

15-600

No. _____

Supreme Court, U.S.
FILED

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In the
Supreme Court of the United States

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

Petitioner,

v.

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

Respondent.

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

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

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

The questions presented are:

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

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

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

PARTIES TO THE PROCEEDING

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

CORPORATE DISCLOSURE STATEMENT

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

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PETITION FOR WRIT OF CERTIORARI

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

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

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

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

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

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

* * *

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

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

OPINIONS BELOW

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

JURISDICTION

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

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

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

STATEMENT OF THE CASE

A. SCUTPA's Broad Reach and Amorphous Standards

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

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

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

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

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

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

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

B. Janssen's Introduction of Risperdal

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

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

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

Janssen has also closely studied the potential risk of hyperprolactinemia, which is a type of hormonal imbalance that results in elevated levels of prolactin. As early as 1993, Janssen included in the “Precautions” section of its FDA-approved label a statement that “Risperdal elevates prolactin levels.” R.979, 1038. Janssen communicated repeatedly with the FDA about this potential risk. In August 2007—pursuant to new FDA labeling regulations²—Janssen moved the discussion of hyperprolactinemia that had been in the “Precautions” section to a newly-combined “Warnings and Precautions” section. According to the State’s experts, the Risperdal package insert was “inadequate” because the discussion of hyperprolactinemia was included in the “Precautions” section rather than the formerly standalone “Warnings” section between 1994 and 2007. R.675, 856.

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

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

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

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

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

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

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

C. Proceedings Before the Trial Court

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

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

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

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

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

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

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

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

D. The South Carolina Supreme Court’s Decision

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

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

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

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

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

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

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

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

REASONS FOR GRANTING THE PETITION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

“unfair” or “deceptive” conduct are not applied in a manner that will inevitably chill protected speech.⁵

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CONCLUSION

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

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November 5, 2015