and Assistant Deputy Attorney General Clyde H. Jones, Jr., all of Columbia, Fletcher V. Trammell, Robert W. Cowan, and Elizabeth W. Dwyer, all of Bailey Peavy Bailey, of Houston Texas, for Respondent.

Gray T. Culbreath and Laura W. Jordan, both of Gallivan White & Boyd, P.A., of Columbia, for Amici Curiae, The South Carolina Chamber of Commerce, South Carolina Business and Industry Political Education Committee and The South Carolina Manufacturer's Alliance.

JUSTICE KITTREDGE: 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.

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

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

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*,

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

555 U.S. 555, 566 (2009) (citation omitted). The FDCA's "most substantial innovation was its provision for premarket approval of new drugs." *Id.* 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.[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 (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*: (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.

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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 (2005) (citations omitted).

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 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

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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).

> 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.

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, post-marketing

[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

studies, some as early as 1994, revealed Risperdal posed a serious risk of substantial weight gain, increased prolactin levels,[7] 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 diabetes mellitus, which can have very serious, even life-threatening consequences. By 1997, Janssen also had

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relative comparison sales technique is not new. *See P. Lorillard Co. v. Fed. Trade 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.

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 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

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

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. 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 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]."

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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.

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 $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

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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).

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, 422 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] 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

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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 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.

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 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]

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

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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. 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.

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 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.

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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 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).

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 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.

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

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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.").

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 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

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[17] 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 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.

[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 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 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 representations had a *tendency to*

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.

[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.

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 its motion for JNOV, Janssen failed to raise any First Amendment issues in its motion for a

[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.

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[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 (1980) (internal citations omitted). The State correctly notes that commercial speech is not protected by the First

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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.

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 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).

The trial court charged the jury:

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[22] 15 U.S.C. §§ 41–77 (2012).

> 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*.

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] Whether Janssen's actions and representations to the

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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 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 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).

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 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.[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.

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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.

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.[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.

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 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

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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.

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

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 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)).[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 asserts the DDL claim is based solely on a violation of the FDCA, which provides no private right of action. Janssen thus

[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).

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. 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 (citing 21 C.F.R. § 201.80(e); 21 C.F.R. § 314.80(b); 73 Fed. Reg. 49605).

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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."

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.[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. 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

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 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]

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))).

[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

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

A.
Violations and Reduced Civil Penalty

1.
Labeling Claim

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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.

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

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 (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 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 (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.[33]

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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

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 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 (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 (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 (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

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rely on average settlements as dispositive, especially when we are constrained by an abuse of discretion standard of review.

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.

JUSTICE PLEICONES: 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.

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

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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.

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, 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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[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).